

Pós-Graduação em Cirurgia Translacional





RELATÓRIO FINAL DE PÓS-DOUTORADO

RESSONÂNCIA NUCLEAR MAGNÉTICA VERSUS ULTRASSONOGRAFIA PARA O DIAGNÓSTICO DAS LESÕES DO MANGUITO ROTADOR: Revisão sistemática

Mário Lenza

São Paulo - SP

2014

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Relatório final de pós-doutorado apresentado à Universidade Federal de São Paulo.

Supervisor: Prof. Dr. Flávio Faloppa

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ESCOLA PAULISTA DE MEDICINA - EPM

Programa	de Pós-Gradua	ção em	Cirurgia	Translacional
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Coordenador: Prof. Dr. Miguel Sabino Neto

Supervisor: Prof. Dr. Flávio Faloppa

Professor Titular do Departamento de Ortopedia e Traumatologia da EPM - UNIFESP

"Há pessoas que choram por saber que as rosas
têm espinho, há outras que sorriem por saber que os espinhos têm rosas!"
Machado de Assis

Dedicatórias

À minha querida esposa, Marina,

Por toda a dedicação em todos os momentos e por trazer mais vida aos dias da minha vida.

Ao meu filho, Rafinha,

Que tirou minhas noites de sono para descansar e as transformou em lúdicas para sonhar...

Agradecimentos

Agradeço a todos, que de maneira direta ou indiretamente, colaboraram para que este projeto. De maneira particular, sou muito grato:

Ao Professor Doutor **Flávio Faloppa**, que sempre me apoiou na busca de demonstrar que a medicina é uma ciência de verdades transitórias.

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LISTA DE ABREVIATURAS

artro-RNM – artro-ressonância nuclear magnética

CAPES – Coordenação de Aperfeiçoamento de Pessoal de Nível Superior

CCSG - Cochrane Collaboration Steering Group

CRG - Cochrane Review Group

DARE – Database of abstracts of reviews of effects

DNA – Ácido desoxirribonucleico

Dr. – Doutor

DTA – Diagnostic test accuracy

EMBASE – Excerpta Medica Database

etc. – Et cetera

LILACS - Literatura Latino-Americana em Ciências da Saúde

MEDLINE - Medlars Online

Prof. – Professor

REUNI – Reestruturação e expansão das universidades federais

RNM – Ressonância nuclear magnética

US – ultrassonografia (US)

Resumo

Os objetivos preestabelecidos no plano do projeto inicial foram atingidos. A pesquisa seguiu o desenho de estudo de revisão sistemática de estudos de diagnósticos cujos resultados foram referentes de 20 estudos de acurácia (1147 pacientes) incluídos na análise. Os estudos avaliaram a comparação de exames de imagem para o diagnóstico da lesão do manguito rotador. Muitos estudos incluídos tinham falhas metodológicas, com o potencial de viés, limitando assim a força de suas descobertas.

Nós encontramos evidências com diferenças significativas na acurácia entre os exames de ressonância nuclear magnética (RNM), ultrassonografia (US) e artro-ressonância (artro-RNM) para detectar quaisquer lesões do manguito rotador (P = 0,01). A sensibilidade e a especificidade da RNM com intervalo de confiança de 95% (seis estudos, 347 ombros) foram de 96,9% (91,2% a 99,0%) e 81,6% (63,0% para 92,0%), respectivamente. A sensibilidade e a especificidade da ultrassonografia (13 estudos, 854 ombros) foram de 90,4% (81,0% a 95,4%) e 82,9% (69,2% para 91,2%), respectivamente. A sensibilidade e a especificidade da artro-RNM (3 estudos, 183 ombros) foram de 97,5% (88,5% a 99,5%) e 70,1% (29,1% para 93,1%), respectivamente. A sensibilidade da artro-RNM foi significativamente mais elevada do que a da US (P = 0,04), mas não foi significativamente mais elevada do que da RNM (P = 0,8). A sensibilidade da RNM foi significativamente mais elevada do que a da US (P = 0,04). As diferenças na especificidade não foram estatisticamente significativas, para qualquer par de testes.

O protocolo desta pesquisa e a revisão foram publicados na "The Cochrane Library".

Há a necessidade premente de novos projetos na área de Medicina Baseada em Evidências aplicada à Ortopedia e Traumatologia, que se configura com o intuito de incentivar a disseminação da metodologia para realização de estudos clínicos e seus conceitos. O desenvolvimento desta pesquisa proporcionou adquirir experiência com a metodologia das revisões de estudos de diagnóstico e fomentar a formação de grupos de estudos para a confecção de revisões sistemáticas.

Dados do projeto

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1. DADOS DO PROJETO

1.1. Projeto

Ressonância nuclear magnética versus ultrassonografia para o diagnóstico das lesões do

manguito rotador: revisão sistemática

Supervisor: Prof. Dr. Flávio Faloppa

Instituições de Execução do Projeto:

- Universidade Federal de São Paulo

Programa de Pós-Graduação em Cirurgia Translacional – (EPM/UNIFESP) / Rua Napoleão de

Barros, 715 – 4º andar – Vila Clementino, Cep: 04024-002 / São Paulo-SP, Brasil. Telefones:

(11) 5576-4118 / 5571-6579.

- Cabrini Hospital

Monash Department of Clinical Epidemiology, Cabrini Institute; and Department of

Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine,

Monash University – 181-183 Wattletree Rd, Malvern VIC 3144, Australia. Phone: (03) 9508

1222

- Australasian Cochrane Centre

School of Public Health and Preventive Medicine - The Alfred Centre / 99 Commercial Road

Melbourne VIC 3004, Australia. Phone: +61 3 9903 0366.

- Monash University

900 Dandenong Road Caulfield East Victoria 3145 Melbourne, Australia. Phone: + 61 3 990

32000

Vigência: setembro de 2010 a julho de 2014.

Período no exterior: Australia: março de 2011 a setembro de 2011

Bolsa REUNI - CAPES: 01/09/2010 a 28/02/2011 e 01/09/2011 a 31/05/2012

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Dados do projeto

1.2. Dados do Pós-Doutorando

Nome: Mário Lenza

Formação profissional: Graduação em medicina (Faculdade de Ciências Médicas de Santos, FCMS - Lusiadas / 1997-2003), Residência médica em Ortopedia e Traumatologia (Universidade Federal de São Paulo / 2004-2007), Especialização em cirurgia do ombro e cotovelo (Universidade Federal de São Paulo / 2007-2008), Doutor em Ciências pelo Programa de Ortopedia e Traumatologia (Universidade Federal de São Paulo / 2008-2010). Pósdoutorando pelo Programa de Cirurgia Translacional da Universidade Federal de São Paulo,

2010-Atual.

1.3. Dados do Supervisor

Nome: Flávio Faloppa

Formação profissional: Graduação em medicina (Universidade Federal de São Paulo / 1979), Residência/Especialização em Ortopedia e Traumatologia (Universidade Federal de São Paulo / 1980-1981), Mestre em Ciências Programa de Pós-graduação em Ortopedia e Cirurgia Plástica Reparadora (Universidade Federal de São Paulo / 1985), Doutor em Ciências Programa de Pós-graduação em Ortopedia e Cirurgia Plástica Reparadora (Universidade Federal de São Paulo / 1988), Livre-Docência no Departamento de Ortopedia da EPM/UNIFESP em 1994.

1.4. Atividades no exterior

Por estar em processo de desenvolvimento na Colaboração Cochrane, a metodologia dos estudos de revisão sistemática de diagnóstico permanece restrita aos centros internacionais e está em fase inicial de estruturação no centro Cochrane da Austrália. Seu aprendizado, portanto, só se configurou na medida em que fui agente participativo da construção de sua metodologia. Ao estar vinculado a estes centros, foi possível não apenas ter me capacitado na nova metodologia, mas também participar de seu aprimoramento, criando uma base de conhecimento alinhada a todos os valores e princípios da Colaboração Cochrane.

2. LITERATURA

A medicina baseada em evidências foi recentemente noticiada como um dos maiores marcos da medicina dos últimos 160 anos, juntamente com a descoberta do DNA, o desenvolvimento de vacinas e antibióticos e o uso de anestésicos em cirurgias (Watts, 2007). Trata-se de uma modalidade de pesquisa que busca relacionar a melhor evidência disponível no campo da literatura científica com a experiência clínica individual e os valores do paciente. Em sua prática, recomenda-se o uso consciencioso da melhor evidência disponível para embasar o processo de tomada de decisão quanto à saúde dos pacientes. Na busca destas evidências mais relevantes, as revisões sistemáticas apresentam um papel significativo (Akobeng, 2005; Atallah et al, 2003).

O ensino da medicina baseada em evidências vem sendo gradativamente incorporado às instituições de pesquisa na área de Ortopedia e Traumatologia, e crescente atenção tem sido despendida por parte destas instituições no sentido de promover o desenvolvimento de habilidades específicas nos profissionais interessados em seu aprendizado, capacitando-os a navegar pelo afluxo constante da literatura médica e a extrair as informações relevantes (Degen et al, 2008).

2.1. Revisão sistemática da acurácia de testes diagnósticos

Revisão sistemática é uma metodologia de pesquisa que visa reunir toda a evidência empírica compatível com os critérios de elegibilidade pré-definidos, a fim de responder a uma questão específica. Esta modalidade de pesquisa permite identificar os estudos com alto risco de viés, que podem ser tendenciosos e que muitas vezes superestimam a importância de seus achados (Manchikanti et al. 2009; Moreno, Pantoja, 2009; Virgili et al. 2009). Por meio de uma síntese objetiva da qualidade metodológica e dos desfechos de todos os estudos pesquisados em certo tópico, as revisões sistemáticas ajudam a separar estudos irrelevantes ou redundantes dos estudos mais importantes e críticos, que são dignos de reflexão. Esta característica é especialmente interessante na atualidade, por conta do excesso de informação científica com o qual se deparam diariamente, profissionais e gestores da área da saúde, pacientes e pesquisadores. É improvável que todos tenham tempo, habilidades e recursos para encontrar, avaliar e interpretar os dados obtidos por meio destas informações, incorporando-os em suas tomadas de decisão no cuidado à saúde.

Outra propriedade das revisões sistemáticas é identificar não só o que é sabido, mas o que é desconhecido em uma área específica, indicando necessidades de novas pesquisas em

campos ainda inexplorados (<u>Alexander, Stafford, 2009</u>; <u>Manchikanti et al, 2009</u>). A informação que se obtém por meio de revisões sistemáticas de estudos de diagnóstico possibilita determinar o uso apropriado e a eficácia de testes diagnósticos na prática clínica, fornecendo uma base sólida para fundamentar a criação de normas e diretrizes nos serviços primários da saúde. Também permite analisar o desempenho e o status de certa técnica diagnóstica, bem como avaliar a qualidade dos estudos primários de diagnóstico (<u>Gatsonis, 2003</u>; <u>Gatsonis, Paliwal, 2006</u>).

Revisões sistemáticas e metanálises de estudos de diagnóstico podem ser usadas para a obtenção de estimativas mais relevantes em estudos que descreverem o mesmo teste e nos quais pacientes em um mesmo contexto estiverem disponíveis. Também são úteis para estabelecer se e como variam os achados científicos em subgrupos particulares, além de proverem o efeito estimado com uma generalização superior à que os estudos individuais fornecem (Irwig et al, 1994; Leeflang et al, 2009).

No campo das revisões sistemáticas de estudos de diagnósticos, há dificuldades metodológicas específicas. Dentre elas, a dificuldade em analisar os resultados obtidos. Diferentemente das revisões sistemáticas de estudos de intervenção, que avaliam apenas um desenho de estudo específico (como os ensaios clínicos randomizados), as revisões sistemáticas de diagnóstico acessam e comparam vários modelos de desenhos de estudo simultaneamente, o que dificulta a análise de seus resultados.

Outro desafio inerente às revisões diagnósticas é a identificação de estudos de diagnóstico. Nas principais bases de dados da literatura atual, não há uma palavra-chave ou termo indexado específico para a busca destes estudos; ao contrário do que ocorre com os estudos de intervenção terapêutica, para os quais o termo "randomized controlled trial" foi definido. A utilização dos termos Mesh (Medical Subject Heading), "sensitivity / specificity", é aceitável; no entanto, aplicá-los nas principais bases de dados da literatura produz achados inconsistentes. Além disso, os dados dos estudos de diagnóstico podem ser ocultados em estudos que não relatam as estimativas da acurácia dos testes nos seus objetivos principais, o que dificulta a identificação de estudos de diagnóstico em bases de dados como a MEDLINE. Até que os sistemas de indexação codifiquem propriamente os termos de estudos de diagnóstico, a busca por eles permanecerá desafiadora, e haverá necessidade de realizar buscas manuais adicionais, por exemplo, em listas de referência (Haynes et al, 1994; Leeflang et al, 2008).

Outra dificuldade no preparo de uma revisão sistemática de estudos de diagnóstico em relação às revisões de estudos de intervenção consiste na forma de relatar os resultados. Enquanto

nas revisões de estudos de intervenção os resultados são relatados utilizando uma única medida de efeito - tal como diferença entre médias, diferença entre riscos, ou risco relativo - os estudos de diagnóstico relatam pelo menos dois tipos de análises, como sensibilidade e especificidade, valor preditivo positivo e negativo, entre outros (<u>Gatsonis</u>, <u>Paliwal</u>, <u>2006</u>; <u>Leeflang et al</u>, 2008).

Com a intenção de minimizar estas dificuldades e definir diretrizes metodológicas, a Colaboração Cochrane decidiu, em 2003, preparar-se para a inclusão de revisões sistemáticas de estudos de diagnóstico em sua base de dados de revisões sistemáticas (Manchikanti et al. 2009).

A Colaboração Cochrane, fundada em 1993, é a maior organização internacional cuja meta principal é assistir pesquisadores na preparação, manutenção e promoção de revisões sistemáticas (por meio da realização de colóquios, *workshops*, treinamentos e constantes encontros presenciais entre os colaboradores). A organização também objetiva promover o acesso à informação de alta qualidade, e assim, auxiliar pessoas na tomada de decisões no cuidado à saúde (Allen et al., 2007; Green et al., 2008).

Em outubro de 2006, no encontro do *Cochrane Collaboration Steering Group* (CCSG), definiuse que as publicações de revisões (e protocolos) de diagnóstico na Cochrane Library devem requerer aprovação prévia do grupo de revisão da Cochrane (*Cochrane Review Group* - CRG) e do grupo editorial de acurácia de testes diagnósticos (*Diagnostic test accuracy* - DTA) (Leeflang et al. 2008). Recentemente, para dar suporte aos novos autores, a Colaboração Cochrane instituiu a formação do grupo DTA, dando-lhe como incumbências: aprimorar a metodologia de revisões sistemáticas de estudos diagnósticos; desenvolver um programa de computação para análise dos dados; e a elaboração de um guia (ainda em construção), com orientações específicas para a elaboração de revisões na nova metodologia (*Handbook*). A primeira revisão de estudos de diagnóstico foi publicada na base de dados da Cochrane em outubro de 2008 (Leeflang et al. 2008). Até o momento, existem apenas duas revisões publicadas com esta metodologia pela Colaboração.

Como ferramenta de treinamento para o aprendizado desta nova metodologia de estudo, os autores deste projeto propuseram um protocolo, cujo título foi registrado na Cochrane Library em setembro de 2009, para o desenvolvimento de uma revisão sistemática de estudos que comparam a acurácia dos testes diagnósticos ressonância nuclear magnética versus ultrassonografia, para o diagnóstico das lesões do manguito rotador.

2.2. Condição clínica a ser diagnosticada

O manguito rotador é composto pelos tendões dos músculos subescapular, supraespinhal, infraespinhal e redondo menor. A porção longa do tendão do bíceps também contribui com a função do manguito, que é a de estabilizar a cabeça umeral na cavidade da glenóide, prevenindo a migração superior da cabeça umeral (<u>Favard et al, 2007</u>; <u>Matsen, 2008</u>).

Alterações musculoesqueléticas sintomáticas do ombro são muito comuns. Uma avaliação do sistema primário de saúde em Cambridge, Reino Unido, demonstrou uma incidência de 9,5 por 1.000 pacientes com dor no ombro. Destes, 86% apresentavam tendinopatia do manguito rotador (Ostör et al, 2005).

As causas mais comuns de incapacidade e dor no ombro são as doenças relacionadas ao manguito rotador em decorrência de lesão ou sobrecarga dos tendões. No ano de 2002, mais de 4,5 milhões de consultas médicas e aproximadamente 40.000 internações para tratamento cirúrgico foram realizadas nos Estados Unidos devido a doenças relacionadas ao manguito rotador (Oh et al, 2007).

Comumente, a tendinopatia do manguito rotador pode resultar em lesão do tendão supraespinhal e progredir para os demais tendões. Lewis (2008), em uma revisão narrativa sobre fisiopatologia das lesões do manguito rotador, propôs uma teoria multifatorial com a combinação de fatores extrínsecos e intrínsecos. Os fatores extrínsecos podem ser divididos em causas anatômicas, tais como: forma do acrômio (curvo ou ganchoso), espessamento do ligamento acromiclavicular, os acromiale, esporão acromial (Bigliani et al, 1991; Lewis, 2008; Nho et al, 2008); e causas ambientais, tais como: envelhecimento, uso excessivo do ombro, tabagismo, obesidade e distúrbios metabólicos, como a diabetes (Chen et al, 2003; Harryman et al, 2003). Os fatores intrínsecos incluem: áreas de hipoperfusão dos tendões, processos inflamatórios e alterações celulares dos tendões, como a desorganização da arquitetura do colágeno, entre outros (Lewis, 2008; Rees, 2008).

As lesões do manguito rotador podem ser descritas de várias maneiras, de acordo com sua duração (aguda ou crônica), tamanho (parciais, totais ou extensas) e etiologia (traumática ou degenerativa); diversos sistemas de classificação foram propostos para caracterizar estas lesões (Kuhn et al, 2007).

Atualmente, a indicação para o tratamento cirúrgico baseia-se na persistência dos sintomas e/ou fraqueza muscular e/ou tamanho da lesão. Em geral, quando se opta pela cirurgia, o diagnóstico por imagem pode auxiliar no planejamento do tratamento cirúrgico, uma vez que possibilita mensurar a extensão da lesão (parcial ou total) e discriminar quais tendões estão envolvidos (supraespinhal, infraespinhal, etc.).

2.3. Descrição dos testes de diagnóstico por imagem (teste índice)

A RNM e/ou a US são os exames de escolha para caracterizar as lesões do manguito rotador em pacientes que possuem indicação de procedimento cirúrgico. A qualidade destes exames de imagem tem progredido substancialmente ao longo do tempo, propiciando uma avaliação mais precisa do tamanho e extensão da lesão do manguito rotador e um planejamento mais acurado para realização da intervenção cirúrgica (Rees, 2008).

O exame de US do ombro é um exame não invasivo, praticamente sem efeitos colaterais associados e que permite a avaliação dinâmica das estruturas durante o movimento (Al-Shawi et al, 2008). Pode ser utilizada no setor primário de avaliação da saúde para a investigação da integridade dos tendões do manguito. No entanto, possui algumas limitações, como a de ser um exame operador-dependente e possuir uma longa curva de aprendizado (O'Connor et al, 2005; Rutten et al, 2006), principalmente em vista das roturas parciais do tendão, cuja classificação possui uma alta variabilidade interobservador, conforme relataram Le Corroller et al (2008).

A RNM é um método não invasivo, que gera imagens de alta resolução em múltiplos planos, utilizada com frequência nos setores secundários e terciários de saúde. Consiste em uma avaliação estática dos tecidos, podendo exigir ou não uma injeção intra-articular de contraste radiopaco nos tecidos moles das articulações. A RNM possui algumas contraindicações absolutas: clipes de aneurisma intracerebral, marcapassos cardíacos, desfibriladores automáticos, bioestimuladores, dispositivos implantados de infusão, aparelhos auditivos internos e corpo estranho metálico orbital (Witte, 2003). E é um exame de alto custo.

2.4. Descrição dos testes de referência

Os testes de referência para a avaliação das lesões do manguito rotador são exames invasivos de diagnóstico. O teste de referência mais usado comumente é a artroscopia diagnóstica. A artroscopia é um procedimento cirúrgico minimamente invasivo, que consiste na introdução de um artroscópio (tipo de endoscópio de fibra óptica) na articulação, através de uma pequena incisão. A técnica permite ao cirurgião avaliar diretamente os tendões do manguito em suas faces articular e bursal e, ainda, realizar um exame geral das estruturas que compõem a articulação do ombro para detectar e tratar outras potenciais lesões (Dinnes et al, 2003; Matava et al, 2005). Limitações associadas ao exame diagnóstico da artroscopia do ombro incluem a curva de aprendizado e algumas variações interobservadores durante a classificação das principais lesões (Kuhn et al, 2007).

A cirurgia aberta do ombro (incluindo a *mini-open*) também pode ser utilizada como teste de referência para as lesões do manguito rotador. Entretanto, é menos precisa do que a artroscopia, porque o acesso às lesões intra-articulares e à região inferior do manguito está prejudicado nesta abordagem cirúrgica.

2.5. Importância de realizar este estudo

Os exames de US e/ou RNM estão sendo cada vez mais usados para avaliar a presença e extensão da lesão do manguito rotador com o objetivo de realizar o planejamento da intervenção cirúrgica. O aprimoramento das técnicas para realizar estes testes de imagem não invasivos resultou no aumento da confiabilidade destes exames, fazendo com que venham substituindo parcialmente o uso da artroscopia diagnóstica, embora esta ainda seja comumente realizada como parte do tratamento cirúrgico das doenças do ombro. Ambos, US e RNM são operador e/ou avaliador dependentes e a RNM é um exame de alto custo. Permanece incerto se um método é superior a outro e se o uso combinado de ambos melhora a acurácia diagnóstica (Swen et al, 1999), bem como se seus custos justificam sua utilização. Também permanece indefinido se estes testes não invasivos fornecem informações adicionais relevantes em relação à artroscopia diagnóstica, a qual compõe parte do tratamento cirúrgico.

Apenas duas revisões sistemáticas com metanálise estudaram testes de diagnóstico por imagem para as doenças do manguito rotador (de Jesus et al, 2009; Dinnes et al, 2003). A estratégia de busca em ambos os estudos restringiu-se à literatura em língua inglesa. Uma revisão (Dinnes et al, 2003) avaliou a acurácia diagnóstica dos testes clínicos, US e RNM (data da estratégia: outubro, 2001), para detectar lesão do manguito rotador, tomando como teste de referência os exames diagnósticos cirúrgicos e os não cirúrgicos. Concluiu-se que a US e a RNM são equivalentes para diagnosticar lesão total do manguito rotador, embora a RNM tenha maior custo e a US seja superior na detecção de lesões parciais do manguito. De Jesus et al (2009) relataram uma metanálise comparando o diagnóstico da US versus RNM para as lesões do manguito rotador, usando a cirurgia como teste de referência. Foram incluídos nesta revisão 65 estudos (data da estratégia: setembro, 2007), entretanto, a avaliação da qualidade metodológica dos estudos incluídos não foi adequada. Concluiu-se que a US é tão precisa quanto a RNM para diagnosticar tanto lesão parcial como total do manguito rotador; também foi constatado que a US é o teste de imagem de menor custo para detectar as lesões do manguito.

2.6. Objetivos

O objetivo primário desta revisão foi comparar a acurácia dos testes diagnósticos de imagem: ressonância nuclear magnética versus ultrassonografia, para detectar lesões do manguito rotador em pacientes com dor no ombro e que possuem indicação de tratamento cirúrgico. Como objetivo secundário, identificamos qual é o melhor teste de imagem para diagnosticar lesões totais do manguito rotador; e qual é o melhor teste de imagem para diagnosticar lesões parciais do manguito rotador.

2.7. Investigação das fontes de heterogeneidade

As possíveis fontes de heterogeneidade foram investigadas por meio da realização de análises de subgrupo de acordo com as características da população, lesão do manguito, teste de referência, desenho do estudo e qualidade metodológica do estudo.

- População do estudo: idosos ou jovens.
- Tipo de lesão do manguito: aguda ou crônica; parcial, total ou extensa; traumática ou degenerativa.
- Tipo de teste de referência: cirurgia aberta (incluindo mini-open) ou artroscopia.
- Desenho do estudo: estudo transversal ou coorte ou caso-controle; e retrospectivo ou prospectivo.
- Qualidade metodológica do estudo: baixo risco de viés ou de alto risco de viés.

2.8. Hipóteses

Esta revisão pretende testar a seguinte hipótese nula:

Não existe diferença entre a acurácia diagnóstica da ressonância nuclear magnética e a ultrassonografia para detectar lesões (total ou parcial) do manguito rotador em pacientes com dor no ombro e que possuem indicação de tratamento cirúrgico.

3. MÉTODO

O método de realização deste projeto baseou-se nas recomendações propostas pela Cochrane Collaboration Screening and Diagnostic Tests Methods Group para desenvolver revisões sistemáticas de estudos de acurácia (http://srdta.cochrane.org/en/index.html).

Este protocolo de pesquisa foi aprovado pelo Comitê de Ética em Pesquisa (CEP) da Universidade Federal de São Paulo / Escola Paulista de Medicina / número 0154/10 em 26 de fevereiro de 2010 (Apêndice 1). O título foi previamente registrado na Cochrane Library em setembro de 2009.

Cabe salientar que esta revisão sistemática foi publicada na *Cochrane Library*, sendo um protocolo publicado em 2011 (<u>Apêndice 2</u>) e uma revisão sistemática em 2013 (<u>Apêndice 3</u>).

3.1. Critérios a serem considerados nos estudos desta revisão

3.1.1. Tipos de estudos incluídos

Foram incluídos todos os estudos de acurácia que compararam ressonância nuclear magnética (RNM) e/ou ultrassonografia (US) com os testes de referência em pacientes com suspeita de lesão parcial ou total do manguito rotador. Apenas foram incluídos os resultados de estudos completos; quando os estudos foram expostos em resumos ou anais de conferência, somente os dados da publicação completa foram relatados.

Foram excluídos estudos com período excessivamente longo (maior que seis meses) entre o teste diagnóstico e o teste de referência, em vista da doença do manguito rotador ser progressiva.

Estudos em todos os idiomas foram incluídos, quando uma tradução completa para o inglês ou português foi obtida. Artigos que não foram traduzidos de maneira integral foram citados em um apêndice, mas não incluídos na revisão.

Nos casos em que o mesmo estudo for publicado em mais de um artigo, foram incluídos apenas os estudos mais atualizados ou completos. No entanto, as referências das outras publicações foram citadas no âmbito do estudo.

3.1.2. Tipos de participantes

Foram incluídos estudos que avaliaram pacientes com dor no ombro e suspeita de lesão parcial ou total do manguito rotador, com indicação de cirurgia. Estudos que abordaram apenas testes de diagnóstico clínico e/ou pacientes com diagnóstico de dor no ombro por outras causas (instabilidade, artrose, artrite reumatóide, capsulite adesiva, tendinite calcária, neoplasias benignas ou malignas, etc) foram excluídos.

3.1.3. Testes de diagnósticos avaliados (teste índice)

Testes de diagnóstico por imagem que comparam US e/ou RNM (incluindo artro-ressonância nuclear magnética – artro-RNM) com o definido teste de referência foram incluídos. Estudos que compararem exclusivamente exames clínicos, radiografias, artrografias, tomografias computadorizadas não foram incluídos.

3.1.4. Doença avaliada

A doença avaliada nesta revisão foi a lesão do manguito rotador (total ou parcial) em pacientes com dor no ombro e que possuem indicação de tratamento cirúrgico.

3.1.5. Teste de referência

Os testes de referência para definir a doença em questão foram a artroscopia ou a cirurgia aberta (incluindo mini-open). Quando um estudo abordou ambos os testes (artroscopia e cirurgia aberta), apenas a artroscopia foi tid como o teste de referência.

3.2. Estratégia de busca para a identificação dos estudos

Buscas eletrônicas

As pesquisas eletrônicas das bases de dados utilizadas foram: MEDLINE (1966 até março de 2011), EMBASE (1988 até fevereiro de 2011), LILACS (1982 até fevereiro de 2011). Não houve restrições com base no idioma ou status da publicação.

Uma estratégia de busca foi desenvolvida conforme as orientações do capítulo sete do Handbook (de Vet et al. 2008), a qual utilizou termos descritores e seus sinônimos das bases de dados MEDLINE (PubMed), EMBASE (OVID WEB), e LILACS (Bireme), como descrito abaixo e no Anexo 1:

- Teste avaliado ou teste de referência (surgery [mh] OR surge* [tw] OR surgical [mh]OR arthroscopy [mh] OR arthroscop* [tw] OR mini?open* [tw] OR ultrasonography [mh] ultrasound [tw] OR sonograp* [tw] OR magnetic resonance imaging [mh] OR MR imaging [tw]);
- Condição clínica (rotator cuff [mh] OR rotator cuff* [tw] OR tendons, para articular [mh] OR musculotendinous cuff* [tw]) AND (shoulder impingement syndrome [mh] OR tear* [tw] OR torn [tw] OR *thickness [tw]);
- População ((child[mh] OR infant[mh]) NOT (adult[mh] OR adolescent[mh])) OR
 Review[pt] OR case reports[pt] OR (animals[mh] NOT humans[mh]).

Outras fontes de busca

Foram consultados livros didáticos, listas de referências de artigos e resenhas para a busca de possíveis estudos de diagnóstico primários e revisões sistemáticas. Também houve buscas nas bases de dados: DARE (Database of Abstracts of Reviews of Effects - www.york.ac.uk/inst/crd/crddatabases.htm#DARE), e HTA (Health Technology Assessments Database - www.york.ac.uk/inst/crd/crddatabases.htm#HTA).

Os autores desta revisão entraram em contato com os membros do Cochrane Bone. Joint and Muscle Trauma Group e Sociedade Britânica de ombro e cotovelo para a investigação de artigos relevantes. A busca por artigos, publicados ou não, envolveu os encontros anuais da Sociedade Britânica de ombro е cotovelo (2001 até fevereiro de 2011 http://www.bess.org.uk/pages/meetings.php) e da Academia Americana de Cirurgiões Ortopédicos (http://www.aaos.org/).

3.3. Coleta e análise dos dados

A análise dos dados foi realizada e revisada por todos os autores desta revisão.

3.3.1. Cálculo do tamanho da amostra

Para realizar o cálculo amostral, utilizou-se uma amostra por conveniência, porque todos os estudos selecionados foram avaliados para a inclusão ou não na revisão sistemática.

3.3.2. Seleção dos estudos

Dois autores da revisão (ML e RB) selecionaram independentemente potenciais estudos elegíveis para a inclusão na revisão. Estudos duplicados foram excluídos e as referências restantes foram analisadas. Estudos que não se enquadraram nos critérios de inclusão foram

descartados. Para os estudos relevantes, foram obtidas cópias integrais. ML e RB avaliaram independentemente os estudos relevantes e determinar a inclusão ou exclusão dos mesmos. Todas as dúvidas ou divergências foram resolvidas por discussão e, quando necessário um terceiro autor (FF) intercedeu para sua resolução.

3.3.3. Extração e manejo dos dados

ML e RB independentemente coletaram os dados disponíveis dos estudos incluídos utilizando um formulário piloto de extração, sem mascaramento dos autores dos estudos ou outras informações de identificação. Um terceiro autor da revisão (FF) foi consultado para a resolução de eventuais divergências. Quando necessário, informações adicionais ou dados relevantes foram requisitados aos autores dos estudos incluídos.

Estudos de diagnóstico com dados insuficientes para a confecção de tabelas 2x2 foram excluídos das análises estatísticas, mas estes resultados foram incluídos na parte narrativa da revisão.

3.3.4. Avaliação da qualidade metodológica dos estudos incluídos

A qualidade metodológica dos estudos incluídos foi avaliada independentemente por ML e RB e discordâncias foram resolvidas por um terceiro revisor (FF). A qualidade metodológica foi avaliada ao mesmo tempo em que a extração dos dados, utilizando uma lista de dados denominada QUADAS (Whiting et al, 2003), adaptada para a revisão.

3.3.5. Síntese dos dados e análise estatística

Os índices de desempenho do diagnóstico foram extraídos ou derivados dos dados presentes em cada estudo primário de cada exame de imagem. Foram confeccionadas tabelas 2x2 de contingência dos casos verdadeiros positivos, falsos positivos, falsos negativos e verdadeiros negativos. Os autores desta revisão calcularam a sensibilidade e especificidade com 95% de intervalo de confiança para cada teste de imagem, em cada estudo. Os autores também investigaram graficamente, por meio do Gráfico Floresta (Forest Plot), a heterogeneidade estimada entre a sensibilidade e especificidade. Para uma análise descritiva, os resultados das taxas dos verdadeiros positivos (sensibilidade) contra as taxas dos falsos positivos (1 – especificidade) foram analisados graficamente utilizando o sumário da curva ROC (Receiver Operating Characteristic).

Para as metanálises de pares de sensibilidade e especificidade e para formação dos sumários da curva ROC (SROC) utilizou-se o método de hierarquização dos SROC (HSROC) (Rutter et al, 2001). O método HSROC foi fundamentado em uma abordagem de efeitos aleatórios e levará em consideração o grau de heterogeneidade entre os estudos. Foram formalmente avaliadas como potenciais fontes de heterogeneidade, a significância das diferenças entre os testes e a significância das diferenças entre os subgrupos pré-definidos.

3.4. Atualização e aprimoamento da revisão

As atualizações desta revisão sistemática serão realizadas anualmente. A versão atualizada poderá ser encontrada na Cochrane Library. Mesmo se não houver nenhum estudo clínico que se enquadre nos critérios de inclusão nessa atualização anual ou nenhuma correção maior for indicada, a data da última busca dos estudos de diagnóstico será colocada na seção de estratégia de busca desta revisão.

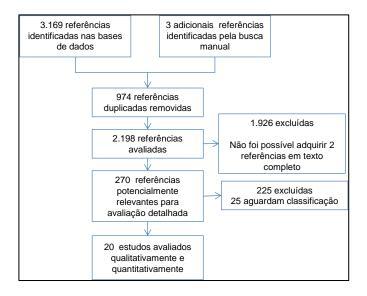
4. RESULTADOS

4.1. Descrição dos estudos – análise qualitativa

4.1.1. Resultado da estratégia de busca

A estratégia de busca identificou 3.169 referências e a busca manual identificou mais três registros adicionais (Figura 1). Destes, 2.902 foram excluídos pela triagem inicial dos títulos e resumos. Havia 974 duplicatas e 1.926 foram consideradas não relevantes ou não preencheram os critérios de inclusão. Não fomos capazes de obter artigos completos de dois estudos porque não estavam disponíveis em bibliotecas ou fornecedores.

Figura 1: Algoritmo da estratégia de busca



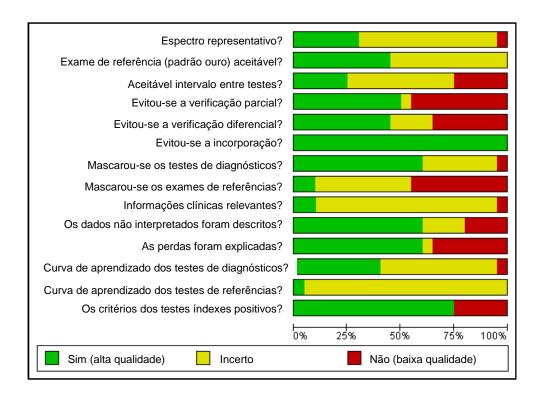
Dos 270 estudos potencialmente elegíveis que ainda restavam e para os quais foram obtidos os textos completos (192 foram descritos em inglês e 78 em outro idioma que não o inglês), vinte preencheram os critérios e foram incluídos na revisão. Três dos estudos incluídos tiveram dados adicionais publicados. Duzentos e dezoito estudos não preencheram os nossos critérios de inclusão, por isso foram excluídos e quatro estudos avaliaram a mesma população ou um subconjunto de um estudo já incluído. Ainda estamos aguardando a tradução de 25 artigos em língua não inglesa, potencialmente relevantes com base em seu título e resumo. Os dados destes estudos serão adicionados em futuras atualizações desta revisão se os estudos forem considerados elegíveis para inclusão. No total incluímos 20 estudos (De Candia et al. 2002; Della Sala et al. 1996; Gagey et al. 1993; Iannotti et al. 2005; Kang et al. 2009; Lambert et al. 2009; Martin-Hervas et al. 2001; Milosavljevic et al. 2005; Misamore et al. 1991; Mohtadi et al. 2004; Nicoletti et al. 1994; Sipola et al. 2010; Stetson et al. 2005; Swen et al. 1998; Swen et al.

1999; Taboury et al, 1992; Teefey et al, 2004; Venu et al, 2002; Wallny et al, 2001; Yen et al, 2004).

4.1.2. Qualidade metodológica dos estudos incluídos

A qualidade metodológica dos 20 estudos incluídos foi considerada baixa ou incerta para a maioria das categorias e está resumido na Figura 2.

Figura 2. Gráfico da qualidade metodológica dos estudos incluídos



O espectro dos participantes (Item1) foi considerado representativo em apenas seis (30%) de 20 estudos. No item 1, para ser julgado representativo, os estudos deveriam: a) ser prospectivos com recrutamento consecutivo, b) o local dos exames deveria ser em serviços secundários ou terciários de saúde e; c) os pacientes deveriam apresentar-se com dor no ombro causada por uma suspeita de ruptura do manguito rotador. Apenas metade dos estudos incluiu um padrão de referência adequado (item 2) e evitou verificação parcial (item 4). A maioria (mais de 50%) dos estudos descreveu de maneira inadequada os seguintes itens da escala de QUADAS: período entre o padrão ouro e os testes diagnósticos (item 3), a verificação diferencial (item 5), o mascaramento dos testes de referência (item8), as informações clínicas relevantes (item 9) e curva de aprendizado e treinamento dos executores dos exames de referência (itens 12 e 13). Os demais itens QUADAS foram bem descritos em 50% a 75% dos estudos incluídos: o mascaramento dos resultados dos testes diagnósticos

(item 7), os resultados dos dados não-interpretáveis (item 10), a descrição adequada das perdas (artigo 11) e critérios para a positividade dos testes diagnósticos (item14). Como antecipamos em nosso protocolo, a resposta para a "incorporação" (ponto 6) foi 'Sim' (sem viés) para todos os estudos incluídos.

4.2. Análise quantitativa

Nossas metanálises foram baseadas em comparações indiretas, porque metanálises de estudos que compararam diretamente os testes não eram possíveis; encontramos apenas seis estudos comparativos. Nenhum estudo comparou diretamente artro-RNM e RNM, ou todas as três modalidades dos testes de diagnósticos. O resumo das sensibilidades e especificidades dos testes diagnósticos é apresentado na Tabela 1. Para artro-RNM, metanálise foi realizada apenas para os estudos que avaliam lesão completa do manguito rotador, devido aos poucos estudos e do grau de heterogeneidade observado nos sumários dos gráficos ROC para os estudos que avaliam lesões parciais do manguito rotador.

<u>Tabela 1</u>. Comparação de RNM, US e artro-RNM para o diagnóstico de quaisquer lesões do manguito rotador

Teste	Estudos	Ombros	Casos	Sensibilidade (95% CI)	Especificidade (95% CI)	LR+	LR-	Teste ¹		
Qualquer lesão do manguito rotador										
RNM	6	347	263	98 (92, 99)	79 (68, 87)	5 (2, 10)	0.03 (0.01, 0.11)	D 0.40		
US	13	854	626	91 (83, 95)	85 (74, 92)	6 (3, 12)	0.11 (0.05, 0.22)	P = 0.13		
Lesão total	do manguit	to rotador								
RNM	7	368	193	94 (85, 98)	93 (83, 97)	13 (6, 29)	0.06 (0.02, 0.16)			
Artro-RNM	3	183	107	94 (80, 98)	92 (83, 97)	12 (5, 30)	0.06 (0.02, 0.23)	P = 0.7		
US	10	729	386	92 (82, 96)	93 (81, 97)	12 (5, 34)	0.09 (0.04, 0.20)			
Lesão parcial do manguito rotador										
RNM	6	347	83	74 (59, 85)	93 (84, 97)	10 (4, 26)	0.28 (0.17, 0.48)	D 100		
US	8	660	121	52 (33, 70)	93 (85, 97)	8 (3, 19)	0.52 (0.33, 0.80)	P = 1.00		

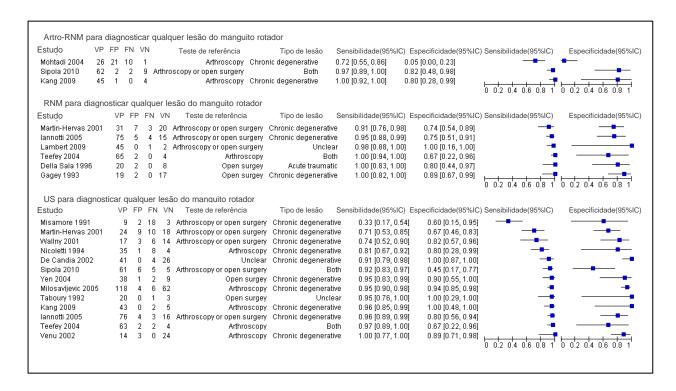
¹Probabilidade teste da razão para a evidência de uma diferença de sensibilidade e/ou especificidade entre os testes LR + = razão de verossimilhança positiva; LR- = razão de verossimilhança negativa.

Dois estudos (<u>lannotti et al, 2005</u>; <u>Milosavljevic et al, 2005</u>) incluíram ambos ombros (bilateral) de um e cinco pacientes, respectivamente. Os demais estudos relataram o mesmo número de pacientes e ombros, com a exceção de <u>Milosavljevic et al (2005)</u>, no qual não havia essa informação.

4.2.1. Diagnóstico de quaisquer lesões do manguito rotador

A <u>Figura 3</u> mostra os gráficos-floresta (forest plots) das estimativas de sensibilidade e especificidade para RNM, US e artro-RNM, para os 17 estudos que avaliaram quaisquer lesões do manguito rotador.

<u>Figura 3</u>. Acurácia da Artro-RNM, RNM e US para o diagnóstico de qualquer lesão do manguito rotador



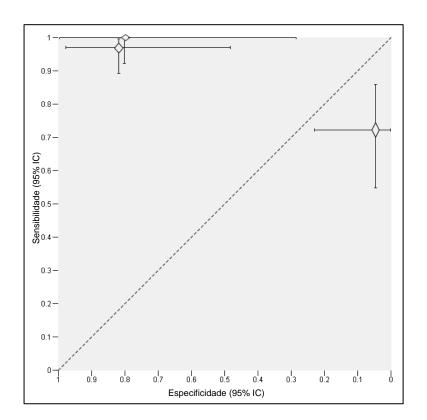
Seis estudos, com um total de 347 ombros, avaliaram a acurácia diagnóstica da RNM. A mediana do tamanho do estudo foi 55 (intervalo de 30-99) e a mediana da prevalência de qualquer ruptura do manguito rotador foi de 73% (intervalo de 50% a 96%). A sensibilidade da RNM variou de 91% a 100%, e a especificidade de 67% a 100%. As estimativas de síntese para a sensibilidade e especificidade (95% IC) da RNM foram de 98% (92% a 99%) e 79% (68% a 87%), respectivamente. As razões de verossimilhança positiva e negativa (95% IC) foram de 5 (2 a 10) e 0,03 (0,01-0,11), respectivamente.

Treze estudos avaliaram a precisão do exame de US para detectar quaisquer lesões do manguito rotador. Os estudos incluíram um total de 854 ombros, com uma mediana do tamanho do estudo de 50 (intervalo 24-190). A prevalência de quaisquer lesões do manguito rotador nos estudos de US foi de 80% (intervalo de 34% a 92%), a sensibilidade variou de 33% a 100% e a especificidade de 45% a 100%. Os sumários de sensibilidade e especificidade (95% IC) do exame de US foram 91% (83% a 95%) e 85% (74% para 92%), respectivamente.

As razões de verossimilhança positiva e negativa (95% IC) foram de 6 (3 a 12) e 0,11 (0,05 a 0,22), respectivamente.

Três estudos, com um total de 183 ombros de 183 participantes, avaliaram a precisão da artro-RNM para detecção de quaisquer lesões do manguito rotador. A mediana do tamanho do estudo foi 58 (intervalo de 50 a 75) e a mediana da prevalência foi de 85% (intervalo de 62% a 90%). A sensibilidade da artro-RNM variou de 72% a 100% e a especificidade de 5% a 80%. Não foi realizada metanálise, mas foi possível estudar as estimativas de especificidade e de sensibilidade (Figura 4).

<u>Figura 4</u>. Estimativas do estudo de sensibilidade e especificidade, com intervalos de confiança de 95%, traçadas no espaço ROC da artro-RNM para a detecção de quaisquer lesões do manguito rotador

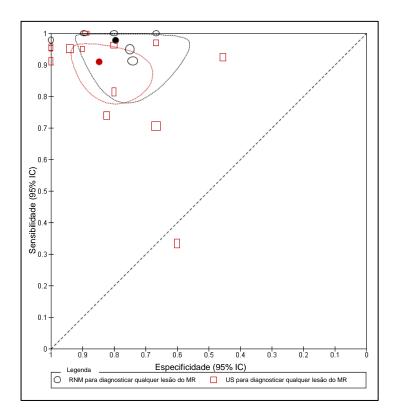


Comparação entre RNM e US para diagnosticar quaisquer lesões do manguito rotador

Usando os 11 estudos que avaliaram a acurácia d a RNM ou US para diagnosticar quaisquer lesões do manguito rotador, nenhum teste apresentou superioridade em termos de sensibilidade e/ou especificidade. Embora a sensibilidade da RNM fosse 7% mais elevada do que a do exame de US e a especificidade de RNM tenha sido 6% mais baixa do que a do exame de US (Figura 5), não há evidência para sugerir uma diferença entre os dois testes (p =

0,13). Na análise restrita aos três estudos (231 ombros) que realizaram comparações da RNM e US em mesmos pacientes, dois estudos relataram maior sensibilidade e especificidade para a RNM comparada com US, enquanto um estudo relatou o inverso. Para comparações entre artro-RNM e US, havia apenas dois estudos (127 ombros). Ambos os estudos relataram maior sensibilidade para a artro-RNM em comparação com o exame de US, mas as estimativas de especificidade foram conflitantes.

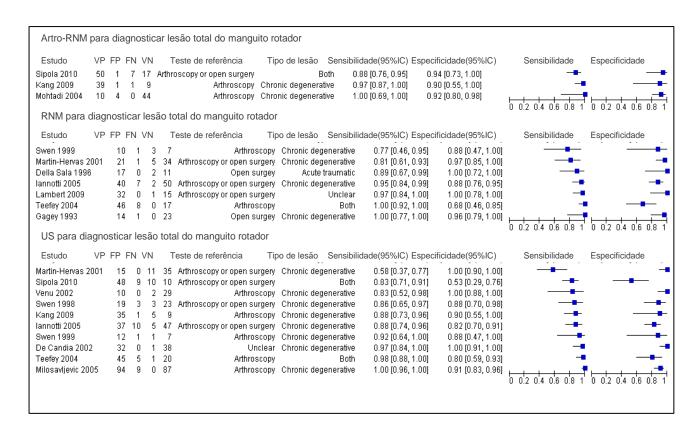
<u>Figura 5</u>. Estimativas do estudo de sensibilidade e especificidade e pontos de resumo, com as regiões de confiança de 95%, traçadas no espaço ROC da RNM e US para diagnosticar quaisquer lesões do manguito rotador



4.2.2. Diagnóstico de lesões completas do manguito rotador

As estimativas da sensibilidade e especificidade para os 14 estudos que avaliaram a acurácia da RNM, US e artro-RNM para o diagnóstico de lesões totais do manguito rotador são demonstradas na Figura 6.

<u>Figura_6</u>. Acurácia dos exames de artro-RNM, RNM e US para o diagnóstico de lesões completas do manguito rotador



Sete estudos, com um total de 368 ombros, avaliaram a acurácia diagnóstica da RNM. A mediana do tamanho do estudo foi 48 (intervalo de 21-99) e a mediana da prevalência de lesões totais do manguito rotador foi de 62% (intervalo de 37% a 69%). A sensibilidade variou de 77% a 100% e a especificidade de 68% a 100%. Os sumários dos valores de sensibilidade e especificidade (95% IC) do diagnóstico da RNM foram de 94% (85% a 98%) e 93% (83% a 97%), respectivamente. As razões de verossimilhança positiva e negativa (95% IC) foram de 13 (6, 29) e 0,06 (0,02-0,16), respectivamente.

Dez estudos (729 ombros) avaliaram a acurácia do exame de US para diagnosticar lesão completa do manguito rotador. A mediana do tamanho do estudo foi 66 (intervalo 21-190) e a mediana da prevalência foi de 48% (intervalo de 29% a 80%), com variação de sensibilidade de 58% a 100%, e especificidade de 53% para 100%. Os sumários de sensibilidade e especificidade do exame de US foram de 92% (82% a 96%) e 93% (81% a 97%), respectivamente. As razões de verossimilhança positiva e negativa (IC 95%) foram de 12 (5 a 34) e 0,09 (0,04-0,20), respectivamente.

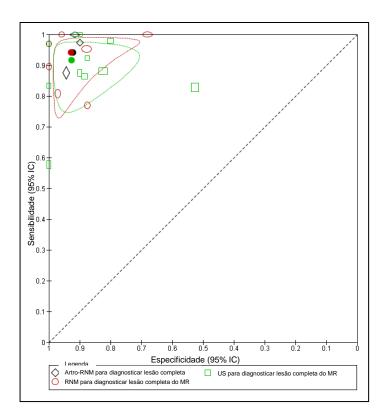
Três estudos (da mesma forma que os estudos que avaliaram a quaisquer lesões do manguito rotador) avaliaram a acurácia da artro-RNM para diagnosticar lesões completas do manguito

rotador, com sensibilidade que variou de 88% a 100% e especificidade de 90% a 94%. A mediana da prevalência foi de 76% (intervalo de 17% a 80%) e os sumários da sensibilidade e especificidade da artro-RNM foram de 94% (80% a 98%) e 92% (83% a 97%), respectivamente. As razões de verossimilhança positiva e negativa (IC 95%) foram de 12 (5 a 30) e 0,06 (0,02-0,23), respectivamente.

Comparações dos exames de RNM, artro-RNM e US para diagnosticar lesões completas do manguito rotador

Com base nos 14 estudos que avaliaram a acurácia dos exames de RNM, artro-RNM e US para diagnosticar lesões completas do manguito rotador, os sumários de sensibilidade e especificidades foram muito semelhantes (Figura 7) e não apresentaram nenhuma evidência para sugerir diferenças de sensibilidade e/ou especificidade (P = 0,7). Quatro estudos (252 ombros) compararam diretamente RNM e US, sem nenhuma consistência entre os estudos a respeito de qual teste foi superior tanto em termos de sensibilidade quanto em especificidade. Dois estudos (127 ombros) compararam diretamente artro-RNM e US, ambos os estudos relataram maior sensibilidade para artro-RNM quando comparado ao exame de US.

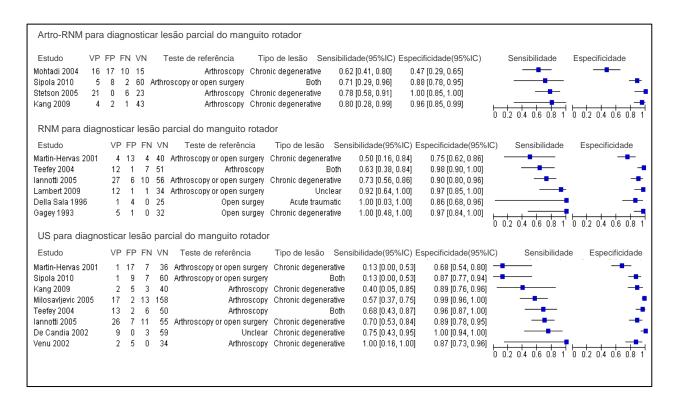
<u>Figura 7</u>. Estimativas do estudo de sensibilidade e especificidade e pontos de resumo, com as regiões de confiança de 95%, traçadas no espaço ROC da Artro-RNM, RNM e US para diagnostico de lesões completas do manguito rotador



4.2.3. Diagnóstico de lesões parciais do manguito rotador

A <u>Figura 8</u> mostra as estimativas de sensibilidade e especificidade para os 13 estudos que avaliaram os exames de artro-RNM, RNM e US para o diagnóstico de lesões parciais do manguito rotador.

<u>Figura 8</u>. Acurácia dos exames de artro-RNM, RNM e US para o diagnóstico de lesões parciais do manguito rotador



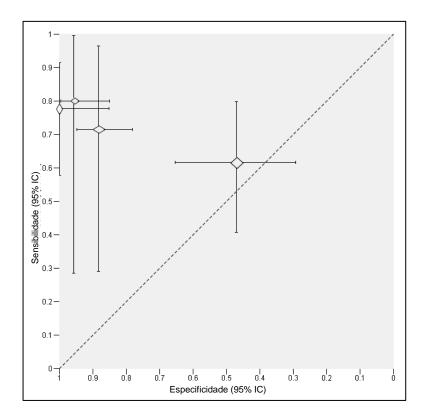
Todos os seis estudos que avaliaram a acurácia da RNM para o diagnóstico de quaisquer lesões do manguito rotador também avaliaram sua acurácia para as lesões parciais. A mediana da prevalência para as lesões parciais foi de 20% (intervalo de 3% a 37%), a sensibilidade variou de 50% a 100% e a especificidade de 75% a 98%. Os sumários da sensibilidade e especificidade (95% IC) do exame de RNM foram de 74% (59% a 85%) e 93% (84% a 97%), respectivamente. As razões de verossimilhança positiva e negativa (IC 95%) foram de 10 (4 a 26) e 0,28 (0,17-0,48), respectivamente.

Oito estudos (660 ombros) avaliaram a acurácia do exame de US para o diagnóstico de lesões parciais, com sensibilidade que variou entre 13% e 100% e especificidade entre 68% e 100%. A mediana da prevalência foi de 14% (intervalo de 5% a 37%). Os sumários de sensibilidade e especificidade (95% IC) do exame de US foram 52% (33% a 70%) e 93% (85% a 97%),

respectivamente. As razões de verossimilhança positiva e negativa (IC 95%) foram 8 (3 a 19) e 0,52 (0,33 e 0,80), respectivamente.

Quatro estudos, somando um total de 233 ombros de 233 pacientes, avaliaram a acurácia do exame de artro-RNM para diagnóstico de lesões parciais, com sensibilidade que variou entre de 62% e 80% e especificidade entre 47% e 100%. A mediana da prevalência foi de 27% (intervalo de 9% para 54%). Não foi realizada metanálise, mas as estimativas de especificidade são apresentadas no espaço ROC, com intervalos de confiança de 95% na Figura 9.

<u>Figura 9</u>. Estimativas do estudo de sensibilidade e especificidade, com intervalos de confiança de 95%, traçadas no espaço ROC da artro-RNM para o diagnóstico de lesões parciais do manguito rotador

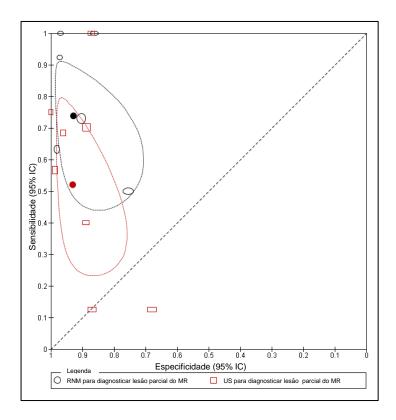


Comparações dos exames de RNM, artro-RNM e US para diagnosticar lesões parciais do manguito rotador

A acurácia diagnóstica da RNM e US para o diagnóstico de lesões parciais foi avaliada em 11 estudos. Não havia nenhuma evidência para sugerir diferenças na sensibilidade e/ou especificidade (P = 1,0). As estimativas de estudos individuais de sensibilidade e especificidade, com pontos de síntese e as regiões de confiança de 95%, para cada ensaio são apresentados no espaço ROC (Figura 10). As sensibilidades dos exames de RNM e US foram

geralmente inferiores para detecção de rupturas de espessura parcial do que para a detecção de quaisquer lesões do manguito rotador e lesões completas. A sensibilidade (95% IC) do exame de US para o diagnóstico de lesões parciais foi de apenas 52% (33% a 70%).

<u>Figura_10</u>. Estimativas do estudo de sensibilidade e especificidade e pontos de resumo, com as regiões de confiança de 95%, traçadas no espaço ROC da Artro-RNM, RNM e US para diagnóstico de lesões parciais do manguito rotador



4.2.4. Diagnóstico de quaisquer lesões do subescapular

Apenas um estudo, Mohtadi et al, 2004, avaliou a acurácia do exame de artro-RNM para o diagnóstico de lesões do tendão do subscapular. O estudo incluiu 58 ombros de 58 pacientes. Os autores descreveram uma prevalência de 33% das lesões do subscapular. A sensibilidade e especificidade (95% IC) do exame de artro-RNM foram 79% (54% a 94%) e 72% (55% a 85%), respectivamente.

4.3. Análises de sensibilidade

Havia poucos estudos de RNM e artro-RNM, o que impossibilitou realizar análises de sensibilidade para estes testes. Realizamos análises de sensibilidade para os estudos que avaliaram os exames de US para cada uma das condições previstas. Pudemos investigar o

impacto de dois (resultados de teste padrão de referência aceitável e teste índice mascarado) dos cinco itens de qualidade que tínhamos especificado, porque poucos estudos marcaram "sim" nos outros três itens (espectro representante, atraso aceitável entre os testes, e os resultados dos testes de referência mascarados). Havia pequenas diferenças em termos de sensibilidade e/ou especificidade. Observou-se a maior diferença entre a sensibilidade de resumo dos exames de US para o diagnóstico de lesões completas (52% (95% IC: 33% a 70%)) e o sumário de sensibilidade (62% (45% a 77%)) com base em apenas estudos em que o nível de referência foi aceitável. No entanto, os intervalos de confiança foram comparáveis e as especificidades foram semelhantes. A exclusão de estudos que não satisfizeram os critérios não afetou nossos achados.

5. DISCUSSÃO

5.1. Resumo dos principais resultados

Esta revisão teve como objetivo avaliar as evidências para a acurácia dos exames de RNM, artro-RNM e US para diagnosticar lesões do manguito rotador em pacientes com dor no ombro. Estes exames de imagem geralmente são realizados para caracterizar as lesões do manguito rotador, a fim de planejar uma cirurgia. Foram incluídos apenas estudos prospectivos que avaliaram a acurácia de pelo menos um dos testes. Foram identificados 20 estudos (1147 ombros), dos quais seis avaliaram a acurácia de dois dos testes, com comparações pareadas.

Não encontramos evidências que sugerem diferenças nas sensibilidades e especificidades dos exames de diagnóstico de RNM, artro-RNM e US para o diagnóstico de lesões completas ou parciais do manguito rotador em pacientes com dor no ombro. As estimativas foram muito semelhantes e os testes demonstraram boa capacidade discriminatória para diagnosticar as lesões do manguito rotador. RNM e US apresentaram menor sensibilidade para diagnosticar as lesões parciais quando comparadas com as lesões completas ou quaisquer lesões, o diagnóstico com US apresenta sensibilidade de apenas 52% (95% IC: 33% a 70%); isso indica que o exame com US podem ser apenas marginalmente melhor do que a possibilidade de excluir uma lesão parcial. As especificidades dos três testes foram, em geral, adequadas; exceto para detecção de quaisquer lesões do manguito rotador. As estimativas de sensibilidade e especificidade para quaisquer lesões do manguito rotador sugerem que, em uma população de 100 pacientes com dor no ombro, se a prevalência foi de 80%, a investigação com RNM pode não diagnosticar dois casos (2/80, 3%), enquanto que a investigação com US pode não diagnosticar sete casos (7/80, 9%).

Por outro lado, entre os pacientes sem uma ruptura do manguito rotador (20 em 100), quatro pacientes avaliados usando a RNM podem ter uma ruptura do manguito rotador erroneamente diagnosticada (4/20, 20%) e podem passar por uma cirurgia desnecessária. Um número semelhante de indivíduos (3/20, 15%) também pode ser tratado desnecessariamente, se foi utilizado o exame de US. Nossos resultados foram baseados em uma alta prevalência de pacientes com lesões do manguito rotador e estes resultados de uma população altamente selecionada não podem ser generalizados para outros contextos, tais como cuidados de saúde primária, onde a prevalência de lesões do manguito rotador é menor.

5.2. Qualidade da evidência

Esta revisão foi planejada e conduzida seguindo critérios e métodos definidos em um protocolo previmente publicado (Apêndice 2). Os resultados foram baseados em uma estratégia de busca abrangente e sensível da literatura e teve por objetivo identificar todos os estudos publicados. Usamos termos de pesquisa abrangentes, vários bancos de dados eletrônicos, e não utilizamos filtros de pesquisa para termos de diagnóstico, uma vez que eles têm utilidade limitada (de Vet 2008). Outros pontos fortes desta revisão foram a avaliação qualitativa dos estudos e a síntese dos dados metodológicos; em ambos foram utilizados resumos meta-analítico baseados em métodos recomendados. Para aumentar a aplicabilidade e a confiabilidade das conclusões, foram incluídos apenas estudos prospectivos que investigaram pacientes com dor no ombro devido a suspeita de lesão do manguito rotador. Foram excluídos estudos retrospectivos por causa do seu potencial para o alto risco de espectro e verificação (Bossuyt 2003; Van der Schouw 1995).

Entretanto, a revisão tem algumas limitações. Nossos resultados foram baseados em estudos com baixo poder analítico e estudos com descrição inadequada da estrutura do desenho. A maioria dos itens de qualidade QUADAS foi considerada incerta. Por exemplo, apenas 25% dos estudos incluídos relataram o intervalo de tempo entre os exames de teste e o padrão de referência. Para algumas análises, observou-se uma considerável heterogeneidade na sensibilidade e/ou especificidade que pode ser devida a vários fatores, incluindo a variação nos critérios de positividade do teste (testes de índice e padrão de referência), detalhes técnicos dos testes, a variação da população e a experiência dos operadores dos testes.

Outra limitação importante desta revisão se dá por conta da restrição de recursos. Vinte e cinco estudos potencialmente elegíveis, publicados em idiomas que não o inglês, permanecem à espera de tradução. Estes estudos abordaram mais de 2900 participantes, um número expressivo e que poderia fornecer dados fundamentais para análises. Estes estudos serão considerados para inclusão em uma futura atualização da revisão.

5.3. Comparações com outras revisões existentes

Foram identificadas seis revisões sistemáticas de estudos de diagnóstico que avaliaram os exames de imagem para as lesões do manguito rotador (<u>de Jesus et al, 2009</u>; <u>Dinnes et al, 2003</u>; <u>Kelly et al, 2009</u>; <u>Ottenheijm et al, 2010</u>; <u>Shahabpour et al, 2008</u>; <u>Smith et al, 2012</u>). Apenas nossa revisão limitou os critérios de inclusão para estudos prospectivos.

As revisões anteriores relataram resultados semelhantes. De Jesus et al (2009) compararam o exame de US com a RNM para o diagnóstico de lesões do manguito rotador, usando cirurgia como padrão de referência. Os autores incluíram 65 estudos (data da estratégia de busca foi setembro de 2007) e concluíram que o exame de US é tão preciso quanto o exame de RNM para diagnosticar ambas as lesões do manguito rotador (completa e parcial). Dinnes et al (2003) avaliaram a acurácia de testes clínicos, US e RNM para diagnóstico de lesões do manguito rotador (data da estratégia de busca foi outubro de 2001), como padrão de referência eles usaram testes cirúrgicos e não-cirúrgicos (resultados também relatado em Kelly et al, 2009). Ambos Dinnes et al (2003) e Shahabpour et al (2008) também concluíram que o exame de US e a RNM foram equivalentes para o diagnóstico de lesões completas do manguito rotador, mas Dinnes et al (2003), concluíram que a RM é melhor no diagnóstico de lesões parciais do manguito rotador. Shahabpour et al (2008) concluíram que os exames de artro-RNM e US são mais precisos para o diagnóstico de lesões parciais do manguito rotador quando comparados com a RNM. Enquanto os nossos resultados sugerem que a RNM pode ser mais sensível do que o exame de US, a diferença não foi estatisticamente significativa.

Ottenheijm et al (2010) avaliaram a acurácia do exame de US para diagnosticar doenças do espaço subacromial em pacientes de setores primários e secundários de saúde (data da estratégia de busca foi entre 2001 e junho de 2010). Eles incluíram 23 estudos e as metanálises de sensibilidade e especificidade foram semelhantes aos nossos resultados para o diagnóstico de lesões completas do manguito rotador (95% versus 92% e 96% versus 93%, respectivamente: 95% IC). No entanto, para as lesões parciais do manguito rotador, os autores relataram uma sensibilidade combinada muito mais elevada, de 72% em comparação com a nossa, de 52% (95% IC: 33% a 70%). Smith et al (2012) avaliaram a acurácia diagnóstica da RNM e identificaram 44 estudos (retrospectivos e prospectivos) publicados até maio de 2011. A sensibilidade combinada foi de 91% (95% IC: 86% a 94%) e a especificidade agrupada foi de 97% (95% IC: 96% a 98%).

Os resultados são em geral consistentes entre as diferentes revisões sistemáticas, embora houvesse diferenças de critérios de inclusão e métodos de análise. Apesar de a nossa revisão ter a estratégia de busca mais atualizada, incluímos um número muito menor de estudos (20 estudos) do que as outras revisões, por conta de termos restringido nossas análises apenas para estudos prospectivos, como forma de reduzir o risco de viéses de espectro e de verificação.

5.4. Aplicabilidade dos resultados

A aplicabilidade dos nossos resultados é limitada, porque apenas 25% dos estudos incluídos relatou um espectro suficientemente representativo de pacientes. Além disso, a verificação parcial foi evitada em 50% dos estudos.

Os exames de RNM, artro-RNM e US apresentam acurácia semelhante para o diagnóstico de lesões completas do manguito rotador. A sensibilidade de ambos os exames RNM e US para o diagnóstico de lesões parciais do manguito rotador é muito inferior que a sensibilidade para o diagnóstico de quaisquer lesões ou lesões copmpletas. Embora a diferença de sensibilidade entre RNM e US para o diagnóstico de lesões parciais não tenha sido estatisticamente significativa. As especificidades dos três testes foram, em geral, altas.

Em muitos países, o exame de US é mais rápido para ser executado, barato e mais facilmente disponível nos serviços secundários e terciários de saúde. Apesar dos exames de RNM e artro-RNM serem semelhantes para o diagnóstico de lesões completas do manguito rotador, a escolha do teste pode depender do custo e disponibilidade.

6. CONCLUSÃO

6.1. Implicações para a prática

O desempenho diagnóstico dos exames de RNM e US dependem da extensão da lesão do manguito rotador (ou seja parcial ou total/completa). Nossos resultados sugerem que a RNM, US e artro-RNM possuem boa acurácia diagnóstica e quaisquer destes testes podem igualmente serem usados para o diagnóstico de lesões completas do manguito rotador. Os exames de RNM e US também possuem boa sensibilidade para o diagnóstico de quaisquer lesões do manguito rotador, mas pouca sensibilidade para o diagnóstico de lesões parciais. A validade e generalização de nossos resultados são limitadas porque foram baseados em estudos pequenos e heterogêneos, não comparativos e com falhas metodológicas.

6.2. Implicações para a pesquisa

Há uma falta de estudos de coorte prospectivos de boa qualidade que comparam diretamente a acurácia dos exames de RNM, artro-RNM e US para pacientes com suspeita de lesões do manguito rotador. Consequentemente, são necessários mais estudos para avaliar a acurácia comparativa destes exames de imagem em tais circunstâncias.

Estudos futuros devem utilizar um desenho tipo coorte prospectivo e consecutivo, com mascaramento dos avaliadores dos exames e limitar a quantidade de tempo entre o teste índice e os testes de referência, porque há evidências que lesões do manguito rotador podem progredir ao longo tempo. Nós sugerimos a artroscopia para ser usada como o teste padrão de referência, pois ela é mais precisa para avaliar o lado de articular e bursal do manguito rotador. Os resultados do teste de índice e do padrão de referência devem ser interpretados por operadores experientes.

7. ANEXO

7.1. Anexo1: Estratégia de busca

MEDLINE (PubMed)

((Ultrasonography [mh] OR ultrasound [tw] OR ultrasonograph* [tw] OR sonograp*[tw] OR us [sh]) OR (Magnetic Resonance Imaging [mh] OR MR imag*[tw] OR magnetic resonance imag* [tw] OR MRI [tw])) AND (Rotator Cuff [mh] OR rotator cuff* [tw] OR musculotendinous cuff* [tw] OR subscapularis [tw] OR supraspinatus [tw] OR infraspinatus OR teres minor [tw]) AND (Rupture [mh:noexp] OR tear* [tw] OR torn [tw] OR thickness [tw] OR lesion* [tw] OR ruptur* [tw] OR injur* [tw])

Total de referências = 1551

EMBASE (OVID WEB)

- 1 'echography'/de AND [embase]/lim (124208)
- 2 ultrasound:ab,ti OR ultrasonograph*:ab,ti OR sonograp*:ab,ti AND [embase]/lim (192495)
- 3 #1 OR #2 (242499)
- 4 'nuclear magnetic resonance imaging'/de AND [embase]/lim (277184)
- 5 (('magnetic resonance' OR mr) NEAR/3 imag*):ab,ti AND [embase]/lim (130882)
- 6 mri:ab,ti AND [embase]/lim (108797)
- 7 #4 OR #5 OR #6 (311974)
- 8 'rotator cuff injury'/de OR 'rotator cuff rupture'/de AND [embase]/lim (3561)
- 9 'rotator cuff' /de AND [embase] /lim (1850)
- 10 'rotator cuff':ab,tiOR 'musculotendinous cuff':ab,tiOR subscapularis:ab,tiOR supraspinatus:ab,tiOR infraspinatus:ab,tiOR 'teres

minor':ab,ti AND [embase]/lim (5679)

- 11 #9 OR #10 (6120)
- 12 'rupture'/de AND [embase]/lim (3798)
- 13 tear*:ab,ti OR torn:ab,ti OR thickness:ab,ti OR lesion*:ab,ti OR ruptur*:ab,ti OR injur*:ab,ti AND [embase]/lim (1001852)

14 #12 OR #13 (1002130)

15 #11 AND #14 (3615)

16 #8 OR #15 (4908)

17 #3 OR #7 (526691)

18 #16 AND #17 (1572)

LILACS

(Mh Ultrasonography OR Tw ultrasound OR Tw ultrasonograph\$ OR Tw Sonograp\$) OR (Mh Magnetic Resonance Imaging OR (Tw magnetic AND Tw resonance AND Tw imag\$) OR Tw MRI) [Words] and Mh Rotator Cuff OR (Tw rotator AND Tw cuff) OR (Tw musculotendinous AND Tw cuff) OR Tw subscapularis OR Tw supraspinatus OR Tw infraspinatus OR (Tw teres AND Tw minor) [Words] andMh Rupture OR Tw tear\$ OR Tw torn OR Tw thickness OR Tw lesion\$ OR Tw rupture\$ OR Tw injur\$ [Words]

Total de referências = 30

8. REFERÊNCIAS

8.1. Referências dos estudos incluídos nesta revisão

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lannotti_2005

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Abstract

Background: Shoulder pain is a very common symptom. Disorders of the rotator cuff tendons due to wear or tear are among the most common causes of shoulder pain and disability. Magnetic resonance imaging (MRI), magnetic resonance arthrography (MRA) and ultrasound (US) are increasingly being used to assess the presence and size of rotator cuff tears to assist in planning surgical treatment. It is not known whether one imaging method is superior to any of the others. Objectives: To compare the diagnostic test accuracy of MRI, MRA and US for detecting any rotator cuff tears (i.e. partial or full thickness) in people with suspected rotator cuff tears for whom surgery is being considered. Search methods: We searched the Cochrane Register of Diagnostic Test Accuracy Studies, MEDLINE, EMBASE, and LILACS from inception to February 2011. We also searched trial registers, conference proceedings and reference lists of articles to identify additional studies. No language or publication restrictions were applied. Selection criteria: We included all prospective diagnostic accuracy studies that assessed MRI, MRA or US against arthroscopy or open surgery as the reference standard, in people suspected of having a partial or full thickness rotator cuff tear. We excluded studies that selected a healthy control group, or participants who had been previously diagnosed with other specific causes of shoulder pain such as osteoarthritis or rheumatoid arthritis. Studies with an excessively long period (a year or longer) between the index and reference tests were also excluded. Data collection and analysis: Two review authors independently extracted data on study characteristics and results of included studies, and performed quality assessment according to QUADAS criteria. Our unit of analysis was the shoulder. For each test, estimates of sensitivity and specificity from each study were plotted in ROC space and forest plots were constructed for visual examination of variation in test accuracy. Meta-analyses were performed using the bivariate model to produce summary estimates of sensitivity and specificity. We were unable to formally investigate potential sources of heterogeneity because of the small number of studies. Main results: We included 20 studies of peoplewith suspected rotator cuff tears (1147 shoulders), of which six evaluatedMRI and US (252 shoulders), or MRA and US (127 shoulders) in the same people. Many studies had design flaws, with the potential for bias, thus limiting the reliability of their findings. Overall, themethodological quality of the studies was judged to be low or unclear. For each test, we observed considerable heterogeneity in study results, especially between studies that evaluated US for the detection of full thickness tears and studies that evaluatedMRA for the detection of partial thickness tears. The criteria for a positive diagnostic test (index tests and reference standard) varied between studies. Meta-analyses were not possible for studies that assessed MRA for detection of any rotator cuff tears or partial thickness tears. We found no statistically significant differences in sensitivity or specificity between MRI

and US for detecting any rotator cuff tears (P = 0.13), or for detecting partial thickness tears (P = 1.0). Similarly, for the comparison between MRI, MRA and US for detecting full thickness tears, there was no statistically significant difference in diagnostic performance (P = 0.7). For any rotator cuff tears, the summary sensitivity and specificity were 98% (95% CI 92% to 99%) and 79% (95% CI 68% to 87%) respectively forMRI (6 studies, 347 shoulders), and 91% (95% CI 83% to 95%) and 85% (95% CI 74% to 92%) respectively for US (13 studies, 854 shoulders). For full thickness tears, the summary sensitivity and specificity were 94% (95% CI 85% to 98%) and 93% (95% CI 83% to 97%) respectively for MRI (7 studies, 368 shoulders); 94% (95% CI 80% to 98%) and 92% (95% CI 83% to 97%) respectively for MRA (3 studies, 183 shoulders); and 92% (95% CI 82% to 96%) and 93% (95% CI 81% to 97%) respectively for US (10 studies, 729 shoulders). Because few studies were direct head-to-head comparisons, we could not perform meta-analyses restricted to these studies. The test comparisons for each of the three classifications of the target condition were therefore based on indirect comparisons which may be prone to bias due to confounding. Authors' conclusions: MRI, MRA and US have good diagnostic accuracy and any of these tests could equally be used for detection of full thickness tears in people with shoulder pain for whom surgery is being considered. The diagnostic performance of MRI and US may be similar for detection of any rotator cuff tears. However, both MRI and US may have poor sensitivity for detecting partial thickness tears, and the sensitivity of US may be much lower than that ofMRI. The strength of evidence for all test comparisons is limited because most studies were small, heterogeneous and methodologically flawed, and there were few comparative studies. Well designed studies that directly compare MRI, MRA and US for detection of rotator cuff tears are needed.

Apêndices

Apêndice 1. Parecer do comitê de ética institucional



Universidade Federal de São Paulo Escola Paulista de Medicina Comitê de Ética em Pesquisa Hospital São Paulo

São Paulo, 26 de fevereiro de 2010. CEP 0154/10

Ilmo(a). Sr(a).

Pesquisador(a) MÁRIO LENZA

Co-Investigadores: Mário Lenza, João Carlos Belloti (orientador), Flávio Faloppa

Disciplina/Departamento: Cirurgia da Mão e Membro Superior da Universidade Federal de São Paulo/Hospital São

Paulo

Patrocinador: Recursos Próprios.

PARECER DO COMITÊ DE ÉTICA INSTITUCIONAL

Ref: Projeto de pesquisa intitulado: "Ressonância nuclear magnética versus ultrassonografia para o diagnóstico das lesões do manguito rotador: Revisão sistemática de estudos de diagnóstico".

CARACTERÍSTICA PRINCIPAL DO ESTUDO: Revisão sistemática.

RISCOS ADICIONAIS PARA O PACIENTE: Sem risco, sem procedimento invasivo.

OBJETIVOS: Comparar a acurácia dos testes diagnósticos de imagem da ressonância nuclear magnética versus a ultrassonografia para detectar lesões do manguito rotador em pacientes com dor no ombro que possuem indicação de tratamento cirúrgico..

RESUMO: Revisão de literatura, de acordo com as recomendações propostas pela Cochrane Collaboration Screening and Diagnostic Testes Methods Group para desenvolver revisões sistemáticas de estudos de acurácia. Serão incluídos todos os estudos de acurácia que comparam ressonância RNM e/ou US com os testes de referência em pacientes com suspeita de lesão parcial ou total do manguito rotador. Serão incluídos os estudos que avaliarem pacientes com dor no ombro e suspeita de lesão parcial ou total do manguito rotador, que possuem indicação de cirurgia. Serão incluídos testes de diagnóstico por imagem que comparem US e/ou RNM com o definido teste de referência (artroscopia ou cirurgia aberta).

FUNDAMENTOS E RACIONAL: Os exames de US e/ou RNM estão sendo cada vez mais usados para avaliar a presença e extensão da lesão do manguito com o objetivo de realizar um melhor planejamento da intervenção cirúrgica. Ambos, US e RNM são operador e/ou avaliador dependentes e a RNM é um exame de alto custo. Permanece incerto se um método é superior a outro e se o uso combinado de ambos melhora a acurácia diagnóstica, bem como se seus custos justificam sua utilização..

MATERIAL E MÉTODO: Estão descritos os procedimentos do estudo, não havendo contato com paciente.

TCLE: Não se aplica.

DETALHAMENTO FINANCEIRO: Sem financiamento externo - R\$ 2150,00.

CRONOGRAMA: 24 meses.

OBJETIVO ACADÊMICO: Pós-Doutorado.

ENTREGA DE RELATÓRIOS PARCIAIS AO CEP PREVISTOS PARA: 21/2/2011 e 21/2/2012.

1

Apêndice



Universidade Federal de São Paulo Escola Paulista de Medicina Comitê de Ética em Pesquisa Hospital São Paulo

O Comitê de Ética em Pesquisa da Universidade Federal de São Paulo/Hospital São Paulo **ANALISOU** e **APROVOU** o projeto de pesquisa referenciado.

- 1. Comunicar toda e qualquer alteração do projeto e termo de consentimento livre e esclarecido. Nestas circunstâncias a inclusão de pacientes deve ser temporariamente interrompida até a resposta do Comitê, após análise das mudanças propostas.
- 2. Comunicar imediatamente ao Comitê qualquer evento adverso ocorrido durante o desenvolvimento do estudo.
- 3. Os dados individuais de todas as etapas da pesquisa devem ser mantidos em local seguro por 5 anos para possível auditoria dos órgãos competentes.

Atenciosamente.

Pin. Dr. José Osmar Medina Pestana Coordenador do Comitê de Ética em Pesquisa da Universidade Federal de São Paulo/ Hospital São Paulo

0154/10

Apêndice_2. Protocolo publicado

Magnetic resonance imaging versus ultrasonography for assessing rotator cuff tears in patients with shoulder pain for whom surgery is being considered (Protocol)

Lenza M, Buchbinder R, Christensen R, Hanchard NCA, Faloppa F



This is a reprint of a Cochrane protocol, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2011, Issue 3

http://www.thecochranelibrary.com



Magnetic resonance imaging versus ultrasonography for assessing rotator cuff tears in patients with shoulder pain for whom surgery is being considered (Protocol)

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[Diagnostic Test Accuracy Protocol]

Magnetic resonance imaging versus ultrasonography for assessing rotator cuff tears in patients with shoulder pain for whom surgery is being considered

Mário Lenza¹, Rachelle Buchbinder², Robin Christensen³, Nigel CA Hanchard⁴, Flávio Faloppa¹

¹Department of Orthopaedics and Traumatology, Universidade Federal de São Paulo, São Paulo, Brazil. ²Monash Department of Clinical Epidemiology at Cabrini Hospital, Department of Epidemiology and Preventive Medicine, Monash University, Malvern, Australia. ³The Parker Institute: Musculoskeletal Statistics Unit (MSU), Copenhagen University Hospital, Frederiksberg, Copenhagen, Denmark, & Institute of Sports Science and Clinical Biomechanics, Faculty of Health Sciences, University of Southern Denmark, Odense, Denmark. ⁴Centre for Rehabilitation Sciences, Health & Social Care Institute, Middlesbrough, UK

Contact address: Mário Lenza, Department of Orthopaedics and Traumatology, Universidade Federal de São Paulo, Rua Borges Lagoa, 783 - 5th Floor, São Paulo, São Paulo, 04038-032, Brazil. mariolenza@yahoo.com.br.

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To compare the diagnostic test accuracy of magnetic resonance imaging (MRI) versus ultrasonography (US) to detect any rotator cuff tears (partial or full thickness) in patients with shoulder pain for whom surgery is being considered.

We will divide our objectives as follows.

- 1. To determine the diagnostic accuracy of US, MRI and magnetic resonance arthrography (MRA) for diagnosing any rotator cuff tears (partial or full thickness).
- 2. To determine the diagnostic accuracy of US, MRI and MRA for diagnosing full thickness rotator cuff tears (one or more tendons).
- 3. To determine the diagnostic accuracy of US, MRI and MRA for assessing the extent of the tear (full thickness or partial thickness) in people with a rotator cuff tear.

We will investigate potential sources of heterogeneity by conducting subgroup analyses according to characteristics of the population, tears and reference test, as described in the methods.

Apêndice_3. Revisão publicada

Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered (Review)

Lenza M, Buchbinder R, Takwoingi Y, Johnston RV, Hanchard NCA, Faloppa F



This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2013, Issue 9

http://www.thecochranelibrary.com



Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered (Review)

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[Diagnostic Test Accuracy Review]

Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered

Mário Lenza¹, Rachelle Buchbinder², Yemisi Takwoingi³, Renea V Johnston², Nigel CA Hanchard⁴, Flávio Faloppa¹

¹Department of Orthopaedics and Traumatology, Universidade Federal de São Paulo, São Paulo, Brazil. ²Monash Department of Clinical Epidemiology at Cabrini Hospital, Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Malvern, Australia. ³Public Health, Epidemiology and Biostatistics, University of Birmingham, Birmingham, UK. 4Health and Social Care Institute, Teesside University, Middlesbrough, UK

Contact address: Mário Lenza, Department of Orthopaedics and Traumatology, Universidade Federal de São Paulo, Rua Borges Lagoa, 783 - 5th Floor, São Paulo, São Paulo, 04038-032, Brazil. mariolenza@yahoo.com.br.

Editorial group: Cochrane Bone, Joint and Muscle Trauma Group. Publication status and date: New, published in Issue 9, 2013. Review content assessed as up-to-date: 22 August 2011.

Citation: Lenza M, Buchbinder R, Takwoingi Y, Johnston RV, Hanchard NCA, Faloppa F. Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered. Cochrane Database of Systematic Reviews 2013, Issue 9. Art. No.: CD009020. DOI: 10.1002/14651858.CD009020.pub2.

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ABSTRACT

Background

Shoulder pain is a very common symptom. Disorders of the rotator cuff tendons due to wear or tear are among the most common causes of shoulder pain and disability. Magnetic resonance imaging (MRI), magnetic resonance arthrography (MRA) and ultrasound (US) are increasingly being used to assess the presence and size of rotator cuff tears to assist in planning surgical treatment. It is not known whether one imaging method is superior to any of the others.

To compare the diagnostic test accuracy of MRI, MRA and US for detecting any rotator cuff tears (i.e. partial or full thickness) in people with suspected rotator cuff tears for whom surgery is being considered.

We searched the Cochrane Register of Diagnostic Test Accuracy Studies, MEDLINE, EMBASE, and LILACS from inception to February 2011. We also searched trial registers, conference proceedings and reference lists of articles to identify additional studies. No language or publication restrictions were applied.

We included all prospective diagnostic accuracy studies that assessed MRI, MRA or US against arthroscopy or open surgery as the reference standard, in people suspected of having a partial or full thickness rotator cuff tear. We excluded studies that selected a healthy control group, or participants who had been previously diagnosed with other specific causes of shoulder pain such as osteoarthritis or rheumatoid arthritis. Studies with an excessively long period (a year or longer) between the index and reference tests were also excluded.

Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered (Review)
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Magnetic resonance imaging versus ultrasonography for assessing rotator cuff tears in patients with shoulder pain for whom surgery is being considered (Protocol)

Lenza M, Buchbinder R, Christensen R, Hanchard NCA, Faloppa F



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[Diagnostic Test Accuracy Protocol]

Magnetic resonance imaging versus ultrasonography for assessing rotator cuff tears in patients with shoulder pain for whom surgery is being considered

Mário Lenza¹, Rachelle Buchbinder², Robin Christensen³, Nigel CA Hanchard⁴, Flávio Faloppa¹

¹Department of Orthopaedics and Traumatology, Universidade Federal de São Paulo, São Paulo, Brazil. ²Monash Department of Clinical Epidemiology at Cabrini Hospital, Department of Epidemiology and Preventive Medicine, Monash University, Malvern, Australia. ³The Parker Institute: Musculoskeletal Statistics Unit (MSU), Copenhagen University Hospital, Frederiksberg, Copenhagen, Denmark, & Institute of Sports Science and Clinical Biomechanics, Faculty of Health Sciences, University of Southern Denmark, Odense, Denmark. ⁴Centre for Rehabilitation Sciences, Health & Social Care Institute, Middlesbrough, UK

Contact address: Mário Lenza, Department of Orthopaedics and Traumatology, Universidade Federal de São Paulo, Rua Borges Lagoa, 783 - 5th Floor, São Paulo, São Paulo, 04038-032, Brazil. mariolenza@yahoo.com.br.

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To compare the diagnostic test accuracy of magnetic resonance imaging (MRI) versus ultrasonography (US) to detect any rotator cuff tears (partial or full thickness) in patients with shoulder pain for whom surgery is being considered.

We will divide our objectives as follows.

- 1. To determine the diagnostic accuracy of US, MRI and magnetic resonance arthrography (MRA) for diagnosing any rotator cuff tears (partial or full thickness).
- 2. To determine the diagnostic accuracy of US, MRI and MRA for diagnosing full thickness rotator cuff tears (one or more tendons).
- 3. To determine the diagnostic accuracy of US, MRI and MRA for assessing the extent of the tear (full thickness or partial thickness) in people with a rotator cuff tear.

We will investigate potential sources of heterogeneity by conducting subgroup analyses according to characteristics of the population, tears and reference test, as described in the methods.

BACKGROUND

Target condition being diagnosed

The rotator cuff is composed of the subscapularis, supraspinatus, infraspinatus and teres minor tendons; the long head of the biceps tendon also contributes to the cuff. The role of the rotator cuff is to stabilise the humeral head into the glenoid cavity, preventing the upward migration of the humeral head. The four muscles are recruited during different arm movements. The subscapularis is recruited in internal rotation, the supraspinatus in elevation, and the infraspinatus and teres minor in external rotation (Clark 1992; Favard 2007; Matsen 2008).

Shoulder pain is very common, with an incidence of 9.5 per 1000 patients in primary care in Cambridge, UK, where amongst them 85% presented with rotator cuff tendinopathy (Ostör 2005). Disorders of the rotator cuff tendons due to either wear or tear are among the most common causes of shoulder pain and disability. In Japan, the prevalence of rotator cuff tears is 20.7% in the general population and 36% in patients with shoulder pain (Yamamoto 2010). More than 4.5 million physician visits occurred and approximately 40,000 inpatient surgeries were performed for rotator cuff problems in the United States in 2002 (Oh 2007).

Rotator cuff tendinopathy can lead to progressive failure of the rotator cuff, typically progressing from partial to a full thickness tear of the supraspinatus tendon then extending into the infraspinatus tendon or the subscapularis tendon, or both. Lewis 2009, in a review on the pathoaetiology of rotator cuff tears, concluded that it is multifactorial and tears are correlated with a combination of extrinsic and intrinsic factors but that more studies are necessary to fully understand the aetiology. The extrinsic factors (that is external to the rotator cuff) can be divided into anatomical factors, such as the shape of the acromion (curved or hooked) and coracoacromial ligament, os acromiale and acromial spurs (Baring 2007; Bigliani 1991; Lewis 2009; Neer 1972; Neer 1983; Nho 2008), and environmental factors including aging, shoulder overuse, smoking, obesity and some metabolic disorders such as diabetes (Chen 2003; Galatz 2006; Harryman 2003; Lewis 2009; Nho 2008; Wendelboe 2004). The intrinsic factors include, among others, repetitive microtrauma, areas of hypoperfusion in the tendons, inflammation and cellular changes in the tendons such as disorganisation of the architecture of collagen (Biberthaler 2003; Levy 2008; Lewis 2009; Nirschl 1989; Rees 2008).

The diagnosis of rotator cuff tears is mainly based on the patient's history and physical examination. The clinical manifestations vary widely among patients (Duckworth 1999; Matsen 2008). Patients with acute, traumatic full thickness cuff tears may present with sudden onset of weakness during elevation of the arm after a trauma in which the arm has been forced to the side (like a fall with the arm out to the side or on catching a heavy falling object with the arm extended) (Matsen 2008). Patients with chronic degenerative cuff defects may present with progressive pain and weakness, with concomitant loss of active motion. Pain in the lateral area

of the shoulder is commonly present at night. Passive motion initially remains full until the pain limits active motion (Baring 2007; Matsen 2008). However, there are many people with degenerative rotator tears who are asymptomatic (Reilly 2006; Zanetti 2000). The value of physical examination of the shoulder is the subject of a separate Cochrane Review that is in preparation (Hanchard 2008).

Decisions about whether to order a diagnostic test include consideration of whether the results are likely to affect treatment. Plain radiographs of the shoulder may be useful to differentiate rotator tears from osteoarthritis of the glenohumeral or acromioclavicular joints and calcific tendonitis. Ultrasonography (US) and magnetic resonance imaging (MRI) are increasingly being used to detect rotator cuff tears, although who orders these tests may vary by setting. In some settings they are mainly ordered by specialists but in other settings they are being ordered by primary care physicians or clinicians (Al-Shawi 2008; Miller 2008). In the context of specialist care, US or MRI, or both, is usually performed to determine the characteristics of the rotator cuff tears in order to plan surgery. In some settings, however, there has been a significant rise in the number of diagnostic US being performed in primary care. For example, in Australia there has been a more than four fold increase, from 104,252 in the year 2000 to 2001 to 440,172 in 2008 to 2009 (Medicare Australia 2010), although the utility of the test to affect treatment in primary care is unknown.

Tears of the rotator cuff can be classified in several ways. These are by duration (acute or chronic), aetiology (traumatic or degenerative) or size (partial or full thickness, or massive). These three factors all influence treatment decisions (Kuhn 2007).

Acute full thickness rotator cuff tears are uncommon and account for less than 10% of all rotator cuff tears. People with acute full thickness tears usually present with a history of acute trauma, such as a fall or dislocation, and immediate pain and weakness. Prompt surgical treatment, ideally within six weeks, is the recommended treatment (Rees 2008). For all other full thickness rotator cuff tears, surgical treatment is usually reserved for those who fail to improve after a period of conservative treatment, although the most effective surgical intervention and its timing remain uncertain (Coghlan 2008; Dunn 2005; Oh 2007; Rees 2008). For example, a delay in surgical repair of a large tear may allow the injured tendon to retract and the muscle to atrophy (Matsen 2008; Oh 2007). On the other hand, asymptomatic tears are common. A recent review reported the prevalence of full thickness tears as 30.24% in 2553 unselected cadavers (Rees 2008). Furthermore, the pathogenesis and progression to symptomatic tears remains unclear (Rees 2008). In addition, in contrast to acute full thickness tears, symptoms due to acute or chronic partial thickness cuff tears frequently improve with conservative interventions (Matava 2005; Matsen 2008).

While spontaneous healing of a partial thickness tear is unlikely in most cases, the explanation for the 'cure' with conservative treatment is due to the likely resolution of the accompanying inflam-

mation over time and may also be related to the residual cuff muscles compensating for the mechanical deficiency of the torn cuff (Fukuda 1996; Fukuda 2003; Matava 2005; Matsen 2008). As with full thickness tears, no simple treatment algorithm for partial thickness rotator cuff tears exists. Surgical treatment, however, is normally indicated for patients with persisting symptoms despite conservative treatment and in whom imaging suggests the presence of a partial thickness tear or tears. The ideal timing of surgical intervention also remains unclear (Fukuda 2003; Matava 2005). However, case series and anecdotal evidence suggest that satisfactory results are usually achieved with surgery provided there is a good blood supply to the tendon, contact between the torn ends, absence of retraction and adequate trophic quality of the muscle (Fukuda 2003).

Another recognised category of tears is massive complete tears, in which a large area of the humeral head is uncovered (Wolfgang 1974). Post 1983 defined a massive tear as greater than 5 cm. These tears, which are difficult to repair, are more commonly found in women over 65 years of age and are associated with advanced atrophy, degeneration and progressive fatty infiltration of the rotator cuff muscles (Dines 2007; Gerber 2000). Treatment options for these massive, retracted tears are limited as they are often deemed irreparable. In younger patients, consideration can be given to tendon transfers to improve pain and function (Neri 2009).

The indications for surgical treatment of rotator cuff tears have not been fully defined. A recent systematic review of 14 trials for rotator cuff disease, including tears, was unable to draw firm conclusions about the effectiveness of surgery; although it did suggest that there were no significant differences in outcomes between open or arthroscopic surgery and non-operative treatment (Coghlan 2008). However, many studies have demonstrated that the size of the tear is correlated to the final outcome and the likelihood of a satisfactory surgical result (Bianchi 2005; Bryant 2002; Fotiadou 2008).

Index test(s)

Currently, US or MRI, or both, is usually performed in patients contemplating surgery for rotator cuff tears to determine the characteristics of the tears. The accuracy of these imaging tests is considered to have improved significantly over time, enabling useful assessment of the size and extent of the rotator cuff tear when planning surgery (Rees 2008).

US is a diagnostic imaging technique used to visualize deep structures of the body by recording the echoes of pulsed ultrasonic waves directed into the tissues and reflected by tissue planes to the transducer. These echoes are converted into 'pictures' of the tissues under examination. Seltzer 1979 was the first to describe ultrasonographic evaluation of rotator cuff diseases. US of the shoulder is utilised in secondary, tertiary and, increasingly, primary healthcare settings to evaluate the integrity of the rotator cuff. It consists of a non-invasive examination that has practically no side effects

and allows the dynamic visualisation of the tendons during movement of the shoulder (Al-Shawi 2008). However, operator dependence and a long learning curve are frequently considered to be its limitation (O'Connor 2005; Rutten 2006), principally in views of partial thickness tears for which Le Corroller 2008 described a high interobserver variability.

MRI uses a powerful magnetic field to align the hydrogen atoms of water and other molecules in the body. Pulses of radiofrequency are applied which excite the magnetised atoms. These movements of hydrogen atoms, which vary in different tissues, are captured and the signal can be manipulated to build up an image of the body (Witte 2003). The first article about the use of MRI in the shoulder was published in 1986 (Kneeland 1986). Since then, this technique has been widely used in secondary and tertiary healthcare practice. MRI is a non-invasive method of imaging which is unique in allowing high resolution images in multiple planes. It is a static examination that may be enhanced by an intra-articular injection of radiopaque dye (this is named magnetic resonance arthrography), which acts as contrast material that helps to delineate intra-articular structures and outline abnormalities. Magnetic resonance arthrography (MRA) of the shoulder is also useful for assessing the rotator cuff integrity. In comparison with conventional MRI, MRA may improve diagnostic performance in detecting shoulder diseases; however, any potential benefit from this additional procedure must be set against the invasiveness and additional discomfort to patients.

MRI has some absolute contraindications, namely the presence of intracerebral aneurysm clips, cardiac pacemakers, automatic defibrillators, biostimulators, implanted infusion devices, cochlear implants and metallic orbital foreign bodies (Witte 2003). It is also expensive and time consuming.

Alternative test(s)

The alternative reference tests for diagnosis of rotator cuff tears are invasive. The most common reference test is diagnostic arthroscopy. Arthroscopy is a minimally invasive surgical procedure that involves insertion of an arthroscope, a type of fibre-optic endoscope, into the joint through a small incision. This allows the surgeon to inspect and probe the articular (joint) and bursal side of the rotator cuff tendons, to assess accurately the rotator cuff insertion (footprint) and to perform a general examination of the shoulder joint in order to identify and treat other potential lesions (Dinnes 2003; Matava 2005). However, limitations associated with diagnostic shoulder arthroscopy include the need for anaesthesia, hospital admission and some interobserver variation in the classification of tears (Kuhn 2007).

Open surgery (including mini-open) has also been used as a reference test although it is more limited than arthroscopy because joint surface or inferior surface tears are difficult to access and identify using an open approach. Other available diagnostic imaging tests include plain radiographs, arthrography and computed

tomography, although these are generally recognised as not being useful for detecting failure of the rotator cuff.

Rationale

Ultrasound (US) and MRI are being increasingly used to assess the presence and size of rotator cuff tears to assist in planning the surgical approach. Improved techniques have resulted in increased reliance on these tests, in place of a separate diagnostic arthroscopy, although arthroscopic examination of the shoulder joint is still commonly performed as part of the surgical treatment. Both US and MRI are operator and reader dependent and MRI is expensive. It is not known whether one method is superior to the other or whether performing both enhances their value (Swen 1999). It is also not known whether they provide useful additional information compared with diagnostic arthroscopy, which is an accepted part of the surgical treatment; nor whether they are cost-effective.

We have located two relevant systematic reviews with meta-analyses which studied diagnostic imaging tests for rotator cuff disease (de Jesus 2009; Dinnes 2003). The literature search in both reviews was restricted to English language only. The earlier review (Dinnes 2003) evaluated the diagnostic accuracy of clinical testing, US and MRI (search date October 2001) for detecting rotator cuff tears using both surgical and non-surgical tests as the reference standard. They concluded that US or MRI were equivalent for detecting full thickness rotator cuff tears, although MRI was more expensive and US may be better at detecting partial tears. de Jesus 2009 reported a meta-analysis comparing the diagnostic of US and MRI for rotator cuff tears using surgery as the reference standard. The authors included 65 studies (search date September 2007) but the appraisal of the methodological quality of the included studies was unclear or insufficient. They concluded that US is as accurate as MRI for both full and partial thickness rotator cuff tears and also suggested that US may be the most cost-effective imaging test for screening rotator cuff tears (de Jesus 2009). In as much as important improvements in both US and MRI have been made after the search strategies of both studies, and new accuracy studies have been developed to evaluate these advances in both US and MRI, our review will perform an updated search for diagnostic accuracy studies for rotator cuff tears and will also include non-English references.

OBJECTIVES

To compare the diagnostic test accuracy of magnetic resonance imaging (MRI) versus ultrasonography (US) to detect any rotator cuff tears (partial or full thickness) in patients with shoulder pain for whom surgery is being considered.

We will divide our objectives as follows.

- 1. To determine the diagnostic accuracy of US, MRI and magnetic resonance arthrography (MRA) for diagnosing any rotator cuff tears (partial or full thickness).
- 2. To determine the diagnostic accuracy of US, MRI and MRA for diagnosing full thickness rotator cuff tears (one or more tendons).
- 3. To determine the diagnostic accuracy of US, MRI and MRA for assessing the extent of the tear (full thickness or partial thickness) in people with a rotator cuff tear.

Investigation of sources of heterogeneity

We will investigate potential sources of heterogeneity by conducting subgroup analyses according to characteristics of the population, tears and reference test, as described in the methods.

METHODS

Criteria for considering studies for this review

Types of studies

All diagnostic accuracy studies that compare one or both index tests with one or both of the reference tests in patients suspected of having a partial or full thickness rotator cuff tear will be included. Studies which selected a healthy control group will be excluded. Studies with an excessively long period (more than six months) between the index and reference tests will also be excluded because rotator cuff tears can progress over time. We will only include results from full reports. If studies have been reported in abstracts or conference proceedings we will search for the full publications. We will include English and commonly used European-origin languages articles in which a full translation can be obtained. Non-English articles where a full translation cannot be obtained will be cited in an Appendix but not included in the review.

In cases in which the same study has been published in more than one report, we will include only the most updated or complete report. Nevertheless, the references to other publications will be cited under the study identification (ID).

Participants

Patients with shoulder pain and suspected of having a rotator cuff tear for whom surgery is being considered. Studies that included patients who have been previously diagnosed with other specific shoulder pain (for example shoulder instability, osteoarthritis, rheumatoid arthritis, frozen shoulder (adhesive capsulitis), benign or malignant tumours or referred pain) will be excluded.

Index tests

US, MRI or MRA. We anticipate that criteria for positivity will vary, and we will report them in detail on a study by study basis in the 'Characteristics of included studies' table. To standardise classification for this review, rotator cuff tears will be dichotomised to absence and presence of any, full and partial thickness tears.

Target conditions

Studies will require at least one of three target conditions to be included:

- presence of any rotator cuff tears (partial or full thickness);
- presence of full thickness tears (one or more tendons);
- presence of partial thickness tears (any tendon).

Reference standards

Arthroscopy or open (including mini-open) surgery findings. If any study addresses both (arthroscopy and open surgery), we will select arthroscopy as the reference standard.

Search methods for identification of studies

Electronic searches

We will search relevant computerised databases for eligible diagnostic studies: MEDLINE (PubMed) (1966 to present), EMBASE (Elsevier) (1980 to present), and LILACS (Bireme) (1982 to present). We will also search the Cochrane Register of Diagnostic Test Accuracy Studies. There will be no restrictions based on language, date or publication status. When possible, non-English articles will be assessed through selective translation by a native speaker.

We have developed a sensitive search strategy (Appendix 1), as recommended in Chapter 7 of the Cochrane Handbook (de Vet 2008), for MEDLINE (PubMed), EMBASE (Elsevier) and LILACS (Bireme) (*see* Appendix 1 for the MEDLINE and EMBASE search strategies).

Searching other resources

We will check the reference lists of articles, reviews and text-books for possibly relevant primary diagnostic studies and systematic reviews. We will also search DARE (Database of Abstracts of Reviews of Effects) and the HTA Database (Health Technology Assessments Database) for other related diagnostic test accuracy reviews, and we will check the reference lists of those reviews that are relevant for additional studies. We will also search the US Health Services Research Projects in Progress and the UK Clinical Research Network Portfolio Database for ongoing and recently completed studies.

We will handsearch abstracts of the British Elbow and Shoulder Society annual meetings (2005 to present) and American Academy of Orthopaedic Surgeons annual meetings (2005 to present).

We will also contact experts in the field. When necessary, we will contact main investigators of relevant ongoing studies for further information.

Data collection and analysis

We will use the methods suggested by the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy (Deeks 2009).

Selection of studies

Two review authors (ML and RB) will independently screen the titles and abstracts of retrieved records to identify potentially relevant studies for inclusion. Duplicates will be removed and the remaining references will be examined. Studies which clearly do not meet the inclusion criteria will be excluded, and copies of the full text of potentially relevant references will be obtained. ML and RB will independently assess full text reports and determine inclusion or exclusion of the studies. Any uncertainties or disagreements will be resolved by discussion and, if necessary, with adjudication by a third author (FF). We will document reasons for exclusion.

Data extraction and management

Two review authors (ML and RB) will independently collect the available data using a piloted data extraction form without masking of study authors and other identifying information. A third review author (FF) will be consulted for resolution of any disagreements. When necessary, we will send requests to study authors for additional information or data.

Diagnostic studies presenting insufficient data for construction of a two-by-two table will be excluded from statistical analysis but will be included in the narrative part of this review.

The following data will be retrieved.

- 1. General information: title, journal, year, publication status, country of study, period of study, primary objective and study design (prospective versus retrospective and consecutive versus nonconsecutive).
- 2. Sample size: number of participants meeting the criteria and total number screened.
- 3. Baseline characteristics: baseline diagnosis, age, sex, side, nature of onset (e.g. traumatic or non-traumatic), duration of symptoms, prior treatment, inclusion and exclusion criteria.
- 4. Target condition, as reported.
- 5. Index test: description of technique, criteria for positive result, timing of test and expertise of the tester. All cut-offs will be tested.
- 6. Reference standard test: description of technique, criteria for positive result, time from index to reference test and expertise of the tester. All cut-offs will be tested.

- 7. Side effects or complications due to index test(s) and reference standard test(s).
- 8. Number of true positive (TP), true negative (TN), false positive (FP) and false negative (FN). These data will be extracted for each cut-off presented (e.g. any, full or partial thickness tears).

Assessment of methodological quality

The methodological quality of the included studies will be assessed independently by two review authors (ML and RB) and

disagreement on study quality will be resolved by a third review author (FF). At the same time as data extraction, the methodological quality of selected studies will be assessed using a modified version of the QUADAS checklist (Whiting 2003), following the guidelines provided in Chapter 9 of the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy (Reitsma 2009). For each study, a methodological quality table will be filled. Table 1 explains how the authors will interpret the QUADAS items in terms of the diagnosis of rotator cuff tears.

Table 1. Assessment of methodological quality: QUADAS and additional items

Item definition	Item question	Assessment
Representative spectrum	1. Was the spectrum of patients representative of the patients who will receive the test in practice?	Yes: (a) the setting was secondary or tertiary care AND (b) the population was patients with shoulder pain suspected of a rotator cuff tear for whom surgery is being considered AND (c) the study was prospective AND (d) recruitment was consecutive. Unclear: if insufficient information was given on the setting, selection criteria, or selection procedure to make a judgment. No: (a) the setting was primary care OR (b) the population was unselected but defined by shoulder pain OR (c) the study was not prospective OR (d) recruitment was not consecutive.
Acceptable reference standard	2. Is the reference standard likely to classify the target condition correctly?	Yes: if the reference standard was arthroscopy or a combination of arthroscopy and open surgery (including mini-open). Unclear: if the target condition was partial thickness rotator cuff tears and the refer- ence standard was open surgery (including mini-open). No: not applicable.
Acceptable delay between tests	3. Is the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between the two tests?	Yes: if the average interval between reference standard and index test was one month or less. Unclear: if the interval between tests was not clearly reported. No: if the average interval between reference standard and index test was longer than one month.
Partial verification avoided	4. Did the whole sample or a random selection of the sample, receive verification using the intended reference standard?	Yes: If all patients who received the index test went on to receive verification of their disease status using a reference stan-

Table 1. Assessment of methodological quality: QUADAS and additional items (Continued)

		dard (Score 'Yes' even if different reference tests were used). Unclear: if insufficient information was given on relation of index test and reference standard. No: if not all the patients who received the index test underwent a reference standard to verify their true disease status.
Differential verification bias	5. Did patients receive the same reference standard irrespective of the index test result?	Yes: if all patients received the same reference standard, regardless of the result of their index test. Unclear: If it is unclear whether different reference standards were used. No: if the result of the index test influenced the choice of the reference standard.
Incorporation bias	6. Was the reference standard independent of the index test (i.e. the index test did not form part of the reference standard)?	Should be considered 'Yes' for all studies because the index test is not part of the reference standard.
Index test results blinded	7. Were the reference standard results interpreted without knowledge of the results of the index test?	Yes: if the reference standard results were performed blind to the results of the index test. Unclear: if insufficient information was given on independent or blind assessment of the reference standard. No: if the results of the index tests were known to the person interpreting the reference tests or the study was retrospective.
Reference standard results blinded	8. Were the index test results interpreted without knowledge of the results of the reference standard?	Yes: if the person undertaking the index test was blinded to the results of the standard reference. Unclear: if insufficient information was given on independent or blind assessment of the index test. No: if the results of the reference tests were known to the person undertaking the index tests or the study was retrospective.
Relevant clinical information	9. Were the same clinical data available when test results were interpreted as would be available when the test is used in practice?	Yes: if clinical data would normally be available when the test is interpreted in practice and similar data were available when interpreting the index test in the study. Unclear: if insufficient information was given to explain which clinical information was available at the time of assessment. No: if clinical data were not available when

Table 1. Assessment of methodological quality: QUADAS and additional items (Continued)

		index test(s) was(were) interpreted.
Uninterpretable results reported	10. Were uninterpretable/ intermediate test results reported?	Yes: If the number of uninterpretable test results is stated, or if the number of results reported agrees with the number of patients recruited (indicating no uninterpretable test results). Unclear: if insufficient information was given to permit judgement. No: If it states that uninterpretable test results occurred or were excluded and does not report how many.
Withdrawals explained	11. Were withdrawals from the study explained?	Yes: if the number and reasons of all withdrawals from the study were explained (ideally by a flow chart) or if no participants were excluded from the analysis. Unclear: if insufficient information was given on the withdrawals. No: if not all withdrawals were explained.
Learning curve / training reported of index test	12. Had index test operators had appropriate training or experience in musculoskeletal diseases?	Yes: (a) if the index test(s) executors were radiologists or shoulder surgeons AND (b) if the tests interpreters had experience in diagnostic of musculoskeletal diseases. Unclear: if insufficient information was given to permit judgement. No: (a) if the index test(s) executors were not radiologists or shoulder surgeons OR (b) if the tests interpreters had no experience in diagnostic of musculoskeletal diseases.
Learning curve / training reported of reference standard	13. Had reference standard test operators had appropriate training or experience in shoulder surgery?	Yes: (a) if the reference standard(s) executors were shoulder surgeons AND (b) if the results interpreters had experience in shoulder diseases. Unclear: if insufficient information was given to permit judgement. No: (a) if the reference standard(s) executors were not shoulder surgeons OR (b) if the results interpreters had no experience in shoulder diseases.

Statistical analysis and data synthesis

We will analyse data on studies which make both direct and indirect comparisons between the index tests US, MRI and MRA. The

main aim is to identify the test with better accuracy for diagnosing and visualising soft tissues tears in the shoulder.

Indices of diagnostic performance will be extracted or derived from data presented in each primary study for each index test. The review authors will construct two-by-two contingency tables of true positive cases, false positive cases, false negative cases and true negative cases according to the three target conditions (any, full and partial thickness tears). The first step in a given meta-analysis will be to graphically present the results of the individual studies. In addition, a scatterplot of study-specific estimates of true positive (sensitivity) and false positive rates (1-specificity) will be used to display the data in the receiver operating characteristic (ROC) space.

Where adequate data are available, we will conduct meta-analyses using the hierarchical summary ROC (HSROC) model, which takes into account both within and between study variability (Macaskill 2010). We will apply SAS (version 9.2) software for the hierarchical model.

The differences between the tests will be formally assessed in a HSROC model, as well as the differences between subgroups predefined as potential sources of heterogeneity.

Investigations of heterogeneity

Heterogeneity will be investigated in the first instance through visual examination of forest plots of sensitivities and specificities and through visual examination of the ROC plot of the raw data. We will also explore heterogeneity by examining differences in diagnostic accuracy according to pre-defined subgroup analyses: by age of the population, tears and reference test, as specified below.

• The study population: old (65 years and older) or young population.

- Type of tears: acute or chronic, and traumatic or degenerative.
- Type of reference test: open (including mini-open) surgery or arthroscopy.

Sensitivity analyses

If possible on the basis of the amount of data (that is the number of eligible studies) we will compare the results of all studies with the results of subsets of studies that comply with the following methodological quality items of the QUADAS checklist (Whiting 2003)

- Representative spectrum.
- Acceptable reference standard.
- Acceptable delay between tests.
- Index test results blinded.
- Reference standard results blinded.

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* Indicates the major publication for the study

APPENDICES

Appendix I. Search strategies

MEDLINE (PubMed)

((Ultrasonography [mh] OR ultrasound [tw] OR ultrasonograph* [tw] OR sonograp*[tw] OR us [sh]) OR (Magnetic Resonance Imaging [mh] OR MR imag*[tw] OR magnetic resonance imag* [tw] OR MRI [tw])) AND (Rotator Cuff [mh] OR rotator cuff* [tw] OR musculotendinous cuff* [tw] OR subscapularis [tw] OR supraspinatus [tw] OR infraspinatus OR teres minor [tw]) AND (Rupture [mh:noexp] OR tear* [tw] OR torn [tw] OR thickness [tw] OR lesion* [tw] OR ruptur* [tw] OR injur* [tw])

EMBASE (Elsevier)

- 1. 'echography'/de AND [embase]/lim
- 2. ultrasound:ab,ti OR ultrasonograph*:ab,ti OR sonograp*:ab,ti AND [embase]/lim
- 3. #1 OR #2
- 4. 'nuclear magnetic resonance imaging'/de AND [embase]/lim
- 5. (('magnetic resonance' OR mr) NEAR/3 imag*):ab,ti AND [embase]/lim
- 6. mri:ab,ti AND [embase]/lim
- 7. #4 OR #5 OR #6
- 8. 'rotator cuff injury'/de OR 'rotator cuff rupture'/de AND [embase]/lim
- 9. 'rotator cuff'/de AND [embase]/lim
- 10. 'rotator cuff':ab,ti OR 'musculotendinous cuff':ab,ti OR subscapularis:ab,ti OR supraspinatus:ab,ti OR infraspinatus:ab,ti OR 'teres minor':ab,ti AND [embase]/lim
- 11. #9 OR #10
- 12. 'rupture'/de AND [embase]/lim
- 13. tear*:ab,ti OR torn:ab,ti OR thickness:ab,ti OR lesion*:ab,ti OR ruptur*:ab,ti OR injur*:ab,ti AND [embase]/lim
- 14. #12 OR #13
- 15. #11 AND #14
- 16. #8 OR #15
- 17. #3 OR #7
- 18. #16 AND #17

HISTORY

Protocol first published: Issue 3, 2011

CONTRIBUTIONS OF AUTHORS

All authors contributed to the development of the protocol and commented on and approved the final version. The guarantor of this protocol is Mario Lenza.

DECLARATIONS OF INTEREST

None known.

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• Teesside University, UK.

External sources

• No sources of support supplied

Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered (Review)

Lenza M, Buchbinder R, Takwoingi Y, Johnston RV, Hanchard NCA, Faloppa F



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[Diagnostic Test Accuracy Review]

Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered

Mário Lenza¹, Rachelle Buchbinder², Yemisi Takwoingi³, Renea V Johnston², Nigel CA Hanchard⁴, Flávio Faloppa¹

¹Department of Orthopaedics and Traumatology, Universidade Federal de São Paulo, São Paulo, Brazil. ²Monash Department of Clinical Epidemiology at Cabrini Hospital, Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Malvern, Australia. ³Public Health, Epidemiology and Biostatistics, University of Birmingham, Birmingham, UK. ⁴Health and Social Care Institute, Teesside University, Middlesbrough, UK

Contact address: Mário Lenza, Department of Orthopaedics and Traumatology, Universidade Federal de São Paulo, Rua Borges Lagoa, 783 - 5th Floor, São Paulo, São Paulo, 04038-032, Brazil. mariolenza@yahoo.com.br.

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ABSTRACT

Background

Shoulder pain is a very common symptom. Disorders of the rotator cuff tendons due to wear or tear are among the most common causes of shoulder pain and disability. Magnetic resonance imaging (MRI), magnetic resonance arthrography (MRA) and ultrasound (US) are increasingly being used to assess the presence and size of rotator cuff tears to assist in planning surgical treatment. It is not known whether one imaging method is superior to any of the others.

Objectives

To compare the diagnostic test accuracy of MRI, MRA and US for detecting any rotator cuff tears (i.e. partial or full thickness) in people with suspected rotator cuff tears for whom surgery is being considered.

Search methods

We searched the Cochrane Register of Diagnostic Test Accuracy Studies, MEDLINE, EMBASE, and LILACS from inception to February 2011. We also searched trial registers, conference proceedings and reference lists of articles to identify additional studies. No language or publication restrictions were applied.

Selection criteria

We included all prospective diagnostic accuracy studies that assessed MRI, MRA or US against arthroscopy or open surgery as the reference standard, in people suspected of having a partial or full thickness rotator cuff tear. We excluded studies that selected a healthy control group, or participants who had been previously diagnosed with other specific causes of shoulder pain such as osteoarthritis or rheumatoid arthritis. Studies with an excessively long period (a year or longer) between the index and reference tests were also excluded.

Data collection and analysis

Two review authors independently extracted data on study characteristics and results of included studies, and performed quality assessment according to QUADAS criteria. Our unit of analysis was the shoulder. For each test, estimates of sensitivity and specificity from each study were plotted in ROC space and forest plots were constructed for visual examination of variation in test accuracy. Meta-analyses were performed using the bivariate model to produce summary estimates of sensitivity and specificity. We were unable to formally investigate potential sources of heterogeneity because of the small number of studies.

Main results

We included 20 studies of people with suspected rotator cuff tears (1147 shoulders), of which six evaluated MRI and US (252 shoulders), or MRA and US (127 shoulders) in the same people. Many studies had design flaws, with the potential for bias, thus limiting the reliability of their findings. Overall, the methodological quality of the studies was judged to be low or unclear. For each test, we observed considerable heterogeneity in study results, especially between studies that evaluated US for the detection of full thickness tears and studies that evaluated MRA for the detection of partial thickness tears. The criteria for a positive diagnostic test (index tests and reference standard) varied between studies.

Meta-analyses were not possible for studies that assessed MRA for detection of any rotator cuff tears or partial thickness tears. We found no statistically significant differences in sensitivity or specificity between MRI and US for detecting any rotator cuff tears (P = 0.13), or for detecting partial thickness tears (P = 1.0). Similarly, for the comparison between MRI, MRA and US for detecting full thickness tears, there was no statistically significant difference in diagnostic performance (P = 0.7). For any rotator cuff tears, the summary sensitivity and specificity were 98% (95% CI 92% to 99%) and 79% (95% CI 68% to 87%) respectively for MRI (6 studies, 347 shoulders), and 91% (95% CI 83% to 95%) and 85% (95% CI 74% to 92%) respectively for US (13 studies, 854 shoulders). For full thickness tears, the summary sensitivity and specificity were 94% (95% CI 85% to 98%) and 93% (95% CI 83% to 97%) respectively for MRI (7 studies, 368 shoulders); 94% (95% CI 80% to 98%) and 92% (95% CI 83% to 97%) respectively for MRA (3 studies, 183 shoulders); and 92% (95% CI 82% to 96%) and 93% (95% CI 81% to 97%) respectively for US (10 studies, 729 shoulders).

Because few studies were direct head-to-head comparisons, we could not perform meta-analyses restricted to these studies. The test comparisons for each of the three classifications of the target condition were therefore based on indirect comparisons which may be prone to bias due to confounding.

Authors' conclusions

MRI, MRA and US have good diagnostic accuracy and any of these tests could equally be used for detection of full thickness tears in people with shoulder pain for whom surgery is being considered. The diagnostic performance of MRI and US may be similar for detection of any rotator cuff tears. However, both MRI and US may have poor sensitivity for detecting partial thickness tears, and the sensitivity of US may be much lower than that of MRI. The strength of evidence for all test comparisons is limited because most studies were small, heterogeneous and methodologically flawed, and there were few comparative studies. Well designed studies that directly compare MRI, MRA and US for detection of rotator cuff tears are needed.

BACKGROUND

Target condition being diagnosed

The rotator cuff is composed of the subscapularis, supraspinatus, infraspinatus and teres minor tendons; the long head of the biceps tendon also contributes to the cuff. The role of the rotator cuff is to stabilise the humeral head into the glenoid cavity, preventing the upward migration of the humeral head. The four muscles are recruited during different arm movements. The subscapularis is

recruited in internal rotation, the supraspinatus in elevation, and the infraspinatus and teres minor in external rotation (Clark 1992; Favard 2007; Matsen 2008).

Rotator cuff tendinopathy can lead to progressive failure of the rotator cuff, typically progressing from partial to a full thickness tear of the supraspinatus tendon then extending into the infraspinatus tendon or the subscapularis tendon, or both. A review by Lewis 2009 concluded that the pathoaetiology of rotator cuff tears is multifactorial and that tears are correlated with a combination of extrinsic and intrinsic factors, but that more research is necessary to fully understand the aetiology of rotator cuff tears. The extrin-

sic factors (i.e. those external to the rotator cuff) can be divided into anatomical factors, such as the shape of the acromion (i.e. curved or hooked) and coracoacromial ligament, os acromiale and acromial spurs (Baring 2007; Bigliani 1991; Lewis 2009; Neer 1972; Neer 1983; Nho 2008), and environmental factors including aging, shoulder overuse, smoking, obesity and some metabolic disorders such as diabetes (Chen 2003; Galatz 2006; Harryman 2003; Lewis 2009; Nho 2008; Wendelboe 2004). The intrinsic factors include, among others, repetitive microtrauma, areas of hypoperfusion in the tendons, inflammation and cellular changes in the tendons such as disorganisation of the architecture of collagen (Biberthaler 2003; Levy 2008; Lewis 2009; Nirschl 1989; Rees 2008).

Shoulder pain is very common, with an incidence of 9.5 per 1000 patients in primary care in Cambridge, UK, where amongst them 85% presented with rotator cuff tendinopathy (Ostör 2005). Disorders of the rotator cuff tendons due to either wear or tear are among the most common causes of shoulder pain and disability. In Japan, the prevalence of rotator cuff tears is 20.7% in the general population and 36% in patients with shoulder pain (Yamamoto 2010). More than 4.5 million physician visits occurred and approximately 40,000 inpatient surgeries were performed for rotator cuff problems in the United States in 2002 (Oh 2007).

The diagnosis of rotator cuff tears is mainly based on the patient's history and physical examination. The value of physical examination of the shoulder has been addressed in another Cochrane review (Hanchard 2013). The clinical manifestations vary widely (Duckworth 1999; Matsen 2008). Acute, traumatic full thickness cuff tears may present with sudden onset of weakness during elevation of the arm after a trauma in which the arm has been forced to the side (like a fall with the arm out to the side or on catching a heavy falling object with the arm extended) (Matsen 2008). Chronic degenerative cuff defects may present with progressive pain and weakness, with concomitant loss of active motion. Pain in the lateral area of the shoulder is commonly present at night. Passive motion initially remains full until the pain limits active motion (Baring 2007; Matsen 2008). However, there are many people with degenerative rotator tears who are asymptomatic (Reilly 2006; Zanetti 2000).

Decisions about whether to order a diagnostic test include consideration of whether the results are likely to affect treatment. Plain radiographs of the shoulder may be useful to differentiate rotator tears from osteoarthritis of the glenohumeral or acromioclavicular joints and calcific tendonitis. Ultrasonography (US), magnetic resonance imaging (MRI) and magnetic resonance arthrography (MRA) are increasingly being used to detect rotator cuff tears, although who orders these tests may vary by setting. In some settings, these tests are mainly ordered by specialists but in other settings they are being ordered by primary care physicians or clinicians (Al-Shawi 2008; Miller 2008). In the context of specialist care, US or MRI, or both, are usually performed to determine the characteristics of the rotator cuff tears in order to plan surgery.

In some settings, however, there has been a significant rise in the number of diagnostic US being performed in primary care. For example, in Australia there has been a more than fourfold increase, from 104,252 in the year 2000 to 2001 to 440,172 in 2008 to 2009 (Medicare Australia 2010). However, the utility of the test to affect treatment in primary care is unknown.

Tears of the rotator cuff can be classified in several ways: duration (acute or chronic), aetiology (traumatic or degenerative) or size (partial or full thickness). Radiologists often describe the size of tear in millimetres or centimetres or descriptively as small, medium, large or massive. All three factors (duration, aetiology and size) influence treatment decisions (Kuhn 2007).

Acute full thickness rotator cuff tears are uncommon and account for less than 10% of all rotator cuff tears. People with acute full thickness tears usually present with a history of acute trauma, such as a fall or dislocation, and immediate pain and weakness. Prompt surgical treatment, ideally within six weeks, is the recommended treatment (Rees 2008). For all other full thickness rotator cuff tears, surgical treatment is usually reserved for those who fail to improve after a period of conservative treatment, although the most effective surgical intervention and its timing remain uncertain (Coghlan 2009; Dunn 2005; Oh 2007; Rees 2008). For example, a delay in surgical repair of a large tear may allow the injured tendon to retract and the muscle to atrophy (Matsen 2008; Oh 2007). On the other hand, asymptomatic tears are common; these are chronic tears that normally do not compromise the function of the shoulder. A recent review reported the prevalence of full thickness tears in 2553 unselected cadavers as 30% (Rees 2008). Furthermore, the pathogenesis and progression to symptomatic tears remains unclear (Rees 2008). In addition, in contrast to acute full thickness tears, symptoms due to acute or chronic partial thickness cuff tears frequently improve with conservative interventions (Matava 2005; Matsen 2008).

While spontaneous healing of a partial thickness tear is unlikely in most cases, the explanation for the 'cure' with conservative treatment is due to the likely resolution of the accompanying inflammation over time and may also be related to the residual cuff muscles compensating for the mechanical deficiency of the torn cuff (Fukuda 1996; Fukuda 2003; Matava 2005; Matsen 2008). As with full thickness tears, no simple treatment algorithm for partial thickness rotator cuff tears exists. Surgical treatment, however, is normally indicated for people with persisting symptoms despite conservative treatment and in whom imaging suggests the presence of a partial thickness tear or tears. The ideal timing of surgical intervention also remains unclear (Fukuda 2003; Matava 2005). However, case series and anecdotal evidence suggest that satisfactory results are usually achieved with surgery provided there is a good blood supply to the tendon, contact between the torn ends, absence of retraction and adequate trophic quality of the muscle (Fukuda 2003).

Another recognised category of tears is massive complete tears, in which a large area of the humeral head is uncovered (Wolfgang

1974). Post 1983 defined a massive tear as greater than 5 cm. These tears, which are difficult to repair, are more commonly found in women over 65 years of age and are associated with advanced atrophy, degeneration and progressive fatty infiltration of the rotator cuff muscles (Dines 2007; Gerber 2000). Treatment options for these massive, retracted tears are limited as they are often deemed irreparable. In younger people, tendon transfers may be considered (Neri 2009).

The indications for surgical treatment of rotator cuff tears have not been fully defined. A systematic review of surgical treatment for rotator cuff disease (including tears), which included 14 trials, was unable to draw firm conclusions about the effectiveness of surgery (Coghlan 2009). Nonetheless, the review suggested that there were no significant differences in outcomes between open or arthroscopic surgery and non-surgical treatment (Coghlan 2009). Many studies have demonstrated that the size of the tear is correlated to the final outcome; partial or small full thickness tears usually have a satisfactory surgical result (Bianchi 2005; Bryant 2002; Fotiadou 2008).

Index test(s)

Currently, US, MRI or MRA are usually performed in patients contemplating surgery for rotator cuff tears to determine the characteristics of the tears. With the improvement of technology, the accuracy of these imaging tests is considered to have improved significantly over time, enabling useful assessment of the size and extent of the rotator cuff tear when planning surgery (Rees 2008). US is a diagnostic imaging technique used to visualise deep structures of the body by recording the echoes of pulsed ultrasonic waves directed into the tissues and reflected by tissue planes to the transducer. These echoes are converted into 'pictures' of the tissues under examination. Seltzer 1979 was the first to describe ultrasonographic evaluation of rotator cuff diseases. US of the shoulder is utilised in secondary, tertiary and, increasingly, primary healthcare settings to evaluate the integrity of the rotator cuff. It consists of a non-invasive examination that has practically no adverse effects and allows dynamic visualisation of the tendons during movement of the shoulder (Al-Shawi 2008). However, operator dependence and a long learning curve are frequently considered to be its limitation (O'Connor 2005; Rutten 2006), principally in view of partial thickness tears for which Le Corroller 2008 described a high interobserver variability.

MRI uses a powerful magnetic field to align the hydrogen atoms of water and other molecules in the body. Pulses of radiofrequency are applied which excite the magnetised atoms. These movements of hydrogen atoms, which vary in different tissues, are captured and the signal can be manipulated to build up an image of the body (Witte 2003). The first article about the use of MRI in the shoulder was published in 1986 (Kneeland 1986). Since then, this technique has been widely used in secondary and tertiary healthcare practice. MRI is a non-invasive method of imaging that is

unique in allowing high resolution images in multiple planes. It is a static examination that may be enhanced by an intra-articular injection of radiopaque dye (this is called magnetic resonance arthrography). The radiopaque dye acts as contrast material that helps to delineate intra-articular structures and outline abnormalities. MRA of the shoulder is also useful for assessing the rotator cuff integrity. In comparison with conventional MRI, MRA may improve diagnostic performance in detecting shoulder diseases; however, any potential benefit from MRA must be weighed against the invasiveness and additional discomfort caused by the procedure.

MRI and MRA have some absolute contraindications, such as the presence of intracerebral aneurysm clips, cardiac pacemakers, automatic defibrillators, biostimulators, implanted infusion devices, cochlear implants and metallic orbital foreign bodies (Witte 2003). They are also expensive and time consuming procedures. The strength of the magnet, the sequences used in the examinations and the person (e.g. consultant radiologist, musculoskeletal radiologist or trainee) interpreting and reporting the test may all affect the results.

Summary of diagnostic pathway

The evaluation of patients with suspected rotator cuff tear(s) should initiate with a full history of the patient's complaints and a thorough clinical examination of the shoulder. Decisions for using an imaging diagnostic test may be supported by whether the results are likely to affect treatment. For example, MRI, MRA or US might confirm a possible full thickness tear. The three index tests considered can also be used as triage tests in people suspected of having partial thickness tears. People whose tests were positive can be treated as having partial tears, while people with rotator cuff symptoms whose tests were negative can undergo further diagnostic procedures, such as diagnostic arthroscopy.

Reference tests

The reference tests for diagnosis of rotator cuff tears are invasive. The most common reference test is diagnostic arthroscopy. Arthroscopy is a minimally invasive surgical procedure that involves insertion of an arthroscope, a type of fibre-optic endoscope, into the joint through a small incision. This allows the surgeon to inspect and probe the articular (joint) and bursal side of the rotator cuff tendons, to assess accurately the rotator cuff insertion (footprint) and to perform a general examination of the shoulder joint in order to identify and treat other potential lesions (Dinnes 2003; Matava 2005). However, limitations associated with diagnostic shoulder arthroscopy include the need for anaesthesia, hospital admission and some interobserver variation in the classification of tears (Kuhn 2007).

Open surgery (including mini-open) has also been used as a reference test although it is more limited than arthroscopy because joint

surface or inferior surface tears are difficult to access and identify using an open approach. Thus open surgery is less accurate than arthroscopy for detecting partial rotator cuff tears.

Rationale

US, MRI and MRA are increasingly being used to assess the presence and size of rotator cuff tears to assist in planning surgical treatment. Improved techniques have resulted in increased reliance on these tests, in place of a separate diagnostic arthroscopy, although arthroscopic examination of the shoulder joint is still commonly performed as part of surgical treatment. US, MRI and MRA are operator and reader dependent. It is not known whether any one test is superior to either of the two others or whether performing US and MRI or US and MRA enhances their value (Swen 1999). It is also not known whether these diagnostic tests provide useful additional information compared with diagnostic arthroscopy, which is an accepted part of the surgical treatment. While, the units costs of MRI and MRA are greater than US, the cost-effectiveness of the three tests has not been determined.

We identified two relevant systematic reviews with meta-analyses that assessed diagnostic imaging tests for rotator cuff disease (De Jesus 2009; Dinnes 2003). The literature search in both reviews was restricted to English language only. Dinnes 2003 evaluated the diagnostic accuracy of clinical testing of US, MRI and MRA for detecting rotator cuff tears using both surgical and non-surgical tests as the reference standard. The authors included 38 studies that assessed the accuracy of US, 29 studies that assessed the accuracy of MRI and 6 studies that assessed the accuracy of MRA and concluded that US or MRI were equivalent for detecting full thickness rotator cuff tears, although MRI was more expensive and US may be better at detecting partial tears. The search date for the review was October 2001. A later review with a search date in September 2007, De Jesus 2009, conducted a meta-analysis comparing the diagnostic accuracy of US and MRI for rotator cuff tears using surgery as the reference standard. This systematic review included 65 studies but the appraisal of the methodological quality of the included studies was unclear or inadequate. De Jesus 2009 concluded that US is as accurate as MRI for both full and partial thickness rotator cuff tears and also suggested that US may be the most cost-effective imaging test for detecting rotator cuff

Important technological improvements in US, MRI and MRA have been made since the search dates of both systematic reviews, and new studies evaluating US, MRI and MRA have been published. Our review involves an updated search for diagnostic accuracy studies for rotator cuff tears and will not be restricted to English language publications.

To compare the diagnostic test accuracy of magnetic resonance imaging (MRI), magnetic resonance arthrography (MRA) and ultrasonography (US) for detecting any rotator cuff tears (i.e. partial or full thickness) in people with shoulder pain for whom surgery is being considered.

We divided our objectives as follows.

- To compare the diagnostic accuracy of US, MRI and MRA for diagnosing any rotator cuff tears (partial or full thickness)
- To compare the diagnostic accuracy of US, MRI and MRA for diagnosing full thickness rotator cuff tears (one or more tendons)
- To compare the diagnostic accuracy of US, MRI and MRA for diagnosing partial thickness rotator cuff tears

Investigation of sources of heterogeneity

We planned to investigate the following potential sources of heterogeneity:

- Type of tear: acute traumatic and chronic degenerative
- Type of reference standard: open (including mini-open) surgery or arthroscopy

METHODS

Criteria for considering studies for this review

Types of studies

All diagnostic accuracy studies that compared one or more of the index tests with one or both of the reference tests in patients suspected of having a partial or full thickness rotator cuff tear were included. We only included results from full reports of prospective studies. Studies with an excessively long period of time (i.e. a year or longer) between the index and reference tests were excluded because there is evidence that rotator cuff tears can progress over time (Mall 2010; Melis 2010); however, the rate of progression is not clearly defined.

We included articles in English and languages for which a full translation could be obtained. Non-English articles where a full translation could not be obtained are cited in the Characteristics of studies awaiting classification but not included in the review. For studies reported in multiple publications, we included only the most recent or complete report. References to the other publications were cited under the same study identifier.

OBJECTIVES

Participants

We included people with shoulder pain suspected of having a rotator cuff tear for whom surgery was being considered. Studies that included healthy controls or participants who had been previously diagnosed with other specific shoulder pain (e.g. shoulder instability, osteoarthritis, rheumatoid arthritis, frozen shoulder, benign or malignant tumours or referred pain) were excluded. Studies that included participants with shoulder pain, but in which it was unclear if all the participants were suspected of having rotator cuff tears, were also excluded.

Index tests

Studies that assessed the accuracy of US, MRI or MRA were included.

Target conditions

We included studies that evaluated the index tests for detection of at least one of three target conditions:

- presence of any rotator cuff tears (partial or full thickness);
- presence of full thickness tears;
- presence of partial thickness tears.

To standardise classification for this review, rotator cuff tears were dichotomised as absence or presence of any, full and partial thickness tears.

Reference standards

We required arthroscopy or open (including mini-open) surgery findings to be the reference standards.

Search methods for identification of studies

Electronic searches

We searched relevant computerised databases for eligible diagnostic studies: MEDLINE (PubMed) (1966 to March 2011), EMBASE (Elsevier) (1980 to February 2011), LILACS (Bireme) (1982 to February 2011) and the Cochrane Register of Diagnostic Test Accuracy Studies (February 2011). We also searched DARE (Database of Abstracts of Reviews of Effects), the HTA Database (Health Technology Assessments Database) and the MEDION database (February 2011) for other related diagnostic test accuracy reviews, and we checked the reference lists of those reviews that were relevant for additional studies. We also searched the US Health Services Research Projects in Progress and the UK Clinical Research Network Portfolio Database for ongoing and recently completed studies. When possible, non-English articles were assessed through translation by a native speaker.

We used a sensitive search strategy as recommended by the Cochrane Collaboration for MEDLINE (PubMed), EMBASE (Elsevier) and LILACS (Bireme) (De Vet 2008). See Appendix 1 for the MEDLINE and EMBASE search strategies.

Searching other resources

We checked the reference lists of articles, reviews and textbooks for relevant primary diagnostic studies and systematic reviews. We handsearched abstracts of the British Elbow and Shoulder Society annual meetings (2005 to July 2011) and American Academy of Orthopaedic Surgeons annual meetings (2005 to July 2011). We also contacted experts in the field.

Data collection and analysis

We used the methods suggested in the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy (Deeks 2009).

Selection of studies

Two review authors (ML and RJ) independently screened the titles and abstracts of retrieved records to identify potentially relevant studies for inclusion. Duplicates were removed and the remaining references were examined. Studies which clearly did not meet the inclusion criteria were excluded, and copies of the full text of potentially relevant references were obtained. ML and RJ independently assessed full text reports and determined inclusion or exclusion of the studies. Any uncertainties or disagreements were resolved by discussion and, when necessary, by adjudication from a third author (RB).

Data extraction and management

Two review authors (ML and RJ) independently collected the available data using a piloted data extraction form without masking of study authors or other identifying information. A third review author (RB) was consulted for resolution of any disagreements. When necessary, we sent requests to study authors for additional information or data. Diagnostic accuracy studies that reported insufficient data for construction of two-by-two tables were excluded from the review.

We retrieved the following data.

- 1. General information: title, journal, year, publication status, country of study, period of study, primary objective and study design (i.e. prospective versus retrospective and consecutive versus non-consecutive).
- 2. Sample size: number of participants meeting the criteria and total number screened.
- 3. Baseline characteristics: baseline diagnosis, age, sex, dominant arm, nature of onset (e.g. traumatic or non-

traumatic), duration of symptoms, prior treatment, inclusion and exclusion criteria.

- 4. Target condition as reported.
- 5. Index test: description of technique, criteria for positive result, timing of test and expertise of the clinician or technician performing the test.
- 6. Reference standard test: description of technique, criteria for positive result, time from index to reference test and expertise of the clinician or technician performing the test.
- 7. Adverse effects or complications due to index test(s) and reference standard test(s).
- 8. Number of true positives (TP), true negatives (TN), false positives (FP) and false negatives (FN). We extracted data for operational definitions for category of tear (e.g. partial, full or any thickness tears). Multiple outcome categories are often reported for rotator cuff tears: partial thickness tear, full thickness tear and no tears (i.e. three-by-three tables). Currently available methods for evaluating diagnostic tests rely on dichotomised disease status. Therefore, for the assessment of each target condition, we dichotomised rotator cuff tears using a strategy based on the options for treatment. To create two-by-two tables for partial thickness tears, data for full thickness tears were included with those for no tears. We did not exclude data for any category. We included data for partial thickness tears with those for full thickness tears to create two-by-two tables for any tears.

Assessment of methodological quality

The methodological quality of the included studies was assessed independently by two review authors (ML and RJ) and disagreement on study quality was resolved by a third review author (RB). At the same time as data extraction, the methodological quality of selected studies was assessed using a modified version of the QUADAS checklist (Whiting 2003), following the guidelines provided in Chapter 9 of the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy (Reitsma 2009). Appendix 2 explains how we applied the QUADAS items for assessing the included studies.

Statistical analysis and data synthesis

Our unit of analysis was the shoulder. For each test and target condition, estimates of sensitivity and specificity from each study were plotted in receiver operating characteristic (ROC) space and forest plots for visual examination of variation in test accuracy. Where adequate data were available, we conducted meta-analyses using the bivariate model (Chu 2006; Reitsma 2005). In the bivariate model, the logit-transformed sensitivities and specificities, and the correlation between them across studies are modelled directly. The model accounts for sampling variability within studies and also accounts for between study variability through the inclusion of random-effects. In preliminary meta-analyses for each

target condition, we fitted the bivariate model separately for each test. We examined the variance of the random-effects parameters to consider the magnitude of heterogeneity and to judge whether there were differences in heterogeneity in sensitivities and specificities between tests, before comparing the tests in a single model for formal assessment of comparative accuracy.

Comparative accuracy studies are scarce (Takwoingi 2013). Therefore, whenever possible, we included all studies of US, MRI and MRA (i.e. an indirect comparison) in the main comparative metaanalysis for each target condition. Due to few studies of MRA and considerable heterogeneity in study results, we only performed pairwise comparisons of MRI and US for detection of partial thickness tears and any tears but compared the three tests for detection of full thickness tears. We compared test accuracy by adding covariate terms for test type to the parameters of the bivariate model to determine which test was superior in terms of sensitivity or specificity or both. The variance coefficients from the preliminary meta-analysis and summary ROC plot for each test indicated differences in heterogeneity between tests and so we extended the bivariate model to allow the variances of the random-effects to vary with test type. We assessed the statistical significance of the difference in sensitivity or specificity between tests by using likelihood ratio tests comparing models with and without the covariate terms in the bivariate model. The summary sensitivities and specificities (i.e. average operating points) were plotted on summary ROC plots with corresponding 95% confidence regions. Summary positive and negative likelihood ratios were derived from functions of the bivariate model parameters, with 95% confidence intervals computed using the delta method.

Indirect comparisons of tests are not ideal and are susceptible to bias because other factors, such as participant and study design characteristics, may confound differences between tests. Thus in secondary analyses, we restricted the test comparisons to only studies that evaluated the tests in the same population. Because the studies were few, we were unable to perform meta-analyses but used linked summary ROC plots where estimates for each of the two tests from each study are joined by a line to illustrate the results. Furthermore, for each target condition, we quantified the difference in sensitivities and specificities between pairs of tests by computing differences in these proportions together with the corresponding 95% CI. Thus we visually and numerically demonstrated the change and consistency of the direction of the change in test performance between the tests. We used the xtmelogit command in Stata version 11.2 (StataCorp, College Station, Texas) to fit the bivariate models.

Investigations of heterogeneity

Heterogeneity was investigated in the first instance through visual examination of forest plots and summary ROC plots. The type of tear and type of reference standard reported in each study were presented on forest plots along with the estimates of sensitivity and

specificity. In exploratory analyses, we ordered studies on the forest plots by each of the two covariates in turn and also by sensitivity or specificity to examine the pattern of variation between studies. If there were sufficient data we planned to formally investigate heterogeneity by adding covariates to the bivariate model for each potential source of heterogeneity.

Sensitivity analyses

If there were sufficient studies, we performed sensitivity analyses by comparing results based on all studies with results of subsets of studies that complied (scored 'Yes') with the following methodological quality items of the QUADAS checklist (Whiting 2003).

- Representative spectrum
- Acceptable reference standard
- Acceptable delay between tests
- Index test results blinded
- Reference standard results blinded

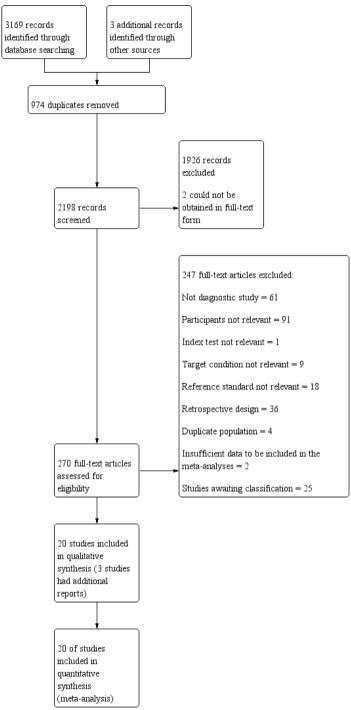
We also investigated the effect of unit of analysis by excluding studies that included both shoulders for any individual.

RESULTS

Results of the search

The search strategy identified 3169 references and the handsearch identified an additional three records (Figure 1). Of these, 2902 were excluded by initial screening of reference titles and abstracts. There were 974 duplicates and 1926 were either not relevant or did not meet the inclusion criteria. We were unable to obtain full text articles for two studies because they were not available from libraries or vendors.

Figure I. Study flow diagram



Of the 270 potentially eligible studies that were remaining and for which full reports were obtained (192 were reported in English and 78 in a non-English language), 20 studies met our inclusion criteria and were included in the review. Three of the included studies had additional published data. Two hundred and eighteen studies did not meet our inclusion criteria and were excluded (see Characteristics of excluded studies) and four reported on the same population or a subset of an already excluded study. At the time of publication, we are still awaiting translation of 25 non-English articles that are potentially relevant based upon their title and abstract; these are listed in Studies awaiting classification. Data from these studies will be added in future updates of this review if the studies are found to be eligible for inclusion.

Among the 20 included studies, six (Iannotti 2005; Kang 2009; Martin-Hervas 2001; Sipola 2010; Swen 1999; Teefey 2004) evaluated the accuracy of two different tests against the reference standard(s). See the Characteristics of included studies for details of the individual studies.

Methodological quality of included studies

The methodological quality of the 20 included studies was judged to be low or unclear for most categories and is summarised in Figure 2. The quality assessment results for the individual studies can be found in Figure 3 and details are given in the Characteristics of included studies.

Figure 2. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies

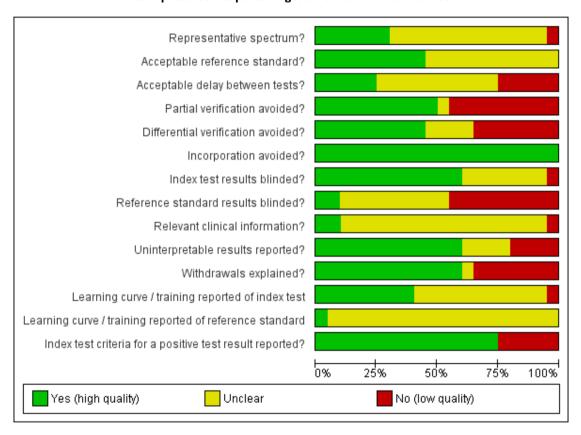
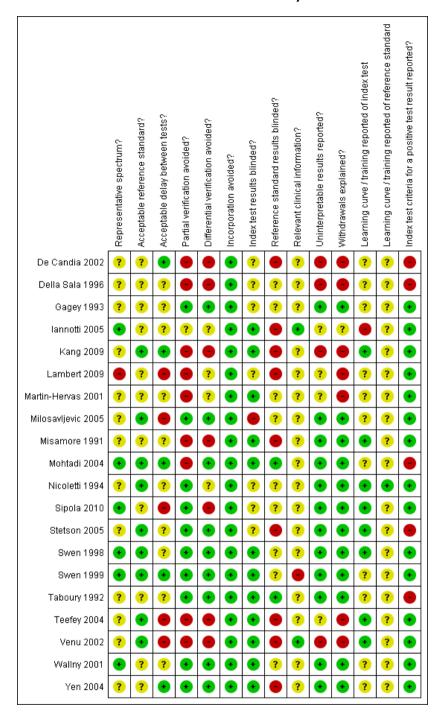


Figure 3. Methodological quality summary: review authors' judgements about each methodological quality item for each included study



The spectrum of participants (item 1) was judged to be representative in only 6 (30%) of the 20 studies. To be judged representative, studies had to be prospective with consecutive recruitment. The setting had to be secondary or tertiary care and the patients had to present with shoulder pain caused by a suspected rotator cuff tear for which surgery was being considered for treatment. Only half of the studies included an appropriate reference standard (item 2) and avoided partial verification (item 4). The majority (more than 50%) of studies poorly described the following QUADAS items: time period between reference standard and index test (item 3), differential verification bias (item 5), reference standard results blinded (item 8), relevant clinical information (item 9), and learning curve and training reported for both the index and reference standard readers (items 12 and 13) (see Appendix 2 for further explanation of these items). The remaining QUADAS items were well described in 50% to 75% of the included studies: index test results blinded (item 7), un-interpretable results reported (item 10), withdrawals explained (item 11) and index test criteria for a positive result (item 14). Criteria for test positivity was reported by 15 studies and varied between studies; the criteria are presented in detail in the Characteristics of included studies. As we anticipated in our protocol, the answer for 'incorporation avoided' (item 6) was 'Yes' (no bias) for all included studies.

Findings

Our meta-analyses were based on indirect comparisons because meta-analyses of studies that directly compared tests were not possible; there were only six comparative studies. No study directly compared MRA and MRI, or all three modalities in the same patients for any of the target conditions. The summary sensitivities and specificities for the tests are shown in Table 1 for each target condition. For MRA, meta-analysis was performed only for studies evaluating detection of full thickness tears due to the few studies and the degree of heterogeneity observed on summary ROC plots for studies evaluating partial thickness tears and any rotator cuff tears.

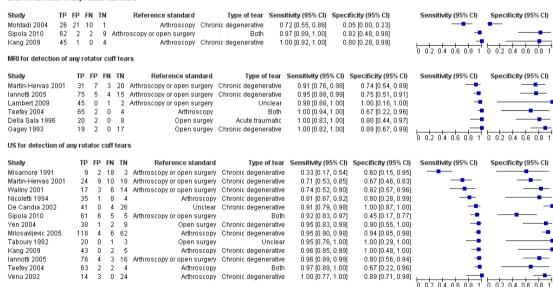
Two studies (Iannotti 2005; Milosavljevic 2005) included both shoulders of one and five patients respectively. The remaining studies reported the same number of patients and shoulders, with the exception of Milosavljevic 2005 where this information was missing.

Detection of any rotator cuff tears

Figure 4 shows the forest plots of the sensitivity and specificity estimates for MRI, US and MRA for the 17 studies that assessed any rotator cuff tears.

Figure 4. Accuracy of MRA, MRI and US for detecting any rotator cuff tears (forest plot)

MRA for detection of any rotator cuff tears

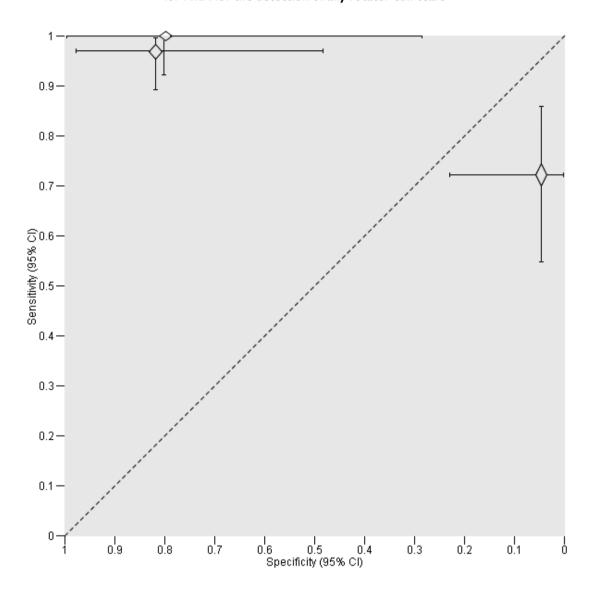


Six studies, based on 347 shoulders from 346 patients, assessed the diagnostic accuracy of MRI. The median study size was 55 (range 30 to 99), and the median prevalence of any rotator cuff tear was 73% (range 50% to 96%). The sensitivity of MRI reported in the studies ranged from 91% to 100%, and specificity from 67% to 100%. The summary estimates for the sensitivity and specificity of MRI were 98% (95% CI 92% to 99%) and 79% (95% CI 68% to 87%) respectively. The positive and negative likelihood ratios were 5 (95% CI 2 to 10) and 0.03 (95% CI 0.01 to 0.11) respectively.

Thirteen studies assessed the accuracy of US to detect any rotator cuff tears. The studies included a total of 854 shoulders from 848 patients with a median study size of 50 (range 24 to 190). The prevalence of any rotator cuff tears in the US studies was 80% (range 34% to 92%), and the sensitivities ranged from 33% to 100%, specificities from 45% to 100%. The summary sensitivity and specificity of US were 91% (95% CI 83% to 95%) and 85% (95% CI 74% to 92%) respectively. The positive and negative likelihood ratios were 6 (95% CI 3 to 12) and 0.11 (95% CI 0.05 to 0.22) respectively.

Three studies, based on 183 shoulders from 183 participants, assessed the accuracy of MRA for detection of any rotator cuff tears. The median study size was 58 (range 50 to 75), and the median prevalence was 85% (range 62% to 90%). The sensitivity of MRA ranged from 72% to 100%, and specificity from 5% to 80%. Meta-analysis was not performed but study specific estimates of sensitivity and specificity were plotted in ROC space with 95% CI in Figure 5.

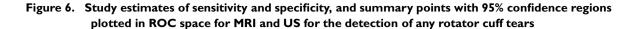
Figure 5. Study estimates of sensitivity and specificity with 95% confidence intervals plotted in ROC space for MRA for the detection of any rotator cuff tears

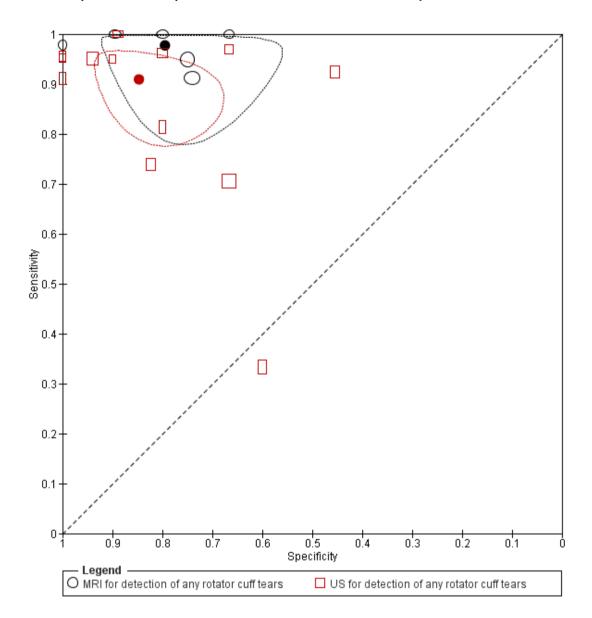


Comparison of MRI and US for detection of any rotator cuff tears

Using the 11 studies that evaluated the accuracy of either MRI or US for detection of any rotator cuff tears, neither test was found to be superior in terms of sensitivity or specificity. Although the sensitivity of MRI was 7% higher than that of US and the specificity of MRI was 6% lower than that of US (Figure 6; Table 1), there was no statistically significant difference between the two tests (P = 0.13). In the analysis restricted to the three studies

(231 shoulders from 230 patients) that performed head-to-head comparisons of MRI and US within the same patients (Table 2, see Appendix 3 for additional figure), two studies reported higher sensitivity and specificity for MRI compared to US while the other study reported higher sensitivity and specificity for US compared to MRI. For head-to-head comparisons of MRA and US, there were only two studies (127 shoulders from 127 patients). Both studies reported higher sensitivity for MRA compared to US but the estimates of specificity were conflicting (Table 3).

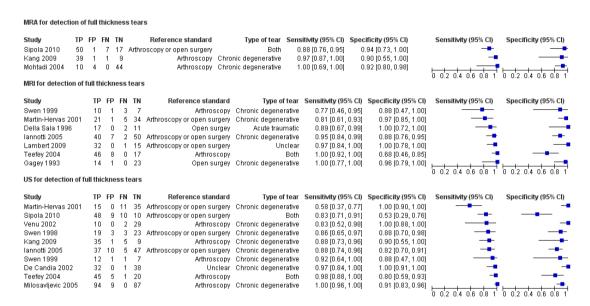




Detection of full thickness rotator cuff tears

The estimates of sensitivity and specificity for the 14 studies that evaluated either MRI, US or MRA for the detection of full thickness rotator cuff tears are shown in Figure 7.

Figure 7. Accuracy of MRA, MRI and US for detecting full thickness rotator cuff tears (forest plot)



Seven studies, based on 368 shoulders from 367 patients, assessed the diagnostic accuracy of MRI. The median study size was 48 (range 21 to 99), and the median prevalence of full thickness rotator cuff tear was 62% (range 37% to 69%). The sensitivities ranged from 77% to 100%, and specificities ranged from 68% to 100%. The summary sensitivity and specificity of MRI were 94% (95% CI 85% to 98%) and 93% (95% CI 83% to 97%) respectively. The positive and negative likelihood ratios were 13 (95% CI 6 to 29) and 0.06 (95% CI 0.02 to 0.16) respectively. Ten studies (729 shoulders from 723 patients) assessed the accuracy of US to detect full thickness tears. The median study size was 66 (range 21 to 190), and the median prevalence was 48% (range 29% to 80%). Sensitivities ranged from 58% to 100%. Specificities ranged from 53% to 100%. The summary sensitivity and specificity of US were 92% (95% CI 82% to 96%) and 93% (95% CI 81% to 97%) respectively. The positive and negative

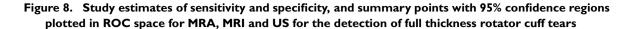
likelihood ratios were 12 (95% CI 5 to 34) and 0.09 (95% CI 0.04 to 0.20) respectively.

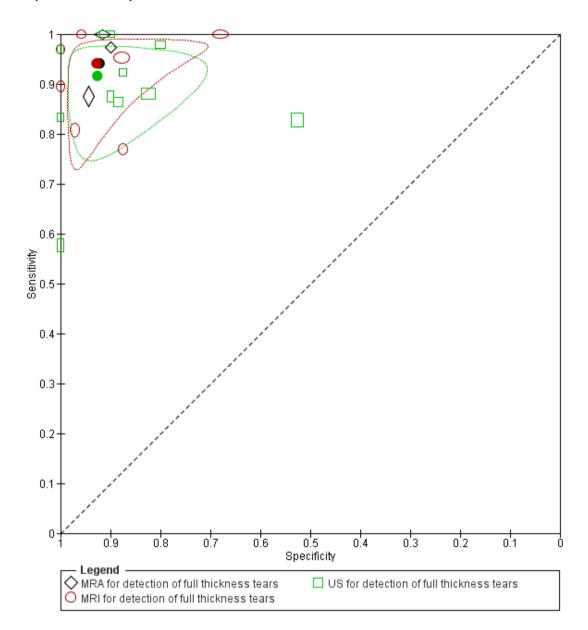
Three studies (the same studies that assessed any rotator cuff tears) assessed the accuracy of MRA to detect full thickness tears with sensitivities ranging from 88% to 100% and specificities ranging from 90% to 94%. The median prevalence was 76% (range 17% to 80%). The summary sensitivity and specificity of MRA were 94% (95% CI 80% to 98%) and 92% (95% CI 83% to 97%) respectively. The positive and negative likelihood ratios were 12 (95% CI 5 to 30) and 0.06 (95% CI 0.02 to 0.23) respectively.

Comparison of MRI, MRA and US for detection of full thickness rotator cuff tears

Based on the 14 studies that assessed the accuracy of MRI, MRA or US for detection of full thickness rotator cuff tears, the summary sensitivities and specificities of MRI, MRA and US were found

to be very similar (Figure 8; Table 1). There was no statistically significant difference in sensitivity or specificity (P = 0.7). Four studies (252 shoulders from 251 patients) directly compared MRI and US (Table 2, see Appendix 3 for additional figure) within the same patients, with no consistency among the studies as to which test was superior in terms of either sensitivity or specificity. Two studies (127 shoulders from 127 patients) directly compared MRA and US (Table 3). Both studies reported higher sensitivity for MRA compared to US. One of the two studies also reported a higher specificity while the other study reported no difference.

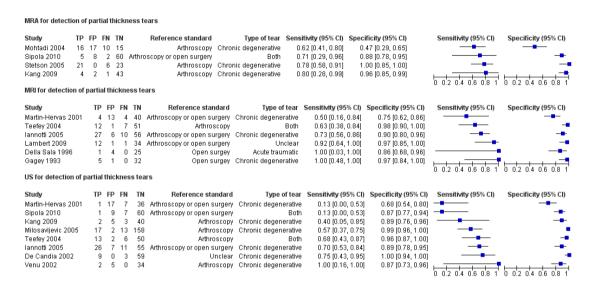




Detection of partial thickness rotator cuff tears

Figure 9 shows the estimates of sensitivity and specificity for the 13 studies that evaluated either MRI, MRA or US for the detection of partial rotator cuff tears.

Figure 9. Accuracy of MRI, US and MRA for detecting partial thickness rotator cuff tears (forest plot)



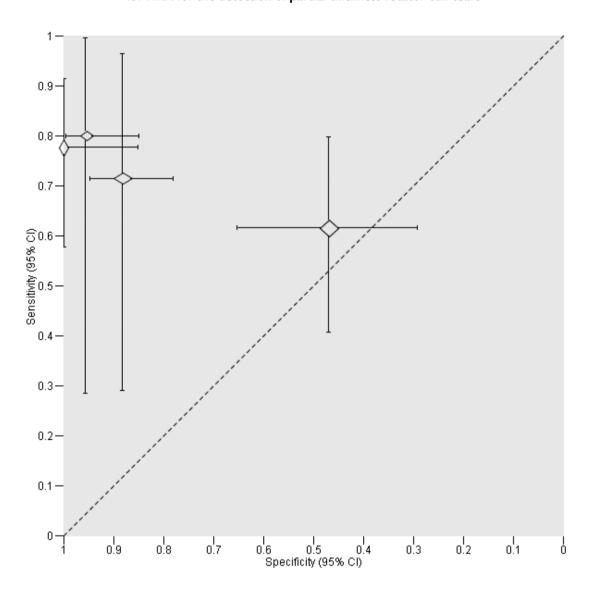
All six studies (347 shoulders from 346 participants) that assessed the accuracy of MRI for the detection of any rotator cuff tears also assessed partial thickness tears. The median prevalence of partial thickness tears was 20% (range 3% to 37%). Sensitivities ranged from 50% to 100% and specificities ranged from 75% to 98%. The summary sensitivity and specificity of MRI were 74% (95% CI 59% to 85%) and 93% (95% CI 84% to 97%) respectively. The positive and negative likelihood ratios were 10 (95% CI 4 to 26) and 0.28 (95% CI 0.17 to 0.48) respectively.

Eight studies (660 shoulders from 654 participants) assessed the accuracy of US to detect partial thickness tears with sensitivities ranging from 13% to 100% and specificities ranging from 68%

to 100%. The median prevalence was 14% (range 5% to 37%). The summary sensitivity and specificity of US were 52% (95% CI 33% to 70%) and 93% (95% CI 85% to 97%) respectively. The positive and negative likelihood ratios were 8 (95% CI 3 to 19) and 0.52 (95% CI 0.33 to 0.80) respectively.

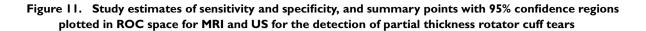
Four studies, based on 233 shoulders from 233 participants, assessed the accuracy of MRA to detect partial thickness tears with sensitivities ranging from 62% to 80% and specificities ranging from 47% to 100%. The median prevalence was 27% (range 9% to 54%). Meta-analysis was not performed but study specific estimates of sensitivity and specificity were plotted in ROC space with 95% CI in Figure 10.

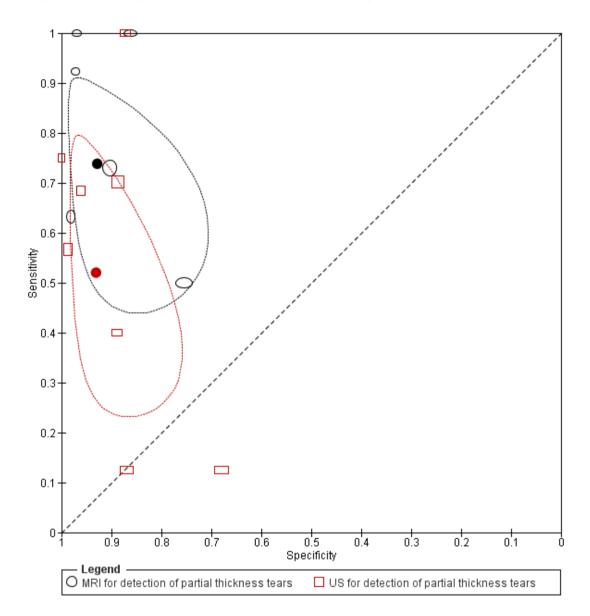
Figure 10. Study estimates of sensitivity and specificity with 95% confidence intervals plotted in ROC space for MRA for the detection of partial thickness rotator cuff tears



Comparison of MRI and US for detection of partial thickness rotator cuff tears

The diagnostic accuracy of MRI and/or US for detecting partial thickness tears was assessed in 11 studies. There was no statistically significant difference in sensitivity or specificity (P = 1.0) (see Table 1). The individual study estimates of sensitivity and specificity, with summary points and 95% confidence regions, for each test are shown in ROC space (Figure 11). The sensitivities for MRI and US were generally lower for detecting partial thickness tears than for detecting any or full thickness rotator cuff tears. The sensitivity of US for detecting partial thickness tears was only 52% (95% CI 33% to 70%).





The sensitivities and specificities of the three studies that directly compared MRI and US are shown in a ROC space (see Appendix 3 for figure) and differences between the sensitivities and specificities of the tests are presented for each study in Table 2. Two of the studies reported better sensitivity for MRI than US while all three studies reported better specificity for MRI compared to US. Two studies directly compared MRA and US for detection of any rotator cuff tears. Both studies reported better sensitivity and specificity for MRI compared with those of US (Table 3). The same studies also assessed partial thickness tears.

Detection of any subscapularis tendon tears

One study, Mohtadi 2004, assessed the accuracy of MRA for detection of any subscapularis tendon tears, and included 58 shoulders from 58 participants. The study had a prevalence of 33% for subscapularis tendon tears. The sensitivity and specificity of MRA were 79% (95% CI 54% to 94%) and 72% (95% CI 55% to 85%) respectively.

Investigation of heterogeneity

The type of tear and the reference standard used in each study are shown by forest plots for each target condition in Figure 4, Figure 7 and Figure 9. The studies on each plot were ordered according to sensitivity and specificity to demonstrate any pattern in the observed estimates of test accuracy. Based on these descriptive analyses and the magnitude of the variances of the random-effects parameters, we observed greater variability in sensitivity and specificity across studies of US than across studies of MRI or

MRA. We were unable to formally investigate potential sources of heterogeneity because the number of studies available for each test was either inadequate or the same value of a covariate was reported by most studies.

Sensitivity analyses

There were few studies of MRI and MRA, and so we could not perform sensitivity analyses for these tests. We performed sensitivity analyses for US for each of the target conditions. We were only able to investigate the impact of two (acceptable reference standard and index test results blinded) of the five quality items we had specified because few studies scored 'Yes' on the other three items (representative spectrum, acceptable delay between tests, and reference test results blinded). There were small differences in sensitivity and/ or specificity (Appendix 4). The largest difference was observed between the summary sensitivity of US for detecting partial thickness tears based of all studies (52%, 95% CI 33% to 70%) and the summary sensitivity (62%, 45% to 77%) based on only studies where the reference standard was acceptable. However, the confidence intervals were comparable and the specificities were similar. The exclusion of studies that did not meet either criteria made no difference to our findings. Two studies included both shoulders for six participants and one study did not report the number of participants so it is unclear whether more than one shoulder was included per participant. We investigated the impact of the unit of analysis on the findings for MRI and US by excluding the three studies, thus assuming the individual as the unit of analysis; the results were found to be consistent with the main analyses based on shoulders.

Summary of findings

What is the best imaging modality for rotator cuff tears?				
Patient population	Patients with shoulder pain suspected of having a rotator cuff tear for whom surgery is being considered			
Prior testing	Clinical examination.			
Settings	Secondary or tertiary care.			
Index tests	Magnetic resonance imaging (MRI), magnetic resonance arthroscopy (MRA) and ultrasonography (US)			
Reference standard	Arthroscopy and/or open (including mini-open) surgery findings			
Target condition	Rotator cuff tears: any tear or full or partial thickness tears			
Importance	Imaging tests are usually performed to determine the characteristics of the rotator cuff tears in order to plan surgery			
Included studies	We included 20 (1147 shoulders) prospective accuracy studies that evaluated at least of one of the tests Six of the 20 studies reported results for 2 tests evaluated in the same patients			
Quality concerns	Patient characteristics and study design were poorly reported Most of the QUADAS items were scored unclear for many studies			
Limitations	We observed considerable variation in results between studies, especially for US studies Criteria for test positivity (index tests and reference standard) varied between studies We could not formally investigate potential sources of heterogeneity due to the number of studies available for each test or because most studies reported the same value for a covariate Our findings were based on small studies with poor reporting of patient characteristics and study design Because there were few comparative studies, test comparisons relied on indirect evidence which may be confounded by differences in patient and study design characteristics No study evaluated MRA, MRI and US in the same population.			
Test	Studies Cases/Shoulders Summary sensitivity Summary specificity Consequences in a cohort of 100 (95% CI)			

					Madian	Na: 2	0
					Median prevalence% (range) ¹	MISSEG Cases ²	Over treated ²
Any rotator cuff tears							
MRI	6	263/347	98 (92, 99)	79 (68, 87)	80 (34 to 96)	2	4
US	13	626/854	91 (83, 95)	85 (74, 92)	_	7	3
MRA ³	3	145/183	-	-		-	-
Full thickness tears							
MRI	7	193/368	94 (85, 98)	93 (83, 97)	56 (17 to 80)	3	3
US	10	386/729	92 (82, 96)	93 (81, 97)	_	4	3
MRA	3	107/183	94 (80, 98)	92 (83, 97)		3	4
Partial thickness tear	'S						
MRI	6	83/347	74 (59, 85)	93 (84, 97)	14 (3 to 54)	4	6
US	8	121/660	52 (33, 70)	93 (85, 97)		7	6
MRA ³	4	65/233	-	-		-	-
Comparisons of the in	maging tests for each	type of tear					
Comparison	Findings						
MRIand US for any rotator cuff tears	We did not perform meta-analysis of MRA studies. The sensitivity of MRA ranged between 72% and 100% and the specificities between 5% and 82% in the three studies There was a 7% difference in the sensitivities of MRI and US, and a 6% difference in specificities. The differences were not statistically significant (P = 0.13) Given a median prevalence of 80%, 80 out of 100 patients will have any rotator cuff tears Of the 80 cases, two will be missed if tested using MRI or seven will be missed if tested using US Of the 20 patients without any rotator cuff tears, four will undergo unnecessary surgery if tested using MRI or three If tested using US						

MRI, US and MRA for full thickness tears	MRA, MRI and US had very similar sensitivities and specificities There was no evidence to suggest a difference in sensitivity or specificity between the tests $(P = 0.7)$
MRI and US for partial thickness tears	We did not perform meta-analysis of MRA studies. The sensitivity of MRA studies ranged between 62% and 80% and the specificities between 47% and 100% in the four studies Comparing MRI and US, the specificities were found to be similar and despite the large difference in sensitivity (22%), there was no evidence to suggest a difference in sensitivity or specificity between both tests (P = 1.0) Given a median prevalence of 14%, 14 out of 100 patients will have partial thickness tears Of the 14 cases, two will be missed if tested using MRI but if tested using US, seven will be missed Of the 20 patients without any rotator cuff tears, four patients will undergo unnecessary surgery if tested using MRI or three patients If tested using US

Conclusions: MRI, US and MRA have good diagnostic accuracy for detection of full thickness tears and may perform similarly

The performance of MRI and US may be comparable for detection of partial thickness tears or for detection of any rotator cuff tears

The strength of the evidence for all test comparisons is limited because most studies were small and methodologically flawed, and there were few comparative studies

Well designed studies that directly compare the three tests for detection of rotator cuff tears are needed

There was limited evidence on the best test to diagnose subscapularis tendons tears

¹ The median prevalence and range were computed using all the studies that evaluated each target condition.

² Missed and over treated numbers were computed using the median prevalence for each target condition.

³ Meta-analyses were not performed for studies that evaluated partial thickness tears and those of any rotator cuff tears because there were few studies and considerable heterogeneity in estimates of sensitivity or specificity.

DISCUSSION

Summary of main results

This review summarised the evidence for the diagnostic accuracy of MRI, MRA and US for detecting rotator cuff tears in people with shoulder pain who were suspected of having a rotator cuff tear and for whom surgery was being considered. These imaging tests are usually carried out to determine the characteristics of the rotator cuff tear in order to plan surgery. We included only prospective accuracy studies that evaluated at least one of the tests. We identified 20 studies (1147 shoulders, 1141 participants), of which six evaluated the accuracy of two of the tests within the same participants (paired comparison).

We found no evidence to suggest differences in the sensitivities and specificities of MRI and US for detecting any rotator cuff tears or partial thickness tears. Similarly, we found no evidence to suggest differences in the sensitivities and specificities of MRI, MRA and US for detecting full thickness tears. The estimates were very similar and the tests demonstrated good discriminatory ability for detecting full thickness tears, with sensitivities and specificities of 92% and above. MRI and US had lower sensitivity for partial thickness tears than for any rotator cuff tears or full thickness tears, with US having a sensitivity of only 52% (95% CI 33% to 70%); this indicates that US may be only marginally better than chance in excluding a partial thickness tear. The specificities of the three tests were generally good except for detection of any rotator cuff tears. The estimates of sensitivity and specificity for any rotator cuff tears suggest that in a population of 100 people with shoulder pain suspected of having a rotator cuff tear and for whom surgery is being considered, if the prevalence was 80%, investigation with MRI may miss two cases (2/80, 3%), while investigation with US may miss seven cases (7/80, 9%). Among patients without a rotator cuff tear (20 out of 100), four patients tested using MRI may have a rotator cuff tear wrongly detected (4/20, 20%) and may undergo unnecessary surgery. A similar number (3/20, 15%) may be over-treated if US is used. The summary of all results are provided in Summary of findings.

It is important to emphasise that our review specifically addressed imaging of the rotator cuff by MRI, MRA or US in people with shoulder pain suspected of having a rotator cuff tear and for whom surgery is being considered, and therefore our results are not generalisable to people who present with shoulder pain in primary care where the prevalence of rotator cuff tears may be lower but importantly the prevalence of asymptomatic tears or people with shoulder pain not contemplating surgery could be much higher. Asymptomatic changes in the rotator cuff are common and increase with age and many observed abnormalities might not require specific treatment (Awerbuch 2008). Despite studies continuing to show that primary care practitioners display an over-reliance upon early imaging for shoulder pain (Buchbinder 2013;

Johal 2008; Patel 2011), at the present time, guidelines for the management of shoulder pain in primary care do not advocate imaging for shoulder pain unless there is a suggestion of serious pathology (Bussières 2007; Geraets 2009).

The unit of analysis used in evaluating the diagnostic accuracy of a test is likely to have an impact on the estimates of sensitivity and specificity of the test. Our unit of analysis was the shoulder. However, only six out of 1080 participants had both shoulders included in 19 of the 20 included studies; it was unclear in one study (Martin-Hervas 2001) whether the number of shoulders was the same as the number of participants. With the exception of Iannotti 2005 and Milosavljevic 2005, the studies reported the same number of participants and shoulders. Both Iannotti 2005 and Martin-Hervas 2001 compared the accuracy of MRI and US while Milosavljevic 2005 evaluated only US. In sensitivity analyses, we examined the impact of the unit of analysis by excluding the two studies that included both shoulders for any participant and the one study where it was unclear if the number of shoulders was the same as the number of participants. Overall, findings from the sensitivity analyses were consistent with findings from the main analyses.

Strengths and weaknesses of the review

This review was planned and conducted following criteria and methods set out in a published protocol (Lenza 2011). Our results were based on a comprehensive and sensitive literature search that aimed to identify all published studies. We used wide search terms and several electronic databases, not limited by language, and we excluded search filters for diagnostic terms, as they have limited utility (De Vet 2008). Other strengths of this review are our quality assessment of studies and our synthesis of studies with similar methodological features into a meta-analytic summary based on recommended methods. To increase the applicability and reliability of the summary findings, we included only prospective studies that investigated people with shoulder pain due to a suspected rotator cuff tear and for whom surgery was being considered. We excluded retrospective studies because of their potential for high risk of spectrum and verification bias (Bossuyt 2003; Van der Schouw 1995).

Our review has some limitations. Our findings were based on small studies with poor reporting of participant characteristics and study design. Most of the QUADAS items were scored as unclear for many studies. For example, only 25% of the included studies reported the time interval between the index tests and the reference standard. For some analyses, we observed considerable heterogeneity in sensitivity and/or specificity, which may be due to several factors including variation in the criteria for a positive diagnostic test for both the index tests and the reference standard, technical details of the tests, variation in population, and variation in operator or reader experience. The three diagnostic tests are known to be operator and reader dependent which may account

for some of the observed variation between studies, especially for studies of US which were found to be very heterogeneous. We could not formally investigate potential sources of heterogeneity due to the number of studies available for each test or because most studies reported the same covariate value. Our comparative meta-analyses were based mainly on non-comparative studies because only a small number of studies made direct comparisons between the tests. Consequently, it is possible that observed differences between tests may be confounded by differences in participant and study design characteristics. It is unclear to what extent these limitations influenced our findings.

An important weakness of this review is that due to resource limitations, 25 potentially eligible studies published in non-English languages are still awaiting translation. Good quality translation will be required to reliably extract data from these papers due to the complexity of diagnostic accuracy studies. The studies contain more than 2900 participants that could potentially provide data for analyses and they will be considered for inclusion in a future update of the review.

Comparison with existing reviews

We identified six previous systematic reviews of imaging tests to detect rotator cuff tears (De Jesus 2009; Dinnes 2003; Kelly 2009; Ottenheijm 2010; Shahabpour 2008; Smith 2012). Our review limited inclusion to prospective studies whereas the other systematic reviews allowed the inclusion of retrospective studies. Our literature search failed to identify a study (Ruiz Santiago 2000) which was included in the review by Smith 2012. However, this study would not have been eligible for inclusion in our review because arthrography or arthrographic computed tomography was also used as an index test.

Previous reviews reported similar results. De Jesus 2009 compared US with MRI for detecting rotator cuff tears using surgery as the reference standard. De Jesus 2009 included 65 studies and concluded that US was as accurate as MRI for diagnosing both full and partial thickness rotator cuff tears. Dinnes 2003 assessed the diagnostic accuracy of clinical testing, US and MRI for detecting rotator cuff tears using surgical and non-surgical tests as the reference standard (results also reported in Kelly 2009). Dinnes 2003 concluded that US and MRI were equivalent for detecting full thickness rotator cuff tears, and that MRI may be better at detecting partial thickness tears than US. Shahabpour 2008 also concluded that US and MRI were equivalent for detecting full thickness rotator cuff tears. However, in contrast Shahabpour 2008 concluded that MRA and US may be more accurate at detecting partial thickness tears than MRI. We did not pool MRA studies for detection of partial thickness tears. While our results suggested that MRI may be more sensitive than US, the difference was not statistically significant.

Ottenheijm 2010 assessed the accuracy of US for detecting sub-acromial diseases in patients presenting in primary and secondary care settings (search date 2001 to June 2010). This systematic re-

view included 23 studies and reported pooled sensitivity and specificity values that were comparable with our results for detecting full thickness tears. Ottenheijm 2010 reported a sensitivity of 95% for detecting full thickness tears compared to 92% (95% CI 82% to 96%) in our systematic review and a specificity of 93% compared with 93% (95% CI 81% to 97%) in our systematic review. However, for detection of partial thickness tears, Ottenheijm 2010 reported a much higher pooled sensitivity of 72% compared with our finding of 52% (95% CI: 33% to 70%). Smith 2012, which included both retrospective and prospective studies, assessed the diagnostic accuracy of MRI and identified 44 studies published up to May 2011. This systematic review reported pooled sensitivity and specificity values that were similar to our results for detecting full thickness tears and partial thickness tears. Smith 2012 reported a pooled sensitivity of 91% (95% CI 86% to 94%) for detecting full thickness tears which was comparable to our result of 94% (95% CI 85% to 98%). Smith 2012 reported a pooled specificity of 97% (95% CI: 96% to 98%) for detecting full thickness tears which is similar to our specificity of 93% (95% CI 83% to 97%). Smith 2012 reported a pooled sensitivity of 80% (95% CI 79% to 84%) for detecting partial thickness tears which is comparable to our sensitivity of 74% (95% CI 59% to 85%); and a pooled specificity of 95% (95% CI 94% to 97%) which is similar to our specificity of 93% (95% CI 84% to 97%). Overall, the results are generally consistent across the different reviews even though there were differences in inclusion criteria and review methods. Despite our study being the most up-to-date published systematic review, we included a much smaller number of studies (20 studies) than some of the previous reviews because we restricted our analyses to only prospective studies thus reducing the risk of spectrum and verification bias.

Applicability of findings to the review question

The applicability of our findings is limited because only 30% of the included studies reported an adequately representative spectrum of consecutive patients from secondary or tertiary care. Furthermore, partial verification was avoided in only 50% of the studies. MRI, MRA and US may have similar accuracy for detecting full thickness rotator cuff tears. The sensitivity of both MRI and US for partial thickness rotator cuff tears appeared to be much lower than their sensitivity for any rotator cuff tears or for full thickness tears. While the difference in sensitivity between MRI and US for detecting partial thickness tears was not statistically significant, US showed a much lower sensitivity (52%) than MRI (74%). A sensitivity of 52% suggests that US may not be any better than chance for detecting partial thickness rotator cuff tears. The specificities of the three tests were generally high except for the detection of any rotator cuff tears.

In many countries, US is less time consuming and less expensive and more readily available in secondary and tertiary care than MRI or MRA. Despite MRI and MRA being comparable for detection of full thickness rotator cuff tears, the choice of test may depend upon cost and availability. As the scope of this review was to limited to test accuracy, we were not able to determine if applying any imaging test prior to surgery results in different surgical interventions or benefits in terms of pain relief and shoulder function following surgery.

AUTHORS' CONCLUSIONS

Implications for practice

The diagnostic performance of MRI and US depends on the extent (i.e. partial or full thickness) of rotator cuff tears. Our findings suggest that MRI, US and MRA have good diagnostic accuracy and any of these tests could equally be used for detection of full thickness tears in people with shoulder pain for whom surgery is being considered. MRI and US also have good sensitivity for detecting any rotator cuff tears but poor sensitivity for detection of partial thickness tears. The validity and generalisability of our findings are limited because they were based on small, heterogeneous, non-comparative studies with methodological flaws.

Implications for research

There is a lack of good quality prospective cohort studies that directly compare the accuracy of MRI, MRA and US shoulder

imaging tests for people in secondary and tertiary care, with suspected rotator cuff tears, for whom surgery is being considered. Consequently, further studies are needed in order to evaluate the comparative accuracy of these imaging tests in such circumstances. Future studies should use a blinded design and should limit the amount of time between the index and reference tests as much as possible because there is evidence that rotator cuff tears can progress over time. We suggest that arthroscopy be used as the reference standard test because it is accurate for assessing the articular and bursal side of the rotator cuff. The results of the index test(s) and reference standard should be interpreted by experienced operators.

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^{*} Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

De Candia 2002

Clinical features and settings	Inclusion criteria: Participants with clinical suspicion of rotator cuff tear who underwent surgery Exclusion criteria: Not reported Duration of symptoms: Not reported Previous treatments: Not reported Care setting: Not reported
Participants	Place of study: Udine, Italy Period of study: January 2000 to December 2000 Number of participants eligible: 157 participants Number of participants enrolled IT and RS: - US and surgery: 71 participants Data available for analyses: - US and surgery: 71 participants Age (range): 34 to 80 years Male/Female: 31/40 Dominant arm: Not reported Nature of onset: Not reported
Study design	Primary objective: To determine the values of the US real time compound imaging in the evaluation of supraspinatus tendon in subacromial impingement disease Study design: Prospective, accuracy cohort study Unclear whether consecutive recruitment Language: English
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Surgery, unclear whether arthroscopy or open surgery - Description of technique: Not reported - Criteria for a positive result: Not reported
Index and comparator tests	Index test(s): US - Description of technique: Scanner: 7 to 12 MHz linear-array probe applying the soon CT digital algorithm Technique: Images were obtained in static and dynamic evaluations as described in (Martino 1998; Teefey 2000) Patient position: Static evaluation was performed on the patient's arm in standard position; dynamic evaluation was performed first with the patient's arm positioned from the internal rotation and extended position to abduction and internal rotation (forearm flexed and the back face of fingertips pointing to the scapula); the second part of the evaluation was performed by moving the patient's arm in adduction and keeping the internal rotation - Criteria for a positive result: Not reported - Time from symptoms to index test: Not reported

De Candia 2002 (Continued)

	- Time from index test to reference standard: Index test was performed on the day before reference standard
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
Notes	Part of population of this study was also reported in De Candia 2003 Although De Candia 2003 is more updated than this study, there were no extra data available to be included in the analyses The rotator cuff tears were focused on only supraspinatus tendon tears A two-by-two table of the ITs and RS was given, which tallied with the reported summary data

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Unclear whether consecutive recruitment
Acceptable reference standard? All tests	Unclear	The reference standard was surgery (unclear whether arthroscopy or open surgery) and the target conditions were presence of any rotator cuff tears, full thickness tears and partial thickness tears
Acceptable delay between tests? All tests	Yes	Index test was performed on the day before reference standard
Partial verification avoided? All tests	No	Not all the patients who received the index test underwent a reference standard to verify their true disease status Of the 157 eligible participants, only 71 (45.2%) underwent to reference standard
Differential verification avoided? All tests	No	The result of the index test probably influenced the choice of the reference standard
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Reference standard results blinded? All tests	No	The results of the index tests were probably known to the person interpreting the reference tests
Relevant clinical information? All tests	Unclear	Not reported

De Candia 2002 (Continued)

Uninterpretable results reported? All tests	No	The results of 86 (54.8%) patients were not reported
Withdrawals explained? All tests	No	Some of the eligible patients who entered the study did not complete it and these patients were not accounted for
Learning curve / training reported of index test? All tests	Unclear	The interpreters of index tests were two radiologists; however, the training/expertise was not described
Learning curve / training reported of reference standard? All tests	Unclear	Insufficient information was given to permit judgement
Index test criteria for a positive test result reported? All tests	No	Not reported

Della Sala 1996

Clinical features and settings	Inclusion criteria: Patients with recent trauma without documented articular bone defect radiologically, shoulder pain and disability persisting after appropriate conservative treatment, clinical examination suggestive of rotator cuff tears and/or impingement Exclusion criteria: Patients with suspected shoulder instability Duration of symptoms: Not reported Previous treatments: Not reported Care setting: Tertiary or secondary
Participants	Place of study: Trento, Italy Period of study: January 1993 to December 1994 Number of participants eligible: 80 participants Number of participants enrolled IT and RS: - MRI and open surgery: 30 participants Data available for analyses: - MRI and open surgery: 30 participants Age: mean 50.1 years (range 21 to 71 years) Male/Female: 23/7 Dominant arm: Not reported Nature of onset: Traumatic and chronic injury
Study design	Primary objective: Not reported Study design: Unclear whether prospective design. Non-consecutive recruitment Language: Italian
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Open surgery

Della Sala 1996 (Continued)

	- Description of technique: Open surgery: as described by Neer 1983 - Criteria for a positive result: Not reported
Index and comparator tests	Index test(s): MRI - Description of technique: MRI unit: 1.0 T scanner Sequences and Planes: Spin-echo T1-weighted (TR/TE: 786/17) in coronal and sagittal oblique planes; and TR/TE 450/12 in axial plane Patient position: Not reported - Criteria for a positive result: Full-thickness tears: an increase signal on the T1-weighted in the entire extension of the rotator cuff Partial thickness tears: an increased signal in not whole extension of the cuff - Time from symptoms to index test: Not reported - Time from index test to reference standard: Not reported
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
Notes	Raw data were given and it was possible to back-calculate this from the reported summary data

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Insufficient information was given to permit judgement
Acceptable reference standard? All tests	Unclear	The reference standard was open surgery and the target conditions were presence of any rotator cuff tears, full thickness tears and partial thickness tears
Acceptable delay between tests? All tests	Unclear	The study did not report the time elapsed between the index tests and reference standard
Partial verification avoided? All tests	No	Not all the patients who received the index test underwent a reference standard to ver- ify their true disease status Of the 80 eligible participants, only 30 re- ceived the reference standard
Differential verification avoided? All tests	No	The result of the index test probably influenced the choice of the reference standard

Della Sala 1996 (Continued)

Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Reference standard results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Relevant clinical information? All tests	Unclear	Not reported
Uninterpretable results reported? All tests	No	The results of 50 (62.5%) patients were not reported
Withdrawals explained? All tests	No	Some of the eligible patients who entered the study did not complete it and these patients were not accounted for
Learning curve / training reported of index test? All tests	Unclear	Insufficient information was given to permit judgement
Learning curve / training reported of reference standard? All tests	Unclear	Insufficient information was given to permit judgement
Index test criteria for a positive test result reported? All tests	No	Not reported

Gagey 1993

Clinical features and settings	Inclusion criteria: Patients with a rotator cuff syndrome resistant to any medical treatment and indication for surgery Exclusion criteria: Not reported Duration of symptoms: Not reported Previous treatments: Not reported Care setting: Tertiary
Participants	Place of study: Paris, France Period of study: 15 months period Number of participants eligible: 38 participants Number of participants enrolled IT and RS: - MRI and open surgery: 38 participants Data available for analyses: - MRI and open surgery: 38 participants Age (mean): 47 years

Gagey 1993 (Continued)

All tests

All tests

Acceptable reference standard?

	Male/Female: 14/24 Dominant arm: Not reported Nature of onset: Not reported	
Study design	Primary objective: To compare the results of the MRI with the open surgery Study design: Prospective accuracy cohort study. Unclear whether consecutive recruitment Language: French	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Open surgery - Description of technique: Not reported - Criteria for a positive result: Visual identification of the tears by the surgeon	
Index and comparator tests	Index test(s): MRI - Description of technique: MRI unit: 1.5 T surface circular coil Sequences: Spin-echo T2-weighted (TR/TE: 2000/25 to 75; TR/TE 1500/25 to 75) and TR/TE 300 to 500/20 Planes: Sagittal and coronal Patient position: Not reported - Criteria for a positive result: Increased signal on T2-weighted images - Time from symptoms to index test: Not reported - Time from index test to reference standard: Not reported	
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported	
Notes	Mr Jean-Philippe Regnaux and Mr Ludovic Trinquart kindly translated into English and extracted the data of this study The same population of this study was also reported in Gagey 1991 No two-by-two table of the ITs and RS was given, but it was possible to back-calculate this from the reported summary data	
Table of Methodological Quality		
Item	Authors' judgement	Description
Representative spectrum?	Unclear	Insufficient information was given to per-

mit judgement

and partial thickness tears

The reference standard was open surgery

and the target conditions were presence of any rotator cuff tears, full thickness tears

Unclear

Gagey 1993 (Continued)

Acceptable delay between tests? All tests	Unclear	The study did not report the time elapsed between the index tests and reference standard
Partial verification avoided? All tests	Yes	All patients who received the index test went on to receive verification of their dis- ease status using a reference standard
Differential verification avoided? All tests	Yes	All patients received the same reference standard, regardless of the result of their index test
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Reference standard results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Relevant clinical information? All tests	Unclear	Not reported
Uninterpretable results reported? All tests	Yes	The number of results reported agrees with the number of patients recruited
Withdrawals explained? All tests	Yes	No participants were excluded from the analysis
Learning curve / training reported of index test? All tests	Unclear	Insufficient information was given to permit judgement
Learning curve / training reported of reference standard? All tests	Unclear	Insufficient information was given to permit judgement
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Iannotti 2005

Inclusion criteria: Participants with a clinical diagnosis of rotator cuff symptoms, consisting of pain, decreased function, and/or weakness Exclusion criteria: Not reported Duration of symptoms: Not reported Previous treatments: Not reported Care setting: Tertiary and secondary
Place of study: Cleveland, Ohio, USA Period of study: Not reported Number of participants eligible: 98 participants (99 shoulders) Number of participants enrolled IT and RS: - MRI and arthroscopy or open surgery: 98 participants (99 shoulders) - US and arthroscopy or open surgery: 98 participants (99 shoulders) Data available for analyses: - MRI and arthroscopy or open surgery: 98 participants (99 shoulders) - US and arthroscopy or open surgery: 98 participants (99 shoulders) Age: Not reported Gender: Not reported Dominant arm: Not reported Nature of onset: Not reported
Primary objective: To define the accuracy of US, when performed in an orthopaedic surgeon's office, for the diagnosis of rotator cuff tears Study design: Prospective, consecutive, accuracy cohort study with fully paired direct comparison between MRI and US Language: English
Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy or open surgery - Description of technique(s): Not reported - Criteria for a positive result: Full thickness tears: a gap in the tendon; the involved tendons were measured with a calibrated probe or ruler, and the total tendon gap was measured in centimetres prior to débridement of the tendon edges Partial thickness tears: on either the bursal or the articular surface was identified as tendon-fraying and loss of tendon substance The size of the partial thickness tears was measured after débridement of the frayed portions of the tendon
Index test(s): MRI and US - Description of technique: MRI MRI unit: 1.5-T magnet Sequences and Planes: T1 and T2-weighted image sequences in the sagittal and coronal oblique and axial planes Patient position: Not reported US Scanner: 7.5 MHz transducer

Technique: Static and dynamic examinations

Images were obtained in transverse plane scans of the biceps tendon; longitudinal and parallel scans of the subscapularis tendon; perpendicular and parallel scans of the supraspinatus and infraspinatus tendons

Patient position: Both the patient and the examiner seated on backless stools facing each other

The patient positioned the arm at the side with the elbow bent to 90°

- Criteria for a positive result:

MRI: Full thickness tears: a fluid filled the gap in the tendon on the T2-weighted sagittal or coronal oblique images

Partial thickness tears: an increase signal on the T1-weighted images, with brighter signal on the T2-weighted paired image

The location of the tear was defined by the tendon(s) involved

US: Full thickness tears: a gap in the tendon substance with retraction with increased echogenic signal from the exposed articular cartilage of the humeral head

Partial thickness tears: an increase echogenic signal intensity or a focal decrease in the thickness of the tendon or both

The location of the tear was defined by the tendon(s) involved

- Time from symptoms to index test: Not reported
- Time from US to MRI: Not reported
- Time from index test to reference standard: Not reported

Follow-up

Adverse events due to index test(s): Not reported

Adverse events due to reference standard test(s): Not reported

Notes A two-by-two table of the ITs and RS was given, which tallied with the reported summary data

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Tertiary or secondary care, participants with suspected of having any rotator cuff tears The study was prospective and recruitment was consecutive
Acceptable reference standard? All tests	Unclear	The reference standard was arthroscopy or open surgery and the target conditions were presence of full thickness tears and partial thickness tears
Acceptable delay between tests? All tests	Unclear	The study did not report the time elapsed between the index tests and reference standard
Partial verification avoided? All tests	Unclear	The study did not report how many patients had US and did not proceed to

Iannotti 2005 (Continued)

		surgery
Differential verification avoided? All tests	Unclear	Insufficient information was given to permit judgement
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Yes	The study was prospective and the results of the index tests were interpreted before the reference standard
Reference standard results blinded? All tests	No	The results of the index tests were known to the person interpreting the reference tests
Relevant clinical information? All tests	Yes	The authors had knowledge of history, physical findings and radiographs
Uninterpretable results reported? All tests	Unclear	Insufficient information was given to permit judgement
Withdrawals explained? All tests	Unclear	Insufficient information was given to permit judgement
Learning curve / training reported of index test? All tests	No	Performace of index tests was not by radiologist or surgeon and they had only two training sections
Learning curve / training reported of reference standard? All tests	Unclear	Insufficient information was given to permit judgement
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Kang 2009

Rang 200)	
Clinical features and settings	Inclusion criteria: Participants with clinical findings of impingement and suspected rotator cuff tear referred for MRA Exclusion criteria: Participants with previous rotator cuff repair, dislocation, previous humeral fracture, and infectious or inflammatory arthritis were excluded from the study Participants who showed clinical improvement while scheduled for surgery and refused it Duration of symptoms: Not reported Previous treatments: Not reported Care setting: Not reported
Participants	Place of study: Seoul, Korea Period of study: February 2007 to August 2008 Number of participants eligible: 128 participants Number of participants enrolled IT and RS: - MRA and arthroscopy: 50 participants - 3D-US and arthroscopy: 50 participants Data available for analyses: - MRA and arthroscopy: 50 participants - 3D-US and arthroscopy: 50 participants - 3D-US and arthroscopy: 50 participants - 3D-US and arthroscopy: 50 participants Male/Female: 32/18 Dominant arm: Not reported Nature of onset: Not reported
Study design	Primary objective: To compare the diagnostic performance of three-dimensional (3D) US and MRA for both the detection of supraspinatus tendon tears and the quantification of their size, with arthroscopic findings used as the standard Study design: Prospective, consecutive, accuracy cohort study with fully paired direct comparison between MRA and 3D-US Language: English
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy - Description of technique: In a partial thickness tear or in which the initial arthroscopic findings differed from those reported on the imaging, the rotator cuff was examined from both the articular side and the bursal side Cuff tear size was measured with a calibrated probe using the posterior portal to measure the anterior-posterior dimension and the lateral portal to measure the medial-lateral dimension - Criteria for a positive result: The presence or absence of a full or partial thickness tear was noted at the arthroscopy An estimate of tear size was performed by the location of the medial edge of the tear
Index and comparator tests	Index test(s): MRA and 3D-US - Description of technique: MRA MRI unit: 3.0 T magnet with a dedicated shoulder coil

Notes	A two-by-two table of the ITs and RS was given, which tallied with the reported summary data
	The rotator cuff tears were focused on only supraspinatus tendon tears
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
	Sequences and Planes: Fat-suppressed T1-weighted spin-echo images (TR/TE, 650 to 750/12) in the transverse plane, sagittal oblique plane and coronal oblique plane. T2-weighted turbo spin-echo (TSE) images (4000 to 4500/70) in the sagittal oblique and coronal oblique plane Contrast and procedure: 12 to 15 mL of diluted gadopentetate dimeglumine with a concentration of 2.0 mmol/L The procedure involved direct intra-articular injection with fluoroscopic guidance Patient position: Supine with the arm in neutral position 3D US Scanner: 8 to 15 MHz with a dedicated 3D-volume transducer Technique: Images were obtained in longitudinal scans of supraspinatus tendon 3D-US data were transferred to a separate workstation which was equipped with various post-processing software that allowed display and interactive analysis of the 3D data In the section mode the volume data were visualised in three orthogonal scan planes, i. e., longitudinal, transverse, and the C-plane (parallel to the surface of the transducer) Patient position: Patients with the arm in internal rotation, as the patient placed his or her arm on the buttock - Criteria for a positive result: MRA: Full-thickness tears: the extension of the contrast medium through the entire thickness of the rotator cuff or presence of the contrast medium in the subacromial-subdeltoid bursa or both Partial thickness tears: a hypoechoic zone extending through the entire substance of the cuff or segmental or complete loss of rotator cuff substance with visualised tear margins or non-visualisation of the cuff Partial thickness tear: a focal hypoechoic zone extending through the entire substance of the cuff or segmental or complete loss of rotator cuff substance with visualised tear margins or non-visualisation of the cuff Partial thickness tear: a focal hypoechoic or anechoic defect in the tendon involving either the bursal or the articular surface and manifesting in both longitudinal transverse planes - Time from symptoms to index test: Not reported - Time from 3D-

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Population was patients with suspected of having any rotator cuff tears The study was prospective and recruitment was consecutive

Kang 2009 (Continued)

		The care setting was not specified
Acceptable reference standard? All tests	Yes	The reference standard was arthroscopy and the target conditions were presence of full thickness tears and partial thickness tears
Acceptable delay between tests? All tests	Yes	The average interval between reference standard and index test was less than one month
Partial verification avoided? All tests	No	Not all the patients who received the index test underwent a reference standard to verify their true disease status Of the 128 eligible participants only 50 (39%) underwent to reference standard 16 patients (12.5%) refused surgery as they had improved and it was unclear why the other patients did not receive the reference standard
Differential verification avoided? All tests	No	Probably the result of the index test influenced the choice of the reference standard
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Yes	The index tests were interpreted before and without knowledge of the reference standard results
Reference standard results blinded? All tests	No	The results of the index tests were probably known to the person interpreting the reference tests
Relevant clinical information? All tests	Unclear	Not reported
Uninterpretable results reported? All tests	No	The results of 78 (41%) patients were not reported
Withdrawals explained? All tests	No	Some of the eligible patients who entered the study did not complete it and these patients were not accounted for
Learning curve / training reported of index test? All tests	Yes	The interpreter of MRA was a musculoskeletal radiologist with 15 years experience The interpreters of US were two radiologists with respectively 5 and 10 years expe-

Kang 2009 (Continued)

		rience performing musculoskeletal US
Learning curve / training reported of reference standard? All tests	Unclear	Insufficient information was given to permit judgement
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Lambert 2009

Lambert 2009	
Clinical features and settings	Inclusion criteria: Not reported Exclusion criteria: Not reported Duration of symptoms: Not reported Previous treatments: Not reported Care setting: Tertiary or secondary
Participants	Place of study: Dijon, France Period of study: November 2005 to June 2007 Number of participants eligible: 192 participants Number of participants enrolled IT and RS: - MRI and arthroscopy or open surgery: 48 participants Data available for analyses: - MRI and arthroscopy or open surgery: 48 participants Age (mean): 56 years Gender: Not reported Dominant arm: Not reported Nature of onset: Not reported
Study design	Primary objective: To demonstrate the value of 3.0 T MRI for the detection of rotator cuff tendon tears Study design: Prospective, accuracy cohort study Unclear whether consecutive recruitment Language: English
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy or open surgery - Description of technique: Not reported - Criteria for a positive result: Not reported
Index and comparator tests	Index test(s): MRI - Description of technique: MRI unit: 3.0 T scanner with a shoulder coil Sequences and Planes: Fat suppressed TSE T2-weighted in three planes (TR/TE 3000/39) A sagittal T1-weighted sequence to detect fatty muscle atrophy Patient position: Not reported

Lambert 2009 (Continued)

	- Criteria for a positive result: Full thickness tears: presence of hyperintense fluid signal with a communication between the glenohumeral joint and subacromial space Partial thickness tears: hyperintense fluid signal or irregularity at the articular or bursal surface of the tendon - Time from symptoms to index test: Not reported - Time from index test to reference standard: mean 77.6 days (range 22 to 169 days)
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
Notes	A two-by-two table of the ITs and RS was given, which tallied with the reported summary data

Item	Authors' judgement	Description
Representative spectrum? All tests	No	Unknown why patients had MRI shoulder as included all people who had one at their institution of a period of time November 2005 to June 2007
Acceptable reference standard? All tests	Unclear	The reference standard was shoulder arthroscopy or open surgery and the target condition were presence of any rotator cuff tears, full thickness tears and partial thickness tears
Acceptable delay between tests? All tests	No	The average interval between reference standard and index test was 77.6 days
Partial verification avoided? All tests	No	Not all the patients who received the in- dex test underwent a reference standard to verify their true disease status. Of the 192 eligible participants, only 48 underwent to reference standard
Differential verification avoided? All tests	Unclear	Insufficient information was given to permit judgement
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Reference standard results blinded? All tests	No	The results of the index tests were known to the person interpreting the reference tests

Lambert 2009 (Continued)

Relevant clinical information? All tests	Unclear	Not reported
Uninterpretable results reported? All tests	Unclear	Insufficient information was given to permit judgement
Withdrawals explained? All tests	No	Some of the eligible patients who entered the study did not complete it and these patients were not accounted for
Learning curve / training reported of index test? All tests	Unclear	Insufficient information was given to permit judgement
Learning curve / training reported of reference standard? All tests	Unclear	Insufficient information was given to permit judgement
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Martin-Hervas 2001

Clinical features and settings	Inclusion criteria: Patients with shoulder pain and limited movement Exclusion criteria: Patients with claustrophobia, metallic implants, and pacemaker Duration of symptoms: Not reported Previous treatments: Not reported Care setting: Not reported
Participants	Place of study: Madrid, Spain Period of study: During 1998 Number of participants eligible: 140 shoulders Number of participants enrolled IT and RS: - MRI and arthroscopy or open surgery: 61 shoulders - US and arthroscopy or open surgery: 72 shoulders Data available for analyses: - MRI and arthroscopy or open surgery: 61 shoulders - US and arthroscopy or open surgery: 61 shoulders Age: Not reported Male/Female: 25/36 Dominant arm: Not reported Nature of onset: Not reported
Study design	Primary objective: To compare the accuracy of US and MRI in the diagnosis of rotator cuff injuries (focusing on supraspinatus tears) using arthroscopy or open surgery findings as the gold standard Study design: Prospective accuracy cohort study with fully paired direct comparison between US and MRI

Martin-Hervas 2001 (Continued)

	Unclear whether consecutive recruitment Language: English
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy or open surgery - Description of technique: Not reported - Criteria for a positive result: Not reported
Index and comparator tests	Index test(s): MRI and US - Description of technique: MRI MRI unit: 0.5 T superconducting magnet Sequences: Spin echo T1-weighted sequences for coronal and oblique plane images and gradient echo T2*-weighted sequences for axial and oblique coronal images; when the supraspinatus tendon showed a suggestive increased signal intensity, spin echo T2-weighted sequences were performed Planes: Axial, oblique coronal and oblique sagittal images Patient position: Patient in a supine position and the arm in a neutral position US Scanner: 7.5 MHz high-resolution linear electronic transducer Technique and Patient position: Images were obtained in transverse and longitudinal plane scans on the anterior plane of a shoulder with a neutrally rotated humerus to visualise bicipital and subscapularis bursae and axilla Next, sections of the shoulder were performed with internal humeral rotation, and the transducer was moved laterally to visualise the supraspinatus tendon and subacromial bursa The last images were obtained in the posterior plane with the humerus in a neutral position to visualise the infraspinatus and teres minor tendons - Criteria for a positive result: MRI: Full thickness tears: hypersignal on the T1- and T2-weighted images or any irregularity in the borders of the entire thickness of the tendon Partial thickness tears: any irregularity within the tendon or at the bursal or joint surfaces US: Full thickness tears: normeltee absence of the tendon, focal atrophy, a concave border, liquid-filled hypoechoic bands, and/or lineal hyperechoic bands Partial thickness tears: heterogeneous tendon with hypoechoic areas (> 3 mm) that do not reach both sides of the tear and an irregular or indented border - Time from MRI and US: Not reported - Time from index test to reference standard: Less than 6 months
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
Notes	The rotator cuff tears were focused on only supraspinatus tendon tears No two-by-two table of the ITs and RS was given, but it was possible to back-calculate this from the reported summary data
Table of Methodological Quality	

Martin-Hervas 2001 (Continued)

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Tertiary or secondary care, participants with suspected of having any rotator cuff tears The study was prospective It was unclear whether consecutive recruitment
Acceptable reference standard? All tests	Unclear	The reference standard was arthroscopy or open surgery and the target conditions were presence of any rotator cuff tears, full thickness tears and partial thickness tears
Acceptable delay between tests? All tests	Unclear	The interval between tests was not clearly reported
Partial verification avoided? All tests	No	Not all the patients who received the index test underwent a reference standard to ver- ify their true disease status
Differential verification avoided? All tests	Unclear	Insufficient information was given to permit judgement
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Yes	The study was prospective and the results of the index tests were interpreted before the reference standard
Reference standard results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Relevant clinical information? All tests	Unclear	Not reported
Uninterpretable results reported? All tests	Unclear	Insufficient information was given to permit judgement
Withdrawals explained? All tests	No	Some of the eligible patients who entered the study did not complete it and these patients were not accounted for
Learning curve / training reported of index test? All tests	Unclear	The interpreter of index test was a musculoskeletal radiologist Experience was not reported

Martin-Hervas 2001 (Continued)

Learning curve / training reported of reference standard? All tests	Unclear	Insufficient information was given to permit judgement
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Milosavljevic 2005

Clinical features and settings	Inclusion criteria: Participants with shoulder symptoms longer than 3 months duration and clinical findings of impingement and suspected rotator cuff tears were referred for US of the shoulder The patients had pain at rest and during motion, the pain-provoking test was positive, and some patients had weakness of the rotator cuff muscles Exclusion criteria: Not reported Duration of symptoms: Participants with shoulder symptoms longer than 3 months duration Previous treatments: Not reported Care setting: Not reported
Participants	Place of study: Uppsala, Sweden Period of study: February 1999 to October 2002 Number of participants eligible: 185 participants (190 shoulders) Number of participants enrolled IT and RS: - US and arthroscopy: 185 participants (190 shoulders) Data available for analyses: - US and arthroscopy: 185 participants (190 shoulders) Age: mean 57 years (range 22 to 78 years) Male/Female: 114/71 Dominant arm: Not reported Nature of onset: Not reported
Study design	Primary objective: To evaluate the accuracy of high-resolution shoulder US compared with arthroscopy in a large group of consecutive patients with clinically suspected rotator cuff disease Study design: Prospective consecutive accuracy cohort study Language: English
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy - Description of technique: Patient in the beach-chair position under general anaesthesia Posterior and anterior portal were used The cartilage of the humeral head and the glenoid fossa, the labrum ligament complex, the biceps tendon, the intraarticular portion of the subscapular tendon, and the underside of the rotator cuff were inspected

Milosavljevic 2005 (Continued)

	- <u>Criteria for a positive result:</u> In the same manner as for the US findings, i.e. intact cuff, full thickness tears, or partial thickness tears (see below)
Index and comparator tests	Index test(s): US - Description of technique: Scanner: 10 MHz linear-array transducer Technique: All tendons were examined in longitudinal and transversal plane Patient position: Both patient and examiner seated on rotatable chairs without armrests The examiner faced the patient and was seated at the patient's right side - Criteria for a positive result: Full thickness tears: defect (hypoechoic zone) extending through the entire substance of the cuff; focal, mixed hyper- and hypoechoic lesion extending through the entire substance of the cuff; focal thinning with visible margins of the tear; and non-visualisation of the cuff Partial thickness tears: mixed hyper- and hypoechoic focus or a hypoechoic lesion visualised in two orthogonal imaging planes located within the tendon substance but not extending to the surface or with either articular or bursal extension - Time from symptoms to index test: More than 3 months - Time from index test to reference standard: mean 6 months (range 1 day to 18 months)
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
Notes	A two-by-two table of the ITs and RS was given, which tallied with the reported summary data

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Population was patients with suspected of having any rotator cuff tears The study was prospective and recruitment was consecutive The care setting was not specified
Acceptable reference standard? All tests	Yes	The reference standard was arthroscopy and the target conditions were presence of any rotator cuff tear, full thickness tears and partial thickness tears
Acceptable delay between tests? All tests	No	The average interval between reference standard and index test was 6 months
Partial verification avoided? All tests	Yes	All patients who received the index test went on to receive verification of their dis- ease status using a reference standard

Milosavljevic 2005 (Continued)

Differential verification avoided? All tests	Yes	All patients received the same reference standard regardless of the result of their index test
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	No	When there was disagreement between in- dex test and reference standard findings the results of index test (US) were re-evaluated to explain discrepancy
Reference standard results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Relevant clinical information? All tests	Unclear	Not reported
Uninterpretable results reported? All tests	Yes	The study was prospective, recruitment was consecutive and results were reported for all initially included participants
Withdrawals explained? All tests	Yes	No participants were excluded from the analysis
Learning curve / training reported of index test? All tests	Unclear	The interpreter of index tests was a radiologist Training and expertise were not described
Learning curve / training reported of reference standard? All tests	Unclear	The reference standards were performed by three shoulder surgeons Training and ex- pertise were not described
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Misamore 1991

Wilsamore 1//1	
Clinical features and settings	Inclusion criteria: Participants with symptoms and physical findings consistent with chronic tendinitis or with degeneration or a tear of the rotator cuff Patients who had signs indicating stage II or stage III impingement were included Exclusion criteria: Patients who had an acute injury or who had symptoms for less than one year were excluded Patients were excluded if they had a previous operation on the affected shoulder, if they had any associated disorders of the shoulder (such as arthritis or instability), or if they had cervical radiculopathy or peripheral neuropathy Duration of symptoms: Not reported Previous treatments: Not reported Care setting: Not reported
Participants	Place of study: Indianapolis, Indiana, USA Period of study: January 1988 to June 1989 Number of participants eligible: 82 participants Number of participants enrolled IT and RS: - US and arthroscopy or open surgery: 32 participants Data available for analyses: - US and arthroscopy or open surgery: 32 participants Age: mean 47 years (range 35 to 65 years) Male/Female: 26/6 Dominant arm: Not reported Nature of onset: Not reported
Study design	Primary objective : To compare the accuracy of arthrography compared with US in the evaluation of thirty-two patients who had a degenerative lesion of the rotator cuff Study design : Prospective consecutive accuracy cohort study Language : English
Target condition and reference standard(s)	Target conditions: Presence of full thickness tears and partial thickness rotator cuff tears Reference standard(s): Shoulder arthroscopy or open surgery - Description of technique: Not reported - Criteria for a positive result: Not reported
Index and comparator tests	Index test(s): US - Description of technique: Not reported - Criteria for a positive result: Full thickness tear: an obvious defect localised to the tendon of the rotator cuff was seen or alternatively when there was no echo of the rotator cuff An abnormality of echogenicity alone was not considered to be a tear - Time from symptoms to index test: Not reported - Time from index test to reference standard: Not reported
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
Notes	No two-by-two table of the ITs and RS was given, but it was possible to back-calculate this from the reported summary data for detecting any rotator cuff tears

Table of Methodological Quality		
Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Population was patients with suspected of having any rotator cuff tears The study was prospective and recruitment was consecutive The care setting was not specified
Acceptable reference standard? All tests	Unclear	The reference standard was arthroscopy or open surgery and the target conditions were presence of full and partial thickness tears
Acceptable delay between tests? All tests	Unclear	The study did not report the time elapsed between the index tests and reference standard
Partial verification avoided? All tests	No	Not all the patients who received the index test underwent a reference standard to verify their true disease status Of the 82 eligible participants, 32 patients received the reference standard For 50 patients the symptoms were not severe enough to justify surgery or satisfactory improvement was achieved with conservative treatment
Differential verification avoided? All tests	No	Probably the result of the index test influenced the choice of the reference standard
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Yes	The index tests were interpreted before and without knowledge of the reference standard results
Reference standard results blinded? All tests	No	The results of index tests were probably known to the person interpreting the reference standard
Relevant clinical information? All tests	Unclear	Not reported
Uninterpretable results reported? All tests	Yes	Results were reported for all initially in- cluded participants

Misamore 1991 (Continued)

Withdrawals explained? All tests	Yes	The number and reasons of all withdrawals from the study were explained
Learning curve / training reported of index test? All tests	Yes	The interpreters of index tests were radiologists who were skilled in the technique
Learning curve / training reported of reference standard? All tests	Unclear	The reference standards were performed by one of the authors (orthopaedic surgeon)
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Mohtadi 2004	
Clinical features and settings	Inclusion criteria: Patients with shoulder pain at night or with overhead activity greater than 3 months duration or both A minimum of 3 of the following 6 clinical findings: a painful arc of motion in the scapular plane (60° to 120°) of elevation; pain-related weakness on resisted elevation in the scapular plane; Neer's impingement sign; Hawkin's impingement sign; point of maximal tenderness over the supraspinatus tendon; and positive impingement xylocaine test Failure of conservative management The patients consented to undergo shoulder arthroscopy and subacromial decompression Exclusion criteria: Patients with symptoms of instability Signs of instability Point of maximum tenderness over the acromioclavicular joint Any signs or symptoms consistent with associated cervical spine pathology Previous surgery, arthrography, ultrasound, or MRI Duration of symptoms: More than 3 months of symptoms Previous treatments: Conservative management (nonsteroidal anti-inflammatory drugs, physiotherapy, home-based rehabilitation, cortisone injections, and modification of activity) Care setting: Tertiary or secondary
Participants	Place of study: Calgary, Alberta, Canada Period of study: 1998 to 2000 Number of participants eligible: 73 participants Number of participants enrolled IT and RS: - Indirect MRA and arthroscopy: 58 participants Data available for analyses: - Indirect MRA and arthroscopy: 58 participants Age: mean 46.2 years (range 21 to 73 years) Male/Female: 43/15 Dominant arm: Not reported Nature of onset: Of these 58 patients, 91.4% reported pain at night and 96.6% reported

Mohtadi 2004 (Continued)

	pain with activity above shoulder level	
Study design	Primary objective: To determine the diagnostic ability of MRI compared with a reference standard, arthroscopy, in patients presenting with shoulder pain consistent with the signs and symptoms of shoulder impingement Study design: Prospective, consecutive accuracy cohort study Language: English	
Target condition and reference standard(s)	Target conditions: Presence full thickness tears and partial thickness supraspinatus tendon tears Presence of any infraspinatus tendon tears Presence of any subscapularis tendon tears Reference standard(s): Shoulder arthroscopy - Description of technique: In accordance with the standardised 15-point protocol of Snyder classification This included standard posterior and anterior portal examination with subsequent visualisation in the subacromial bursa The subacromial (bursal) examination was not performed All surgeries were videotaped - Criteria for a positive result: Not reported	
Index and comparator tests	Index test(s): Indirect MRA - Description of technique: MRI unit: 1.5 T with conventional shoulder coil Sequences and Planes: Axial water density (TR/TR 1000/20) and multi-planar gradient recalled (TR/TE 400/20, flip angle20°) Oblique coronal fast multi-planar inversion recovery (TR/TE 4600/28, inversion time 150) Oblique coronal post-gadolinium fat-saturated T1-weighted (TR/TE 400/8) and sagittal T1-weighted (TR/TE 400/8) Contrast and procedure: Intravenous gadolinium administration Patient position: Supine with the arm in a neutral position - Criteria for a positive result: Not reported - Time from symptoms to index test: More than 3 months of symptoms - Time from index test to reference standard: Upon entry into the study patients were scheduled to undergo MRI within 1 week before arthroscopy	
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported	
Notes	The analyses of rotator cuff tears were focused on only supraspinatus and subscapularis tendons tears No two-by-two table of the ITs and RS was given, but it was possible to back-calculate this from the reported summary data	
Table of Methodological Quality		
Item	Authors' judgement	Description

Mohtadi 2004 (Continued)

Representative spectrum? All tests	Yes	Tertiary or secondary care, participants with suspected of having any rotator cuff tears The study was prospective and recruitment was consecutive
Acceptable reference standard? All tests	Yes	The reference standard was arthroscopy and the target conditions were presence full thickness tears and partial thickness supraspinatus tendon tears; presence of any infraspinatus tendon tears; presence of any subscapularis tendon tears
Acceptable delay between tests? All tests	Yes	Patients were scheduled to undergo MRI within 1 week before arthroscopy
Partial verification avoided? All tests	No	Not all the patients who received the index test underwent a reference standard to verify their true disease status Of the 73 eligible participants, eight cancelled the surgery and seven did not undergo MRI within a week and were excluded but their results were not reported
Differential verification avoided? All tests	Yes	All patients received the same reference standard regardless of the result of their index test
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Yes	The index tests were interpreted before and without knowledge of the reference standard results
Reference standard results blinded? All tests	Yes	Before and during diagnostic arthroscopy, the surgeon was blinded to the MRI results
Relevant clinical information? All tests	Unclear	Not reported
Uninterpretable results reported? All tests	Yes	The study was prospective recruitment was consecutive and results were reported for all initially included participants
Withdrawals explained? All tests	Yes	The number and reasons of all withdrawals from the study were explained

Mohtadi 2004 (Continued)

Learning curve / training reported of index test? All tests	Unclear	The interpreter of index tests was a musculoskeletal radiologist Training and expertise were not described
Learning curve / training reported of reference standard? All tests	Unclear	The reference standards were performed by two experienced orthopaedic surgeons Training and expertise were not described
Index test criteria for a positive test result reported? All tests	No	Not reported

Nicoletti 1994

Nicoletti 1994	
Clinical features and settings	Inclusion criteria: Patients who had shoulder pain and signs and symptoms of rotator cuff tears with failure of conservative treatment Exclusion criteria: Patients with suspected of instability and neurologic symptoms Duration of symptoms: More than 3 months Previous treatments: Physiotherapy Care setting: Tertiary
Participants	Place of study: Sao Paulo, Brazil Period of study: Not reported Number of participants eligible: 48 participants Number of participants enrolled IT and RS: - US and arthroscopy: 48 participants Data available for analyses: - US and arthroscopy: 48 participants Age: mean 48 years (range 19 to 79 years) Male/Female: 16/32 Dominant arm: 65% Nature of onset: Not reported
Study design	Primary objective: To evaluate the sensitivity, specificity and accuracy of arthrography and US to detect rotator cuff tears Study design: Unclear whether prospective design Unclear whether consecutive recruitment Language: Portuguese
Target condition and reference standard(s)	Target conditions: Presence any rotator cuff tears Reference standard(s): Shoulder arthroscopy - Description of technique: Patient in lateral position with traction in the operative limb The posterior and anterior portals were used to visualise the glenohumeral and subacromial spaces - Criteria for a positive result: Not reported

Nicoletti 1994 (Continued)

Index and comparator tests	Index test(s): US - Description of technique: Scanner: 5 or 7 MHz linear transducer in real time Technique and Patient position: As described by Crass 1985 - Criteria for a positive result: US signs were: focal or diffuse thinning or non-visualisation of tendon(s) - Time from symptoms to index test: Not reported - Time from index test to reference standard: Not reported
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
Notes	A two-by-two table of the ITs and RS was given which tallied with the reported summary data

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Unclear whether prospective design and consecutive recruitment
Acceptable reference standard? All tests	Yes	The reference standard was arthroscopy and the target condition was presence of any rotator cuff tears
Acceptable delay between tests? All tests	Unclear	The study did not report the time elapsed between the index tests and reference standard
Partial verification avoided? All tests	Yes	All patients who received the index test went on to receive verification of their dis- ease status using a reference standard
Differential verification avoided? All tests	Unclear	Insufficient information was given to permit judgement
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Reference standard results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Relevant clinical information? All tests	Unclear	Not reported

Nicoletti 1994 (Continued)

Uninterpretable results reported? All tests	Yes	The number of results reported agrees with the number of patients recruited
Withdrawals explained? All tests	Yes	No participants were excluded from the analysis
Learning curve / training reported of index test? All tests	Yes	The interpreter of index tests was a musculoskeletal radiologist
Learning curve / training reported of reference standard? All tests	Yes	The reference standards were performed by an experienced shoulder surgeon
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Sipola 2010

Clinical features and settings	Inclusion criteria: Participants with acute or chronic shoulder pain and suspicion of rotator cuff tears Patients who had undergone conservative treatment without sufficient symptom relief Exclusion criteria: Time elapsed between index test and reference standard was more than 12 months Duration of symptoms (pain): mean 21 months (range 2 to 144 months Previous treatments: Conservative treatment including physiotherapy for at least 3 months Care setting: Tertiary or secondary
Participants	Place of study: Kuopio, Finland Period of study: Not reported Number of participants eligible: 79 participants Number of participants enrolled IT and RS: - MRA and arthroscopy or open surgery: 75 participants - US and arthroscopy or open surgery: 77 participants Data available for analyses: - MRA and arthroscopy or open surgery: 75 participants - US and arthroscopy or open surgery: 77 participants - US and arthroscopy or open surgery: 77 participants Age: mean 57 years (range 42 to 76 years) Male/Female: 40/37 Dominant arm: Not reported Nature of onset: The etiology of suspected tear was traumatic in 22% and degenerative in 78% of the participants
Study design	Primary objective : To compare the accuracy of US and MRA for the detection and measurement of rotator cuff tears using surgical findings as the standard in a prospective study setting

Sipola 2010 (Continued)

	Study design : Prospective, consecutive, accuracy cohort study with fully paired direct comparison between MRA and US Language : English
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy or mini-open - Description of technique: Not reported - Criteria for a positive result: The size and type (partial/full thickness) of tendon tear was determined and measured from anterior to posterior and from lateral to medial dimensions A sterile ruler or a calibrated arthroscopic probe was used to define both the anteroposterior and the mediolateral size of the tear
Index and comparator tests	Index test(s): MRA and US - Description of technique: MRA MRI unit: 1.5 T scanner equipped with a flexible surface coil Sequences and Planes: Oblique coronal T1-weighted spin-echo (TR/TE 650/20); a T2-weighted far-saturated dual-echo fast spin-echo (FSE), 3500/16; oblique sagittal T2-weighted dual-echo FSE, 3500/16, 98; axial T2*-weighted gradient echo two-dimensional FLASH, 580/15, flip angle 15°; a T1-weighted far-saturated SE, 800/20; T1-weighted far-saturated spin-echo 800/20 images in the sagittal oblique, coronal oblique and axial planes, and T2-weighted FSE 4500/96 images in the coronal oblique plane Contrast and procedure: 10 to 20 mL of gadopentetate dimeglumine in a concentration of 469.01 mg/mL was diluted in 250 mL of saline The procedure involved direct intra-articular injection Patient position: Not reported Seven participants underwent to MRI only (without an intra-articular contrast) US Scanner: 7.5 MHz linear-array transducers in real-time Technique: Images were obtained on the long and short axes of the tendon Patient position: The subscapularis tendon was evaluated with the forearm rotated externally The supraspinatus tendon was assessed with the arm on the ipsilateral side The supraspinatus was assessed with the hand behind the patient's back (Crass position) or on the waist (modified Crass position) (Crass 1987; Ferri 2005) The infraspinatus tendon was assessed with the patient placed the ipsilateral hand across the chest on top of the contralateral shoulder - Criteria for a positive result: MRA: Full thickness tears: the contrast agent was detected on the MR image throughout the full thickness tears: the contrast agent was detected on the bursal surface to the articular surface of the tendon Otherwise the tear was diagnosed as a partial thickness tear - Time from symptoms to index test: mean 21 months (range 2 to 144 months

Sipola 2010 (Continued)

	- Time from MRA and US: in the same day - Time from index test to reference standard: mean 2.3 months (range 0 to 9.5 months)	
Follow-up	Adverse events due to index test(s): Of the 77 patients, two (3%) could not undergo MRA due to claustrophobia Adverse events due to reference standard test(s): Not reported	
Notes	A two-by-two table of the ITs and RS was given, which tallied with the reported summary data	

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Tertiary or secondary care, participants with suspected of having any rotator cuff tears The study was prospective and recruitment was consecutive
Acceptable reference standard? All tests	Unclear	The reference standard was arthroscopy or open surgery and the target conditions were presence of any rotator cuff tears, full thickness tears and partial thickness tears
Acceptable delay between tests? All tests	No	The average interval between reference standard and index test was 2.3 months
Partial verification avoided? All tests	Yes	Only two patients (2.5%) were excluded of study because of delay in surgery 12 months due to medical illness
Differential verification avoided? All tests	No	The choice of reference standard (arthroscopy or open surgery) varied between individuals
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Reference standard results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Relevant clinical information? All tests	Unclear	Not reported

Sipola 2010 (Continued)

Uninterpretable results reported? All tests	Yes	The study was prospective, recruitment was consecutive and results were reported for all initially included participants
Withdrawals explained? All tests	Yes	The number and reasons of all withdrawals from the study were explained
Learning curve / training reported of index test? All tests	Yes	The interpreter of MRA was a radiologist who had 1 year of experience in musculoskeletal MRI at the beginning of the study The interpreters of US were three radiologists each with more than 10 years experience in shoulder US
Learning curve / training reported of reference standard? All tests	Unclear	The reference standards were performed by three experienced orthopaedic surgeons Training and expertise were not described
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Stetson 2005

Clinical features and settings	Inclusion criteria: Patients with chronic shoulder pain who were suspected of having a rotator cuff abnormality underwent MRA with use of an intra-articular injection of gadolinium Exclusion criteria: Not reported Duration of symptoms: Not reported Previous treatments: Not reported Care setting: Tertiary or secondary
Participants	Place of study: Burbank, California, USA Period of study: During 2 years Number of participants eligible: 50 participants Number of participants enrolled IT and RS: - MRA and arthroscopy: 50 participants Data available for analyses: - MRA and arthroscopy: 50 participants Age: Not reported Gender: Not reported Dominant arm: Not reported Nature of onset: Not reported
Study design	Primary objective: To detect partial thickness articular-sided rotator cuff tears using an intra-articular injection of gadolinium and MRI Study design: Prospective accuracy cohort Unclear whether consecutive recruitment

Stetson 2005 (Continued)

	Language: English
Target condition and reference standard(s)	Target conditions: Presence partial articular-side thickness tears Reference standard(s): Shoulder arthroscopy - Description of technique: All participants were taken to surgery and underwent a complete 15-point glenohumeral arthroscopic examination The presence or absence of articular-sided rotator cuff tears was recorded - Criteria for a positive result: Not reported
Index and comparator tests	Index test(s): MRA - Description of technique: MRI unit: 1.5 T scanner. Sequences and Planes: Axial proton-density-weighted image with fat suppression, oblique coronal proton-density-weighted image, oblique coronal T2-weighted with fat suppression, oblique sagittal T1-weighted, and oblique sagittal proton-density-weighted image with fat suppression. In addition, axial T1-weighted with fat suppression, oblique coronal T1-weighted with fat suppression Contrast and procedure: 1.5 mL of gadolinium with normal saline solution intra-articularly into the glenohumeral joint under fluoroscopic control Patient position: Supine in neutral position and abduction and external rotation images were also acquired - Criteria for a positive result: Not reported - Time from symptoms to index test: Not reported - Time from index test to reference standard: Not reported
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
Notes	The authors described as false positive the four patients who were incorrectly diagnosed with MRA, as having a full thickness tear, but, at the time of shoulder arthroscopy, they had partial thickness articular-sided tears To make concordance with our analyses we described these participants as false negative No two-by-two table of the ITs and RS was given, but it was possible to back-calculate this from the reported summary data

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	The study was prospective and the population was participants with shoulder pain and suspected of having any rotator cuff tears. However, it was unclear whether there was consecutive recruitment
Acceptable reference standard? All tests	Yes	The reference standard was arthroscopy and the target condition was presence of partial articular-side rotator cuff tears

Stetson 2005 (Continued)

Acceptable delay between tests? All tests	Unclear	The study did not report the time elapsed between the index tests and reference standard
Partial verification avoided? All tests	Yes	All patients who received the index test went on to receive verification of their dis- ease status using a reference standard
Differential verification avoided? All tests	Yes	All patients received the same reference standard, regardless of the result of their index test
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Reference standard results blinded? All tests	No	The results of the index tests were probably known to the person interpreting the reference tests
Relevant clinical information? All tests	Unclear	Insufficient information was given to permit judgement
Uninterpretable results reported? All tests	Yes	The number of results reported agrees with the number of patients recruited
Withdrawals explained? All tests	Yes	No participants were excluded from the analysis
Learning curve / training reported of index test? All tests	Yes	The interpreter of index tests was a fellow- ship-trained musculoskeletal radiologist
Learning curve / training reported of reference standard? All tests	Unclear	Insufficient information was given to permit judgement
Index test criteria for a positive test result reported? All tests	No	Not reported

Swen 1998	
Clinical features and settings	Inclusion criteria: Patients awaiting surgery because of clinically suspected of rotator cuff tears The clinical diagnosis of rotator cuff tears was based on marked difficulty in initiating abduction of the arm with weakness and limitation of movement Lidocaine was injected below the acromion, if after the injection the strength of the rotator cuff was still decreased; this was considered to indicate rotator cuff tears Exclusion criteria: Patients with neurologic origins of the weakness Duration of symptoms: mean 2.3 years (range 0.3 to 10 years) Previous treatments: Not reported Care setting: Not reported, probably tertiary or secondary
Participants	Place of study: The Netherlands Period of study: January 1993 to December 1995 Number of participants eligible: 48 participants Number of participants enrolled IT and RS: - US and arthroscopy or open surgery: 48 participants Data available for analyses: - US and arthroscopy or open surgery: 48 participants Age: mean 55 years (range 30 to 76 years) Male/Female: 28/20 Dominant arm: Not reported Nature of onset: Not reported
Study design	Primary objective: To compare the diagnostic value of US performed by the rheumatologist with that of arthrography by a radiologist for otherwise healthy patients with suspected rotator cuff tears Study design: Prospective consecutive accuracy cohort study Language: English
Target condition and reference standard(s)	Target conditions: Presence full thickness tears Reference standard(s): Shoulder arthroscopy and open surgery - Description of technique: Not reported - Criteria for a positive result: A full-thickness was diagnosed if free communication was found between the bursal and humeral sides of the cuff
Index and comparator tests	Index test(s): US - Description of technique: Scanner: 7.5 MHz linear array and the 5.0 MHz curved array transducers Technique: The shoulder was examined in the anterior, lateral, and posterior directions, in both the transverse and the longitudinal planes as described by Van Holsbeeck 1991 Patient position: The patients were seated For the anterior approach, the patient's upper arm was visualised in internal rotation, which was achieved by placing the patient's hand behind the back - Criteria for a positive result: Full thickness tears: a discontinuity in the rotator cuff extending from the bursal to the humeral side of the rotator cuff - Time from symptoms to index test: Not reported - Time from index test to reference standard: Not reported

Swen 1998 (Continued)

Follow-up		Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported A two-by-two table of the ITs and RS was given which tallied with the reported summar data	
Notes	_		
Table of Methodological Quality			
Item	Authors' judgement	Description	
Representative spectrum? All tests	Yes	Tertiary or secondary care Participants with suspected of having an rotator cuff tears The study was prospectiv and recruitment was consecutive	
Acceptable reference standard? All tests	Yes	The reference standard was arthroscopy of open surgery and the target conditions were presence of full thickness tears	
Acceptable delay between tests? All tests	Unclear	The study did not report the time elapse between the index tests and reference standard	
Partial verification avoided? All tests	Yes	All patients who received the index tes went on to receive verification of their dis ease status using a reference standard	
Differential verification avoided? All tests	Yes	All patients received the same reference standard, regardless of the result of their in dex test	
Incorporation avoided? All tests	Yes	The index test did not form part of th reference standard	
Index test results blinded? All tests	Yes	The study was prospective and the result of the index tests were interpreted befor the reference standard	
Reference standard results blinded? All tests	Unclear	Insufficient information was given to per mit judgement	
Relevant clinical information? All tests	Unclear	Not reported	
Uninterpretable results reported? All tests	Yes	The study was prospective, recruitment was consecutive and results were reported for	

all initially included participants

Swen 1998 (Continued)

Withdrawals explained? All tests	Yes	No participants were excluded from the analysis
Learning curve / training reported of index test? All tests	Yes	The interpreter of index tests was a rheumatologist with experience in this technique
Learning curve / training reported of reference standard? All tests	Unclear	Insufficient information was given to permit judgement
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Swen 1999

Clinical features and settings	Inclusion criteria : Patients awaiting surgery because of a clinically suspected rotator cuff	
	tears	
	The clinical diagnosis of rotator cuff tears was based on marked difficulty in initiating	
	abduction of the arm with weakness and limitation of movement Lidocaine was injected	
	below the acromion, if after the injection the strength of the rotator cuff was still de-	
	creased; this was considered to indicate rotator cuff tears	
	Exclusion criteria: Patients with neurologic origins of the weakness	
	Duration of symptoms: mean 2.3 years (range 0.3 to 8 years)	
	Previous treatments: Not reported	
	Care setting: Not reported	
	Probably tertiary or secondary	
Participants	Place of study: The Netherlands	
	Period of study: Not reported	
	Number of participants eligible: 21 participants	
	Number of participants enrolled IT and RS:	
	- MRI and arthroscopy: 21 participants	
	- US and arthroscopy: 21 participants	
	Data available for analyses:	
	- MRI and arthroscopy: 21 participants	
	- US and arthroscopy: 21 participants	
	Age (mean/SD): 54/12 years	
	Male/Female: 12/9	
	Dominant arm: Not reported	
	Nature of onset: In four patients the shoulder complaints could be attributed to trauma	
Study design	Primary objective: To evaluate the ability of US and MRI to detect full thickness rotator	
Study design	cuff tears in patients with a clinically suspected rotator cuff tears as a solitary non-	
	inflammatory condition	
	Study design: Prospective, consecutive, accuracy cohort study with fully paired direct	
	comparison between MRI and US	

	Language: English
Target condition and reference standard(s)	Target conditions: Presence full thickness tears Reference standard(s): Shoulder arthroscopy - Description of technique: First the arthroscope was introduced in the glenohumeral joint and then into the sub acromial space After introducing the scope into the subacromial space, the bursa was removed to enable examination of the bursal side of the cuff - Criteria for a positive result: A full-thickness was diagnosed if free communication was found between the bursal and humeral sides of the cuff
Index and comparator tests	Index test(s): MRI and US - Description of technique: MRI MRI unit: 1.0T system with a dedicated shoulder coil as receiver Sequences: T1-weighted (TR/TE 680/15) and a standard T2 coronal spin-echo sequence (TR/TE 3000/15,105 ms) Planes: Oblique coronal Patient position: Supine position US Scanner: 7.5 MHz linear array and the 5.0 MHz curved array transducers Technique: The shoulder was examined in the anterior, lateral, and posterior directions in both the transverse and the longitudinal planes as described by Van Holsbeeck 1991 Patient position: The patients were seated For the anterior approach, the patient's upper arm was visualised in internal rotation which was achieved by placing the patient's hand behind the back - Criteria for a positive result: MRI: Full-thickness tears: a focal, well-defined area of increased signal intensity on T1 weighted and T2-weighted images that extended through the entire thickness of the tendon US: Full-thickness tears: a discontinuity in the rotator cuff, extending from the bursat to the humeral side of the rotator cuff - Time from symptoms to index test: Not reported - Time from Conventional MRA and 3D isotropic MRA: Not reported - Time from index test to reference standard: MRI and US were performed within is weeks before surgery
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
Notes	The results of index test were interpreted by two experienced musculoskeletal radiologist. The data of only one reader (reader 1) were arbitrarily chosen to be included in our analyses. Raw data were given and it was possible to back-calculate this from the reported summary data.

Swen 1999 (Continued)

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Tertiary or secondary care, participants with suspected of having any rotator cuff tears The study was prospective and recruitment was consecutive
Acceptable reference standard? All tests	Yes	The reference standard was arthroscopy and the target condition was presence of full thickness tears
Acceptable delay between tests? All tests	Yes	The index tests were performed within 3 weeks of surgery
Partial verification avoided? All tests	Yes	All patients who received the index test went on to receive verification of their dis- ease status using a reference standard
Differential verification avoided? All tests	Yes	All patients received the same reference standard, regardless of the result of their index test
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Yes	The study was prospective and the results of the index tests were interpreted before the reference standard
Reference standard results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Relevant clinical information? All tests	No	The interpreters were blinded to history and physical examination
Uninterpretable results reported? All tests	Yes	The study was prospective, recruitment was consecutive and results were reported for all initially included participants
Withdrawals explained? All tests	Yes	No participants were excluded from the analysis
Learning curve / training reported of index test? All tests	Unclear	A rheumatologist and a radiologist, both experienced with this test In fact they had different results but this was not examined in this study

Swen 1999 (Continued)

Learning curve / training reported of reference standard? All tests	Unclear	The reference standards were performed by a single experienced surgeon
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Taboury 1992

Taboury 1992	
Clinical features and settings	Inclusion criteria: Not reported Exclusion criteria: Not reported Duration of symptoms: Not reported Previous treatments: Not reported Care setting: Tertiary
Participants	Place of study: Paris, France Period of study: Not reported Number of participants eligible: 24 participants Number of participants enrolled IT and RS: - US and open surgery: 24 participants Data available for analyses: - US and open surgery: 24 participants Age: Not reported Gender: Not reported Dominant arm: Not reported Nature of onset: Not reported
Study design	Primary objective: To compare the results of US to open surgery in order to evaluate the characteristics of the rotator cuff tears Study design: Prospective accuracy cohort study Unclear whether consecutive recruitment Language: French
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears Reference standard(s): Open surgery - Description of technique: Not reported - Criteria for a positive result: Not reported
Index and comparator tests	Index test(s): US - Description of technique: Scanner: 5 to 10 MHz linear or vectorial short focal probe Technique: Static and dynamic examination of rotator cuff tendons Patient position: Patients seated with the arm in adduction and internal rotation by asking the patients to place their arm behind their back - Criteria for a positive result: Not reported - Time from symptoms to index test: Not reported - Time from index test to reference standard: Not reported

Taboury 1992 (Continued)

Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
Notes	Mr Jean-Philippe Regnaux and Mr Ludovic Trinquart kindly translated into English and extracted the data of this study A two-by-two table of the ITs and RS was given, which tallied with the reported summary data

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Unclear whether consecutive recruitment
Acceptable reference standard? All tests	Unclear	The reference standard was open surgery and the target condition was presence of any rotator cuff tears
Acceptable delay between tests? All tests	Unclear	The study did not report the time elapsed between the index tests and reference standard
Partial verification avoided? All tests	Yes	All patients who received the index test went on to receive verification of their dis- ease status using a reference standard
Differential verification avoided? All tests	Yes	All participants included in the analyses received open surgery, regardless of the results of their index test
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Yes	The person undertaking the index test was blinded to the results of the standard reference
Reference standard results blinded? All tests	Yes	The reference standard results were performed blind to the results of the index test
Relevant clinical information? All tests	Unclear	Insufficient information was given
Uninterpretable results reported? All tests	Yes	The number of results reported agrees with the number of patients recruited
Withdrawals explained? All tests	Yes	No participants were excluded from the analysis

Taboury 1992 (Continued)

Learning curve / training reported of index test? All tests	Unclear	Insufficient information was given
Learning curve / training reported of reference standard? All tests	Unclear	Insufficient information was given
Index test criteria for a positive test result reported? All tests	No	Not reported

Teefey 2004

Clinical features and settings	Inclusion criteria: Acute or chronic shoulder pain accompanied by a high clinical suspicion of rotator cuff disease Exclusion criteria: Participants with severe claustrophobia, which is a contraindication for magnetic resonance imaging; a previous operation on the shoulder; a humeral fracture; and inflammatory arthritis Duration of symptoms: Not reported Previous treatments: Not reported Care setting: Not reported, probable tertiary or secondary
Participants	Place of study: St. Louis, Missouri, USA Period of study: December 1998 and April 2001 Number of participants eligible: 130 participants Number of participants enrolled IT and RS: - MRI and arthroscopy: 71 shoulders - US and arthroscopy: 71 shoulders Data available for analyses: - MRI and arthroscopy: 71 shoulders - US and arthroscopy: 71 shoulders - US and arthroscopy: 71 shoulders - US and arthroscopy: 71 shoulders Age: mean 59 (range 31 to 80 years) Male/Female: 41/30 Dominant arm: Not reported Nature of onset: Not reported
Study design	Primary objective: To compare the diagnostic performances of US and MRI for both the detection of a rotator cuff tear and the quantification of its size, with use of arthroscopic findings as the standard Study design: Prospective, consecutive, accuracy cohort study with fully paired direct comparison between US and MRI Language: English
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy - Description of technique:

Teefey 2004 (Continued)

	The rotator cuff was examined from both the articular and the bursal side. A tagged suture (number-1 PDS [polydioxanone]) was placed, during intra-articular viewing, through the suspected region of the cuff tear to guide arthroscopic bursal imaging - Criteria for a positive result: The presence or absence of a rotator cuff tear and the size and extent of the tear, when present, were recorded. Specifically, the presence or absence of a full thickness tear or of a bursal or articular-side partial thickness tear and the width (perpendicular to the long axis of the cuff fibres) of any tear that was found were recorded
Index and comparator tests	Index test(s): MRI and US - Description of technique: MRI MRI unit: 1.5 T with high field strength with a two-piece shoulder array coil (54 participants); and with flexible local coils (17 participants) Sequences: Fat-suppressed, fast-spin-echo, proton-density-weighted, spin-echo, or fast-spin-echo and transverse, T2-weighted, fast-spin-echo images with or without fat suppression Planes: Oblique coronal and oblique sagittal Patient position: Not reported US Scanner: 7.5 to 9 MHz linear-array transducer in real-time Technique and Patient position: As previously described (Teefey 2000). - Criteria for a positive result: MRI: Full thickness tears: complete disruption of all tendon fibres or when the signal within the cuff tendons was isointense compared with fluid on the T2-weighted images and extended from the articular to the bursal surface on one or more images. Partial thickness tears: fluid-intensity signal within the tendons was in contact with only one of the surfaces US: Full thickness tears: non-visualisation of rotator cuff or a focal defect in the rotator cuff created by a variable degree of retraction of the torn tendon ends. Partial thickness tears: minimal flattening of the bursal side of the rotator cuff (bursal-side tear) or a distinct hypoechoic or mixed hyperechoic and hypoechoic defect visualized in both the longitudinal and the transverse plane at the deep articular side of the rotator cuff (articular-side tear) - Time from US and MRI: MRI was performed on the same day as the US for all but three patients, two of whom had the studies six days apart and one of whom had them one day apart - Time from index test to reference standard: mean 56 days (range 2 to 190 days)
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
Notes	Part of population (only the participants with full thickness rotator cuff tears) of this study was also reported in Teefey 2005 A two-by-two table of the ITs and RS was given, which tallied with the reported summary data with a few discrepancy
Table of Methodological Quality	

Teefey 2004 (Continued)

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Insufficient information was given to permit judgement
Acceptable reference standard? All tests	Yes	The reference standard was arthroscopy and the target condition were presence of any rotator cuff tears, full thickness tears and partial thickness tears
Acceptable delay between tests? All tests	No	The average interval between reference standard and index test was 56 days
Partial verification avoided? All tests	No	Not all the patients who received the index test underwent a reference standard to verify their true disease status Of the 130 eligible participants 71 underwent to reference standard
Differential verification avoided? All tests	No	The result of the index test probably influenced the choice of the reference standard
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Yes	The person undertaking the index test was blinded to the results of the standard reference
Reference standard results blinded? All tests	No	The results of the index tests were known to the person interpreting the reference tests
Relevant clinical information? All tests	Unclear	Not reported
Uninterpretable results reported? All tests	Unclear	Insufficient information was given to permit judgement
Withdrawals explained? All tests	No	Some of the eligible patients who entered the study did not complete it and these patients were not accounted for
Learning curve / training reported of index test? All tests	Yes	The interpreter of MRI was one of six radiologists with extensive experience in musculoskeletal magnetic resonance imaging. The interpreter of US was one of two radiologists who were very experienced with the technique and who had conducted more than 2500 examinations during a 10-year

Teefey 2004 (Continued)

		period
Learning curve / training reported of reference standard? All tests	Unclear	The reference standards were performed by an experienced orthopaedic surgeon
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Venu 2002

Clinical features and settings	Inclusion criteria: Participants with clinical supraspinatus impingement syndrome and failure of clinical improvements with conservative treatment within one year of onset of symptoms Exclusion criteria: Not reported Duration of symptoms: Probably more than one year Previous treatments: Shoulder physiotherapy and sub-acromial steroid injections Care setting: Not reported
Participants	Place of study: Eastbourne, UK Period of study: June 1997 to June 1999 Number of participants eligible: 276 participants Number of participants enrolled IT and RS: - US and arthroscopy: 41 participants Data available for analyses: - US and arthroscopy: 41 participants Age: mean 54 years (range 34 to 79 years) Male/Female: 24/17 Dominant arm: Not reported Nature of onset: Not reported
Study design	Primary objective: To determine the accuracy of ultrasound compared with arthroscopy in the evaluation of the symptomatic supraspinatus tendon and to identify whether ultrasound diagnosis was helpful in pre-operative planning Study design: Prospective, consecutive, accuracy cohort study Language: English
Target condition and reference standard(s)	Target conditions: Presence of normal tendon, tendinopathy, partial thickness tear, full thickness tear, and rotator cuff rupture Reference standard(s): Shoulder arthroscopy - Description of technique: Not reported - Criteria for a positive result: Not reported
Index and comparator tests	Index test(s): US - Description of technique: Scanner: 5 to 10 MHz using a linear array transducer Technique: Longitudinal and transverse views of the supraspinatus Patient position: Patient probably seated with the shoulder internally rotated to visualise

Venu 2002 (Continued)

	the supraspinatus tendon - Criteria for a positive result: Tendinopathy: thickened and often decreased echogenicity Partial thickness tears: a hypo-or hyperechoic tendon defect not involving the full thickness of the tendon Full thickness tears: a hypo or hyperechoic tendon defect involving the full thickness of the tendon Rupture: the tendon was absent with often only the retracted proximal tendon visualised - Time from symptoms to index test: More than 1 year
	- Time from index test to reference standard (mean): 6 months
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
Notes	The study reported five categories to classify the tendon (normal tendon, tendinopathy, partial thickness tear, full thickness tear, and rotator cuff rupture) In our analyses we classified the categories 'normal' and 'tendinopathy' as normal tendon; and 'full' and 'rupture' as full thickness tear No two-by-two table of the ITs and RS was given but it was possible to back-calculate this from the reported summary data

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Population was patients with suspected of having any rotator cuff tears The study was prospective and recruitment was reported as consecutive The care setting was not specified
Acceptable reference standard? All tests	Yes	The reference standard was arthroscopy and the target conditions were presence of normal tendon, tendinopathy, partial thickness tear, full thickness tear, and rota- tor cuff rupture
Acceptable delay between tests? All tests	No	The average interval between reference standard and index test was 6 months
Partial verification avoided? All tests	No	Not all the patients who received the index test underwent a reference standard to verify their true disease status Of the 276 eligible participants only 41 (15%) received the reference standard
Differential verification avoided? All tests	No	The result of the index test influenced the choice of the reference standard

Venu 2002 (Continued)

Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Yes	The study was prospective and the results of the index tests were interpreted before the reference standard
Reference standard results blinded? All tests	No	The surgeon knew the US diagnosis prior to surgery
Relevant clinical information? All tests	Yes	Clinical data and plain radiographs were available at the time of performing the US examination
Uninterpretable results reported? All tests	No	The results of 235 (85%) patients were not reported
Withdrawals explained? All tests	No	Some of the eligible patients who entered the study did not complete it and these patients were not accounted for
Learning curve / training reported of index test? All tests	Yes	The interpreters of index tests were two radiologists specialised in shoulder US
Learning curve / training reported of reference standard? All tests	Unclear	Insufficient information was given to permit judgement
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Wallny 2001

Clinical features and settings	Inclusion criteria: Participants suffering from shoulder pain with histories and physical examinations suggestive of rotator cuff lesions Exclusion criteria: Participants with prior shoulder surgery or previous fracture of the humeral head Duration of symptoms: Not reported Previous treatments: Not reported Care setting: Tertiary or secondary
Participants	Place of study: Bonn, Germany Period of study: Not reported Number of participants eligible: 40 participants Number of participants enrolled IT and RS: - Two-dimensional (2D) US and arthroscopy or open surgery: 40 participants

Wallny 2001 (Continued)

	- Tree-dimensional (3D) US and arthroscopy or open surgery: 40 participants Data available for analyses: - 2D US and arthroscopy or open surgery: 40 participants - 3D US and arthroscopy or open surgery: 40 participants Age: mean 54 years (range 38 to 79 years) Male/Female: 25/15 Dominant arm: Not reported Nature of onset: Not reported
Study design	Primary objective: To determine the validity of 3D US in the diagnosis of rotator cuff lesions Study design: Prospective, consecutive, accuracy cohort study with fully paired direct comparison between 3D US and 2D US Language: English
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy or open surgery - Description of technique: Not reported - Criteria for a positive result: Not reported
Index and comparator tests	Index test(s): 3-D US and 2-D US - Description of technique: Scanner: 10 MHz electronic linear array in broad bandwidth technology, 192 fine pitch elements, frequency ranges: resolution: 4.5 to 13 MHz, penetration: 2.5 to 10 MHz Technique and Patient position: Not reported The region of interest was defined by 2D US before 3D US could be undertaken - Criteria for a positive result: Full thickness tear was defined as: marked thinning, sudden changes of calibre, hyperand/or hypoechoic zones and total absence of the cuff Partial thickness tear was defined as: constituting no more than loss of 1/4 to 1/2 of full thickness of the intact rotator cuff - Time from symptoms to index test: Not reported - Time from 2D US and 3D US: in the same examination - Time from index test to reference standard: Not reported
Follow-up	Adverse events due to index test(s): Not reported Adverse events due to reference standard test(s): Not reported
Notes	The study reported that the target conditions were presence of any rotator cuff tears, full thickness tears and partial thickness tears Only the data for analysing presence of any rotator cuff tears were available The study reported the data of two different types of US (three-dimensional and two-dimensional) Inasmuch as the 2D US examinations are more often used in clinical practice we arbitrarily chose 2D US to be included in our analyses A two-by-two table of the ITs and RS was given which tallied with the reported summary data

Table of Methodological Quality		
Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Tertiary or secondary care, participants with suspected of having any rotator cuff tears The study was prospective and recruitment was consecutive
Acceptable reference standard? All tests	Unclear	The reference standard was arthroscopy or open surgery and the target conditions were presence of full thickness tears and partial thickness tears
Acceptable delay between tests? All tests	Unclear	The study did not report the time elapsed between the index tests and reference standard
Partial verification avoided? All tests	Yes	All patients who received the index test went on to receive verification of their dis- ease status using a reference standard
Differential verification avoided? All tests	Yes	The indication for surgery was based on the results of clinical assessment and an MRI scan but independent of the result of the index test
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard
Index test results blinded? All tests	Yes	The study was prospective and the results of the index tests were interpreted before the reference standard
Reference standard results blinded? All tests	Unclear	Insufficient information was given to permit judgement
Relevant clinical information? All tests	Unclear	Not reported
Uninterpretable results reported? All tests	Yes	The study was prospective Recruitment was consecutive and results were reported for all initially included par- ticipants
Withdrawals explained? All tests	Yes	No participants were excluded from the analysis

Wallny 2001 (Continued)

Learning curve / training reported of index test? All tests	Unclear	Insufficient information was given to permit judgement
Learning curve / training reported of reference standard? All tests	Unclear	The reference standards were performed by a single orthopaedic surgeon
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

Yen 2004

Clinical features and settings	Inclusion criteria: Patients with shoulder pain and suspected of rotator cuff tears Exclusion criteria: Not reported Duration of symptoms: Not reported Previous treatments: Not reported Care setting: Not reported
Participants	Place of study: Taiwan, China Period of study: Not reported Number of participants eligible: 50 participants Number of participants enrolled IT and RS: - US and open surgery: 50 Data available for analyses: - US and open surgery: 50 Age: mean 63 years (range 17 to 81 years) Male/Female: 26/24 Dominant arm: Not reported Nature of onset: Not reported
Study design	Primary objective: To prospectively compare the US and operative findings of rotator cuff tears Study design: Prospective accuracy cohort study Unclear whether consecutive recruitment Language: English
Target condition and reference standard(s)	Target conditions: Presence any rotator cuff tears Reference standard(s): Open surgery - Description of technique: Not reported - Criteria for a positive result: Not reported
Index and comparator tests	Index test(s): US - Description of technique: Scanner: 7 MHz linear transducer Technique: Longitudinal, transverse and oblique scans of the tendons were used Patient position: Probably patient seated with the arm in

	External rotation for scanning the subscapularis tendon
	Neutral position for the long head of the biceps tendon
	Internal rotation and with the patient's hand behind the back with extreme internal
	rotation for the supraspinatus tendon
	Flexion and adduction for infraspinatus and teres minor tendons
	- Criteria for a positive result:
	Six US signs were used: non-visualisation;
	Floating bright spots
	Focal depression
	Focal thinning
	Focal hypoechoic cleft
	Focal heterogeneous hypoechogenicity
	- Time from symptoms to index test: Not reported
	- Time from index test to reference standard: within 1 month
Follow-up	Adverse events due to index test(s): Not reported
rollow-up	
	Adverse events due to reference standard test(s): Not reported
Notes	A two-by-two table of the ITs and RS was given which tallied with the reported summary data

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Population was patients with suspected of having any rotator cuff tears The study was prospective It was unclear whether consecutive recruitment
Acceptable reference standard? All tests	Unclear	The reference standard was open surgery and the target condition was presence of any rotator cuff tears
Acceptable delay between tests? All tests	Yes	The reference standard was performed within 1 month after the index test
Partial verification avoided? All tests	Yes	All patients who received the index test went on to receive verification of their dis- ease status using a reference standard
Differential verification avoided? All tests	Yes	All patients received the same reference standard regardless of the result of their in- dex test
Incorporation avoided? All tests	Yes	The index test did not form part of the reference standard

Yen 2004 (Continued)

Index test results blinded? All tests	Yes	The index tests were interpreted before and without knowledge of the reference standard results
Reference standard results blinded? All tests	No	The results of the index tests were known to the person interpreting the reference tests
Relevant clinical information? All tests	Unclear	Not reported
Uninterpretable results reported? All tests	Yes	The study was prospective and results were reported for all initially included participants
Withdrawals explained? All tests	Yes	No participants were excluded from the analysis
Learning curve / training reported of index test? All tests	Unclear	All of the procedures were performed by one sonologist and the findings were interpreted by two or three sonologists in consensus prior to surgery
Learning curve / training reported of reference standard? All tests	Unclear	Insufficient information was given to permit judgement
Index test criteria for a positive test result reported? All tests	Yes	The study reported the definition of a positive index test result

<: less than

>: more than

IT: Index test

MHz: Megahertz

RS: Reference standard

T: Tesla

T1-weighted: Short TR and short TE sequences T2-weighted: Long TR and long TE sequences

TE: Echo time TR: Repetition time

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Adams 2010	This was a retrospective study with a possible risk of spectrum and verification bias
Al-Shawi 2008	Reference standard not relevant: Arthroscopy or MRI was used as reference standard
Aliabadi 1991	Type of study not relevant: Narrative review
Aliprandi 2006	Participants not relevant: Participants with suspected of chronic or traumatic rotator cuff tear, congenital atraumatic or traumatic glenohumeral instability, traumatic rotator cuff tear and glenohumeral instability, and "frozen shoulder" were enrolled
Allmann 1999	Type of study not relevant: Technique report
Ardic 2006	Reference standard not relevant: MRI was used as reference standard
Auethavekiat 2006	Type of study not relevant: Case report
Awerbuch 2008	Type of study not relevant: Narrative review
Balich 1997	Participants not relevant: Participants with shoulder pain were enrolled; however, it was unclear if all participants were suspected of having rotator cuff tears
Bencardino 2010	Type of study not relevant: Narrative review
Blanchard 1999a	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Blanchard 1999b	Type of study not relevant: Questionnaire study
Blum 1993	Index test not relevant: Arthrographic computed tomography was used as index test
Boisrenoult 1999	Type of study not relevant: Index test was not compared with reference standard(s)
Boorstein 1992	Type of study not relevant: Narrative review
Brandt 1989	Reference standard not relevant: Arthrography or surgery was used as reference standard
Brasseur 1994	Type of study not relevant: Anatomic description
Brenneke 1992	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Bryant 2002	Type of study not relevant: The purpose of this study was to determine how well the size of rotator cuff tears could be estimated noninvasively by ultrasonography and MRI and how well arthroscopy could detect the size of rotator cuff tears
Burk 1989	Reference standard not relevant: Arthrography or surgery was used as reference standard

Chang 2002	Participants not relevant: Participants with shoulder pain; however, it was unclear if all participants were
<u>o</u>	suspected of having rotator cuff tears
Chaubal 2007	Type of study not relevant: Narrative review
Chen 1996	Target condition not relevant: The aim of the study was to determine the MRI findings that are associated with full thickness rotator cuff tears
Chiodi 1994	Participants not relevant: Selective population that all participants had full thickness tears (100% of prevalence) and the study was retrospective and reported non-consecutive recruitment
Chiodi 1995	Participants not relevant: Selective population that all participants had rotator cuff tears (100% of prevalence) The study also included patients that were reported in Chiodi 1994
Chiou 1999	This was a retrospective study with a possible risk of spectrum and verification bias
Chucair 2008	Type of study not relevant: Narrative review
Chun 2010	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Crass 1987	Type of study not relevant: Case report
Crass 1988	This was a retrospective study with a possible risk of spectrum and verification bias
Cullen 2007	This was a retrospective study with a possible risk of spectrum and verification bias
Cusmano 2000	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
D'Erme 1993	Reference standard not relevant: Surgery or arthrography was used as reference standard
Davidson 2005	Target condition not relevant: To determine the MRI criteria for predicting rotator cuff tear pattern and method of repair
Davis 1991	Type of study not relevant: Technique report
De Muynck 1994	Reference standard not relevant: Arthrography or arthroscopy or open surgery was used as reference standard
Demouy 1993	Type of study not relevant: Narrative review
Deutsch 1997	Participants not relevant: Selective population, restricted to subscapularis tendon tear (retrospective, so selected out patients with the diagnosis)
Dhagat 2002	Type of study not relevant: Index test (US) was not compared with reference standard(s)

Dinter 2008	Participants not relevant: Participants with shoulder pain; however, it was unclear if all participants were suspected of having rotator cuff tears
Drakeford 1990	Participants not relevant: Asymptomatic participants were included
El-Dalati 2005	Insufficient data to be included in the meta-analyses
El-Kouba 2010	This was a retrospective study with a possible risk of spectrum and verification bias
Evancho 1988	Reference standard not relevant: Arthroscopy or arthrography as reference standard
Fabis 1999a	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Fabis 1999b	Participants not relevant: The aim was to evaluate US images of rotator cuff integrity after surgical repair
Farin 1995	Participants not relevant: Participants with shoulder pain were enrolled; however, it was unclear if all participants were suspected of having rotator cuff tears
Farin 1996a	Participants not relevant: Participants with shoulder pain were enrolled; however, it was unclear if all participants were suspected of having rotator cuff tears
Farin 1996b	Participants not relevant: Selective population that all participants had full thickness tears (100% of prevalence) and the study was retrospective and reported non-consecutive recruitment
Farley 1992	Target condition not relevant: The aim of the study was to determine the MRI findings that are associated with full thickness rotator cuff tears
Ferrari 2002	Participants not relevant: Selective population that all participants had full thickness tears (100% of prevalence) and the study reported non-consecutive recruitment
Ferri 2005	Target condition not relevant: The aim of the study is to assess the accuracy of the Crass and modified Crass positions
Flannigan 1990	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Fotiadou 2008	This was a retrospective study with a possible risk of spectrum and verification bias
Frei 2008	This was a retrospective study with a possible risk of spectrum and verification bias
Fritz 1992	Type of study not relevant: Letter
Furtschegger 1988	This was a retrospective study with a possible risk of spectrum and verification bias
Girard 1995	Type of study not relevant: Narrative review
Goergen 1996	Type of study not relevant: Technique report

Goldberg 2003	Reference standard not relevant: Arthrography findings and clinical examination were used as reference standard
Hedtmann 2002	Type of study not relevant: Narrative review
Heijne 2004	Type of study not relevant: Editorial letter
Herold 2006	Participants not relevant: A history of trauma was reported in 17 (33%) of 51 patients Fourteen (27%) of 51 patients had previous shoulder dislocation, and 36 (71%) presented with clinical signs of impingement
Herzog 1997	Type of study not relevant: Narrative review
Herzog 1998	Type of study not relevant: Narrative review
Hodler 1987	Reference standard not relevant: Arthrography was used as reference standard
Hodler 1988	This was a retrospective study with a possible risk of spectrum and verification bias
Hodler 1992	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Hollister 1995	Target condition not relevant: The aim of the study was to determine the association between bursal and joint effusion (index tests findings) that are associated with rotator cuff tears
Homsi 1989	This was a retrospective study with a possible risk of spectrum and verification bias
Horii 1998	Participants not relevant: Selective population that all participants had full thickness tears (100% of prevalence) and the study was retrospective and reported non-consecutive recruitment
Iannotti 1991	Participants not relevant: Asymptomatic participants were enrolled
Imhoff 1992	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Imhoff 1993	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Imhoff 1996	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Iovane 2001	Participants not relevant: Selective population that all participants had full thickness tears (100% of prevalence) and the study was retrospective and reported non-consecutive recruitment
Iyengar 2010	Type of study not relevant: Technique report
Jacobson 2003	Type of study not relevant: Narrative review
Jacobson 2004	Target condition not relevant: The aim of the study was to determine which US signs are important for the diagnosis of a surgically identifiable supraspinatus tendon tear

Jaovisidha 1999	Type of study not relevant: The time elapsed between the index and reference tests was during a 26-month follow-up
Jeyam 2008	This was a retrospective study with a possible risk of spectrum and verification bias
Jung 2009	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Jung 2010	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Kaneko 1994	Participants not relevant: A control group without suspected of rotator cuff tears was included
Kautzner 2008	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Kelly 2009	Type of study not relevant: Diagnostic Test Accuracy review
Kerkovsky 2008	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Kluger 2003	Target condition not relevant: The aim of this study was to evaluate the accuracy of MRA and US in millimetres for both width and retraction of full-thickness rotator cuff tears, and not to detect the tears
Kneeland 1987	Reference standard not relevant: Arthroscopy or arthrography was used as reference standard
Kujat 1986	Type of study not relevant: Technique report
Kurol 1991	This was a retrospective study with a possible risk of spectrum and verification bias
Lawson 1991	Type of study not relevant: Narrative review
Lee 2002	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Lipman 1992	Type of study not relevant: Letter
Loew 2000	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Lopez 2007	This was a retrospective study with a possible risk of spectrum and verification bias
Low 1998	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Lucas 1991	Type of study not relevant: Narrative review
Mack 1988	This was a retrospective study with a possible risk of spectrum and verification bias
Magee 2003a	Participants not relevant: Participants with shoulder pain; however, it was unclear if all participants were suspected of having rotator cuff tears
Magee 2003b	Participants not relevant: Participants with shoulder pain; however, it was unclear if all participants were suspected of having rotator cuff tears

Magee 2006	Participants not relevant: Participants with shoulder pain; however, it was unclear if all participants were suspected of having rotator cuff tears
Magee 2007	Participants not relevant: Participants with clinical diagnosis of pain or instability or both were enrolled
Magee 2009	Participants not relevant: Participants with shoulder pain; however, it was unclear if all participants were suspected of having rotator cuff tears
Malvestiti 1997	Reference standard not relevant: Arthroscopy or MRI or arthrography was used as reference standard
Martin 2008	Type of study not relevant: Technique report
Masaoka 1999	Participants not relevant: Participants who underwent index test after surgery were enrolled
Masciocchi 1989	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Meister 2004	This was a retrospective study with a possible risk of spectrum and verification bias
Mendieta-Sevilla 2009	Reference standard not relevant: Surgery or MRI or arthrography or rehabilitation was used as reference standard
Merl 1996	Type of study not relevant: Narrative review
Middleton 1993	Type of study not relevant: Letter
Miller 2008	This was a retrospective study with a possible risk of spectrum and verification bias
Montrucchio 1997	This was a retrospective study with a possible risk of spectrum and verification bias
Monu 1994	Participants not relevant: The study included selective participants without rotator cuff tears
Moosmayer 2005	Participants not relevant: Participants with other shoulder complaints, including symptoms from the long head of the biceps muscle were enrolled
Moosmayer 2007	Participants not relevant: Participants with shoulder pain; however, it was unclear if all participants were suspected of having rotator cuff tears
Morrison 1990	Reference standard not relevant: Arthrography or arthroscopy or open surgery was used as reference standard
Naqvi 2009	This was a retrospective study with a possible risk of spectrum and verification bias
Narbona 2007	Target condition not relevant: The aim of this study was to detect SLAP lesion in patients with rotator cuff tears
Needell 1997	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled

Nelson 1991	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Nogueira-Barbosa 2002	This was a retrospective study with a possible risk of spectrum and verification bias
Norregaard 2002	Participants not relevant: Participants with clinical suspicion of labral or rotator cuff lesion were enrolled
Oh 2009	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Oh 2010	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Ostlere 1997	Type of study not relevant: Narrative review
Ozcakar 2005	Type of study not relevant: Letter
Paavolainen 1994	This was a retrospective study with a possible risk of spectrum and verification bias
Palmer 1993	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Palmer 1994	Type of study not relevant: Narrative review
Parsa 1997	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Pattee 1988	This was a retrospective study with a possible risk of spectrum and verification bias
Patten 1994	Reference standard not relevant: Arthroscopy, arthrography and non-surgical therapy were used as reference standard
Peetrons 1986	Type of study not relevant: Index test was not compared with reference standard(s)
Pfirrmann 1999	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Pfirrmann 2004	Participants not relevant: Asymptomatic participants were included
Pigeau 1992	Participants not relevant: Participants with shoulder pain were enrolled; however, it was unclear if all participants were suspected of having rotator cuff tears
Poey 1990	Participants not relevant: Participants with shoulder pain were enrolled; however, it was unclear if all participants were suspected of having rotator cuff tears
Porcellini 1994	Reference standard not relevant: Surgery or arthrography was used as reference standard
Prendergast 1992	Type of study not relevant: Narrative review
Quinn 1995	This was a retrospective study with a possible risk of spectrum and verification bias
Rafii 1990	Participants not relevant: Asymptomatic participants were included

Read 1998	Participants not relevant: Participants with shoulder pain were enrolled; however, it was unclear if all participants were suspected of having rotator cuff tears
Recht 1993	Type of study not relevant: Narrative review.
Recht 1994	Type of study not relevant: Narrative review.
Reinus 1995	Participants not relevant: Participants with shoulder pain; however, it was unclear if all participants had suspected of having rotator cuff tears
Roberts 1998	Reference standard not relevant: MRI or arthrography was used as reference standard
Roberts 2001	Participants not relevant: Participants with other shoulder complaints, including adhesive capsulitis and osteoarthritis were enrolled
Robertson 1995	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Rouaud 1989	Type of study not relevant: Index test (US) was not compared with reference standard(s)
Rubin 1997	Type of study not relevant: Letter
Rutten 2010a	Participants not relevant: Participants with shoulder pain were enrolled; however, it was unclear if all participants were suspected of having rotator cuff tears
Rutten 2010b	Participants not relevant: Participants with shoulder pain were enrolled; however, it was unclear if all participants were suspected of having rotator cuff tears
Sahin-Akyar 1998	Participants not relevant: Participants with rotator cuff tear and other disorders were enrolled
Sartoris 1992	Type of study not relevant: Narrative review
Sasaki 1990	Participants not relevant: Asymptomatic participants were included
Schneider 2003	Insufficient data to be included in the meta-analyses
Schreinemachers 2009	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Schultz 1994	Type of study not relevant: Letter
Seeger 1988	Type of study not relevant: The study did not describe the comparison between the index test and the reference standard
Sheah 2009	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Shellock 1996	Type of study not relevant: Narrative review

Shellock 2001	Participants not relevant: The authors reported that participants with suspected of 'shoulder pathology' were included, probable included participants with suspected of rotator cuff tears and shoulder instability
Shiv 1990	Type of study not relevant: Index test (US) was not compared with reference standard(s)
Singer 1995	Type of study not relevant: Index test was not compared with reference standard(s)
Singson 1996	Participants not relevant: Participants with shoulder pain were enrolled; however, it was unclear if all participants were suspected of having rotator cuff tears
Skib 1998	Type of study not relevant: Letter
Soble 1989	This was a retrospective study with a possible risk of spectrum and verification bias
Sonin 1996	This was a retrospective study with a possible risk of spectrum and verification bias
Sonnabend 1997	This was a retrospective study with a possible risk of spectrum and verification bias
Soto Araiza 1998	Reference standard not relevant: Surgery or MRI was used as reference standard
Steinbach 2000	Type of study not relevant: Narrative review
Strauss 1998	This was a retrospective study with a possible risk of spectrum and verification bias
Suder 1994	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Sunde 2001	Type of study not relevant: Letter
Sunde 2008	Type of study not relevant: Letter
Taboury 1995	Participants not relevant: Selective population that all participants had full thickness tears (100% of prevalence) and the study was retrospective and reported non-consecutive recruitment
Takagishi 1993	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Takagishi 1996	This was a retrospective study with a possible risk of spectrum and verification bias
Teefey 2000	Participants not relevant: Participants with shoulder pain were enrolled; however, it was unclear if all participants were suspected of having rotator cuff tears
Teefey 2009	Type of study not relevant: Case report
Theodoropoulos 2010	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Tirman 1994	Participants not relevant: Selective population of five professional throwing athletes were evaluated; and, these participants had other shoulder complaints, including instability

Torstensen 1999	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled	
Touzard 1991	Reference standard not relevant: Surgery or arthrography was used as reference standard	
Toyoda 2005	Participants not relevant: Selective population that all participants had full thickness tears (100% of prevalence) and the study was retrospective and reported non-consecutive recruitment	
Traughber 1992	This was a retrospective study with a possible risk of spectrum and verification bias	
Traughber 1996	Type of study not relevant: Letter	
Traughber 2006	Type of study not relevant: Letter	
Tuite 1994	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled	
Tuite 1995	Participants not relevant: It was unclear if all participants were suspected of having rotator cuff tears; furthermore, the study reported that part of participants of Tuite 1994 were included Thus, participants with other shoulder complaints, including instability were enrolled	
Tuite 1998	Participants not relevant: It was unclear if all participants were suspected of having rotator cuff tears; furthermore, the study reported that part of participants of Tuite 1994 were included Thus, participants with other shoulder complaints, including instability were enrolled	
Tuite 2001	Participants not relevant: It was unclear if all participants were suspected of having rotator cuff tears; probable the study included participants with shoulder instability	
Turrin 1997	This was a retrospective study with a possible risk of spectrum and verification bias	
Vahlensieck 2001	Type of study not relevant: Letter	
Van Dyck 2009	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled	
Van Holsbeeck 1995	This was a retrospective study with a possible risk of spectrum and verification bias	
Van Moppes 1995	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled	
Vander Maren 1995	Participants not relevant: Participants with shoulder pain were enrolled; however, it was unclear if all participants were suspected of having rotator cuff tears	
Vanecek 2000	Type of study not relevant: Narrative review	
Waldt 2007	Participants not relevant: Participants with symptomatic shoulder; however, it was unclear if all participants were suspected of having rotator cuff tears	
Wallny 1999	Type of study not relevant: Technique report The study described an index to improve the accuracy of diagnosis of chronic rotator cuff tears	

Walz 2007	Target condition not relevant: The aim of this study was a description of delamination tears of the supraspinatus, subscapularis, infraspinatus or teres minor tendons, as well as for mention of partial or full thickness tears
Wang 1994	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Weinstabl 1988	Type of study not relevant: Technique report
Wiener 1993	This was a retrospective study with a possible risk of spectrum and verification bias
Wilson 1994	Type of study not relevant: Letter
Wnorowski 1997	Participants not relevant: Participants with shoulder problems were enrolled; however, it was unclear if all participants were suspected of having rotator cuff tears The study reported that in the majority of the participants the primary diagnosis was unclear after the clinical evaluation
Wu 2003	This was a retrospective study with a possible risk of spectrum and verification bias
Yagci 2001	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Yamakawa 2001	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Yeh 2003	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled
Yeu 1994	This was a retrospective study with a possible risk of spectrum and verification bias
Zehetgruber 2002	This was a retrospective study with a possible risk of spectrum and verification bias
Ziegler 2004	This was a retrospective study with a possible risk of spectrum and verification bias
Zlatkin 1989	This was a retrospective study with a possible risk of spectrum and verification bias
Zlatkin 2004	Participants not relevant: Participants with other shoulder complaints, including instability were enrolled

Characteristics of studies awaiting classification [ordered by study ID]

Engebretsen 1994

Clinical features and settings	
Participants	Number of participants eligible: 41 participants Number of participants enrolled IT and RS: - MRI and surgery: 25 participants
Study design	

Engebretsen 1994 (Continued)

Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears Reference standard(s): Surgery Unclear whether arthroscopy or open surgery
Index and comparator tests	Index test(s): MRI
Follow-up	
Notes	Awaiting translation - Norwegian article The information was collected from titles and abstracts that were reported in English
Farin 1990	
Clinical features and settings	
Participants	Number of participants eligible: 301 participants Number of participants enrolled IT and RS: - US and surgery: 66 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears Reference standard(s): Surgery Unclear whether arthroscopy or open surgery
Index and comparator tests	Index test(s): US
Follow-up	
Notes	Awaiting translation - German article The information was collected from titles and abstracts that were reported in English
Guo 2000	
Clinical features and settings	
Participants	Number of participants eligible: 53 participants Number of participants enrolled IT and RS: - MRI and surgery: 53 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears

Reference standard(s): Open surgery or arthroscopy

Guo 2000 (Continued)

Index and comparator tests	Index test(s): MRI
Follow-up	
Notes	Awaiting translation - Chinese article The information was collected from titles and abstracts that were reported in English
Habermeyer 1984	

Clinical features and settings	
Participants	Number of participants eligible: 49 participants Number of participants enrolled IT and RS: - US and surgery: 17 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears Reference standard(s): Open surgery
Index and comparator tests	Index test(s): US
Follow-up	
Notes	Awaiting translation - German article The information was collected from titles and abstracts that were reported in English

Hedtmann 1995

Clinical features and settings	
Participants	Number of participants eligible: 4172 participants Number of participants enrolled IT and RS: - US and surgery: 1227 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears Reference standard(s): Open surgery
Index and comparator tests	Index test(s): US
Follow-up	

Hedtmann 1995 (Continued)

Notes	Awaiting translation - German article The information was collected from titles and abstracts that were reported in English
Heininger-Biner 2000	
Clinical features and settings	
Participants	Number of participants eligible: 88 participants Number of participants enrolled IT and RS: - MRI and surgery: 88 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears Reference standard(s): Surgery Unclear whether arthroscopy or open surgery
Index and comparator tests	Index test(s): MRI
Follow-up	
Notes	Awaiting translation - German article The information was collected from titles and abstracts that were reported in English
Kayser 2005	
Clinical features and settings	
Participants	Number of participants eligible: 239 participants Number of participants enrolled IT and RS: - US and surgery: 239 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy
Index and comparator tests	Index test(s): US
Follow-up	
Notes	Awaiting translation - German article The information was collected from titles and abstracts that were reported in English

Kenn 2000

Clinical features and settings	
Participants	Number of participants eligible: 40 participants Number of participants enrolled IT and RS: - US and surgery: 40 participants - MRI and surgery: 40 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Surgery Unclear whether arthroscopy or open surgery
Index and comparator tests	Index test(s): MRI and US
Follow-up	
Notes	Awaiting translation - German article The information was collected from titles and abstracts that were reported in English

Kumagai 1991

Clinical features and settings	
Participants	Number of participants eligible: 30 participants Number of participants enrolled IT and RS: - MRI and surgery: 30 participants - MRA and surgery: 30 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears Reference standard(s): Surgery Unclear whether arthroscopy or open surgery
Index and comparator tests	Index test(s): MRI and MRA
Follow-up	
Notes	Awaiting translation - Japanese article The information was collected from titles and abstracts that were reported in English

Kumagai 1992

Clinical features and settings	
Participants	Number of participants eligible: 115 participants Number of participants enrolled IT and RS: - MRI and surgery: unclear
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Surgery Unclear whether arthroscopy or open surgery
Index and comparator tests	Index test(s): MRI
Follow-up	
Notes	Awaiting translation - Japanese article The information was collected from titles and abstracts that were reported in English

Kumagai 1995

Clinical features and settings	
Participants	Number of participants eligible: 94 participants Number of participants enrolled IT and RS: - MRI and surgery: 21 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of full thickness tears Reference standard(s): Surgery Unclear whether arthroscopy or open surgery
Index and comparator tests	Index test(s): MRI
Follow-up	
Notes	Awaiting translation - Japanese article

Labanauskaite 2002

Clinical features and settings	
Participants	Number of participants eligible: 31 participants Number of participants enrolled IT and RS: - US and surgery: 31 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy
Index and comparator tests	Index test(s): US
Follow-up	
Notes	Awaiting translation - Lithuanian article The information was collected from titles and abstracts that were reported in English

Manych 2007

Clinical features and settings	
Participants	Number of participants eligible: 275 participants Number of participants enrolled IT and RS: - MRA and surgery: 197 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy
Index and comparator tests	Index test(s): MRA
Follow-up	
Notes	Awaiting translation - German article The information was collected from titles and abstracts that were reported in English

Nagamori 1995

Clinical features and settings	
Participants	Number of participants eligible: 45 participants Number of participants enrolled IT and RS: - MRI and surgery: 45 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Surgery Unclear whether arthroscopy or open surgery
Index and comparator tests	Index test(s): MRI
Follow-up	
Notes	Awaiting translation - Japanese article The information was collected from titles and abstracts that were reported in English

Qu 2008

Clinical features and settings	
Participants	Number of participants eligible: 57 participants Number of participants enrolled IT and RS: - MRI and surgery: 57 participants - MRA and surgery: 57 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy
Index and comparator tests	Index test(s): MRI and MRA
Follow-up	
Notes	Awaiting translation - Chinese article The information was collected from titles and abstracts that were reported in English

Rudolph 2000

Clinical features and settings	
Participants	Number of participants eligible: 63 participants Number of participants enrolled IT and RS: - MRA and surgery: 32 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy
Index and comparator tests	Index test(s): MRI
Follow-up	
Notes	Awaiting translation - German article The information was collected from titles and abstracts that were reported in English

Sakuragi 1989

Clinical features and settings	
Participants	Number of participants eligible: unclear number of participants Number of participants enrolled IT and RS: - US and surgery: unclear number of participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Surgery Unclear whether arthroscopy or open surgery
Index and comparator tests	Index test(s): US
Follow-up	
Notes	Awaiting translation - Japanese article The information was collected from titles and abstracts that were reported in English

Sasaki 1991

Clinical features and settings	
Participants	Number of participants eligible: 30 participants Number of participants enrolled IT and RS: - MRI and surgery: 15 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Surgery Unclear whether arthroscopy or open surgery
Index and comparator tests	Index test(s): MRI
Follow-up	
Notes	Awaiting translation - Japanese article The information was collected from titles and abstracts that were reported in English

Schedel 1990

Clinical features and settings	
Participants	Number of participants eligible: 30 participants Number of participants enrolled IT and RS: - US and surgery: unclear number of participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Surgery Unclear whether arthroscopy or open surgery
Index and comparator tests	Index test(s): US
Follow-up	
Notes	Awaiting translation - German article The information was collected from titles and abstracts that were reported in English

Schroder 2003

Clinical features and settings	
Participants	Number of participants eligible: 80 participants Number of participants enrolled IT and RS: - MRI and surgery: 80 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Open surgery or shoulder arthroscopy
Index and comparator tests	Index test(s): MRI
Follow-up	
Notes	Awaiting translation - German article The information was collected from titles and abstracts that were reported in English

Sell 1992

Clinical features and settings	
Participants	Number of participants eligible: 37 participants Number of participants enrolled IT and RS: - MRI and surgery: unclear number of participants - US and surgery: unclear number of participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Open surgery or shoulder arthroscopy
Index and comparator tests	Index test(s): MRI and US
Follow-up	
Notes	Awaiting translation - German article The information was collected from titles and abstracts that were reported in English

Sperner 1993

Clinical features and settings	
Participants	Number of participants eligible: 375 participants Number of participants enrolled IT and RS: - US and surgery: 375 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Open surgery
Index and comparator tests	Index test(s): US
Follow-up	
Notes	Awaiting translation - German article The information was collected from titles and abstracts that were reported in English

Vahlensieck 1996

Clinical features and settings	
Participants	Number of participants eligible: 25 participants Number of participants enrolled IT and RS: - MRI and surgery: 25 participants - US and surgery: 25 participants - MRA and surgery: 25 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy
Index and comparator tests	Index test(s): MRI, US and MRA
Follow-up	
Notes	Awaiting translation - German article The information was collected by titles and abstracts that were reported in English

Wallny 2000

Clinical features and settings	
Participants	Number of participants eligible: 25 participants Number of participants enrolled IT and RS: - US and surgery: 25 participants
Study design	
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Surgery Unclear whether arthroscopy or open surgery
Index and comparator tests	Index test(s): US
Follow-up	
Notes	Awaiting translation - German article The information was collected from titles and abstracts that were reported in English

Wang 2009

Clinical features and settings					
Participants	Number of participants eligible: 40 participants Number of participants enrolled IT and RS: - MRA and surgery: 40 participants				
Study design					
Target condition and reference standard(s)	Target conditions: Presence of any rotator cuff tears, full thickness tears and partial thickness tears Reference standard(s): Shoulder arthroscopy				
Index and comparator tests	Index test(s): MRA				
Follow-up					
Notes	Awaiting translation - Chinese article The information was collected from titles and abstracts that were reported in English				

IT: index test

RS: reference standard

MRI: magnetic resonance imaging MRA: magnetic resonance arthrography

US: ultrasound

DATA

Presented below are all the data for all of the tests entered into the review.

Tests. Data tables by test

Test	No. of studies	No. of participants
1 MRA for detection of any rotator cuff tears	3	183
2 MRA for detection of full thickness tears	3	183
3 MRA for detection of partial thickness tears	4	233
4 MRI for detection of any rotator cuff tears	6	347
5 MRI for detection of full thickness tears	7	368
6 MRI for detection of partial thickness tears	6	347
7 US for detection of partial thickness tears	8	660
8 US for detection of full thickness tears	10	729
9 US for detection of any rotator cuff tears	13	854
11 MRA for detection of any subscapularis tendon tears	1	58

Test I. MRA for detection of any rotator cuff tears.

Review: Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered

Test: I MRA for detection of any rotator cuff tears

Study	TP	FP	FN	TN	Sensitivity	Specificity			Sens	itivity					Spec	ificity		
Kang 2009	45	I	0	4	1.00 [0.92, 1.00]	0.80 [0.28, 0.99]					-	•					-	
Mohtadi 2004	26	21	10	I	0.72 [0.55, 0.86]	0.05 [0.00, 0.23]				_	•		4	-				
Sipola 2010	62	2	2	9	0.97 [0.89, 1.00]	0.82 [0.48, 0.98]					-	•					-	-
									_						_			
							0	0.2	0.4	0.6	0.8	ı	0	0.2	0.4	0.6	0.8	

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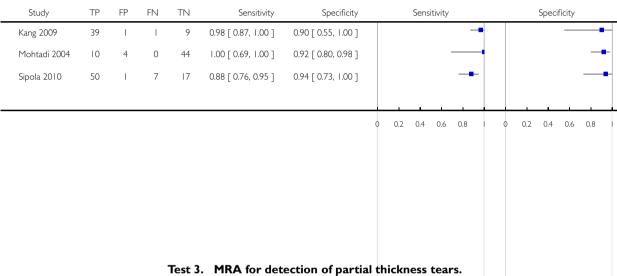
Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered (Review)

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Test 2. MRA for detection of full thickness tears.

Review: Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered

Test: 2 MRA for detection of full thickness tears



Review: Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered

Test: 3 MRA for detection of partial thickness tears

Study	TP	FP	FN	TN	Sensitivity	Specificity		Sen	sitivity				Speci	ificity		
Kang 2009	4	2	1	43	0.80 [0.28, 0.99]	0.96 [0.85, 0.99]				-	-				_	-
Mohtadi 2004	16	17	10	15	0.62 [0.41, 0.80]	0.47 [0.29, 0.65]		_	•					_		
Sipola 2010	5	8	2	60	0.71 [0.29, 0.96]	0.88 [0.78, 0.95]									-	-
Stetson 2005	21	0	6	23	0.78 [0.58, 0.91]	1.00 [0.85, 1.00]			_	-					_	4
							.									
							0 0.2	0.4	0.6	0.8	ı	0 0.2	0.4	0.6	0.8	ı

Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered (Review)

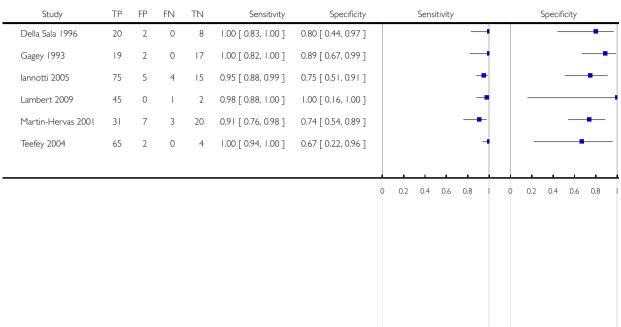
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Test 4. MRI for detection of any rotator cuff tears.

Review: Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered

Test: 4 MRI for detection of any rotator cuff tears



Test 5. MRI for detection of full thickness tears.

Review: Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered

Test: 5 MRI for detection of full thickness tears

Study	TP	FP	FN	TN	Sensitivity	Specificity	Sensitivity	Specificity
Della Sala 1996	17	0	2	П	0.89 [0.67, 0.99]	1.00 [0.72, 1.00]		
Gagey 1993	14	1	0	23	1.00 [0.77, 1.00]	0.96 [0.79, 1.00]		
lannotti 2005	40	7	2	50	0.95 [0.84, 0.99]	0.88 [0.76, 0.95]		
Lambert 2009	32	0	1	15	0.97 [0.84, 1.00]	1.00 [0.78, 1.00]		
Martin-Hervas 2001	21	I	5	34	0.81 [0.61, 0.93]	0.97 [0.85, 1.00]		
Swen 1999	10	I	3	7	0.77 [0.46, 0.95]	0.88 [0.47, 1.00]		
Teefey 2004	46	8	0	17	1.00 [0.92, 1.00]	0.68 [0.46, 0.85]	-	
							0 0.2 0.4 0.6 0.8	0 0.2 0.4 0.6 0.8

Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered (Review)

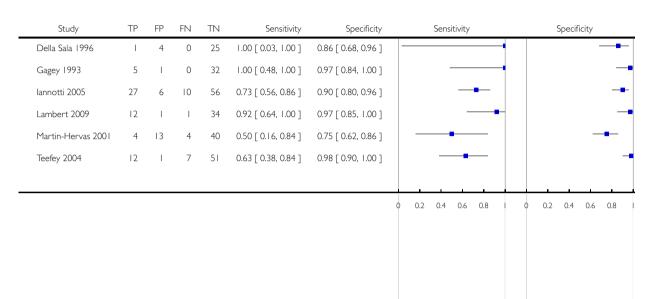
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Test 6. MRI for detection of partial thickness tears.

Review: Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered

Test: 6 MRI for detection of partial thickness tears



Test 7. US for detection of partial thickness tears.

Review: Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered

Test: 7 US for detection of partial thickness tears

Study	TP	FP	FN	TN	Sensitivity	Specificity		Sensitivit	У			Specif	icity	
De Candia 2002	9	0	3	59	0.75 [0.43, 0.95]	1.00 [0.94, 1.00]			•	-				
lannotti 2005	26	7	П	55	0.70 [0.53, 0.84]	0.89 [0.78, 0.95]		_	•					-
Kang 2009	2	5	3	40	0.40 [0.05, 0.85]	0.89 [0.76, 0.96]		•						-
Martin-Hervas 2001	1	17	7	36	0.13 [0.00, 0.53]	0.68 [0.54, 0.80]	-						-	_
Milosavljevic 2005	17	2	13	158	0.57 [0.37, 0.75]	0.99 [0.96, 1.00]		-						
Sipola 2010	1	9	7	60	0.13 [0.00, 0.53]	0.87 [0.77, 0.94]	-							-
Teefey 2004	13	2	6	50	0.68 [0.43, 0.87]	0.96 [0.87, 1.00]			•					_
Venu 2002	2	5	0	34	1.00 [0.16, 1.00]	0.87 [0.73, 0.96]	-			4				-
							0 0.2	0.4 0.6	6 0.8	İ	0 0.2	0.4	0.6	0.8

Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered (Review)

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Test 8. US for detection of full thickness tears.

Review: Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered

Test: 8 US for detection of full thickness tears

Study	TP	FP	FN	TN	Sensitivity	Specificity	Sensitivity	Specificity
De Candia 2002	32	0	I	38	0.97 [0.84, 1.00]	1.00 [0.91, 1.00]	-	-
lannotti 2005	37	10	5	47	0.88 [0.74, 0.96]	0.82 [0.70, 0.91]		
Kang 2009	35	1	5	9	0.88 [0.73, 0.96]	0.90 [0.55, 1.00]		
Martin-Hervas 2001	15	0	11	35	0.58 [0.37, 0.77]	1.00 [0.90, 1.00]		-
Milosavljevic 2005	94	9	0	87	1.00 [0.96, 1.00]	0.91 [0.83, 0.96]	+	
Sipola 2010	48	9	10	10	0.83 [0.71, 0.91]	0.53 [0.29, 0.76]	-	
Swen 1998	19	3	3	23	0.86 [0.65, 0.97]	0.88 [0.70, 0.98]		
Swen 1999	12	I	1	7	0.92 [0.64, 1.00]	0.88 [0.47, 1.00]		
Teefey 2004	45	5	1	20	0.98 [0.88, 1.00]	0.80 [0.59, 0.93]	-	
Venu 2002	10	0	2	29	0.83 [0.52, 0.98]	1.00 [0.88, 1.00]		-
							0 0.2 0.4 0.6 0.8	0 0.2 0.4 0.6 0.8

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Test 9. US for detection of any rotator cuff tears.

Review: Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered

Test: 9 US for detection of any rotator cuff tears

De Candia 2002 41 0 4 26 0.91 [0.79, 0.98] 1.00 [0.87, 1.00]	Study	TP	FP	FN	TN	Sensitivity	Specificity	Sensitivity	Specificity
Kang 2009 43 0 2 5 0.96 [0.85, 0.99] 1.00 [0.48, 1.00] Martin-Hervas 2001 24 9 10 18 0.71 [0.53, 0.85] 0.67 [0.46, 0.83] Milosavljevic 2005 118 4 6 62 0.95 [0.90, 0.98] 0.94 [0.85, 0.98] Misamore 1991 9 2 18 3 0.33 [0.17, 0.54] 0.60 [0.15, 0.95] Nicoletti 1994 35 1 8 4 0.81 [0.67, 0.92] 0.80 [0.28, 0.99] Sipola 2010 61 6 5 5 0.92 [0.83, 0.97] 0.45 [0.17, 0.77] Taboury 1992 20 0 1 3 0.95 [0.76, 1.00] 1.00 [0.29, 1.00] Teefey 2004 63 2 2 4 0.97 [0.89, 1.00] 0.67 [0.22, 0.96] Venu 2002 14 3 0 24 1.00 [0.77, 1.00] 0.89 [0.71, 0.98] Wallny 2001 17 3 6 14 0.74 [0.52, 0.90] 0.82 [0.57, 0.96]	De Candia 2002	41	0	4	26	0.91 [0.79, 0.98]	1.00 [0.87, 1.00]		
Martin-Hervas 2001 24 9 10 18 0.71 [0.53, 0.85] 0.67 [0.46, 0.83] Milosavljevic 2005 118 4 6 62 0.95 [0.90, 0.98] 0.94 [0.85, 0.98] Misamore 1991 9 2 18 3 0.33 [0.17, 0.54] 0.60 [0.15, 0.95] Nicoletti 1994 35 1 8 4 0.81 [0.67, 0.92] 0.80 [0.28, 0.99] Sipola 2010 61 6 5 5 0.92 [0.83, 0.97] 0.45 [0.17, 0.77] Taboury 1992 20 0 1 3 0.95 [0.76, 1.00] 1.00 [0.29, 1.00] Teefey 2004 63 2 2 4 0.97 [0.89, 1.00] 0.67 [0.22, 0.96] Venu 2002 14 3 0 24 1.00 [0.77, 1.00] 0.89 [0.71, 0.98] Wallny 2001 17 3 6 14 0.74 [0.52, 0.90] 0.82 [0.57, 0.96]	lannotti 2005	76	4	3	16	0.96 [0.89, 0.99]	0.80 [0.56, 0.94]		
Milosavljevic 2005	Kang 2009	43	0	2	5	0.96 [0.85, 0.99]	1.00 [0.48, 1.00]		
Misamore 1991 9 2 18 3 0.33 [0.17, 0.54] 0.60 [0.15, 0.95] Nicoletti 1994 35 1 8 4 0.81 [0.67, 0.92] 0.80 [0.28, 0.99] Sipola 2010 61 6 5 5 0.92 [0.83, 0.97] 0.45 [0.17, 0.77] Taboury 1992 20 0 1 3 0.95 [0.76, 1.00] 1.00 [0.29, 1.00] Teefey 2004 63 2 2 4 0.97 [0.89, 1.00] 0.67 [0.22, 0.96] Venu 2002 14 3 0 24 1.00 [0.77, 1.00] 0.89 [0.71, 0.98] Wallny 2001 17 3 6 14 0.74 [0.52, 0.90] 0.82 [0.57, 0.96]	Martin-Hervas 2001	24	9	10	18	0.71 [0.53, 0.85]	0.67 [0.46, 0.83]		
Nicoletti 1994 35 I 8 4 0.81 [0.67, 0.92] 0.80 [0.28, 0.99]	Milosavljevic 2005	118	4	6	62	0.95 [0.90, 0.98]	0.94 [0.85, 0.98]	-	
Sipola 2010 61 6 5 5 0.92 [0.83, 0.97] 0.45 [0.17, 0.77] Taboury 1992 20 0 1 3 0.95 [0.76, 1.00] 1.00 [0.29, 1.00] Teefey 2004 63 2 2 4 0.97 [0.89, 1.00] 0.67 [0.22, 0.96] Venu 2002 14 3 0 24 1.00 [0.77, 1.00] 0.89 [0.71, 0.98] Wallny 2001 17 3 6 14 0.74 [0.52, 0.90] 0.82 [0.57, 0.96]	Misamore 1991	9	2	18	3	0.33 [0.17, 0.54]	0.60 [0.15, 0.95]		-
Taboury 1992 20 0 I 3 0.95 [0.76, 1.00] 1.00 [0.29, 1.00] Teefey 2004 63 2 2 4 0.97 [0.89, 1.00] 0.67 [0.22, 0.96] Venu 2002 14 3 0 24 1.00 [0.77, 1.00] 0.89 [0.71, 0.98] Wallny 2001 17 3 6 14 0.74 [0.52, 0.90] 0.82 [0.57, 0.96]	Nicoletti 1994	35	1	8	4	0.81 [0.67, 0.92]	0.80 [0.28, 0.99]		-
Teefey 2004 63 2 2 4 0.97 [0.89, 1.00] 0.67 [0.22, 0.96] Venu 2002 14 3 0 24 1.00 [0.77, 1.00] 0.89 [0.71, 0.98] Wallny 2001 17 3 6 14 0.74 [0.52, 0.90] 0.82 [0.57, 0.96]	Sipola 2010	61	6	5	5	0.92 [0.83, 0.97]	0.45 [0.17, 0.77]		
Venu 2002	Taboury 1992	20	0	1	3	0.95 [0.76, 1.00]	1.00 [0.29, 1.00]		
Wallny 2001 17 3 6 14 0.74 [0.52, 0.90] 0.82 [0.57, 0.96]	Teefey 2004	63	2	2	4	0.97 [0.89, 1.00]	0.67 [0.22, 0.96]		-
	Venu 2002	14	3	0	24	1.00 [0.77, 1.00]	0.89 [0.71, 0.98]		_
Yen 2004 38 I 2 9 0.95 [0.83, 0.99] 0.90 [0.55, I.00] ——————————————————————————————————	Wallny 2001	17	3	6	14	0.74 [0.52, 0.90]	0.82 [0.57, 0.96]		
	Yen 2004	38	1	2	9	0.95 [0.83, 0.99]	0.90 [0.55, 1.00]		
0 0.2 0.4 0.6 0.8 0 0.2 0.4 0.6								0 0.2 0.4 0.6 0.8	0 0.2 0.4 0.6 0.8

Test 11. MRA for detection of any subscapularis tendon tears.

Review: Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered

Test: II MRA for detection of any subscapularis tendon tears

TP	FP	FN	TN	Sensitivity	Specificity			Sens	itivity					Speci	ificity		
15	П	4	28	0.79 [0.54, 0.94]	0.72 [0.55, 0.85]					•	-				_	•	
							i	ī		Ī			ī			1	
						0	0.2	0.4	0.6	0.8	ı	0	0.2	0.4	0.6	0.8	
					,	, , , , , , , , , , , , , , , , , , , ,	15 11 4 28 0.79 [0.54, 0.94] 0.72 [0.55, 0.85]	15 11 4 28 0.79 [0.54, 0.94] 0.72 [0.55, 0.85]	15 11 4 28 0.79 [0.54, 0.94] 0.72 [0.55, 0.85]	15 11 4 28 0.79 [0.54, 0.94] 0.72 [0.55, 0.85]	15 11 4 28 0.79 [0.54, 0.94] 0.72 [0.55, 0.85]	15 11 4 28 0.79 [0.54, 0.94] 0.72 [0.55, 0.85]	15 11 4 28 0.79 [0.54, 0.94] 0.72 [0.55, 0.85]	15 11 4 28 0.79 [0.54, 0.94] 0.72 [0.55, 0.85]	15 11 4 28 0.79 [0.54, 0.94] 0.72 [0.55, 0.85]	15 11 4 28 0.79 [0.54, 0.94] 0.72 [0.55, 0.85]	15 11 4 28 0.79 [0.54, 0.94] 0.72 [0.55, 0.85]

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Magnetic resonance imaging, magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered (Review)

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ADDITIONAL TABLES

Table 1. Comparison of MRI, US and MRA for detection of any rotator cuff tears (partial or full thickness) using all studies (indirect comparison)

Index test	Studies	Shoulders	Cases	Summary sensitivity (95% CI)	•	LR+	LR-	Test ¹
Any rotato	r cuff tears	3						
MRI	6	347	263	98 (92, 99)	79 (68, 87)	5 (2, 10)	0.03 (0.01, 0.11)	P = 0.13
US	13	854	626	91 (83, 95)	85 (74, 92)	6 (3, 12)	0.11 (0.05, 0.22)	
Full thickn	ess tears							
MRI	7	368	193	94 (85, 98)	93 (83, 97)	13 (6, 29)	0.06 (0.02, 0.16)	P = 0.7
MRA	3	183	107	94 (80, 98)	92 (83, 97)	12 (5, 30)	0.06 (0.02, 0.23)	
US	10	729	386	92 (82, 96)	93 (81, 97)	12 (5, 34)	0.09 (0.04, 0.20)	
Partial tear	s							
MRI	6	347	83	74 (59, 85)	93 (84, 97)	10 (4, 26)	0.28 (0.17, 0.48)	P = 1.00
US	8	660	121	52 (33, 70)	93 (85, 97)	8 (3, 19)	0.52 (0.33, 0.80)	

Likelihood ratio test for evidence of a difference in sensitivity and/or specificity between the tests.

Table 2. Comparison of MRI and US for detection of rotator cuff tears (any, partial or full thickness) limited to studies in which all participants received both MRI and US (direct comparison)

Study	Cases	Non-cases	MRI US			Difference in	Difference in	
			Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	sensitivity (95% CI)	specificity (95% CI)
Any rotator	cuff tears	s						
Iannotti 2005	79	20	95 (88, 99)	75 (51, 91)	96 (89, 99)	80 (56, 94)	-1 (-8, 5)	-5 (-31, 21)
Martin- Hervas 2001	34	27	91 (76, 98)	74 (54, 89)	71 (53, 85)	67 (46, 83)	21 (3, 39)	7 (-17, 32)
Teefey 2004	65	6	100 (94, 100)	67 (22, 96)	97 (89, 100)	67 (22, 96)	3 (-1, 7)	0 (-53, 53)
Full thickness		U	100 (74, 100)	07 (22, 70)	77 (67, 100)	07 (22, 70)	J (-1, /)	0 (-)3,)3)

LR+ = positive likelihood ratio; LR- = negative likelihood ratio

Table 2. Comparison of MRI and US for detection of rotator cuff tears (any, partial or full thickness) limited to studies in which all participants received both MRI and US (direct comparison) (Continued)

Iannotti 2005	42	57	95 (84, 99)	88 (76, 95)	88 (74, 96)	82 (70, 91)	7 (-5, 19)	5 (-8, 18)
Martin- Hervas 2001	26	35	81 (61, 93)	97 (85, 100)	58 (37, 77)	100 (90, 100)	23 (-1, 47)	-3 (-8, 3)
Swen 1999	13	8	77 (46, 95)	88 (47, 100)	92 (64, 100)	88 (47, 100)	-15 (-42, 12)	0 (-32, 32)
Teefey 2004	46	25	100 (92, 100)	68 (46, 85)	98 (88, 100)	80 (59, 93)	2 (-2, 6)	-12 (-36, 12)
Partial thicks	ness tear	s						
Iannotti 2005	37	62	73 (56, 86)	90 (80, 96)	70 (53, 84)	89 (78, 95)	3 (-18, 23)	2 (-9, 12)
Martin- Hervas 2001	8	53	50 (16, 84)	75 (62, 86)	13 (0, 53)	68 (54, 80)	38 (-4, 79)	8 (-10, 25)
Teefey 2004	19	52	63 (38, 84)	98 (90, 100)	68 (43, 87)	96 (87, 100)	-5 (-35, 25)	2 (-4, 8)

Table 3. Comparison of MRA and US for detection of rotator cuff tears (any, partial or full thickness) limited to studies in which all patients received both MRI and US (direct comparison)

Study	Cases	Non-cases	MRA		US ¹		Difference in	Difference in	
			Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	sensitivity (95% CI)	specificity (95% CI)	
Any rotator of	cuff tears	s							
Kang 2009	45	5	100 (92, 100)	80 (28, 99)	96 (85, 99)	100 (48, 100)	4 (-2, 10)	-20 (-55, 15)	
Sipola 2010	64	11	97 (89, 100)	82 (48, 98)	92 (83, 97)	45 (17, 77)	4 (-3, 12)	36 (-0.9, 74)	
Full thickness	s tears								
Kang 2009	40	10	97 (87, 100)	90 (55, 100)	88 (73, 96)	90 (55, 100)	10 (-1, 21)	0 (-26, 26)	
Sipola 2010	57	18	88 (76, 95)	94 (73, 100)	83 (71, 91)	53 (29, 76)	5 (-8, 18)	42 (17, 67)	
Partial thickness tears									
Kang 2009	5	45	80 (28, 99)	96 (85, 99)	40 (5, 85)	89 (76, 96)	40 (-15, 95)	7 (-4, 18)	

Table 3. Comparison of MRA and US for detection of rotator cuff tears (any, partial or full thickness) limited to studies in which all patients received both MRI and US (direct comparison) (Continued)

Sipola 2010 7	68	71 (29, 96)	88 (78, 95)	13 (0, 53)	87 (77, 94)	59 (18, 99)	1 (-10, 12)

¹ For the three target conditions, there were 2 additional shoulders for US

APPENDICES

Appendix I. Search strategies

MEDLINE (PubMed)

((Ultrasonography [mh] OR ultrasound [tw] OR ultrasonograph* [tw] OR sonograp*[tw] OR us [sh]) OR (Magnetic Resonance Imaging [mh] OR MR imag*[tw] OR magnetic resonance imag* [tw] OR MRI [tw])) AND (Rotator Cuff [mh] OR rotator cuff* [tw] OR musculotendinous cuff* [tw] OR subscapularis [tw] OR supraspinatus [tw] OR infraspinatus OR teres minor [tw]) AND (Rupture [mh:noexp] OR tear* [tw] OR torn [tw] OR thickness [tw] OR lesion* [tw] OR ruptur* [tw] OR injur* [tw])

Total references = 1551

EMBASE (Elsevier)

- 1 'echography'/de AND [embase]/lim (124208)
- 2 ultrasound:ab,ti OR ultrasonograph*:ab,ti OR sonograp*:ab,ti AND [embase]/lim (192495)
- 3 #1 OR #2 (242499)
- 4 'nuclear magnetic resonance imaging'/de AND [embase]/lim (277184)
- 5 (('magnetic resonance' OR mr) NEAR/3 imag*):ab,ti AND [embase]/lim (130882)
- 6 mri:ab,ti AND [embase]/lim (108797)
- 7 #4 OR #5 OR #6 (311974)
- 8 'rotator cuff injury'/de OR 'rotator cuff rupture'/de AND [embase]/lim (3561)
- 9 'rotator cuff'/de AND [embase]/lim (1850)
- 10 'rotator cuff':ab,ti OR 'musculotendinous cuff':ab,ti OR subscapularis:ab,ti OR supraspinatus:ab,ti OR infraspinatus:ab,ti OR 'teres minor':ab,ti AND [embase]/lim (5679)
- 11 #9 OR #10 (6120)
- 12 'rupture'/de AND [embase]/lim (3798)
- 13 tear*:ab,ti OR torn:ab,ti OR thickness:ab,ti OR lesion*:ab,ti OR ruptur*:ab,ti OR injur*:ab,ti AND [embase]/lim (1001852)
- 14 #12 OR #13 (1002130)
- 15 #11 AND #14 (3615)
- 16 #8 OR #15 (4908)
- 17 #3 OR #7 (526691)
- 18 #16 AND #17 (1572)

² 66 cases for detection of any rotator cuff tears using US

³ 8 cases and 69 non-cases for detection of full thickness tears using US

⁴ 58 cases and 19 non-cases for detection of partial thickness tears using US

LILACS (Bireme)

(Mh Ultrasonography OR Tw ultrasound OR Tw ultrasonograph\$ OR Tw Sonograp\$) OR (Mh Magnetic Resonance Imaging OR (Tw magnetic AND Tw resonance AND Tw imag\$) OR Tw MRI) [Words] and Mh Rotator Cuff OR (Tw rotator AND Tw cuff) OR (Tw musculotendinous AND Tw cuff) OR Tw subscapularis OR Tw supraspinatus OR Tw infraspinatus OR (Tw teres AND Tw minor) [Words] and Mh Rupture OR Tw tear\$ OR Tw torn OR Tw thickness OR Tw lesion\$ OR Tw rupture\$ OR Tw injur\$ [Words] Total references = 30

Appendix 2. Assessment of methodological quality: QUADAS and additional items

Item definition	Item question	Assessment
Representative spectrum	1. Was the spectrum of patients representative of the patients who will receive the test in practice?	Yes: (a) the setting was secondary or tertiary care AND (b) the population was patients with shoulder pain suspected of a rotator cuff tear for whom surgery is being considered AND (c) the study was prospective AND (d) recruitment was consecutive Unclear: if insufficient information was given on the setting, selection criteria, or selection procedure to make a judgment No: (a) the setting was primary care OR (b) the population was unselected but defined by shoulder pain OR (c) the study was not prospective OR (d) recruitment was not consecutive
Acceptable reference standard	2. Is the reference standard likely to classify the target condition correctly?	Yes: if the reference standard was arthroscopy or a combination of arthroscopy and open surgery (including mini-open) Unclear: if the target condition was partial thickness rotator cuff tears and the refer- ence standard was open surgery (including mini-open) No: not applicable
Acceptable delay between tests	3. Is the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between the two tests?	Yes: if the average interval between reference standard and index test was one month or less Unclear: if the interval between tests was not clearly reported No: if the average interval between reference standard and index test was longer than one month
Partial verification avoided	4. Did the whole sample or a random selection of the sample, receive verification using the intended reference standard?	Yes: If all patients who received the index test went on to receive verification of their disease status using a reference standard (Score 'Yes' even if different reference

(Continued)

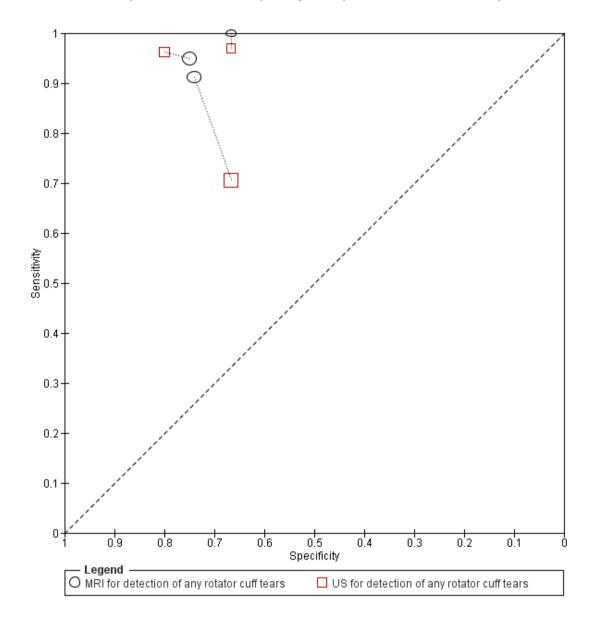
		tests were used) Unclear: if insufficient information was given on relation of index test and reference standard No: if not all the patients who received the index test underwent a reference standard to verify their true disease status
Differential verification bias	5. Did patients receive the same reference standard irrespective of the index test result?	Yes: if all patients received the same reference standard, regardless of the result of their index test Unclear: If it is unclear whether different reference standards were used No: if the result of the index test influenced the choice of the reference standard
Incorporation bias	6. Was the reference standard independent of the index test (i.e. the index test did not form part of the reference standard)?	Should be considered 'Yes' for all studies because the index test is not part of the reference standard
Index test results blinded	7. Were the index test results interpreted without knowledge of the results of the reference standard?	Yes: if the person undertaking the index test was blinded to the results of the standard reference Unclear: if insufficient information was given on independent or blind assessment of the index test No: if the results of the reference tests were known to the person undertaking the index tests
Reference standard results blinded	8. Were the reference standard results interpreted without knowledge of the results of the index test?	Yes: if the reference standard results were performed blind to the results of the index test Unclear: if insufficient information was given on independent or blind assessment of the reference standard No: if the results of the index tests were known to the person interpreting the reference tests
Relevant clinical information	9. Were the same clinical data available when test results were interpreted as would be available when the test is used in practice?	Yes: if clinical data would normally be available when the test is interpreted in practice and similar data were available when interpreting the index test in the study Unclear: if insufficient information was given to explain which clinical information was available at the time of assessment No: if clinical data were not available when index test(s) was(were) interpreted

Uninterpretable results reported	10. Were uninterpretable/ intermediate test results reported?	Yes: If the number of uninterpretable test results is stated, or if the number of results reported agrees with the number of patients recruited (indicating no uninterpretable test results) Unclear: if insufficient information was given to permit judgement No: If it states that uninterpretable test results occurred or were excluded and does not report how many
Withdrawals explained	11. Were withdrawals from the study explained?	Yes: if the number and reasons of all with-drawals from the study were explained (ideally by a flow chart) or if no participants were excluded from the analysis Unclear: if insufficient information was given on the withdrawals No: if not all withdrawals were explained
Learning curve / training reported of index test	12. Had index test operators had appropriate training or experience in musculoskeletal diseases?	Yes: (a) if the index test(s) executors were radiologists or shoulder surgeons AND (b) if the tests interpreters had experience in diagnostic of musculoskeletal diseases Unclear: if insufficient information was given to permit judgement No: (a) if the index test(s) executors were not radiologists or shoulder surgeons OR (b) if the tests interpreters had no experience in diagnostic of musculoskeletal diseases
Learning curve / training reported of reference standard	13. Had reference standard test operators had appropriate training or experience in shoulder surgery?	Yes: (a) if the reference standard(s) executors were shoulder surgeons AND (b) if the results interpreters had experience in shoulder diseases Unclear: if insufficient information was given to permit judgement No: (a) if the reference standard(s) executors were not shoulder surgeons OR (b) if the results interpreters had no experience in shoulder diseases
Index test / criteria for a positive result	14. Index test criteria for a positive result reported??	Yes: (a) if the study provides a clear definition of a positive test result Unclear: if insufficient information was given to permit judgement No: if no definition is given of a positive test result

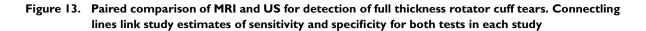
Appendix 3. Additional figures

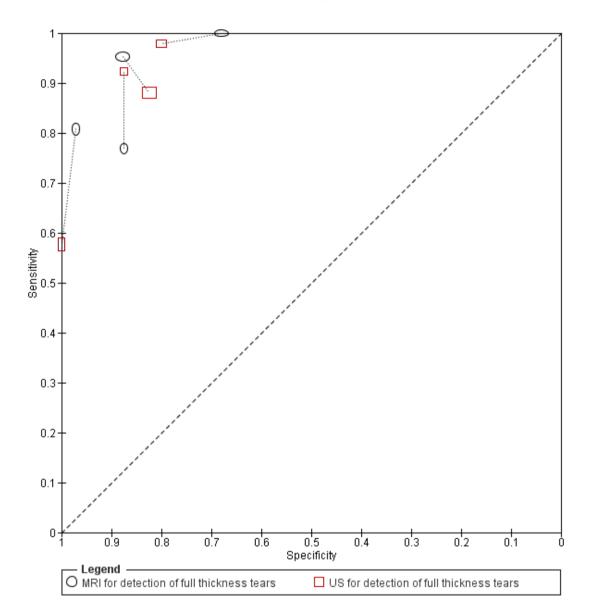
Summary ROC plot of within study comparisons of MRI and US for detection of any rotator cuff tears (Figure 12)

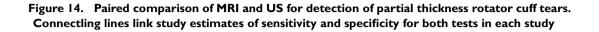
Figure 12. Paired comparison of MRI and US for detection of any rotator cuff tears. Connectling lines link study estimates of sensitivity and specificity for both tests in each study

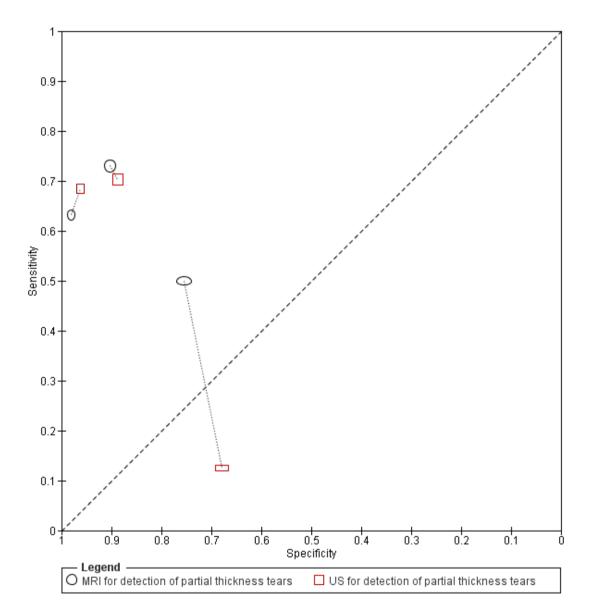


Summary ROC plot of within study comparisons of MRI and US for detection of full thickness rotator cuff tears (Figure 13)









Appendix 4. Sensitivity analyses for US studies for detection of rotator cuff tears (any, partial or full thickness)

	Studies	Shoulders	Cases	Summary sensi-	Summary speci-	LR+	LR-	
				tivity (95% CI)	ficity (95% CI)			
Any rotator cuff tears								
All studies	13	854	626	91 (83, 95)	85 (74, 92)	6 (3, 12)	0.11 (0.05, 0.22)	
Acceptable reference standard	5	400	291	94 (88, 97)	91 (82, 95)	10 (5, 22)	0.06 (0.03, 0.14)	
Index test results blinded	9	468	348	91 (78, 97)	81 (70, 88)	5 (2, 10)	0.11 (0.04, 0.31)	
Full thickness tears								
All studies	10	729	386	92 (82, 96)	93 (81, 97)	12 (5, 34)	0.09 (0.04, 0.20)	
Acceptable reference standard	6	421	227	95 (86, 98)	91 (85, 95)	11 (6, 20)	0.06 (0.02, 0.16)	
Index test results blinded	7	391	201	87 (76, 93)	92 (81, 97)	11 (5, 26)	0.14 (0.08, 0.26)	
Partial tears								
All studies	8	660	121	52 (33, 70)	93 (85, 97)	8 (3, 19)	0.52 (0.33, 0.80)	
Acceptable reference stan- dard	4	352	56	62 (45, 77)	95 (87, 98)	12 (5, 31)	0.40 (0.26, 0.61)	
Index test results blinded	5	322	71	56 (32, 77)	87 (78, 93)	4 (2, 9)	0.51 (0.28, 0.93)	

Footnotes

Sensitivity analyses performed by excluding studies that scored 'Unclear' or 'No' for each of the two QUADAS criteria listed in the

CONTRIBUTIONS OF AUTHORS

All authors contributed to the development of the review and commented on and approved the final version. The guarantor of this review is Mario Lenza.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Universidade Federal de São Paulo, Brazil.
- The Parker Institute, Denmark.

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- Teesside University, UK.
- Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Australia.

In kind support

• Cabrini Institute, Cabrini Hospital, Malvern, Victoria, Australia.

In kind support

External sources

• No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

- 1. We only included studies of participants suspected of having rotator cuff tears. Studies that reported results of people who had been previously diagnosed with, or suspected of having, other specific shoulder diagnoses were excluded. If it was unclear whether or not all participants were suspected of having rotator cuff tears, we also excluded these studies
- 2. Inasmuch as there is no set time point beyond which it is known that rotator cuff tears progress, we accepted studies in which the time between the index test and the reference standard test was up to a year (rather than six months as specified in the protocol).
 - 3. We included the MEDION database in our search strategy.
- 4. We restricted our analyses to prospective studies and excluded retrospective studies because of the high risk of spectrum and verification biases in these studies.
- 5. We made an amendment in the assessment of methodological quality item seven (index test results blinded). We removed "if the study was retrospective" as a reason to say *No* because we included only prospective studies.
- 6. We made an amendment in the assessment of methodological quality item eight (reference standard results blinded). We excluded "if the study was retrospective" as a reason to say N_0 because it was covered by the first part of the sentence.
- 7. We included in the assessment of methodological quality table an additional generic quality item assessing whether or not the criteria for a positive index test result was reported.
- 8. We used the bivariate model for meta-analysis instead of the hierarchical summary ROC (HSROC) model. Given the available information, we assumed a common threshold was applicable but with heterogeneity around this common threshold due to variation in interpretation in practice. Therefore we consider the bivariate model and the estimation of summary points (with 95% confidence regions) appropriate for summarising the results of the review.

9.	9. We conducted sensitivity analyses to examine the effect of unit of analysis.									



São Paulo, 26 de fevereiro de 2010. **CEP 0154/10**

Ilmo(a). Sr(a).

Pesquisador(a) MÁRIO LENZA

Co-Investigadores: Mário Lenza, João Carlos Belloti (orientador), Flávio Faloppa

Disciplina/Departamento: Cirurgia da Mão e Membro Superior da Universidade Federal de São Paulo/Hospital São

Paulo

Patrocinador: Recursos Próprios.

PARECER DO COMITÊ DE ÉTICA INSTITUCIONAL

Ref: Projeto de pesquisa intitulado: "Ressonância nuclear magnética versus ultrassonografia para o diagnóstico das lesões do manguito rotador: Revisão sistemática de estudos de diagnóstico".

CARACTERÍSTICA PRINCIPAL DO ESTUDO: Revisão sistemática.

RISCOS ADICIONAIS PARA O PACIENTE: Sem risco, sem procedimento invasivo.

OBJETIVOS: Comparar a acurácia dos testes diagnósticos de imagem da ressonância nuclear magnética versus a ultrassonografia para detectar lesões do manguito rotador em pacientes com dor no ombro que possuem indicação de tratamento cirúrgico..

RESUMO: Revisão de literatura, de acordo com as recomendações propostas pela Cochrane Collaboration Screening and Diagnostic Testes Methods Group para desenvolver revisões sistemáticas de estudos de acurácia. Serão incluídos todos os estudos de acurácia que comparam ressonância RNM e/ou US com os testes de referência em pacientes com suspeita de lesão parcial ou total do manguito rotador. Serão incluídos os estudos que avaliarem pacientes com dor no ombro e suspeita de lesão parcial ou total do manguito rotador, que possuem indicação de cirurgia. Serão inclduídos testes de diagnóstico por imagem que comparem US e/ou RNM com o definido teste de referência (artroscopia ou cirurgia aberta).

FUNDAMENTOS E RACIONAL: Os exames de US e/ou RNM estão sendo cada vez mais usados para avaliar a presença e extensão da lesão do manguito com o objetivo de realizar um melhor planejamento da intervenção cirúrgica. Ambos, US e RNM são operador e/ou avaliador dependentes e a RNM é um exame de alto custo. Permanece incerto se um método é superior a outro e se o uso combinado de ambos melhora a acurácia diagnóstica, bem como se seus custos justificam sua utilização..

MATERIAL E MÉTODO: Estão descritos os procedimentos do estudo, não havendo contato com paciente.

TCLE: Não se aplica.

DETALHAMENTO FINANCEIRO: Sem financiamento externo - R\$ 2150,00.

CRONOGRAMA: 24 meses.

OBJETIVO ACADÊMICO: Pós-Doutorado.

ENTREGA DE RELATÓRIOS PARCIAIS AO CEP PREVISTOS PARA: 21/2/2011 e 21/2/2012.



O Comitê de Ética em Pesquisa da Universidade Federal de São Paulo/Hospital São Paulo **ANALISOU** e **APROVOU** o projeto de pesquisa referenciado.

- 1. Comunicar toda e qualquer alteração do projeto e termo de consentimento livre e esclarecido. Nestas circunstâncias a inclusão de pacientes deve ser temporariamente interrompida até a resposta do Comitê, após análise das mudanças propostas.
- 2. Comunicar imediatamente ao Comitê qualquer evento adverso ocorrido durante o desenvolvimento do estudo.
- 3. Os dados individuais de todas as etapas da pesquisa devem ser mantidos em local seguro por 5 anos para possível auditoria dos órgãos competentes.

Atenciosamente,

Prof. Dr. José Osmar Medina Pestana

Coordenador do Comitê de Ética em Pesquisa da Universidade Federal de São Paulo/ Hospital São Paulo

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