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Shoulder impingement syndrome: a systematic review of clinical trial participant selection criteria

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Abstract

Background: Shoulder impingement syndrome (SIS) is a common diagnosis for patients with pain and dysfunction of the shoulder. Variations in the signs and symptoms might lead to uncertainty regarding the definition of SIS. The aim of this review is to explore the participant selection criteria used in the literature when investigating SIS and to assess differences in criteria among treating professions.

Methods: This is a PRISMA systematic review of publications from 2009 to 2014 from MEDLINE, PubMed, The Cochrane Library, Embase, Scopus and CINAHL.

Results: Ninety-seven articles met inclusion criteria for this review. Twenty-five different surgical and nonsurgical treatments were investigated. Impingement-specific index tests were used in all studies. Exclusion index tests were used in 62% of studies. Twenty index tests were identified. Radiological investigations were reported in 53% of all studies, of which a further 53% reported using two or more radiological investigations.

Conclusions: This systematic review has illustrated that studies investigating SIS test for various signs and symptoms, which is in keeping with describing the condition as a 'syndrome'. However, there are inconsistencies in participant selection criteria between health disciplines, highlighting a need for harmonization of the selection criteria in the form of an international editorial consensus.

Keywords

assessment criteria, index tests, shoulder impingement syndrome, subacromial impingement

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Introduction

Shoulder impingement syndrome (SIS) is a common diagnosis for patients who present with pain and dysfunction of the shoulder. The aetiology of the condition is recognized as being multifactorial resulting from an interplay of intrinsic and extrinsic factors.[1,2] Since SIS is a clinical syndrome, the diagnosis is determined by a collection of signs and symptoms.[3,4] Variations in the signs and symptoms might lead to uncertainty regarding the definition of SIS. Many studies highlight the difficulty in differentiating impingement from other shoulder pathologies, where shoulder pain can be indicative of other conditions such as joint instability, cervical radiculopathy, calcific tendinitis, adhesive capsulitis, degenerative joint disease, acromioclavicular osteoarthrosis and nerve compression.[2,5–7] Consequently, the use of the term SIS as a diagnostic label has been the subject of debate, as it has been used for a spectrum of other shoulder and cervical conditions[5,6,8–11] Diagnosis of SIS often relies upon a combination of physical examinations and further

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radiological investigations. However, the literature contains no suitable definition for the diagnosis of SIS using ultrasound and magnetic resonance imaging where such investigations play only a supporting role in the exclusion of other conditions.[7,12–14] Multidisciplinary consensus on the clinical criteria used to define SIS is important to avoid inappropriate surgical or nonsurgical intervention and to facilitate the direct comparison of outcomes of various treatment options. If there is no consensus on the selection criteria of study participants between professions and levels of evidence, it is difficult to compare outcomes of various treatment options effectively. The aim of this review was to explore the participant selection criteria for studies investigating SIS and to assess differences in the selection criteria amongst treating professions.

Materials and Methods

This systematic review was conducted and reported according to the protocol outlined by Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA).[15] The protocol for this systematic review was registered on PROSPERO (CRD42014014740).

Search strategy for identification of studies for this review

In order to identify all studies pertaining to the treatment or identification of SIS, the following medical databases were searched: MEDLINE, PubMed, The Cochrane Library, Embase, Scopus and CINAHL, with papers limited to five years of publication from January 2009 to January 2014. The search strategy determined by the two reviewers (AW and BW) with the assistance of a senior medical librarian (RD, who structured the key words using Boolean language and conducted the final search.

Medical Subject Headings (MeSH) were used in combination with relevant keywords in order to retrieve all publications meeting the inclusion criteria. Papers not in the English language were excluded, as were abstracts from scientific meetings, unpublished reports and review articles. The search strategy included the MeSH term 'Shoulder Impingement Syndrome', as well as the terms 'shoulder*' OR 'subacromial' OR 'sub-acromial' AND 'imping*' OR 'burs*'. Where 'burs*' can represent 'bursitis', 'bursa' and 'bursae'.

Inclusion criteria

Studies. The literature search performed for this review was limited to published clinical studies. Studies included in the final sample were limited to articles detailing the clinical criteria used to classify SIS or the participant inclusion criteria for SIS. Studies were only included if they were reporting on investigations of patients selected using the specific diagnostic labels of SIS, subacromial impingement or subacromial bursitis. There were no restrictions on the kind of intervention or the population being studied. There was also no restriction placed on the Level of Evidence (LOE) of included studies. The classification system for LOE was that of the *Journal of Bone and Joint Surgery* (*JBJS*), adapted from the Centre for Evidence-Based Medicine, Oxford, UK.[16] Study designs included randomized controlled trials (RCT), prospective comparative studies, case–control studies, case series and retrospective studies.

Exclusion criteria. Studies assessing conditions other than SIS were excluded, such as investigations into the treatment of rotator cuff tears, adhesive capsulitis (frozen shoulder), shoulder tendinitis and other shoulder pathologies.

Outcome measures. The clinical criterion used in the literature to define SIS was retrieved from the 'materials and methods' section of studies. The studies used terms such as 'eligibility criteria', 'inclusion criteria for participation in the study', 'diagnostic methodology' or 'clinical criteria'. Studies reported on the minimum duration of symptoms for inclusion into the study, the inclusion and exclusion criteria based on medical history, the physical examinations performed, the number of positive physical examinations required for inclusion in the study and the radiological investigations used to supplement the diagnosis of SIS. Secondary information collected from the publications was: the type of specialist assessing the condition, LOE, patients' age range and the type of intervention.

Selection of studies. Studies were reviewed for eligibility based on the title and abstract and if this was insufficient the full manuscript was obtained. All identified studies were independently assessed by two reviewers (AW and BW). Disagreement was resolved by discussion with both reviewers and the senior orthopaedic consultant (JK) until consensus was reached.

Data collection. One reviewer (AW) extracted the outcomes of interest from all included studies. The second reviewer (BW) independently extracted the outcomes of interest from a random selection of twenty percent of included studies to examine the rate of agreement. Any discrepancies were cross-referenced with the original article and disagreements in the data were resolved by discussion.

Assessment of risk of bias in included studies. An assessment of bias was not undertaken as the treatment outcomes were not assessed in this review.

Quantitative method. Analyses were carried out using Stata, version 13.1 (StataCorp, College Station, TX, USA). In order to examine whether the use of index tests is associated with profession type, we examined the eight most commonly used tests [Neer sign, Hawkins–Kennedy, Painful arc, Jobe, Resisted tests, X-rays, ultrasound (USA) and magnetic resonance imaging (MRI)] against two professions: Physiotherapy and Orthopaedics. Comparisons were performed using a chi-squared test or Fisher's exact test, when the assumption for chi-squared test was not met. Studies involving both Physiotherapy and Orthopaedics were excluded from chi-squared analyses. The above eight tests were also examined against the level of evidence (excluding Level IV) for their associations using the chi-squared test. $P < 0.05$ was considered statistically significant.

Results

The search of MEDLINE, PubMed, the Cochrane Library, Embase, Scopus and CINAHL databases provided 3339 citations (Fig. 1). After adjusting for duplicates, 1411 citations remained, and after reviewing the abstracts, 1295 studies were excluded, not having met the inclusion criteria. The full text articles of the remaining 116 studies were examined for eligibility and 97 studies were identified for inclusion in the review.[7,13,17–111]

Characteristics of included studies

The studies selected in the review reported on 25 different interventions for SIS. When assessing the type of health profession conducting the study, the following breakdown was established; 62% Physiotherapy, 27% Orthopaedic surgery, 7% Rehabilitative medicine, 4% Rheumatology, and 1% from each of the following: Radiology, General Practice and Anaesthesiology.

Using the LOE hierarchy; there were 29 Level I evidence studies, 32 Level II, 23 Level III evidence and 11 Level IV evidence. There were no Level V studies. The sample size of the studies ranged from six to 307 patients, with a total of 5514 participants in the studies. The age of patients reported ranged from 14 years to 92 years. The mean minimum duration of pain for inclusion in the studies was 11.7 weeks with an

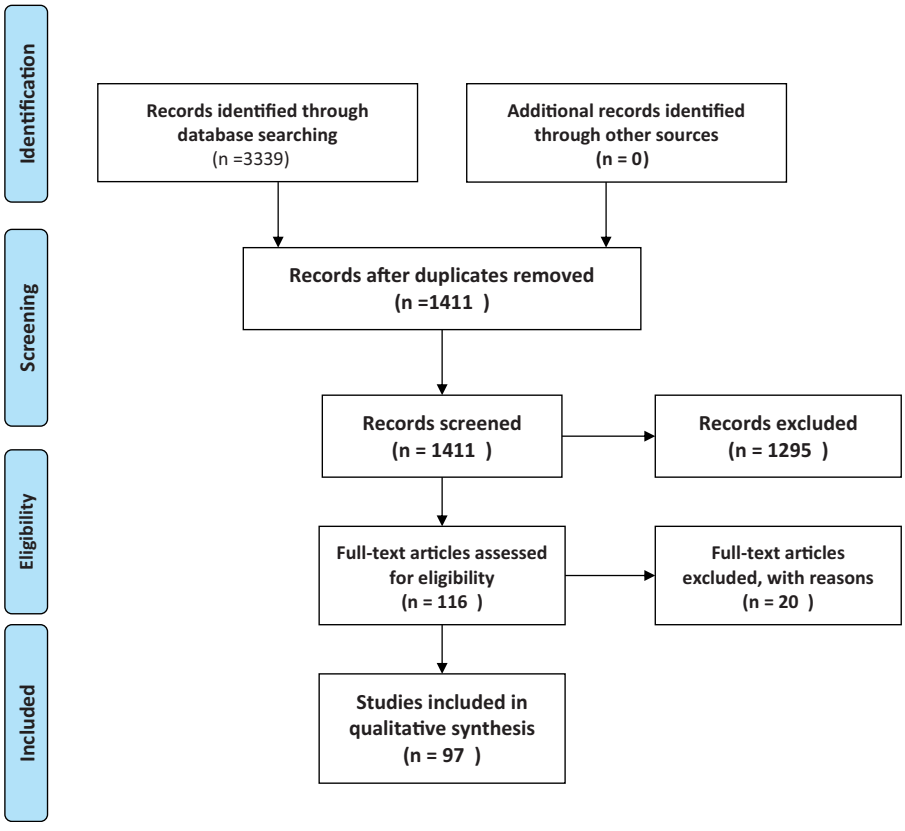

Figure 1. PRISMA flow diagram.

SD of 10.9 and ranged from 1 week to 72 weeks. Thirteen studies stated that patients required a mean minimum visual-analogue pain score of 3.4, with a SD of 0.8 to be included in the study.

Index tests

Physical examination index tests were stated in all but fourteen studies as part of the clinical inclusion criteria used to define SIS, where, in total, 20 different tests were identified in Table 1. Commonly, a combination of index tests were part of the clinical criteria used to define SIS. Of these, 82% used at least one of Neer sign or Hawkins–Kennedy test, 70% used Neer sign and Hawkins–Kennedy together, and 30% used the Neer sign, Hawkins–Kennedy and Painful arc combination. The positive Neer injection test, described as the injection of 10 mL of 1% lignocaine into subacromial space, relieving pain after 10 minutes, was reported in 15 of the studies as part of their criteria for inclusion. Three of the studies relied exclusively on this test to define SIS. Overall, there were 14 different combinations of the five impingement sign tests used in studies included in the present review.

Further index tests excluding other shoulder pathologies were frequently reported in the included literature, forming part of the clinical criteria used to define SIS. Such tests included, the Jobe (empty can) sign, Resisted tests, Apprehension/relocation test, Speed's test, Sulcus sign, Spurling sign, Gerber sign, Drop arm sign, Yergason's test, External rotation lag sign, Walsh test, Crossover test and O'Brien's test. In the included studies, it was found that 39% used the Jobe sign, 25% used Resisted tests, 17% used painful range of motion, and 10% used the Apprehension test. Speeds, Sulcus, Spurling and Drop arm sign were used equally in 4% of studies and the remaining tests were used only once. More commonly, a combination of exclusion index tests where part of the clinical criteria used to define SIS, 50% used at least one of either the Jobe sign or Resisted tests (68% of those used any exclusion tests), 59% used at least one of the Jobe sign or Resisted tests or Pain tange of motion (83% of those used any exclusion tests) and 38% used no exclusion index tests.

Often as part of the inclusion criteria, studies reported patients needed to test positive to a certain number of impingement sign examinations to be eligible for the study. Out of 41 studies that specified a set number of positive tests required for patient eligibility, 35 (85%) reported that they required two or more positive tests for inclusion into the study. Of these studies, a mean of five physical examinations were used in total (range 2 to 9). It was noted that 30 out of this 35 (85.7%), were studies carried out by Physiotherapists. Overall, there were 21 different combinations of the 11 exclusion tests used in the studies included in the present review.

Table 1. Reported use of index tests and radiological investigations.

Impingement specific index tests (%)	
Neer sign	76.3
Hawkins–Kennedy	76.3
Jobe (empty can)	39.2
Neer Injection test	15.5
Yocum	2.1
Painful arc	36.1
Exclusion index tests (%)	
Resisted tests	25.8
Pain range of motion	17.5
Apprehension test	10.3
Speed	8.2
Sulcus	4.1
Spurling	4.1
Gerber	4.1
Drop arm sign	4.1
Yergasons	2.1
External rotation lag sign	1
Crossover	1
Walsh	1
O'Brien	
Use of radiological investigations (%)	
Total	61
X-rays	53
Ultrasound	51
Magnetic resonance imaging	49
Computed tomography scan	3
Magnetic resonance arthography	1

Radiological investigations

Radiological investigations were reported as part of the criteria to aid in identification of SIS in 59 (61%) of the studies. Of those studies, 27 (46%) used more than one investigation. Table 1 shows the studies that reported use of radiological investigations. Further analysis found that 13 (22%) used US only, nine (15%) used MRI only and nine (15%) used X-rays only.

Of the studies using radiological investigations, 14% used X-rays and MRI together and 12% used X-rays and US together. In total, 39% did not include radiological investigations in their diagnostic assessment for SIS. Overall, there were 11 different combinations of the five imaging modalities used in studies included in this review.

Use of index tests and treating professions

The two most common treating professions were Physiotherapy and Orthopaedics; 53 and 19 studies were identified, respectively. The incidence of the different clinical tests used by physiotherapists and orthopaedic surgeons is presented in Table 2. Physiotherapists were significantly more likely to use Neer sign, Hawkins–Kennedy sign, Painful arc and Jobe sign ($p = 0.009$, 0.004, 0.032 and 0.005, respectively), whereas Orthopaedic surgeons were more likely to use X-rays ($p < 0.001$) and MRIs ($p < 0.001$) as part of their diagnostic assessment. US imaging was reported broadly across both professions.

Use of tests and LOE

There were eighty-four studies that had a LOE of III or higher. There was no significant association between the use of tests and level of evidence except for the X-rays, which was more likely to be used with studies with higher level of evidence ($p = 0.024$) (Table 3).

Table 2. Use of index tests and treating professions.

Factor	Physiotherapy	Orthopaedics	*p*-value
n	53	19	
Neer sign	44 (83%)	10 (53%)	0.009
Hawkins–Kennedy	45 (85%)	10 (53%)	0.004
Painful arc	23 (43%)	3 (16%)	0.032
Jobe (empty can)	28 (53%)	3 (16%)	0.005
Resisted tests	17 (32%)	2 (11%)	0.067
X-rays	9 (17%)	13 (68%)	<0.001
Ultrasound	14 (26%)	7 (37%)	0.39
Magnetic resonance imaging	7 (13%)	12 (63%)	<0.001

Table 3. Index tests and level of evidence.

Levels of evidence	I	II	III	*p*-value
n	29	32	23	
Neer sign	21 (72%)	26 (81%)	16 (70%)	0.57
Hawkins–Kennedy	22 (76%)	25 (78%)	16 (70%)	0.76
Painful arc	12 (41%)	10 (31%)	7 (30%)	0.63
Jobe (empty can)	8 (28%)	16 (50%)	7 (30%)	0.15
Resisted tests	10 (34%)	8 (25%)	3 (13%)	0.21
X-rays	15 (52%)	9 (28%)	4 (17%)	0.024
US	8 (28%)	11 (34%)	7 (30%)	0.85
Magnetic resonance imaging	8(28%)	12 (38%)	5 (22%)	0.43

Discussion

The aim of this review was to assess the participant selection criteria when investigating SIS in the literature and to assess variations in methodology amongst treating professions. The descriptive analyses presented herein demonstrate the diverse combination of index examinations and radiological investigations used in current practice. The Neer impingement sign and Hawkins–Kennedy test are the most commonly used physical examinations employed by all professions investigating SIS and across all LOE. However, there is a wide range in the number and choice of tests used in combination with these two tests. In studies where physiotherapy was the nominated profession, there was a reliance on the use of an index test for a diagnosis. On the other hand, a significant reliance on the use of radiological investigations was demonstrated in orthopaedic lead studies. Although this may simply be a reflection of what occurs in standard practice where orthopaedic surgeons have access to imaging and physiotherapists do not, it is encouraging to see an importance placed on the two diagnostic methods in both professions. Physiotherapy and Orthopaedic studies illustrated a wide range in the total number of index tests used; (0 to 9) and (0 to 8) respectively. Thus the use of such a range demonstrates the diversity of signs and symptoms being tested for in the participant

selection criteria for SIS within the professions themselves. These findings demonstrate a strong emphasis on use of a cluster of positive impingement sign tests as well as additional tests to exclude other shoulder pathologies. Although this is consistent with the nature of SIS as a syndrome, there appears to be poor consensus on the combination of tests required to define and ultimately diagnose shoulder impingement.

The use of numerous index tests and radiological investigations may be an indication of the widespread uncertainties in understanding the aetiology of SIS and difficulties in distinguishing SIS from other shoulder pathologies. Level I and II evidence is purportedly a good indicator for common standard of practice, where a 'gold standard' practice may be identified. However, as the Levels of evidence I and II made up 30% and 33% of the included studies, respectively, there does not appear to be a 'gold standard' for the classification of SIS.

In a Cochrane review of RCTs, Hanchard et al.[112] investigated the accuracy of physical tests for SIS and other shoulder pathologies. When a combination of seven positive tests was used, the sensitivity estimate was 5% [95% confidence interval (CI) 1% to 11%] and specificity estimate was 97% (95% CI 86% to 100%). When only a combination of a positive Hawkins' test or Neer's sign was used, the sensitivity estimates increased markedly to 96% (95% CI 79% to 100%) and specificity estimates fell to 41% (95% CI 29% to 54%).[112] Although the combination of the two most commonly used index tests was found to be highly sensitive in detecting impingement sign, a large number of false positives were observed. Hanchard et al.[112] concluded that there are no strong index tests for diagnosing impingement and that greater emphasis should be placed on making a diagnosis based on the exclusion of other shoulder pathologies.

Our review highlighted that there is no preferred current imaging modalities. Furthermore, half used two or more radiological investigations in their diagnostic methodology. Lee et al.[67] discussed that US and MRI often fail to provide useful information for assessing the patients and that these investigations should not be used as diagnostic instruments to identify shoulder lesions. This recommendation was based on findings that radiologic analyses were frequently incompatible with the clinical manifestation.[67]

The literature often reports that X-ray and US imaging are used to confirm a diagnosis of SIS; however, it would be more accurate to state that their primary use is to confirm the exclusion of other pathologies. Neer's original work in 1972 reported using arthrograms to determine rotator cuff integrity, on the grounds that abnormalities such as chronic bursitis, partial-thickness tears, calcium deposits and complete tears could not be distinguished by physical examinations and radiographic findings alone.[113] Although only one study in this systematic review used a magnetic resonance arthrography (MRA) in their method of diagnosis, there is increasing evidence to support the use of MRA when considering surgical treatment.[114]. Pavic et al.,[114] in a study of 200 consecutive patients, compared the accuracy of US, MRI and MRA, where all patients underwent an arthroscopy to confirm diagnosis of shoulder pathology. Interestingly, US was found to be a valuable diagnostic tool in several studies for rotator cuff complete or incomplete tears, MRI was indicated to be accurate in determining Hills–Sach lesions or bony lesions, and MRA was found to be superior in accurately diagnosing labral capsular ligamentous complex lesions such as internal subacromial impingement.[7,114]

This research can be used as an aid for the development of diagnostic and treatment protocols. It highlights the most current methods used to diagnose SIS and can help clinicians reflect on what truly defines a case of impingement syndrome. If SIS is suspected in a patient Neer impingement sign and Hawkins–Kennedy should be tested as they are the only impingement specific and widely validated index tests. Further use of the index tests found in this study are important as they provide the examiner with an overall indication of the integrity and kinematics of a problem shoulder joint. Ultimately, understanding the pathology and awareness of diagnostic tools available may help clinicians distinguish between a need for conservative or surgical treatment of the condition.

Largely, the studies included in this review were testing for a wide range of signs and symptoms, in keeping with the description of the condition as a 'syndrome'.

Strengths and limitations

To our knowledge, this is the first systematic review to assess the participant selection criteria used in studies investigating SIS. This study also assessed the correlation between level of evidence and diagnostic criteria. By PRISMA guidelines, registering the review with PROSPERO and using the *JBJS* evidence hierarchy, this study used a transparent method of assessing and reporting the evidence.

In our search strategy, we did not include grey literature. Incomplete reporting of inclusion criteria and diagnostic methodology in the included studies is also a limitation. It is important to highlight that there may be variances in practices of some countries where the role of the physiotherapist and the orthopaedic specialist will differ.

Conclusions

This review provides insight into the extensive research undertaken in the last 5 years for the treatment and management of Shoulder impingement syndrome. It highlights inconsistencies in selection criteria currently used within and between health disciplines when reporting on their investigations of this syndrome. The use of a wide range of diagnostic index tests and multiple radiological investigations illustrates the complex nature of a condition such as SIS where the pathogenesis remains unclear.

There is little uniformity in the signs and symptoms being tested for, which is reflected in the variety combinations of physical examinations and radiological investigations reported in the 97 papers included in this review. Future research studies investigating SIS should at a minimum use a positive Neer sign and Hawkins–Kennedy test to define the cohort of study patients. Highlighting the poor uniformity is important as current management of SIS is based on evidence derived from clinical trials. If there is no consensus on the selection criteria of study participants between professions and levels of evidence, it is difficult to compare outcomes of various treatment options effectively.

There needs to be harmonization of the selection criteria in the form of an international editorial consensus and more research into the patho-aetiology of SIS. Clarity is pertinent to ensure practitioners and researchers across all disciplines are treating and investigating the same pathology in their quest to establish evidence-based and effective practice. It is possible that the development of a more detailed understanding of, and agreement on, the signs and symptoms of SIS would contribute to our improved understanding of the common pathology.

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Level of evidence

Level IV

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