Shoulder & Elbow

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Choosing patient-reported outcome measures for shoulder pathology

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- This study was designed to identify the most frequent shoulder patient-reported outcome measures (PROMs) reported in high-quality literature.
- A systematic review was performed to identify shoulder PROMs, and their diffusion within the scientific literature was tested with a subsequent dedicated search in MEDLINE.
- 506 studies were included in the final data analysis, for a total number of 36,553 patients.
- The Disabilities of the Arm, Shoulder and Hand questionnaire (DASH), the American Shoulder, Elbow Surgeons Score (ASES) and the Shoulder Pain and Disability Index (SPADI) were the most frequently reported PROMs in the analysed publications, with disease-specific PROMs being used with increasing frequency.
- A core set of outcome measures for future studies on patients with shoulder pathologies, based on the international acceptance and diffusion of each PROM, is needed.
- A combination of the DASH score for shoulder outcome assessment with more specific PROMs, such as the ASES for rotator cuff pathology and osteoarthritis and the SPADI for shoulder stiffness and shoulder pain of unspecified origin, is proposed as a recommended set of PROMs.

Keywords: outcome measures; patient-reported; shoulder

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Introduction

Every year, an increasing number of articles are added to medical literature: restricting a MEDLINE search for the term 'shoulder' to the years 2000 to 2009 produces 18,685 results; a number which almost doubles to 37,015 when restricting the search to the following decade. Drawing out relevant information from all this material is challenging, especially if data are described with different outcome measures.

The development of objective, clinician-based outcomes was the first strategy to enable worldwide comparison of different studies. Since the last decade of the 20th century, in addition to objective measures, the development of validated patient-oriented measures has revolutionized orthopaedic research, adding a new dimension to clinical outcome evaluation. The development of patient-reported outcome measures (PROMs) permitted physicians to register patients' subjective perspectives and measure their functional status through validated instruments.[1] The creation of a new PROM is a complex, stepwise process: all items considered in PROMs should be subjectively evaluated by patients;[2,3] furthermore, to reduce variability and standardize the results, each new PROM must be validated through an extensive process which includes tests for reliability, sensitivity, and responsiveness.[4,5] Those PROMs which pass such rigorous tests work as well as or better than clinician-based objective scoring systems.[6] A useful PROMs should be rigorously developed, commonly used, have large diffusion in the international scientific world and be validated in many languages through an appropriate and rigorous process of translation and cross-cultural adaptation. For shoulder assessment and research purposes, many PROMs are reported in the literature, but few are sufficiently widespread to be considered a standard for outcome assessment of shoulder diseases.[7]

The primary goal of this systematic literature review was to identify the most frequently used shoulder PROMs in order to provide recommendations for researchers, enabling them to choose the most suitable measures for outcome assessment depending on research purpose. Recommendations should be based on the characteristics of a valid PROM: (i) large diffusion in international scientific world, (ii) statistical validity (evidenced by publication in peer-reviewed journals) and (iii) presence of a multi-language validation. The PROMs with the best profile in term of the aforementioned characteristics will be

designated as the 'recommended' instrument for studies on shoulder conditions and proposed as the 'best research tool' to increase homogeneity across studies and increase relevance of aggregated results from both a scientific and practical point of view.

Materials and methods

Phase 1 (PROMs identification)

Search strategy

MEDLINE (1981–2019) and Google Scholar databases were explored to identify upper-limb and shoulder PROMs. The following keywords were used to identify eligible studies: shoulder, upper-extremity, disability, functional status, questionnaire, self-report, self-assessment, outcome measure, outcome assessment (MESH term or text word). The references of relevant review papers were also cross-referenced.

Inclusion criteria

Studies were considered eligible if the main focus of the study was the development and/or the clinometric evaluation of a shoulder disability questionnaire or a questionnaire to collect outcomes after shoulder injuries and/or their treatment. A list of all the identified instruments was created.

Phase 2 (PROMs diffusion study):

Search strategy

A systematic literature review following the PRISMA recommendations was performed by four reviewers to evaluate the diffusion of the selected PROMs. The PROMs identified in Phase 1 were used as single search term to perform a literature search in MEDLINE (1966–2019) restricted to clinical trials using the appropriate PubMed research filters.

Inclusion criteria

Only PubMed-identified clinical trials investigating diagnostic strategies or treatments (conservative and surgical) of pathologies around the shoulder were included, provided that they reported an outcome assessment with at least one of the PROMs retrieved during the identification phase. Technical notes, systematic reviews and meta-analyses were excluded from the analysis. Likewise, studies investigating pathologies of the elbow, wrist or hand, clavicle and acromioclavicular joint were excluded from the analysis.

Data analysis

The full texts of the included papers were analysed by four reviewers. A Level of Evidence was assigned to each study according to the classification proposed by Marx et al.[8] Studies were then grouped into one of the eight subgroups listed in Table 1, based on the target pathology. Finally, data regarding the PROMs used and the number of included patients in each study were extracted and entered into a spreadsheet for analysis.

Table 1. Definition of the subgroups used to classify shoulder pathologies

Shoulder pathologies
Rotator cuff and subacromial pathology, excluding calcific tendinitis
Proximal humerus fractures
Shoulder instability
Glenohumeral arthritis
Shoulder stiffness (including adhesive capsulitis, frozen shoulder)
Calcific tendinitis of the rotator cuff
Shoulder pain of unspecified origin
Other conditions of the shoulder (including infection and neoplasia)

Statistical analysis

Statistical analysis was performed using Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) and GraphPad Prism v 6.0 software (GraphPad Software Inc., La Jolla, CA, USA). Diffusion of a PROM was calculated in terms of number of published papers and volume of evaluated patients. To avoid excessive dispersion of the results, only PROMs appearing at least five times were considered for further analysis. Dichotomous variables were expressed in numbers of cases and frequencies.

Results

Phase 1 (PROM identification phase) allowed us to retrieve 19 different PROMs. Name, acronym, and reference publication for each PROM are listed in Table 2.

In Phase 2 (PROM diffusion phase), the initial research identified a total of 853 clinical trials. Only 12 PROMs were reported in five or more studies (Table 2); therefore, the remaining seven were not included in further analyses. After removal of studies not matching the inclusion criteria, 506 studies were included in the final data analysis (of which 364 were classified as Level I trials), for a total number of 36,553 patients. Table 3 summarizes the characteristics of the included studies, grouped by pathology category. Rotator cuff and subacromial pathologies were the most frequently investigated topics, covering approximately the half of the total number of included patients.

The Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) and the American Shoulder and Elbow Surgeons Score (ASES) scores were the most frequently used PROMs (135 studies [26.7%] and 106 studies [20.9%] respectively). The Shoulder Pain and Disability Index (SPADI) was also reported in more than 15% of the analysed publications (Fig. 1).

Table 2. Shoulder PROMs (patient-reported outcome measures) identified in Phase 1 (PROM identification phase) and, marked with a tic (✓), those appearing at least in two publications, which were included in Phase 2

PROM name	Acronym	Reference number	Phase 2
American Shoulder and Elbow Surgeons Score	ASES	9	✓
Athletic Shoulder Outcome Scoring System	ASOSS	10	
Disabilities of the Arm, Shoulder and Hand questionnaire	DASH	11	✓
Kerlan-Jobe Orthopaedic Clinic Shoulder and Elbow Score	KJOC	12	
L'Insalata Shoulder Rating Questionnaire	–	13	
Melbourne Instability Shoulder Score	MISS	14	
Oxford Shoulder Instability Score	OSIS	15	
Oxford Shoulder Score	OSS	16	✓
Penn Shoulder Score	PENN	17	✓
Rotator Cuff Quality of Life	RC-QOL	18	
Rowe score	–	19	✓
Shoulder Disability Questionnaire	SDQ	20	✓
Shoulder Pain and Disability Index	SPADI	21	✓
Simple Shoulder Test	SST	22	✓
Upper Limb Functional Index Shoulder	ULFI	23	
Walch-Duplay Score	–	24	
Western Ontario Osteoarthritis of the Shoulder	WOOS	25	✓
Western Ontario Rotator Cuff Index	WORC	26	✓
Western Ontario Shoulder Instability Index	WOSI	27	✓

Table 3. Overall characteristics of the studies included in the analysis grouped by pathology category

Pathology category	*N* of articles	% of *N* of articles	*N* of patients	% of *N* of patients
Rotator cuff and subacromial pathology	234	46.2%	18623	50.9%
Proximal humerus fractures	66	13.0%	4572	12.5%
Shoulder instability	60	11.9%	3193	8.7%
Glenohumeral arthritis	20	4.0%	1137	3.1%
Shoulder stiffness	73	14.4%	4696	12.8%
Calcific tendinitis of the rotator cuff	10	2.0%	543	1.5%
Shoulder pain of unspecified origin	40	7.9%	3732	10.2%
Other conditions	3	0.6%	57	0.3%
Overall	**506**	**100%**	**36553**	**100%**

For rotator cuff and subacromial pathologies (Level I studies: 77.8%), ASES was the most frequently used PROM (26%). DASH and SPADI were used in a similar number of papers, with a frequency of 21%. With the exception of the Simple Shoulder Test (SST), Oxford Shoulder Score (OSS) and Western Ontario Rotator Cuff Index (WORC), all the other scores were scarcely or not used at all (Fig. 2).

For proximal humerus fractures (Level I studies: 51.5%), DASH was the most frequently used score (38%), followed by ASES (30%) and SST (17%) (Fig. 3).

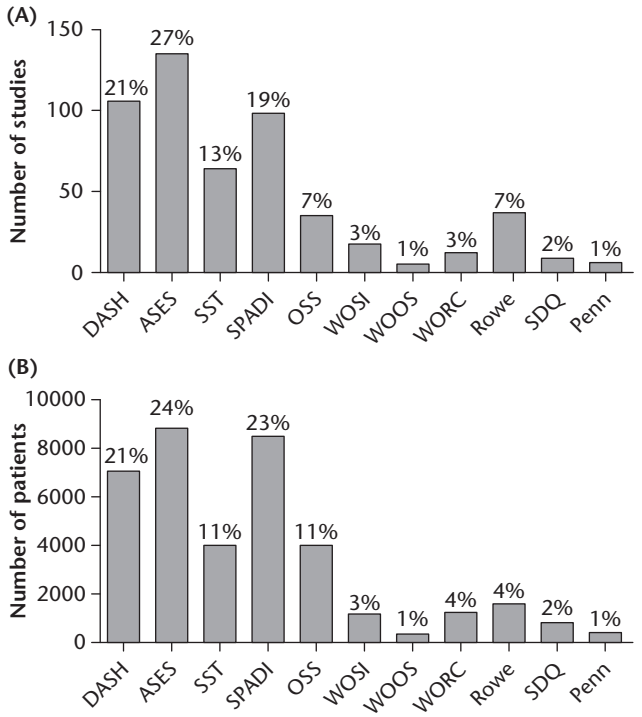

Fig. 1 (A) Frequency distribution of the investigated patient-reported outcome measures (PROMs) among the studies considered. (B) Number of patients analysed with the selected PROMs throughout the studies considered. Since more than one PROM can be used in each study, the sum of all percentages is not necessarily 100%.

Note. DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; ASES, American Shoulder and Elbow Surgeons Score; SST, Simple Shoulder Test; SPADI, Shoulder Pain and Disability Index; OSS, Oxford Shoulder Score; WOSI, Western Ontario Shoulder Instability Index; WOOS, Western Ontario Osteoarthritis of the Shoulder; WORC, Western Ontario Rotator Cuff Index; SDQ, Shoulder Disability Questionnaire.

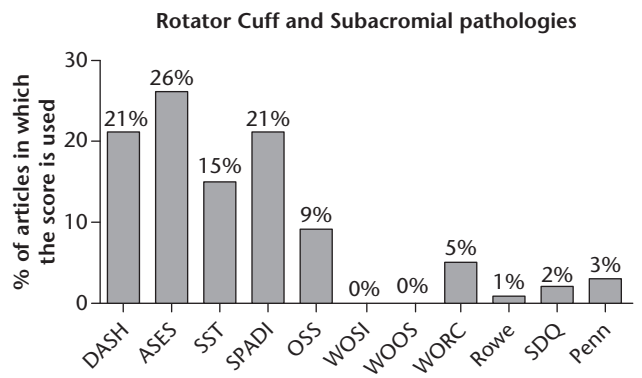

Fig. 2 Frequency of the selected patient-reported outcome measures (PROMs) in the studies about rotator cuff and subacromial pathologies. Since more than one PROM can be used in each study, the sum of all percentages is not necessarily 100%.

Note. DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; ASES, American Shoulder and Elbow Surgeons Score; SST, Simple Shoulder Test; SPADI, Shoulder Pain and Disability Index; OSS, Oxford Shoulder Score; WOSI, Western Ontario Shoulder Instability Index; WOOS, Western Ontario Osteoarthritis of the Shoulder; WORC, Western Ontario Rotator Cuff Index; SDQ, Shoulder Disability Questionnaire.

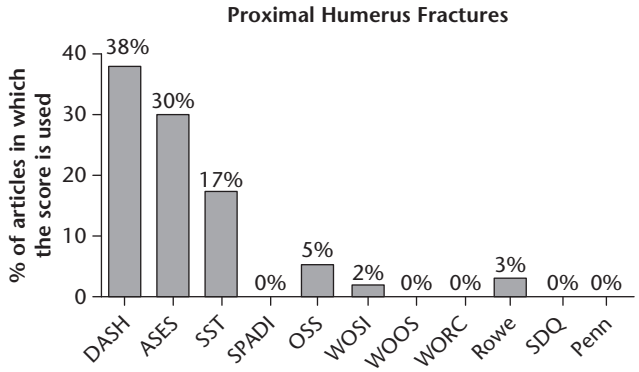

Fig. 3 Frequency of the selected patient-reported outcome measures (PROMs) in the studies about proximal humerus fractures. Since more than one PROM can be used in each study, the sum of all percentages is not necessarily 100%.

Note. DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; ASES, American Shoulder and Elbow Surgeons Score; SST, Simple Shoulder Test; SPADI, Shoulder Pain and Disability Index; OSS, Oxford Shoulder Score; WOSI, Western Ontario Shoulder Instability Index; WOOS, Western Ontario Osteoarthritis of the Shoulder; WORC, Western Ontario Rotator Cuff Index; SDQ, Shoulder Disability Questionnaire.

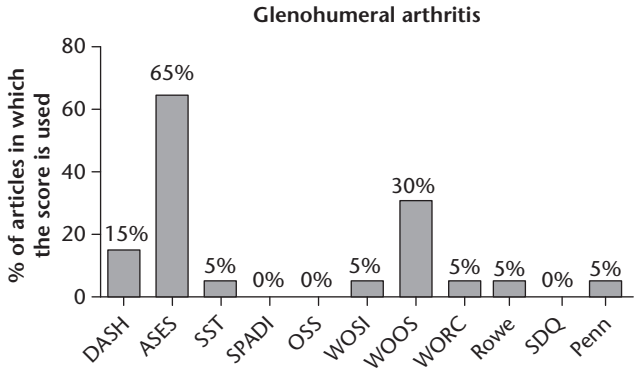

Fig. 5 Frequency of the selected patient-reported outcome measures (PROMs) in the studies about glenohumeral osteoarthritis. Since more than one PROM can be used in each study, the sum of all percentages is not necessarily 100%.

Note. DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; ASES, American Shoulder and Elbow Surgeons Score; SST, Simple Shoulder Test; SPADI, Shoulder Pain and Disability Index; OSS, Oxford Shoulder Score; WOSI, Western Ontario Shoulder Instability Index; WOOS, Western Ontario Osteoarthritis of the Shoulder; WORC, Western Ontario Rotator Cuff Index; SDQ, Shoulder Disability Questionnaire.

For shoulder instability (Level I studies: 48.3%), the Rowe score was used in more than half of all the studies (51%), followed by ASES (40%) and Western Ontario Shoulder Instability Index (WOSI, 19%). All the other PROMs were scarcely used (Fig. 4).

In the evaluation of glenohumeral osteoarthritis (Level I studies: 75.0%), ASES score was found in almost 2/3 of the studies (65%), followed by Western Ontario Osteoarthritis of the Shoulder (WOOS, 30%) and DASH (15%) (Fig. 5).

In the evaluation of the treatment of shoulder stiffness (Level I studies: 82.2%, Fig. 6), calcific tendinitis of the rotator cuff (Level I studies: 80.0%, Fig. 7) and shoulder pain of unspecified origin (Level I studies: 90.0%, Fig. 8), SPADI always prevailed over the other available PROMs, followed by ASES, DASH and SST.

The few studies investigating other conditions of the shoulder, such as infection and neoplasia, showed a homogenous distribution of DASH and ASES.

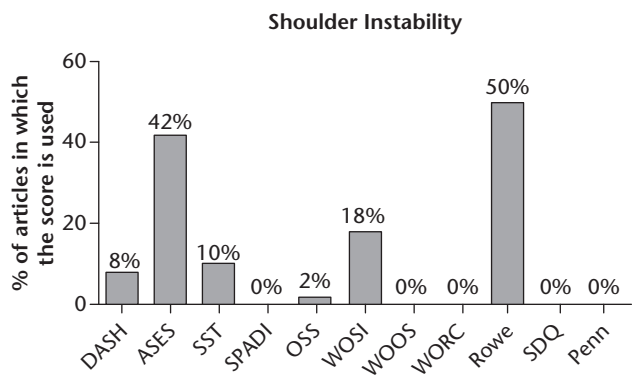

Fig. 4 Frequency of the selected patient-reported outcome measures (PROMs) in the studies about rotator shoulder instability. Since more than one PROM can be used in each study, the sum of all percentages is not necessarily 100%.

Note. DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; ASES, American Shoulder and Elbow Surgeons Score; SST, Simple Shoulder Test; SPADI, Shoulder Pain and Disability Index; OSS, Oxford Shoulder Score; WOSI, Western Ontario Shoulder Instability Index; WOOS, Western Ontario Osteoarthritis of the Shoulder; WORC, Western Ontario Rotator Cuff Index; SDQ, Shoulder Disability Questionnaire.

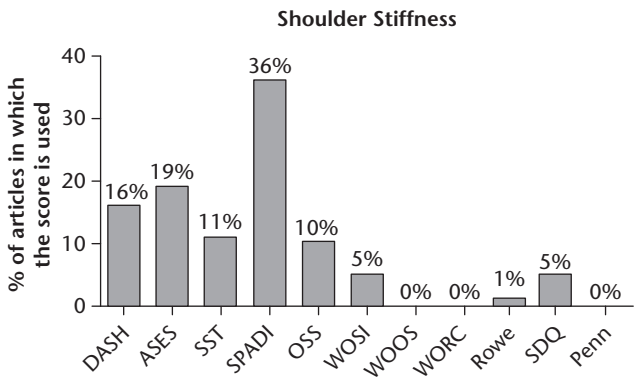

Fig. 6 Frequency of the selected patient-reported outcome measures (PROMs) in the studies about shoulder stiffness. Since more than one PROM can be used in each study, the sum of all percentages is not necessarily 100%.

Note. DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; ASES, American Shoulder and Elbow Surgeons Score; SST, Simple Shoulder Test; SPADI, Shoulder Pain and Disability Index; OSS, Oxford Shoulder Score; WOSI, Western Ontario Shoulder Instability Index; WOOS, Western Ontario Osteoarthritis of the Shoulder; WORC, Western Ontario Rotator Cuff Index; SDQ, Shoulder Disability Questionnaire.

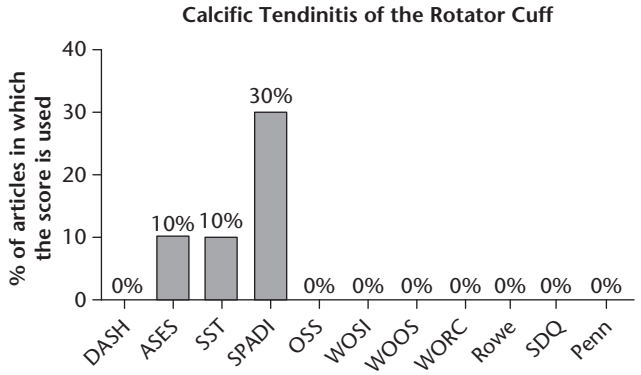

Fig. 7 Frequency of the selected patient-reported outcome measures (PROMs) in the studies about calcific tendinitis of the rotator cuff. Since more than one PROM can be used in each study, the sum of all percentages is not necessarily 100%.

Note. DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; ASES, American Shoulder and Elbow Surgeons Score; SST, Simple Shoulder Test; SPADI, Shoulder Pain and Disability Index; OSS, Oxford Shoulder Score; WOSI, Western Ontario Shoulder Instability Index; WOOS, Western Ontario Osteoarthritis of the Shoulder; WORC, Western Ontario Rotator Cuff Index; SDQ, Shoulder Disability Questionnaire.

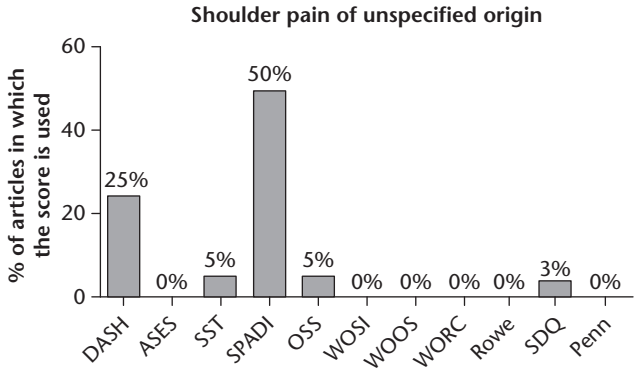

Fig. 8 Frequency of the selected patient-reported outcome measures (PROMs) in the studies about shoulder pain of unspecified origin. Since more than one PROM can be used in each study, the sum of all percentages is not necessarily 100%.

Note. DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; ASES, American Shoulder and Elbow Surgeons Score; SST, Simple Shoulder Test; SPADI, Shoulder Pain and Disability Index; OSS, Oxford Shoulder Score; WOSI, Western Ontario Shoulder Instability Index; WOOS, Western Ontario Osteoarthritis of the Shoulder; WORC, Western Ontario Rotator Cuff Index; SDQ, Shoulder Disability Questionnaire.

Fig. 9 summarizes the results of the PROMs diffusion study, grouping results for the pathology categories reported in Table 1.

Discussion

This review identified the most frequently used PROMs for each specific shoulder condition and described their

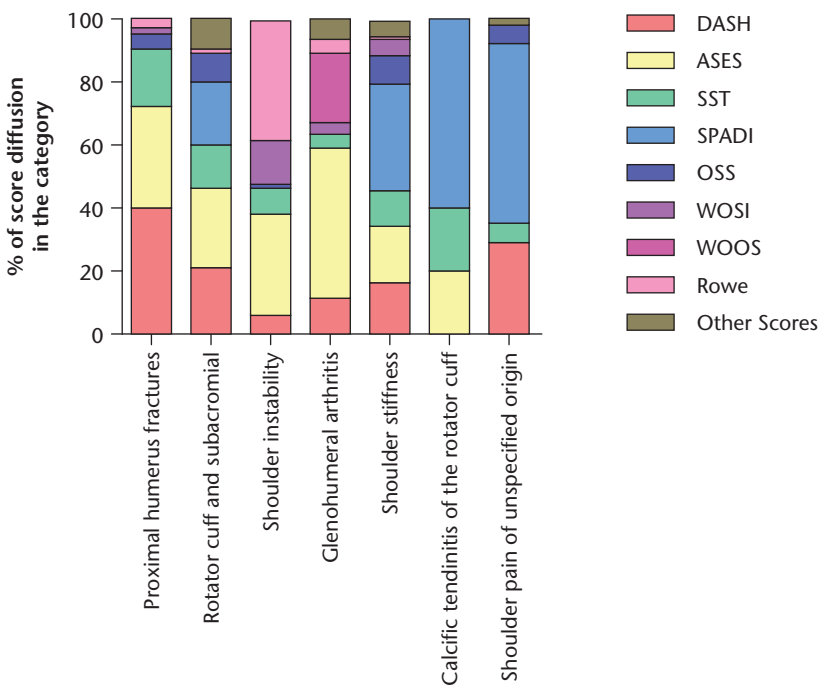

Fig. 9 Percentage of patient-reported outcome measure diffusion within each pathology category.

Note. DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; ASES, American Shoulder and Elbow Surgeons Score; SST, Simple Shoulder Test; SPADI, Shoulder Pain and Disability Index; OSS, Oxford Shoulder Score; WOSI, Western Ontario Shoulder Instability Index; WOOS, Western Ontario Osteoarthritis of the Shoulder.

distribution within a selected subset of high-quality literature. The main finding of this study is the lack of homogeneity in the PROMs used to investigate shoulder-related pathologies. ASES, DASH and SPADI were the most frequently reported PROMs. Disease-specific scores were found to be used in defined pathology subgroups, such as the Rowe score for shoulder instability, the WOOS in glenohumeral osteoarthritis and the SPADI for shoulder stiffness. A relevant clinical consequence of these findings is the possibility to suggest a core set of outcome measures for future studies on patients with shoulder pathologies, based on the international acceptance and diffusion of each PROM.

A consensus on a set of recommended PROMs to use for each specific shoulder condition could improve the quality of literature and the appropriateness of study comparison, allowing clinicians to deduce relevant information from both a scientific and practical point of view. Moreover, since PROMs are chosen as primary outcomes and used to calculate the adequate sample size of the study in many randomized controlled trials, the choice of the most appropriate PROM is crucial in planning high-quality research to guarantee meaningful results.

Since the 1990s, the role of PROMs has been widely accepted.[2,28–30] As a consequence, in the field of shoulder pathologies there has been an impressive flourishing of different instruments to measure outcomes. This review confirmed the presence of papers evaluating the same shoulder condition and addressing the same clinical outcomes but using different outcome measures. This redundancy contributes to the generation of a large number of apparently similar papers, but which are not in fact comparable with each other and therefore hardly useful for secondary literature. Some studies have shown that this selectivity in reporting data using different outcome measures is usually due to the desire to present the most positive or statistically significant results.[31] Such choice may affect the perception of the reader of the clinical trial report, who might be oriented towards a wrong clinical decision on being presented with optimistic but inappropriate data regarding the effect of an intervention. A way to reduce this inconsistency and to increase the power of comparison would be to agree on the most suitable PROM set for assessing each given shoulder condition. First, a correct choice of the most suitable outcome measure with respect to the clinical question should rely on conceptual considerations, such as defining the construct and the target population, but also on practical aspects, including burden for patients and raters. Moreover, quality aspects should be assessed against nine different measurement properties clustered in the domains reliability, validity and responsiveness.[29] The ideal PROM must be statistically validated, have a large diffusion in the literature (in terms of both papers and patients) and be translated and validated in as many equivalent languages as possible. Validation in other languages is a relevant issue, especially for secondary literature. Authors should in fact pay attention to whether the study they include in a systematic review or meta-analysis used PROMs that were validated in the reference population of patients. In studies where this was not the case, the findings of that study should not be included, as the results obtained after administration of an inappropriate translation cannot be considered reliable.

Currently, DASH is the questionnaire for which an official translation and cross-cultural adaptation exists in the largest number of languages.[32–46] Moreover, DASH is valid, reliable and responsive and normative data for this scale have been established.[47] Similarly to DASH, all the other frequently used PROMs have numerous validated version in different languages: the validity, reliability, and responsiveness of ASES have been assessed in a variety of shoulder problems as well and its psychometric properties being well established.[47] The SPADI Shoulder Score is a reliable and valid tool, also having been shown to be responsive to change over time in a variety of patient populations.[48,49] WOSI is a valid, reliable and sensitive assessment for patients with shoulder problems that are associated with instability.[50,51]

Standardization in outcomes and outcome measures in research is highly warranted. This improves consistencies in reporting and decreases difficulties in comparing the findings in systematic reviews and meta-analyses. Mosher and colleagues[1] recently claimed for the need to determine the optimal PROMs for outcome detection. One of the aims of our review was to provide this information basing on the current literature findings. The conclusion of Mosher and colleagues is that the best PROMs setting should be a combination of existing questionnaires. Coherently, we believe that the outcomes of different diseases and treatments should be studied through different PROMs, through an appropriate combination of PROMs. Additionally, as symptoms are often disease-specific, different instruments must be used to achieve the proper sensibility. Questionnaires can consider a whole anatomical area (i.e. upper limb or shoulder) or refer to a specific disease (i.e. shoulder instability or rotator cuff impairment). The more specific they are, the higher is the sensibility. For example, the DASH score includes a wide range of questions that allow for a comprehensive evaluation of the general status of the whole upper limb. As a drawback, discrimination between specific symptoms related to a given condition is, with such a score assessing outcomes for a whole anatomical district, difficult. Conversely, a disease-specific questionnaire has good sensibility in measuring differences between subjects affected by the same condition, but it neglects more general information about other possible shoulder parameters. For these

reasons, a combination of two questionnaires (an anatomical district score and a disease-specific score) could be the best solution for a thorough outcome evaluation. Based on the existing literature, possible combinations of scores to evaluate the different shoulder conditions are provided (Table 4). The authors recommend combining the DASH score for shoulder outcome assessment with more specific PROMs, such as the Rowe score for shoulder instability, ASES for rotator cuff pathology and osteoarthritis, SPADI for shoulder stiffness and shoulder pain of unspecified origin. A disease-specific PROM for proximal humeral fractures could not be identified in this review. This is due to the fact that the peculiar characteristics of trauma surgery make it difficult if not impossible to collect pre-injury scores; therefore, trauma surgeons have relied until now on scores developed and validated on other shoulder pathologies, such as DASH, ASES and SPADI. Regarding calcific tendinitis of the rotator cuff, evidence obtained in this review is too limited to suggest a particular district-specific score.

Assessment of shoulder instability presents a particular feature which distinguishes it from the other investigated pathology categories. In recent years, the use of the very simple and universally accepted Rowe score has decreased, permitting diffusion of more articulated PROMs such as the WOSI score.[1] This suggests that in the near future more modern questionnaires such as WOSI could overtake the Rowe score; therefore, using both WOSI and Rowe for a few years could guarantee an efficient comparison of the new studies with the older ones.

Limitations of this study include the restriction of the research to clinical trials using the appropriate PubMed research filter. This excludes lower-level publications, which nevertheless could pave the way for relevant research in the upcoming years. Furthermore, not all included PROMs were developed with appropriately rigorous methodology and not all published translations underwent an appropriate validation and cross-cultural adaptation process; this means care should be taken when choosing a PROM, since wide diffusion is not the sole criterion to define validity of an instrument. Finally, the extremely widespread Constant–Murley Score[52] and the also frequently used University of California Los Angeles – Shoulder Activity Scale (UCLA) were excluded from this review, since they are not PROMs but clinician-reported outcome measures. In facts, they both include the measurement of strength, which must be performed by a clinician, either with a dynamometer or as manual muscle strength testing, as well as a clinician-based evaluation of the range of motion. Recent efforts to transform the Constant–Murley Score into a PROM have been conducted, however, not yet with a large-scale validation.[53]

Table 4. Recommended combinations of PROMs for different shoulder pathologies

Shoulder pathologies	Suggested PROMs	
	District	Specific
Rotator cuff and subacromial pathology, excluding calcific tendinitis	DASH	ASES
Proximal humerus fractures		n.a.
Shoulder instability		ROWE + WOSI
Glenohumeral arthritis		ASES
Shoulder stiffness (including adhesive capsulitis, frozen shoulder)		SPADI
Calcific tendinitis of the rotator cuff		n.a.
Shoulder pain of unspecified origin		SPADI
Other conditions of the shoulder (including infection and neoplasia)		n.a.

Note. PROMs, patient-reported outcome measures; DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; ASES, American Shoulder and Elbow Surgeons Score; ROWE, Rowe score; WOSI, Western Ontario Shoulder Instability Index; SPADI, Shoulder Pain and Disability Index.

Conclusions

A wide variety of PROMs have been used to assess shoulder conditions. The ASES, DASH and SPADI were the most frequently reported PROMs in the analysed publications, with disease-specific PROMs being used with increasing frequency. Analysing the findings presented in this review (frequency in literature and presence of validated and comparable different languages), a combination of the DASH score for shoulder outcome assessment with more specific PROMs, such as the Rowe score for shoulder instability, ASES for rotator cuff pathology and osteoarthritis, SPADI for shoulder stiffness and shoulder pain of unspecified origin is proposed as a recommended set of PROMS.

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