

Patients' experience of shoulder disorders: a systematic review of qualitative studies for the OMERACT Shoulder Core Domain Set

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Abstract

Objectives: To describe the experiences (including symptoms and perceived impacts on daily living) of people with a shoulder disorder

Methods: Systematic review of qualitative studies. We searched for eligible qualitative studies indexed in Ovid MEDLINE, Ovid Embase, CINAHL (EBSCO), SportDiscus (EBSCO) and Ovid PsycINFO up until November 2017. Two authors independently screened studies for inclusion, appraised their methodological quality using the Critical Appraisal Skills Programme checklist, used thematic synthesis methods to generate themes describing the experiences reported by participants and assessed the confidence in the findings using the Grading of Recommendations Assessment, Development and Evaluation Confidence in Evidence from Reviews of Qualitative research (GRADE-CERQual) approach.

Results: The inclusion criteria were met by eight studies, which included 133 participants (49 females and 84 males) with either rotator cuff disease, adhesive capsulitis, proximal humeral fracture, shoulder instability or unspecified shoulder pain. We generated seven themes to describe what people in the included studies reported experiencing: pain; physical function/activity limitations; participation restriction; sleep disruption; cognitive dysfunction; emotional distress; and other pathophysiological manifestations (other than pain). There were interactions between the themes, with particular experiences impacting on others (e.g. pain leading to reduced activities and sleep disruption). Following grading of the evidence, we considered it likely that most of the review findings were a reasonable representation of the experiences of people with shoulder disorders.

Conclusion: Patients with shoulder disorders contend with considerable disruption to their life. The experiences described should be considered by researchers seeking to select the most appropriate outcomes to measure in clinical trials and other research studies in people with shoulder disorders

Introduction

Shoulder disorders, including rotator cuff disease, adhesive capsulitis, glenohumeral OA and other conditions such as instability and humeral head fractures, affect a considerable proportion of the general population, with an estimated point prevalence ranging from 7 to 26% [1, 2]. Common experiences of people with shoulder disorders include pain that can lead to problems with performing daily activities, such as dressing and bathing [3, 4]. Such experiences should be reflected in outcome measures used to investigate the effectiveness of treatment options for shoulder disorders. However, the outcomes used to evaluate interventions for people with shoulder disorders are not consistently measured in randomized trials. For example, in our previous analysis of shoulder trials published between 1954 and 2015, we found that 90% measured pain, 71% measured performance of activities of daily living and 6% measured participation in work [5]. This diversity in outcome measurement limits our ability to compare findings between studies and to synthesize data in meta-analyses.

The OMERACT Shoulder Core Set Working Group was established in 2015 to develop a core domain set for clinical trials of interventions for shoulder disorders [6]. A core domain set is an agreed minimum set of outcome domains (i.e. constructs such as pain or function) that should be measured and reported in all clinical trials for a particular health condition, which can help reduce the diversity in outcome measurement in future trials [7]. We have used several approaches to inform the development of a core domain set for shoulder disorders. As noted above, we examined what outcome domains (such as pain) have been measured in previous shoulder trials, to generate a list of potentially important domains [5, 8]. We also conducted an international Delphi study, in which patients, clinicians and researchers were asked to consider the domains identified from our previous literature review, judge the importance of each domain and identify any domains missing from the list [4]. Findings of this research were discussed at face-to-face stakeholder meetings prior to and during the OMERACT 2016 conference, where we sought consensus on a preliminary core domain set [9].

Since the OMERACT 2016 conference, greater emphasis has been placed on the value of qualitative research to inform the development of core domain sets [10, 11]. Using qualitative methods to explore the lived experience and perspectives of people with shoulder disorders may identify additional important outcome domains that have not been measured in existing trials or considered within the Delphi process. It may also highlight areas that clinicians should consider, which may improve patient-centred care [12]. We are aware of several qualitative studies that have investigated the lived experience of people with shoulder disorders, but to our knowledge, there has been no attempt to synthesize the findings of these studies. Therefore, we conducted a systematic review of qualitative studies to address the following question: what are the experiences (including symptoms and perceived impacts on daily living) of people with a shoulder disorder?

Methods

We registered our systematic review in PROSPERO in November 2017 (CRD42017082628; a full protocol for the review was uploaded at the same time). We reported our systematic review according to the Enhancing Transparency in Reporting the synthesis of Qualitative re- search statement [13].

Eligibility criteria

We included any study in which the authors used qualitative methods (e.g. focus groups, interviews, nominal group techniques, participant observation) to explore the experiences and perceptions of people living with a shoulder disorder. Eligible shoulder disorders included rotator cuff disease (an umbrella term to classify disorders of the rotator cuff, including subacromial impingement syndrome, rotator cuff tendinopathy or tendinitis, partial or full thickness rotator cuff tear, calcific tendinitis and sub- acromial bursitis [14]), adhesive capsulitis, dislocation or shoulder instability, glenohumeral or acromioclavicular OA, glenoid labrum pathologies, proximal humeral or humeral head fractures, or unspecified shoulder pain. We included full articles (i.e. not conference abstracts) written in English, Dutch, French, Chinese or German (languages spoken by the authors) that were published in peer-re- viewed journals. We included mixed-methods studies (i.e. those that reported both quantitative and qualitative data) but only if the qualitative data could be separated from the quantitative data. We also included mixed-participant studies (i.e. those that included participants with a shoulder disorder or another musculoskeletal condition, such as back pain or neck pain) only if the data on participants with shoulder disorders could be separated from data on participants with other conditions. The primary outcomes of our review included the symptoms of people with shoulder disorders and the perceived impact of these symptoms on their daily lives, and the outcome(s) of most importance to patients, as elicited by qualitative research methods.

We excluded qualitative studies that enrolled participants with systemic inflammatory conditions, such as RA, hemiplegia causing secondary shoulder pain, or pain in the shoulder region as part of a complex myofascial neck/shoulder/arm pain condition (e.g. complex regional pain syndrome). We excluded qualitative studies of health professionals who treat people with shoulder disorders. We also excluded studies that used quantitative instruments to measure patient-reported outcomes (e.g. surveys asking dichotomous or Likert-style questions).

Search methods

We conducted a comprehensive search to seek all avail- able studies, rather than seeking all available concepts until theoretical saturation was achieved. We searched the following bibliographic databases, all from inception until November 2017: Ovid MEDLINE, Ovid Embase,

CINAHL (EBSCO), SportDiscus (EBSCO) and Ovid PsycINFO (see all search strategies in supplementary [Table S1](#), available at Rheumatology online). To capture any papers that may have been missed by the searches, one author (M.J.P.) examined the references of included articles.

Selection of studies

Two review authors (M.J.P. and M.M.) independently screened all titles and abstracts yielded from the searches, and all full text articles considered relevant. All disagreements were resolved via discussion or by consultation with a third review author (R.B.) when necessary. We summarized the selection of studies using a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram [15].

Data collection

Pairs of review authors (M.J.P. and D.A.O. or M.M.) independently extracted the following data from each included study using a standardized data collection form: lead author, year of publication, country, research question, sample size, participant characteristics [age and sex/ gender, type(s) of shoulder disorders], data collection method (e.g. focus group, interview), data analysis method (e.g. thematic analysis), themes and sub-themes relating to individual symptoms and their perceived impacts on daily living that were generated by the study authors, along with any supporting quotes and explanations of each theme. Disagreements were resolved via discussion or through inclusion of a third review author (R.B.) when necessary.

Quality assessment

Pairs of review authors (M.J.P. and R.H. or M.M.) independently assessed the quality of the included studies using the Critical Appraisal Skills Programme (CASP) checklist for qualitative studies [16]. All disagreements were resolved via discussion. The CASP checklist consists of 10 items, each of which includes multiple signaling questions to help users interpret the item (29 signaling questions in total). Following the method employed by Slade et al. [17], we constructed a summary table detailing the frequency of responses ('Yes' or 'No') to each signaling question. A narrative summary of the quality of the included studies is also provided. Summary scores or quality ratings were not generated as the CASP checklist does not have a scoring matrix and a cut-off point has not been established for ratings of the quality of qualitative studies.

Data analysis

We analysed study data using the methods of thematic synthesis outlined by Thomas and Harden [18]. We used an inductive approach to coding. In the first stage, we read each line of extracted text and derived codes based on the meaning and content of each extract (e.g. the line ‘. . . the pain is really quite excruciating when I go to bed . . .’ was coded as ‘pain severe at night’). As each new study was coded, existing codes were reviewed and revised, and new codes were added, when necessary. Once all studies had been coded, all text that had a given code was reviewed to check for consistency of coding across the studies, thus ensuring the translation of concepts from one study to another. One review author (M.J.P.) coded all text line-by-line, and codes were verified by another review author (D.A.O.). Any disagreements were resolved via discussion.

In the next stage, similarities and differences between the codes were reviewed in order to generate themes describing the experiences of people with a shoulder dis- order. For example, all codes relating to the intensity or severity of pain were grouped under a theme labelled ‘pain’. The generation of themes was based closely on what was reported in the included studies (i.e. quotes from patients and interpretations offered by the study authors). Two review authors (M.J.P. and D.A.O.) generated themes independently, then discussed and finalized the themes in consultation with another review author (R.B.).

We drafted ‘review findings’ to summarize each theme describing the experiences of people with a shoulder dis- order [19]. Two review authors (M.J.P. and R.H.) then in- dependently assessed the confidence in each of the review findings using the Grading of Recommendations Assessment, Development and Evaluation Confidence in Evidence from Reviews of Qualitative research (GRADE-CERQual) approach [19]. This approach requires assessors to consider four components: the methodological limitations of the qualitative studies contributing to each review finding (based on the CASP assessments) [20], the coherence of data contributing to each review finding (i.e. how clear and cogent the fit is between the data from the primary studies and a review finding that synthesizes the data) [21], the adequacy of data supporting each review finding (i.e. the degree of richness and the quantity of data supporting a review finding) [22] and the relevance of the studies contributing to each review finding (i.e. the extent to which the body of data from the primary studies sup- porting a review finding is applicable to the context specified in the review question) [23]. After considering the four components, both review authors independently judged the overall confidence in each review finding (i.e. for each theme generated) as: high: highly likely that the review finding is a reasonable representation of the phenomenon of interest; moderate: likely that the review finding is a reasonable representation of the phenomenon of interest; low: possible that the review finding is a reason- able representation of the phenomenon of interest; or very low: unclear whether the review finding is a reasonable representation of the phenomenon of interest

[19]. Disagreements in confidence ratings were resolved via discussion. We presented the review findings, our confidence judgement for each finding and an explanation of the judgement in a Summary of Qualitative Findings table.

Patient involvement

Two patient research partners (P.R. and M.J.H.V.) were involved in the interpretation of the results and writing up of the manuscript.

Results

In total, 3664 records were identified from the searches, of which we retrieved 61 for full text screening (Fig. 1). Inclusion criteria were met by eight studies [24-31]. Most (n=41) of the 53 excluded studies were excluded because they were not qualitative studies. We excluded eight qualitative studies that included either participants with ineligible conditions, or mixed populations, where data on participants with shoulder disorders could not be separated from data on other participants [32-39] ([supplementary Table S2](#), available at Rheumatology online). We also excluded four qualitative studies that explored patients' views about a particular intervention (e.g. manual therapy), rather than the symptoms and perceived impact of their shoulder disorder on daily living [40-43] ([supplementary Table S2](#), available at Rheumatology online).

Across the eight included studies there were 133 participants (Table 1). Participants had diagnoses of rotator cuff disease (three studies), adhesive capsulitis (two studies), proximal humeral fracture, shoulder instability or un- specified shoulder pain (one study each). The studies were conducted in the UK (four studies), Canada (two studies), Finland or New Zealand (one study each). Most participants were at least 40 years old, whereas one study focused on younger athletes with shoulder instability (mean age 27years). There were 49 females and 84 males. Data were gathered using semi-structured inter- views in seven of the studies, whereas focus groups were conducted in one study.

The methodological quality of the included studies varied (Fig. 2; [supplementary Table S3](#), available at Rheumatology online). Strengths that were observed in all studies included clearly stated objectives; clearly stated data collection methods; approval sought from an ethics committee; and sufficient, explicit data presented to support the findings. At least one negative response to a CASP signaling question was recorded in all but one study [30]. The quality of one study [24] was particularly problematic, as responses to 18 of the 29 CASP signaling questions were negative. The following limitations were identified in more than half of the studies: no critical

examination of the researchers' own role, potential bias and influence during formulation of the research question, data collection, analysis and selection of data for presentation; no explanation as to why patients approached for participation were the most appropriate to provide access to the type of knowledge sought by the study; no justification for the setting of data collection; and no description of issues around informed consent or confidentiality (Fig. 2).

We generated seven themes to describe what people in the included studies reported experiencing; these included: pain; physical function/activity limitations; participation restriction; sleep disruption; cognitive dysfunction; emotional distress; and other pathophysiological manifestations (other than pain). Table 2 provides a summary of each review finding and Table 3 presents illustrative quotes reflecting each finding. Not all participants reported having all of the above experiences. For example, while pain, physical function/activity limitations and sleep disruption were experienced by most participants in the studies, fewer participants reported experiencing cognitive dysfunction and other pathophysiological manifestations (e.g. poor muscle strength).

We generated sub-themes for three themes that addressed multiple concepts (Table 2). For example, the 'participation restriction' theme consists of sub-themes on 'work disruption', 'limited recreation' and 'limited social interactions', reflecting the finding that some participants may experience problems in one or multiple aspects of life participation. In addition, we generated sub-themes for 'emotional distress' to reflect the various emotional experiences that can accompany a shoulder disorder. Many people in the included studies reported experiencing frustration because of their shoulder disorder, whereas a smaller subset reported symptoms of depression, anxiety and a perception that their suffering was hidden from the casual observer given the lack of outward signs of their shoulder disorder.

There were interactions between the themes describing the experiences of people with a shoulder disorder (Fig. 3). Pain emerged as the predominant symptom that was perceived to 'affect everything', that is, lead to difficulties with performing activities of daily living, engaging in work and recreation, and getting to and staying asleep. Each of these experiences were perceived by participants to have several follow-on effects. For example, many patients claimed that work disruption caused their emotional distress, including frustration and anxiety about their recovery. Also, some people perceived that sleep disruption resulted in them having less energy to perform activities of daily living and recreational activities, and aggravated their pain, the following day (Fig. 3).

We considered it likely that most of the review findings were a reasonable representation of the experiences of people with shoulder disorders, i.e. we had 'moderate confidence' in most of the review findings (Table 2; a more detailed GRADE-CERQual Qualitative Evidence Profile is available in

[supplementary Table S4](#), available at Rheumatology online). Our judgement of 'moderate' rather than 'high' confidence was driven mostly by the minor concerns we had about methodological limitations of the contributing studies, and minor concerns about the relevance of each contributing study to the review question (given that all data came from only four high-income countries). In contrast, we had very low confidence in the finding that cognitive dysfunction is experienced by people with shoulder disorders, as this finding was based on limited data from two studies, one of which had several methodological limitations. We also had low confidence in the review findings regarding the perception of hidden suffering, and other pathophysiological manifestations, because of concerns about methodological limitations, adequacy of the data and relevance of studies to the review question.

Discussion

Our synthesis suggests that patients with shoulder disorders contend with considerable disruption to their life. They can experience difficulties in performing self-care activities, work and leisure, which can cause considerable distress (particularly frustration and anxiety). Some experiences (e.g. pain, physical function/activity limitations and sleep disruption) are more common than others (e.g. cognitive dysfunction and other pathophysiological manifestations). Also, some experiences appear to impact on others (e.g. pain can lead to avoidance of particular activities and to sleep disruption), which suggests that addressing one may alleviate the other(s) in some patients. We considered it likely that most of the review findings were a reasonable representation of the experiences of people with shoulder disorders.

There are several strengths of our review. We pre-specified our methods and registered our review prior to formal screening of search results against eligibility criteria. Errors in selection, extraction, appraisal and coding of studies were minimized by the involvement of at least two authors in each process. We were able to obtain rich, unpublished data for one of the included studies [30]. We included studies regardless of the type of shoulder disorder, setting or country, which enhances the generalizability of our findings. Unlike most systematic reviews of qualitative research evidence, we formally assessed our confidence in each of the review findings using the recently developed GRADE-CERQual framework [19].

The review findings should be considered in light of some limitations. Our previous research to identify important outcomes for shoulder disorders [4, 5, 9] may have influenced our analysis and selection of data for presentation. We attempted to minimize this influence by having a second researcher not involved in our prior work (D.A.O.) code the studies. Also, we have uploaded our data

collection and coding form to the Open Science Framework (<https://osf.io/rszct>), so that readers can see the text and quotes that underlie each theme generated.

Another limitation is that we were unable to assess the risk of reporting biases on our review findings, given the lack of suitable methods for qualitative evidence syntheses [44]. Finally, our findings may not reflect the experiences of people with glenohumeral or acromioclavicular OA, glenoid labrum pathologies or dislocation of the shoulder, given that no such people were included in the studies we identified.

It is important that clinicians ask patients which problems are arising because of their shoulder disorder and which they would like to focus on. If a mismatch exists between what clinicians and patients consider important in terms of progress and recovery, then patients may not receive the care most appropriate for them. For example, addressing strength or range of movement may not be most helpful to a patient whose main concerns might be night pain or anxiety about certain movements causing further damage, or how to modify activities so that they can continue to work. Addressing treatment expectations and supporting psychosocial needs may help improve outcomes for people with shoulder disorders.

There are several avenues for further research in this area. It would be useful to explore the experiences of people with shoulder disorders in low- and middle- income countries, as these may differ from those documented in this review, which is based on data from high-income countries only. Such research could also be conducted on people with shoulder disorders that were not represented in this review (e.g. glenohumeral OA) or on people underrepresented in this review (e.g. only 11% of participants with rotator cuff tear or instability were women). Finally, more methodological research could be conducted to evaluate the contribution of qualitative evidence syntheses to the development of core domain sets. For example, when we mapped the outcome domains arising from the current review of qualitative studies against the domains included in our 2016 preliminary core domain set for shoulder disorders [9], we uncovered one potentially missing domain—cognitive dysfunction. This and other findings of our review informed discussions at the OMERACT 2018 conference, where we sought endorsement from the wider OMERACT community on our core domain set for shoulder disorders [45].

Our thematic synthesis revealed that patients with shoulder disorders may need to contend with several disruptive experiences, including pain, physical function/activity limitations, participation restriction, sleep disruption, cognitive dysfunction, emotional distress, and other pathophysiological manifestations such as loss of muscle strength or reduced range of shoulder movement. A better understanding of patients' experiences is useful for clinicians who treat them and can also inform

selection of the most appropriate outcomes to measure in clinical trials and other research studies for shoulder disorders.

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Data availability

The study protocol, data collection form and coding for this study are available on the Open Science Framework: <https://osf.io/vq4mz/>.

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