Introduction

Pain assessment is fundamental in orthopedic surgery to evaluate disease severity as well as postoperative improvement. When evaluating new surgical interventions and analgesic methods, clinical trials often use acute postoperative pain as an important outcome. Recent quality improvement guidelines of acute postoperative pain from the American Pain Society [1], a review [2] and a study protocol [3] of acute postoperative pain after shoulder surgery have defined outcomes to be included in postoperative pain trials, such as “pain intensity” [4,5]. However, recommendations for outcome measurements and recordings are lacking [6]. For example, pain intensity may be reported through various pain rating scales. As a result, trials have assessed postoperative pain in a wide variety of ways [2,7,8].

A standardized, validated method of assessing acute postoperative pain would improve the quality of clinical studies and facilitate future systematic reviews and meta-analyses. Thus, the aim of this study was to investigate the methods used in recent literature, focusing on ratings of pain intensity, time points and number of measurements, analgesic consumption, and time to first analgesic request or first pain.

Materials and methods

Data sources and searches

The databases PubMed and CINAHL were used to identify studies on shoulder surgery and postoperative pain. Subject-specific terms relating to any type of shoulder surgery were used as search terms, and full-text articles were screened. Inclusion criteria were arthroscopic rotator cuff surgery with a primary pain-related outcome during the first postoperative week, published in English from 2012 to 2017.

Results

A total of 47 studies were included, all measuring pain intensity using a pain rating scale. Most frequently used was the visual analogue scale using the anchors “no pain” and “worst pain imaginable,” with recordings at 1, 2, 4, 6, 8, 12, and 24 hours postoperatively. A total of 34 studies recorded analgesic consumption, usually as average cumulated consumption in mg. Time to first analgesic request or first pain were recorded in 11 studies, and 4 different starting points were used.

Discussion

This review describes the currently most common methods of assessing acute postoperative pain in clinical trials of arthroscopic shoulder surgery involving rotator cuff repair, and the large variety of methods applied. Based on this study and international guidelines, several recommendations on how to measure and report postoperative pain outcomes in future trials are proposed.

Key words: Rotator cuff surgery, Postoperative pain, Pain intensity, Pain rating scale, Analgesic consumption.
surgery were identified in the MeSH tree, PubMed, and in Headings, CINAHL. Any subject-specific terms unavailable in the indexed headings were searched as free text in title and abstract, such as subacromial decompression. All relevant MeSH terms/headings not exclusive to surgery or pathology of the shoulder, such as arthroscopy or bursitis, were combined with a shoulder-related MeSH term/heading. For MeSH terms introduced in 2012 or later, the previous MeSH term indexing was added to the search. To include articles with incomplete indexing processes in PubMed, a free text search in title and abstract was conducted for the last 2 years, using the subject-specific terms.

Selection of included studies

The identified articles from the systematic literature search were imported to Covidence, a web-based systematic review software (Veritas Health Innovation, Melbourne, Australia) [9]. Two reviewers, JKR and KTB, assessed the articles individually, and consensus was sought through discussion in case of disagreement. The inclusion criteria were: shoulder surgery, report of any kind of pain assessment within the first postoperative week, and published in English from 30 June 2012 to 30 June 2017. As this search provided more relevant studies for inclusion than first anticipated, this review focused on arthroscopic shoulder surgery including rotator cuff surgery, and pain as the primary outcome. If no primary outcome was specified, the first outcome mentioned in the study’s material and methods section was considered primary. Finally, the bibliographies of the included studies and related review articles were manually reviewed for other relevant studies, which were then included if they met the inclusion criteria.

Data collection

From the included studies, the following data was recorded: first author, year of publication, study design, surgical procedure, intervention, total number of patients, primary outcomes, and pain-related outcomes. Details regarding the methods of pain assessment were recorded as follows: data collection by staff (telephone or personal interviews) or by patients themselves (pain diaries or questionnaires), pain scale used, phrasing of pain anchors, measurement at rest or during activity, measurement of present/average/worst pain, time-points of measurements on postoperative day (POD) 1 and number of measurements daily until POD7, analgesic consumption, time to first analgesic request or first pain.

Results

A total of 711 non-duplicate articles eligible for screening of title and abstract were identified, of which 153 were further assessed in full text; 47 studies met the inclusion criteria (Figure 1). The 47 included studies included randomized controlled trials (RCTs) (n = 33), non-randomized comparative studies (n = 6), quasi-RCT (n = 1), cohort studies (n = 4), case series (n = 2), and one up-and-down dose finding study (Table 1). The study populations were patients undergoing arthroscopic rotator cuff surgery exclusively (n = 29) or in combination with other arthroscopic shoulder surgery (n = 18). The number of patients analyzed in the studies ranged from 24 to 1624 (mean 122). Interventions (Table 1) were performed by orthopedic surgeons, anesthesiologists, physiotherapists, nurses, and industry pharmacists.

Primary outcome

Pain intensity was measured using a rating scale in all 47 studies (Table 1), and was the primary outcome in 37 studies. Analgesic consumption was reported in 34 studies and was the primary outcome in 6 studies [10–15]. The time to first pain or analgesic request was reported in 11 studies and was the primary outcome in 5 studies [10,16–19] (one of which also had analgesic consumption as a primary outcome [10]). In 8 studies, a rescue analgesic was given based on pain scale ratings [10–12,15,17,20–22].

Methods for data collection

Staff-administered pain questionnaires were applied in 27 out of 47 included studies [11–14,16–21,23–39]. Nine studies [10,18,39–45] used a patient-administered pain questionnaire, and 12 studies [15,46–56] did not specify their method. One study used a staff-assessed method in the hospital and a self-assessed method after patient discharge [18].

Ratings of pain intensity

Of the 47 studies, 26 used the visual analog scale (VAS), 17 used the numeric rating scale (NRS), 4 used a Likert scale, and a single study used a combined VAS and Faces Pain Scale (Table 1).
Table 1. The 47 included studies containing arthroscopic rotator cuff surgery with pain as the primary outcome.

| Author, year | Study design | Intervention | Pain scale | Analgesic consumption | Time to first request |
|--------------|--------------|--------------|------------|-----------------------|----------------------|
| Abdallah et al., 2016 | RCT | ISB + dexmedetomidine adjuvant vs. IV vs. none | VAS | + | + |
| Ahn et al., 2016 | RCT | Pregabalin vs. placebo before surgery | NRS | + | – |
| Aksu et al., 2015 | RCT | ISB vs. intraarticular bupivacaine vs. none | VAS | + | + |
| Alemanno et al., 2014 | Non-randomized | MIB levobupivacaine vs. levobupivacaine + buprenorphine vs. levobupivacaine + tramadol | VAS | – | + |
| Alemanno et al., 2016 | Non-randomized | MIB levobupivacaine vs. levobupivacaine + thiamine | VAS | – | + |
| Alfuth et al., 2016 | RCT | Cold compression vs. cold pack | VAS | – | – |
| Basat et al., 2016 | Case-series | Suprascapular and axillary nerve block | VAS | – | – |
| Cheng et al., 2016 | Cohort | Correlation of fibromyalgia and postoperative pain | 10-point scale | + | + |
| Cho et al., 2015 Feb | Non-randomized | ISB vs. none | VAS/Faces* | + | – |
| Cho et al., 2015 May | Non-randomized | Zolpidem vs. none | VAS | + | – |
| Choi et al., 2015 | RCT | Stellate ganglion block vs. none | VAS | + | – |
| Cuff et al., 2016 | Cohort | Correlation of preoperative factors and postoperative pain | VAS | – | – |
| D’Ambrosi et al., 2016 | RCT | Platelet rich plasma during surgery vs. none | VAS | – | – |
| Desmet et al., 2015 | RCT | Dexamethasone IV vs. placebo | Likert | + | + |
| Dhir et al., 2016 | RCT | Suprascapular and axillary nerve block vs. ISB | NRS | + | – |
| Erdan et al., 2017 | quasi-RCT | Standard pain assessment protocol vs. routine pain assessment | VAS/NRS | + | – |
| Faria-Silva et al., 2016 | RCT | Block with clonidine vs. block without clonidine | NRS | – | – |
| Han et al., 2013 | RCT | Multimodal local injection vs. i.v. patient-controlled analgesia | VAS | + | – |
| Jo et al., 2014 | RCT | Multimodal local injection vs. placebo | VAS | + | – |
| Khashan et al., 2016 | RCT | Preincisional intraarticular morphine vs. ketamine + morphine vs. placebo | NRS | + | – |
| Kim et al., 2016 | RCT | ISB 0.2% ropivacaine vs. ISB 0.75% ropivacaine vs. cervical epidural block | VAS | + | – |
| Kraeutler et al., 2015 | RCT | Compressive cryotherapy vs. ice | VAS | + | – |
| Lane et al., 2014 | case series | Same day discharge after GA and ISB | NRS | – | – |
| Lee et al., 2015 | RCT | Local anesthetic injection in the GH vs. the SA vs. both | VAS | + | – |
| Lee et al., 2014 | RCT | SSNB + ANB vs. SSNB + placebo | VAS | + | – |
| Lee et al., 2015 | RCT | Arthroscopy guided SSNB vs. placebo | VAS | + | – |
| Lee et al., 2012 | Non-randomized | ISB vs. SSNB + ANB vs. none | VAS | + | – |
| Lehmann et al., 2015 | RCT | GA vs. GA + ISB vs. ISB | NRS | + | + |
| Merivirta et al., 2013 | RCT | Subacromial bupivacaine infusion vs. transdermal fentanyl patch | NRS | – | + |
| Merolla et al., 2015 | RCT | Dietary supplement vs. placebo | VAS | + | – |
| Park et al., 2016 | RCT | SSNB + ANB vs. SSNB vs. none | VAS | – | – |
| Perdreaux et al., 2015 | RCT | Multimodal local injection vs. placebo | VAS | + | – |
| Rubenis et al., 2015 | Non-randomized | Undersurface rotator cuff repair vs. bursal-side rotator cuff repair | Likert | – | – |
| Ryu et al., 2015 | RCT | Supraclavicular brachial plexus block vs. ISB | NRS | + | + |
| Salviz et al., 2013 | RCT | ISB vs. ISC vs. GA | NRS | + | + |
The VAS, NRS, and Likert scale all used similar minimum anchors such as “no pain”. To describe higher pain levels, the scales used 14 different anchors in total (Figure 2) with “worst pain imaginable” [11,12,15,26,36,38,43,48,51,54] being the preferred anchor. The second most frequent anchor was “worst pain” [10,28,33,34] and then successively “most severe pain imaginable” [19,20,37], “severe pain” [18,32,46], and “worst possible pain” [29,41,47]. Twelve studies did not report the used anchors [13,16,17,27,31,35,40,49,50,55-57].

Pain ratings were specified to be at rest or during activity in 11 studies [10,13,16,23,26-28,32,44,55,58], of which 3 studies [10,16,26] specified pain to be exclusively measured at rest. Eight out of the 11 studies described pain during activity and the definitions were: movement during cough and mobilization [27], motion attempts [28], shoulder movements [58] during activities such as dressing or during transfer from lying to sitting [23], passive motion [55], during overhead activities and sleep [44]; two studies did not specify the activity [13,32]. The remaining 36 studies did not specify whether pain was measured during activity or at rest.

The following 6 studies asked patients to rate pain as either present pain, least pain, worst pain, or average pain during a specified period of time, namely average pain score for the day [25], daily average pain [40], overnight pain [29], level of pain during sleep [45], overall pain [32], and average of least and worst pain [13]. The remaining studies did not report these details of the pain recordings.

### Number of measurements and time points

The total number of pain recordings within the first seven PODs was extracted from 45 studies (Figure 3); two studies did not report the total number of recordings [15,54]. The mean number of recordings within the first postoperative week was 6.3 (0–21). The distribution of recordings during the first seven PODs could be extracted from 45 studies (Figure 4). The majority of pain recordings were made on POD1, totaling 60% of cumulated number of recordings within the first postoperative week, equivalent to a mean of 5.1 (0–11) recordings. The number of pain recordings decreased from POD2 to POD6 with a small increase in POD7. The time points in POD1 were specified in 32 of the included studies and represented 28 different time points (Figure 5) [10–12,14,19–21,23,26–28,30,31,33–38,43,46–52,54–57,59]. The most frequently used time points were: postanaesthesia care unit, 1, 2, 4, 6, 8, 12, and 24 hours postoperatively.

### Analgesic consumption

In the 34 studies reporting analgesic consumption, different methods were used. Some studies used more than one method due to variations in analgesic protocols, such as different scheduled analgesics and rescue analgesics. In most cases, only the rescue analgesics were recorded (in mg
or number of doses) [14,21,24,47,49], or the number of patients requesting [34,54,56] (or not requesting) analgesics [19]. For patients using patient-controlled analgesia (PCA, usually with intravenous opioid), the number of attempts, number of doses, and/or cumulated dose (for example during 24 hours) were reported [31,37,41,48,50,52,57]. Some studies reported total consumption of morphine/opioids [12,13,47] or cumulated amount of all analgesics [10,15] during a specific period of time.

**Time to first analgesic request or first pain**

This was the least used primary pain outcome. Studies reporting this outcome were mainly, but not limited to, trials of peripheral nerve blocks. Four studies used time to first pain [10,13,15,34], and seven studies used time to first request of analgesics [12,16–19,37,52]. Different starting points were used when reporting time to first analgesic request or first pain: time from injection of the local anesthetic solution [16,18], time from extubation [52], time...
Discussion

When screening the 711 abstracts for the current study, many of the first discarded 558 studies were found to use questionnaires with joint-specific or health-related quality of life composite scores (such as DASH score, American Shoulder and Elbow Surgeons (ASES) score, Oxford shoulder score, and Western Ontario Rotator Cuff Index). From closure [15], and time from arrival at the post-anesthesia care unit [37].

Since data on pain assessment could not be extracted from these composite scores, these studies were unsuitable for further analysis of postoperative pain. Currently this issue is being investigated by others, for example Gagnier et al. [3] who has published a study protocol with the purpose of creating a core outcome set for clinical trials of people with shoulder pain as the lack of uniformity in outcome measures across clinical trials limits interstudy comparison and the ability to pool data for meta-analyses.

The majority of included studies used the VAS to measure pain intensity. The literature generally indicates...
that the VAS and the NRS are interchangeable, and some studies report coherence between the VAS and NRS pain rating scales [4,60,61]; others found no coherence at specific pain levels [62]. On basis of international guidelines, literature recommendations [1,62,63,65], and practical applications where the NRS is seemingly easier to administer than the VAS [63,64] (since it requires no remedies), this study recommends using the NRS to measure pain intensity.

Though the majority of included studies reported the chosen pain rating scale, such as the VAS or NRS, a description of scale use is rare to find, thus obscuring whether the scales were used as originally intended. In at least two of the included studies, the actual use of the VAS was described as a Faces Pain Scale and the NRS, respectively [24,35].

The pain rating scales used 14 different anchors when phrasing maximum pain levels. Although there was little variation in the phrasing, the lack of consistency is noticeable. Hawker et al.’s [63] review article from 2011 reported that the VAS was designed using the anchor “severe pain”, whereas the NRS was designed with the anchors “pain as bad as you can imagine” and “worst pain imaginable.” Being able to compare future studies, it is important they apply the same scale and anchors, i.e., “no pain” and “worst pain imaginable.”

Few studies reported if pain was measured during activity or at rest. Recording pain during activity increases sensitivity due to higher pain scores, and reflects patients’ functional levels. Based on international recommendations [1,65], it is recommended to report both pain at rest and during activity. Focus is thus drawn on pain during deep breathing and coughing to reduce risks of cardiopulmonary and thromboembolic complications after surgery [4].

The majority of pain recordings within the first postoperative week were recorded on POD1. When looking at the time points on POD1, 28 different time points were used in 32 studies. Naturally, some of the variation is a result of peaks of interest, reflecting different interventions. However, some standardization seems possible. It is thus recommended not to report “post-anesthesia care unit” as a time point but rather to use the most common time points of 1, 2, 4, 6, 8, 12, and 24 hours, preferably starting from injection of local anesthetic or from extubation, dependent on the intervention investigated. Too many measurements will cause problems if not using the proper statistical methods, but this is beyond the scope of this review.

It is important to include the outcome of analgesic consumption, as the pain intensity ratings do not necessarily reflect the patients’ wishes for additional opioids [66,67]. Some studies showed discrepancies between pain levels and analgesic consumption, with one outcome being statistically significant and the other not [10,11,13,18,21, 41,48,50,52]. It is therefore advisable to report both analgesic intake as well as pain intensity ratings [68].

Reporting morphine equivalent doses, as was done in some studies, bears the risk of error in the conversion factors, but may be necessary if the protocol involves more than one opioid and facilitates interstudy comparison.

Time to first analgesic request or first pain is related to the “time to remedication,” often used in studies with nerve blocks, illustrating when patients will need further attention [5]. Time to first pain would be more sensitive, as onset of pain may precede the first analgesic request, especially in patients reluctant to consume medication. It is important to use the recommended starting points here as well, such as time from injection or extubation.

Limitations

Despite a wide-ranging search strategy, the risk of missing relevant studies cannot be excluded. However, the considerable variation regarding outcomes and reported methods indicates that a comprehensive search was conducted. Also, two databases were searched for relevant literature, thus strengthening the study. It is assumed that the findings from the current study can be generalized to other populations with acute postoperative pain as there is no apparent reason to assume that postoperative pain following rotator cuff surgery is measured differently from other types of surgery, but this may be a subject for further investigations.

Conclusion

A large variety in the reporting of postoperative pain outcomes in the 47 included studies was shown. Based on this study and international guidelines, future postoperative pain trials are recommended to include the following outcomes: pain intensity using the NRS with the anchors “no pain” and “worst pain imaginable,” recorded during activity and at rest at 1, 2, 4, 6, 8, 12, and 24 hours postoperatively. Analgesic consumption should also be included and reported as cumulated rescue analgesic medication in mg, if possible converted to morphine equivalents.

Assuming that postoperative pain following rotator cuff surgery is not measured differently from other types of surgery, the applications of this study may be expanded to clinical trials involving patients undergoing other surgical procedures.

Conflict of interest

The authors declare that they have no conflicts of interest in relation to this article.

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