Needling with Irrigation for Rotator Cuff Calcific Tendinosis: A Systematic Review

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Abstract
Background: Calcific deposits in the rotator cuff tendons cause a significant amount of shoulder pain and dysfunction in middle-aged adults, with prevalence estimated at 2.7 to 20%. The intervention of needling with irrigation may play a role in the treatment of the disease. This systematic review examines three studies using the GRADE method of evaluating medical literature.

Method: An extensive search of available medical literature was conducted using PubMed, Web of Science, Medline, and the Cochrane Systematic Reviews with the keywords mentioned below and limiting the results to the English language, humans, and studies published since the last available review, in 2006.

Results: Three studies were included in this review – one randomized controlled trial, one case control trial, and one case series. They examined the efficacy of needling with irrigation on calcific tendinosis based on the outcomes of pain reduction and restored shoulder range of motion (ROM) and function. All studies found statistical and clinical benefit in needling with irrigation in short-termed outcomes for pain, ROM, and shoulder function. Long-term benefit was not seen to be significant in the study with a control. The three studies averaged a GRADE ranking of low-quality evidence for the above outcomes due to limitations in study design.

Conclusion: Needling with irrigation for calcific tendinosis of the shoulder appears to be safe and effective therapy for decreasing pain and restoring ROM and shoulder function.

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Keywords
rotator cuff, subacromial, supraspinatus, infraspinatus, calcification, calcific, tendinitis, tendinosis, tendinopathy, lavage, irrigation, aspiration

Subject Categories
Medicine and Health Sciences

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Needling with Irrigation for Rotator Cuff Calcific Tendinosis: A Systematic Review

JD Burrup

A course paper presented to the College of Health Professions
in partial fulfillment of the requirements of the degree of

Master of Science

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Biography

JD Burrup is a native of Idaho where he majored in Athletic Training at Boise State University. After completion of his undergraduate degree, he remained in Boise working in clinic alongside physical therapists and in the field providing care for local minor league hockey and basketball teams and for youth soccer organizations. After several years he returned to his studies at BSU to finish coursework required for admittance in the Pacific University Physician Assistant (PA) Program. JD is now completing his final year in PA school.

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Background: Calcific deposits in the rotator cuff tendons cause a significant amount of shoulder pain and dysfunction in middle-aged adults, with prevalence estimated at 2.7 to 20%. The intervention of needling with irrigation may play a role in the treatment of the disease. This systematic review examines three studies using the GRADE method of evaluating medical literature.

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Keywords: rotator cuff, subacromial, supraspinatus, infraspinatus, calcification, calcific, tendinitis, tendinosis, tendinopathy, lavage, irrigation, aspiration
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INTRODUCTION

Background

Calcific tendinosis of the rotator cuff is a disorder involving the deposition of calcium salts within the tendon and bursa structures of the shoulder (Firestein et al., 2008). “When these calcific deposits cause bulging in the tendon profile, and hinder the mechanical process, they trigger a chronic inflammatory process in adjacent soft tissues with pain and functional limitations,” (Siliotto, Giacomoni, Dalla Nora, & Ortolani, 2002, p. 66). According to Hughes and Bolton-Maggs (2009), the supraspinatus tendon is the most commonly affected tendon within the shoulder joint, though the infraspinatus, pectoralis major, teres muscles, and the long head of the biceps brachii may well be affected alone or in combination.

Also known as calcific tendinitis, its prevalence is estimated to range from 2.7 to 20% based on radiographs of asymptomatic adults (Gerster, 2007; Firestein et al., 2008; Speed & Hazleman, 1999). The incidence of becoming symptomatic, acutely or chronically, has been estimated to be as high as 50% (Speed, 1999). Maugars et al. (2009, p. 369) report, “between 7 and 17 percent of the chronic painful shoulders are related to tendon calcification.” Lam, Bhatia, van Rooyen, & de Beer report that as much as 10% of all shoulder-pain consultations will be due to calcific tendinosis (2006). The usual age of onset is between 40 and 50 years, with a greater prevalence in women and workers in sedentary jobs (Firestein et al., 2008; Speed, 1999).
Presentation

Though it can be asymptomatic, calcific tendinosis can be a source of significant pain and loss of function to the ipsilateral arm. Patients often present with pain similar to that of shoulder impingement syndrome – painful overhead range of motion (ROM), trouble sleeping due to shoulder pain, and weakness secondary to pain, particularly in abduction (Firestein et al., 2008; Speed, 1999). The resulting decreased ROM and use of the shoulder, places the patient at risk for developing adhesive capsulitis, particularly in patients beyond 40 years of age (Firestein et al., 2008). Therefore, despite being a self-limited disorder in many patients, recognition and effective intervention may be key in maintaining long-term function for some patients. Furthermore, calcific tendinosis is often associated with, and difficult to differentiate from, subacromial-deltoid bursitis, supraspinatus impingement, and tears of the rotator cuff. Thus, radiograph and/or ultrasound are both cost-effective and necessary means for diagnosis and to rule out concomitant pathology.

Classification and treatment

Several articles exist that offer classification definitions based on their findings during treatment trials and case studies; however, classification of calcific tendinosis has yet to be widely standardized. One such study conducted by Gartner (1993) found three differences via radiography. These three types are briefly defined by a distinct and dense deposit (type I), a deposit with both well defined dimensions and transparency (type II), and a deposit with poorly marginated or transparent borders (type III). Gartner (1993) found that complete resorption of the deposit was most likely in type III calcific tendinosis, less so in type II and even less likely in type I.
Another example of classification was mentioned by Maugars et al. (2009). This classification system was standardized by the French Arthroscopic Society and describes three types of calcifications, A, B, and C, similar to the descriptions of Gartner (1993). In fact, some studies have been criticized for not using classification systems; such was the case with the article by Serafini et al. (2009), in which Cacchio and Rompe (2010) submitted a letter to the editor that included criticism for not excluding type III calcifications, suggesting they may have a high rate of self-resolution, which could inaccurately skew results. While no mention of classification-based treatment guidelines was found during the research for this review, it is reasonable to presume that more invasive procedures are reserved for more severe forms of the disease. However, these classification systems were based on radiographic findings alone, and did not consider physical findings or patient reports of pain and dysfunction.

Current treatment standards involve NSAID therapy and corticosteroid injections, particularly during the acute phase (Gerster, 2007). In the event that these do not prove to be successful, acetic acid iontophoresis, ultrasound, extracorporeal shockwave lithotripsy, surgery, and percutaneous needling, with or without irrigation, have been used with varying degrees of success (del Cura, Torre, Zabala & Legorburu, 2007). Much of the available literature on the subject comes from Europe, and to date focuses on extracorporeal shockwave lithotripsy alone, or in combination with needling of the calcific deposits. Though there is relevant research, much of which is scattered over the last two decades, regarding needling combined with irrigation, most of these articles are from observational studies and lack adequate control components.
Though not a new intervention, and documented in various journals and orthopedic texts as early as 1978, the practice of needling with irrigation, either alone or in combination, and often guided by either fluoroscopy or ultrasound, is not yet a standard treatment option in many parts of the U.S. (Serafini et al., 2009; Comfort & Arafiles, 1978). This may be due, in part, to the variety of methods of needle-based treatments and other modalities available, a relative lack of procedure training opportunities, or perhaps to a lack of research comparing needling with irrigation to the other treatments mentioned above.

Purpose of the Study

The purpose of this paper is to perform a systematic review to determine the efficacy of needling with irrigation as an intervention for rotator cuff calcific tendinosis. The review is based on the available current literature, utilizing the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to evaluate the quality of evidence (Guyatt, Rennie, Meade, & Cook, 2008).

METHOD

Searching

An extensive literature search was performed using PubMed, Medline, Web of Science, and Cochrane Systematic Reviews. These databases were accessed through the Pacific University Library system. The keywords searched included “tend*,” “rotator cuff,” “calci*,” “supraspinatus,” “infraspinatus,” “subacromial,” “lavage,” “irrigation,” and “aspiration,” individually and in combination. The original search yielded 159 articles. The search was limited to studies involving human subjects, articles written in
English, and published in 2000 or later. This resulted in 69 articles. Irrelevant topics and treatments were then excluded, yielding 17 articles. Duplicates, descriptive reviews, and letters to the editor were excluded, and after selecting only the relevant randomized controlled trials, case control studies, and case series, eight articles remained. Additionally, the most recent review of literature on this intervention was published in 2006; therefore, only articles published after 2006 that met the inclusion and exclusion criteria discussed below are reviewed in this paper. In the end, three studies met all the inclusion and exclusion criteria and were made part of this systematic review.

Inclusion Criteria

Randomized controlled trials, case control studies, and case series concerning humans, written in English, and published in 2006 or later were included.

Exclusion Criteria

Studies concerning needling only, aspiration without irrigation, shockwave lithotripsy, sonography, acetic acid iontophoresis, or concomitant physical therapy were excluded from this review. Additionally, visual vignettes and instructional articles were excluded.

RESULTS

Sonographically Guided Percutaneous Needle Lavage in Calcific Tendinitis of the Shoulder: Short- and Long-Term Results by del Cura et al. (2007)

The first study reviewed was conducted by del Cura, Torre, Zabala and Legorburu (2007), who performed a case series in Spain that followed 70 patients, two of whom had bilateral shoulder involvement, yielding 72 shoulders with calcific tendinosis treated via
needling and lavage over the course of one year. Patients were recruited from emergency room visits for shoulder pain in which radiographs identified calcifications of the rotator cuff tendons. No patient demographics or exclusionary comorbidities or confounders were given.

Intervention consisted of local anesthesia in the tissues adjacent to the rotator cuff tendons. The calcifications were pierced by needle, and lidocaine was used to irrigate. The aspirate was then drawn back through the needle. This was repeated until the aspirate was clear. The subacromial-subdeltoid bursa was injected with corticosteroid in an effort to prevent bursitis. Patients were discharged with a prescription for nonsteroidal anti-inflammatory medication for pain. Sixteen shoulders were treated again during the follow-up period.

Outcomes focused on pain reduction and restored shoulder function using the Shoulder Pain and Disability Index (SPADI) which measures pain and disability via questionnaire and shoulder ROM. The follow-up periods were at 5 and 10 weeks, and 1 year, though no SPADI information was gathered at week 5. Additionally, 5 patients were lost to follow up at 1 year and were thus removed from the analysis. Significant reductions in pain and disability and increase in ROM were reported at each follow-up (del Cura et al., 2007; see Appendix B, Table 1). The authors concluded that percutaneous needle lavage was an effective short-term (less than 1 year) and long-term (1 year) treatment for symptomatic calcific tendinosis of the shoulder in that it decreases pain and increases function and ROM.
Treatment of shoulder calcifications of the cuff: A controlled study by Maugars et al. (2009)

The second study reviewed was conducted by Maugars et al. (2009) who performed a non-blinded, randomized controlled trial in France involving 96 patients with shoulder calcific tendinosis (96 patients, six of whom had bilateral shoulder involvement). All study participants received an initial corticosteroid injection, and the 53 patients that did not subjectively improve above 70%, on a 0-100% subjective global improvement scale (that was not well-defined by the authors), were randomized into three groups: 17 patients in the control group; 16 in the needling, fragmentation, and irrigation (NFI) group; and 20 in the bursoscopy group. The bursoscopy group is irrelevant to the outcomes under review. Exclusion criteria consisted of known rotator cuff tear, history of shoulder arthritis, fracture, dislocation, surgery, arthroscopy, extracorporeal shockwave lithotripsy, or needling. The mean patient ages for the control, NFI, and bursoscopy groups were 43.5, 46.8, and 48.1 years, respectively; female to male ratios were 13:3, 16:4, and 112:5, respectively. No significant differences were found between the groups (Maugars, 2009).

Intervention for all patients, as mentioned above, began with corticosteroid injection in the area of calcification prior to randomization. The NFI group received local anesthetic in the involved musculotendinous structures and adjacent skin, followed by needling of the calcifications under fluoroscopy. Saline irrigation via two needles was performed until the aspirate was clear. No additional treatment was given. At the 4 month follow-up, control patients who reported less than 70% global improvement from baseline were randomized into one of the two treatment groups.
Outcomes were defined as global improvement to a cutoff of 70% or greater; changes on the visual analogue scale (VAS: subjective scale ranging 0 – 10, with 0 = no pain/dysfunction and 10 = maximum pain/dysfunction), for pain and function, graduated by tens to a percentage (0-100%); and a Constant score, which reflected combined subjective and objective evaluations of pain and function (Constant and Murley, 1987). Follow-up appointments were at 1, 4, 12, and 24 months. The NFI group experienced improvements in all three outcomes over the course of 24 months as compared to the control group with p values < 0.03 (Maugars et al., 2009; see Appendix B, Table 2). The authors concluded that NFI was effective at removing tendon calcification, decreasing pain, and increasing shoulder function in both the short- and long-term. The terms ‘short-’ and ‘long-term’ were not defined. Intent-to-treat analysis, to account for crossover, was not performed.

Rotator cuff calcific tendonitis: Short-term and 10-year outcomes after two-needle US-guided percutaneous treatment-nonrandomized controlled trial by Serafini et al. (2009)

The final study reviewed was performed by Serafini et al. (2009), who conducted a non-blinded and non-randomized controlled trial in Italy with 219 patients in the treatment group and 68 in the control group. Of the 219 patients in the treatment group, 16 had bilateral shoulder involvement, thus totaling 235 shoulders. The control group was chosen based on their refusal to be treated via needling and lavage and included 68 patients and shoulders. Patient demographics included to gender, age, pain and function scores, hand dominance, affected shoulder and tendon, and the presence of bursitis. Patients with an ipsilateral rotator cuff tear, who had prior lithotripsy, iontophoresis, physical therapy, or local steroid injection(s) were excluded. The mean subject age was
40.3 years, with 86 males and 133 females in the treatment group, and 40.2 years with 31 males and 37 females in the control group. Concomitant bursitis was present in 93% of the treatment group and 90% of the control group. The authors report no significant differences between groups (Serafini et al. 2009).

While the control group received no therapy, the treatment group intervention consisted of ultrasound-guided local anesthesia into the subacromial bursa, deltoid muscle, and subcutaneous tissues followed by needle placement into the calcification with saline irrigation and aspiration via a second needle. Once the aspirate was clear of visible calcium, 1 mL of methylprednisolone acetate was injected into the ipsilateral subacromial bursa.

Outcomes were defined by changes in the VAS and Constant scores representing both subjective and objective markers including pain, function, strength, and ROM. The treatment group reported a significant improvement from baseline, and results showed a significant improvement as compared to the control group at 1 and 3 months, and again at 1 year. At 5 and 10 years there were no significant differences between groups (Serafini et al. 2009; see Appendix B, Table 3.) There was a progressive loss to follow-up for both groups, with 70.6% and 61.8% of the treatment and control groups, respectively, showing for the 1-year appointment. Also, data between 1 and 5 years are absent without explanation.

For follow-up visits up to 1 year, p values were < 0.001. At 5 and 10 years, the p values were 0.795 and 0.413, respectively, for Constant scores and 0.981 and 0.449, respectively, for VAS. The authors concluded that two-needle percutaneous lavage
improved function and decreased pain compared to control for up to 1 year. There was no difference between groups at 5 and 10 years.

DISCUSSION

Limitations

While findings were consistent across the three studies, the methodology in all of them was a critical limiting factor in drawing strong implications for patient care. The most significant methodological issues involve study design (specifically blinding) and use of a control group with randomization, although incomplete data sets for follow-up appointments and/or absent or inadequate patient demographics were notable limitations also. (Guyatt et al., 2008). While it is uncertain to what extent demographics may be a factor in the course of calcific tendinosis, the lack of demographic information in these three studies does raise questions of the applicability of their findings.

Methodology

Historically, observational studies are of low methodological quality in regard to determining cause and association, and for the purpose of making recommendations. However, with a large magnitude of treatment effect, adequate sample size, and statistical accounting for confounding factors, the study quality, and therefore utility, can be significantly improved (Guyatt et al., 2008). The del Cura et al. (2007) study falls squarely within the realm of observational study, but does not compensate by using the above methods and thus provides only low quality, supporting evidence to the overall findings of this review.
Additionally, randomized controlled trials are only useful as high quality evidence if the randomization and analysis of results are strict and methodical. For example, Maugars et al. (2009) allowed for control patients to cross over into the NFI or bursocopy treatment group when they no longer felt they had an overall improvement greater than 70%. Though they were randomized at that point, the control group waned until only six patients remained. For that reason, presumably, group comparison was focused on the 4-month follow-up data. As seen in Table 2 in Appendix B, there is no data for the control group beyond 4 months. This crossover possibly weakened any statistical power the study might have had, and the randomization was of little value beyond comparing the two treatments to one another.

Limitations of the third study, by Serafini et al. (2009), consisted primarily of an absence of blinding and randomization, the latter of which was noted by the authors. While double-blinding is not often an option in interventions requiring procedures, blinding of the provider during follow-up and/or data analysis, or single-blinding, would have lent credence to the study results. Also, while the authors accounted for the confounding factors of rotator cuff tears and prior non-conservative treatment by exclusion from the study, they did not mention demographics concerning job duties or recreational activities, all of which may have influenced the outcomes positively or negatively.

Classifying Calcific Deposits within Tendons

Several studies have made use of existing grading criteria to classify the size and extent of calcific deposits in the tendon structures of patients. When creating patient inclusion criteria for their study, Maugars et al. (2009) used a classification system devised by the French Arthroscopic Society. It describes three types of calcific deposits:
“type A: well-defined limits, dense and homogeneous; type B: well-defined limits and fragmented;” and “type C: heterogeneous calcifications with poorly defined limits” (p. 370). Patients with type C calcifications were excluded from this study due to the tendency for spontaneous resolution without treatment (Maugars et al., 2009).

In a response letter to the editor regarding the article by Serafini et al. (2009), Cacchio and Rompe (2010) point out the absence of classification in the study and suggest the system created by Gartner and Simons (1990), proposing that some of the study’s patients could have been of the type III class, which “showed a high probability of spontaneous resolution” (p. 990). Use of a classification system by Serafini et al. in building exclusion criteria and when analyzing the results would have improved the quality of the study.

Finally, while del Cura et al. (2007) did not use an established classification system, they did describe findings on each patient using the criteria of density and well-defined borders versus irregular or linear shape for radiograph, and an absent or weak shadow versus a strong shadow for ultrasound.

While comparison of results from the three studies is nonetheless possible, if all three studies had used an established classification system for calcific deposits, the usable evidence in each study would have been stronger, and the collective body of evidence regarding this treatment would have also been stronger. Future researchers would do well to consider using a classification system when designing their patient selection criteria and accounting for it in their results to produce usable data that is standardized to a greater degree.
Outcomes and GRADE

In order to complete a standardized evaluation of the three studies, the GRADE system was used (Guyatt et al. 2008). This system classifies evidence into one of four levels that describe its quality – high, moderate, low, or very low. To clarify by example, Guyatt et al. (2008, p. 926) stated the following:

Evidence based on randomised controlled trials begins as high quality evidence, but our confidence in the evidence may be decreased for several reasons, including:

• Study limitations
• Inconsistency of results
• Indirectness of evidence
• Imprecision
• Reporting bias

An observational study, such as a case-control study, would initially be ranked as low quality evidence; however, it could later be ranked higher if it identified a large magnitude of effect, if confounding factors were accounted for, or if a relationship between dose and response were to be discovered (Guyatt et al. 2008). Using the GRADE approach, medical literature may be designed to achieve a high level of quality and existing literature can be systematically evaluated.

The evaluation table in this review uses the GRADE system (see Appendix C, Table 4). It is molded to fit the clinical question at hand; in this case, is needling with irrigation an effective treatment for calcific tendinosis of the rotator cuff? The outcomes, study types, and relevant findings are listed in Table 4, and each study was initially ranked based on its design: the randomized controlled trial received a high ranking, and the observational studies received a low ranking. Each study was then evaluated based on
the following GRADE criteria: an initial high-grade study can lose points based on poor study design and implementation, inconsistency within its results, indirectness in measurement, imprecision in analysis, and/or the presence of publication bias. Conversely, an initial low-grade study can earn points for uncovering a large magnitude treatment effect or a dose-response relationship, and/or adequately accounting for confounding factors (Guyatt et al. 2008). Each study’s grade was then adjusted accordingly and the overall average was determined.

Pain Reduction

All three studies specifically addressed the issue of pain relief in the short- and long-term. The observational study by del Cura et al. (2007) had a starting quality grade of low and did not meet the criteria for an upgrade. The randomized controlled trial by Maugars et al. (2009) started with a high grade, but due to significant crossover of groups without intent to treat analysis, absent follow-up data from the control group, and inadequate participant demographics, it was downgraded to a moderate grade. Finally, the controlled trial by Serafini et al. (2009) began with a starting grade of low due to the absence of randomization, which effectively created an observational study, and did not meet criteria for an upgrade.

Ultimately, all three articles suffered from study-design issues, though Maugars et al. (2009) was the only study to lose points, given that it was the only randomized controlled trial. This is because they started at a higher level of evidence due to the fact that they performed controlled trials rather than observational studies. The final GRADE rank for this outcome across all studies was of low-grade evidence.
Restored Range of Motion and Function

All three studies addressed shoulder ROM and function, though del Cura et al. (2007) was the only one to record ROM separately. Maugars et al. (2009) and Serafini et al. (2009) used the Constant scoring system, which combines ROM and function with subjective grading of pain and function, whereas del Cura et al. (2007) used the SPADI scoring system for measurement. Despite different measurement tools, each study reported data which can be compared, due to the limited methods available to assess ROM and function of the shoulder.

The GRADE evaluation for ROM and function evidence was identical to that of pain. With a starting quality grade of low, del Cura et al. (2007) did not meet the criteria for an upgrade. Maugars et al. (2009) started with a high-grade, but again, due to significant cross over without intent to treat analysis, absent control group follow-up data, and with inadequate demographics, it warranted a downgrade to a moderate grade. As stated above, Serafini et al. (2009) began with a starting grade of low and did not meet the criteria for an upgrade. The final GRADE for this outcome across all studies was of low-grade evidence.

Final GRADE for All Studies and All Outcomes

In summary, the three studies’ grade of low-quality evidence for the outcomes of pain reduction, restoration of shoulder function and ROM, is primarily based on their limitations in study design. The definitions of these GRADE rankings are as follows:

High = further research is very unlikely to change our confidence in the estimate of effect; moderate = further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate; low = further research is very likely to have an important impact on our confidence in the
estimate of effect and is likely to change the estimate; very low = any estimate of
effect is very uncertain (Guyatt et al., 2008, p. 926).

Conclusions

Percutaneous needling with irrigation appears to be a safe and effective
intervention for calcific tendinosis of the rotator cuff in the short and long-term with
success rates comparable to those of other available treatments (Maugars et al., 2009,
Serafini et al. 2009). The intervention is associated with a significant improvement in
shoulder function and decrease in pain compared to that of baseline, up to and possibly
beyond one year, after which any benefit over no treatment is uncertain (del Cura et al.,
2007, Maugars et al., 2009, Serafini et al., 2009). This treatment could be utilized at a
lower cost and with fewer risks than surgical management and provides patients and
practitioners with a reasonable treatment option if conservative therapy fails.

Nevertheless, as stated in the discussion section, the overall methodological
quality of the three studies is low, suggesting “further research is very likely to have an
important impact on our confidence in the estimate of effect and is likely to change the
estimate” (Guyatt et al., 2008, p. 926). Based on this GRADE ranking, no
recommendations will be made other than to point out the need for research that more
methodically compares needling and irrigation of rotator cuff calcific tendinosis to other
treatments and to a control. Furthermore, the body of current evidence would benefit
from research that compares the different methods of percutaneous needle lavage.
REFERENCES


APPENDICES
A. Search Flow Diagram

Articles identified through database searching (n = 159)

Articles screened and remaining (n = 69)

Articles screened and remaining (n = 17)

Articles assessed for eligibility (n = 8)

Studies included in systematic review (n = 3)

Non-English, non-human, and articles older than 2000 excluded (n = 90)

Irrelevant articles excluded (different procedures, etc.) (n = 52)

Duplicates, descriptive articles, and letters to the editor excluded (n = 9)

Systematic reviews and articles before most recent review (2006) excluded (n = 5)
B. Results Tables

Table 1. Outcome Scores for del Cura et al. (2007)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>10-week follow-up</th>
<th>1-year follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPADI Pain Score</td>
<td>56.5</td>
<td>32</td>
<td>17.4</td>
</tr>
<tr>
<td>SPADI Disability Score</td>
<td>43.9</td>
<td>22</td>
<td>12.1</td>
</tr>
<tr>
<td>SPADI Total Score</td>
<td>50.2</td>
<td>27</td>
<td>14.7</td>
</tr>
<tr>
<td>Shoulder ROM</td>
<td>1,039</td>
<td>1,187</td>
<td>1,256</td>
</tr>
<tr>
<td>Pain-free ROM</td>
<td>1.5</td>
<td>28</td>
<td>69</td>
</tr>
</tbody>
</table>

SPADI = Shoulder Pain and Disability Index (Roach, 1991)
0 = no pain or disability
100 = maximum pain or disability
Figures reflect the mean percentage of the respective measure, e.g., 50 = 50% pain, disability, etc.

Table 2. Outcome Scores for Maugars et al. (2009)

<table>
<thead>
<tr>
<th></th>
<th>Raw Score</th>
<th>Percentage of Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>1 Month</td>
</tr>
<tr>
<td>VAS-pain (0-100)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>47.6</td>
<td>nd</td>
</tr>
<tr>
<td>NFI</td>
<td>49.1</td>
<td>-14.3</td>
</tr>
<tr>
<td>Constant Score (0-100)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>70.5</td>
<td>nd</td>
</tr>
<tr>
<td>NFI</td>
<td>67.0</td>
<td>+4.2</td>
</tr>
</tbody>
</table>

nd = no data provided in the article
NFI = needling, fragmentation and irrigation
Results for bursoscopy not shown

Table 3. Outcome Scores for Serafini et al. (2009)

<table>
<thead>
<tr>
<th></th>
<th>1 month</th>
<th>3 months</th>
<th>1 year</th>
<th>5 years</th>
<th>10 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS (0-10)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment</td>
<td>4.8 ± 0.6</td>
<td>3.3 ± 0.4</td>
<td>2.7 ± 0.5</td>
<td>2.6 ± 0.5</td>
<td>2.5 ± 0.6</td>
</tr>
<tr>
<td>Control</td>
<td>9.1 ± 0.5</td>
<td>7.3 ± 1.8</td>
<td>4.5 ± 0.9</td>
<td>2.8 ± 0.7</td>
<td>2.7 ± 0.6</td>
</tr>
<tr>
<td>Constant (0-100)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment</td>
<td>73.2 ± 6.2</td>
<td>90.2 ± 2.6</td>
<td>91.7 ± 3.1</td>
<td>90.9 ± 3.6</td>
<td>91.8 ± 5.0</td>
</tr>
<tr>
<td>Control</td>
<td>57.5 ± 3.9</td>
<td>62.6 ± 7.2</td>
<td>78.4 ± 9.5</td>
<td>90.5 ± 4.8</td>
<td>91.3 ± 9.6</td>
</tr>
</tbody>
</table>

VAS = Visual analogue scale
0 = no pain; 10 = maximum pain
Constant = subjective pain and disability plus objective ROM and strength (Constant and Murley, 1987).
0 = complete impairment of shoulder; 100 = no impairment of shoulder
C. GRADE TABLE

Table 4 shows the outcomes considered in this review, the study types, the summarized findings of the included studies, and the GRADE criteria by which the studies were evaluated. As defined by Guyatt et al. (2008), the definitions of the grades are as follows:

High = further research is very unlikely to change our confidence in the estimate of effect; moderate = further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate; low = further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate; very low = any estimate of effect is very uncertain (p. 926).
<table>
<thead>
<tr>
<th>Comparison</th>
<th>Outcome</th>
<th>Quantity and type of evidence</th>
<th>Findings</th>
<th>Decrease GRADE</th>
<th>Increase GRADE</th>
<th>Grade of Evidence for Outcome (high, moderate, low)</th>
<th>Overall GRADE of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needling with irrigation vs. No treatment</td>
<td>Decreased pain in the short- and long-term</td>
<td>1 RCT, 1 CT, 1 Case Series</td>
<td>Positive (Decreased VAS vs. baseline and control up to 1 yr.)</td>
<td>High -1 0 0 0 0 n/a n/a n/a</td>
<td>Low n/a n/a n/a n/a n/a 0 0 0</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Restored function, strength and ROM in the short- and long-term</td>
<td>1 RCT, 1 CT, 1 Case Series</td>
<td>Positive (Increased Constant vs. baseline and control up to 1 yr.)</td>
<td>High -1 0 0 0 0 n/a n/a n/a</td>
<td>Low n/a n/a n/a n/a n/a 0 0 0</td>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>

RCT = Maugars et al. 2009  
CT (controlled trial, no randomization) = Serafini et al. 2009  
Case Series = del Cura et al. 2007  
VAS = visual analogue scale; 0 = no pain, 10 = maximum pain  
Constant = subjective pain and disability plus objective ROM and strength (Constant & Murley, 1987); 0 = complete impairment of shoulder function, 100 = no impairment of shoulder function