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Lavage treatments for calcific rotator cuff tendinopathy

New trial challenges current treatment paradigms

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Calcific tendinopathy is a painful condition characterized by calcium hydroxyapatite deposition within a tendon, most commonly the shoulder. Many factors are classically thought to be important when considering a treatment regimen, such as duration and severity of symptoms, characteristics of the calcification, and the patient's goals.

Subacromial bursal corticosteroid injection with and without ultrasound guided lavage and shockwave therapy are widely studied interventions, and meta-analyses suggest that ultrasound guided lavage with steroid injection is associated with the greatest clinical benefits. However, interventional studies to date have usually lacked a sham treatment control group. In the linked BMJ paper (doi:10.1136/bmj-2023-076447), Moosmayer and colleagues report their multi-arm, double blinded, sham controlled, randomized controlled trial, conducted in an effort to fill this important evidence gap and challenge the claims of previous interventional trials.

Moosmayer and colleagues should be commended on a well conducted randomized controlled trial, representing one of the largest sample sizes to date (220 patients). Patients were randomized to receive ultrasound guided lavage plus subacromial injection with 20 mg triamcinolone and 9 mL of 1% lidocaine (lavage+steroid), sham lavage plus the same subacromial injection (sham lavage+steroid), or sham lavage plus subacromial injection of 10 mL of 1% lidocaine only (sham). Lavage was done using a single needle technique. Participants in all groups were asked to start a home exercise program within a week of treatment, comprising four shoulder exercises twice daily.

Contrary to the results of previous systematic reviews, ⁴⁵ Moosmayer and colleagues found no significant differences among the three groups in scores on the Oxford Shoulder Scale at four month follow-up (primary outcome), and these null findings persisted at 24 months. Although the rate of calcium resolution was higher in the lavage+steroid group compared with the other two groups at four months, this did not seem to affect functional outcome scores.

Additionally, scores on the Oxford Shoulder Scale were similar between patients with no radiographic change in deposit size and those with calcium resolution. In a subgroup of 124 participants with large calcium deposits (≥12.5 mm), the authors also found no differences between treatment groups, although the trial was not powered for this analysis. In secondary analyses, treatment groups that included a steroid injection reported better pain relief than the sham group two and six weeks after treatment, but notably the improvements at four months were no different than sham.

The authors conclude that participants had similar functional outcomes at four and 24 months regardless of treatment received, calcification resolution after treatment, or initial calcification size, but with better short term pain relief among those who received corticosteroids.

The location, size, and density of calcium deposits, and radiographic classifications, have previously been implicated as factors contributing to treatment response. In the linked study, groups were comparable with respect to Mole classification of deposits (types A, B, or C); with type C being the least frequent. Mole type C calcifications are heterogenous with soft contours, and softer less dense calcifications have been reported to respond better to lavage. 6-9 However, the prevalence of radiologically evident calcification in asymptomatic shoulders has been reported to be 7.5-20%. 10 Moreover, evidence suggests that many patients will eventually report improvement of symptoms regardless of initial radiographic characteristics or degree of calcium removed. 6 11 Moosmayer and colleagues further substantiate this finding.

Treatments should aim to improve a patient's pain and function. This study and others suggest that clinicians and patients should focus less on resolution of calcium deposit as an indicator of successful treatment, at least with our current radiographic classification systems. Routine radiographic follow-up to monitor calcium deposit characteristics and guide additional treatment steps may be unnecessary and increase costs. More research is needed to determine whether ultrasonographic classification systems are better able to predict treatment response.

Another consideration when interpreting these results is symptom duration. The mean duration of symptoms across the three groups approached three years. Longer duration of symptoms before lavage interventions has been associated with inferior outcomes, with an increasingly higher odds ratio of treatment failure for each additional month of symptoms. ¹² Moosmayer and colleagues' study population may represent a group with particularly recalcitrant symptoms, and outcomes might have differed had lavage been done earlier in the course of their symptoms.

In summary, this important study challenges the clinical utility of a common intervention, ultrasound guided lavage, currently considered to be evidence driven and therefore best practice in the care of patients struggling with chronic symptomatic calcific rotator cuff tendinopathy. Moosmayer and colleagues found no additional benefit of lavage over sham treatment at four and 24 months. However,

concluding that ultrasound guided lavage or subacromial corticosteroid injection no longer has a role in treating calcific tendinopathy of the shoulder would be premature. These new findings will inform discussions with patients and provide some reassurance to those with a similar, long symptomatic course that time will help and corticosteroids may facilitate short term pain relief. Lavage seems to be overused and may not be as effective as we thought, and better patient selection criteria are needed.

Futureinterventional studies should include a sham control group, assess treatment response earlier in the symptomatic course, and explore whether ultrasonographic classification systems can better predict treatment response. Most importantly, a better understanding of the pathophysiology of pain in this condition is critical for optimizing care. Lastly, we cannot forget that many patients diligently followed their home exercise program, future non-interventional studies comparing a "wait and see" approach with therapeutic exercise would be beneficial.

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- Arirachakaran A, Boonard M, Yamaphai S, Prommahachai A, Kesprayura S, Kongtharvonskul J. Extracorporeal shock wave therapy, ultrasound-guided percutaneous lavage, corticosteroid injection and combined treatment for the treatment of rotator cuff calcific tendinopathy: a network meta-analysis of RCTs. Eur J Orthop Surg Traumatol 2017;27:-90. doi: 10.1007/s00590-016-1839-y pmid: 27554465
- Lafrance S, Doiron-Cadrin P, Saulnier M, etal. Is ultrasound-guided lavage an effective intervention for rotator cuff calcific tendinopathy? A systematic review with a meta-analysis of randomised controlled trials. *BMJ Open Sport Exerc Med* 2019;5:e000506. doi: 10.1136/bmjsem-2018-000506 pmid: 31191964
- Moosmayer S, Ekeberg OM, Hallgren HB, etal. Ultrasound guided lavage with corticosteroid injection versus sham lavage with and without corticosteroid injection for calcific tendinopathy of shoulder: randomised double blinded multi-arm study. BMJ 2023;383:e076447.
- Wu YC, Tsai WC, Tu YK, Yu TY. Comparative Effectiveness of Nonoperative Treatments for Chronic Calcific Tendinitis of the Shoulder: A Systematic Review and Network Meta-Analysis of Randomized Controlled Trials. Arch Phys Med Rehabil 2017;98:-1692.e6. doi: 10.1016/j.apmr.2017.02.030.pmid: 28400182
- 5 Zhang T, Duan Y, Chen J, Chen X. Efficacy of ultrasound-guided percutaneous lavage for rotator cuff calcific tendinopathy: A systematic review and meta-analysis. *Medicine (Baltimore)* 2019;98:e15552. doi: 10.1097/MD.000000000015552 pmid: 31124934
- Vassalou EE, Klontzas ME, Plagou AP, Karantanas AH. Ultrasound-guided percutaneous irrigation of calcific tendinopathy: redefining predictors of treatment outcome. *Eur Radiol* 2021;31:-43. doi: 10.1007/s00330-020-07334-2 pmid: 33040221
- Ogon P, Suedkamp NP, Jaeger M, Izadpanah K, Koestler W, Maier D. Prognostic factors in nonoperative therapy for chronic symptomatic calcific tendinitis of the shoulder. *Arthritis Rheum* 2009;60:-84. doi: 10.1002/art.24845 pmid: 19790063
- Farin PU, Räsänen H, Jaroma H, Harju A. Rotator cuff calcifications: treatment with ultrasound-guided percutaneous needle aspiration and lavage. Skeletal Radiol 1996;25:-4. doi: 10.1007/s002560050133 pmid: 8865489
- 9 Chianca V, Albano D, Messina C, etal. Rotator cuff calcific tendinopathy: from diagnosis to treatment. Acta Biomed 2018;89(1-S):-96,pmid: 29350647
- Speed CA, Hazleman BL. Calcific tendinitis of the shoulder. N Engl J Med 1999;340:-4. doi: 10.1056/NEJM199905203402011 pmid: 10332023
- 11 Cho NS, Lee BG, Rhee YG. Radiologic course of the calcific deposits in calcific tendinitis of the shoulder: does the initial radiologic aspect affect the final results?/ Shoulder Elbow Surg 2010;19:-72. doi: 10.1016/j.jse.2009.07.008 pmid: 19800263
- de Witte PB, van Adrichem RA, Selten JW, Nagels J, Reijnierse M, Nelissen RGHH. Radiological and clinical predictors of long-term outcome in rotator cuff calcific tendinitis. *Eur Radiol* 2016;26:-11. doi: 10.1007/s00330-016-4224-7 pmid: 26945760