To: Editors BMJ, Letter to the Editor/ Rapid Response
From: Gerard Koel, Bart Oudelaar, Jan Louwerens
Concerning: **Response to RCT Moosmayer, BMJ 2023; 383: e076447** (See reference list 1).
3 Pages, 515 words, 1 table and reference list (15 references), December 2023.

Dear Editors

Thank you for publishing the high quality randomized controlled trial by Moosmayer et al. (1), comparing the outcome between ultrasound guided lavage with corticosteroid injection and sham lavage with and without corticosteroid injection in patients with calcific tendinopathy (CT) of the rotator cuff. This study concluded that ultrasound guided lavage with a corticosteroid injection or sham lavage with a corticosteroid injection is not superior compared with sham treatment. Only small and short-term between-group differences in favour of the two treatment groups (lavage with corticosteroid injection and sham lavage with corticosteroid injection) compared to the sham treated patients were found. Interesting is the limited overall treatment effect in the lavage with corticosteroid injection group. In table 1 these results (1) are compared to the results of nine other studies (2-10). Although different outcome measures and follow-up terms were used, it is clear that the KALK-trial patients perform worse.

Study, number of patients real barbotage (+ injection)	Follow up period months Measurement	Results
Del Cura, 2007, n= 65 Observational study	12 months; ROM; SPADI (3 scales), size of deposit	SPADI total: 50 to 14 (> 3*MCID); Full active ROM: 69%; Gone: 78,1%
De Conti, 2010, n= 68 Observational study	6 months CMS, MRI	CMS: 30 to 78 (> 3* MCID) MRI showed normal tendons
Yoo, 2021, n= 35 Observational study	6 months; CMS, Radiology: size of deposit	CMS: 53 to 87 (> 3* MCID) size decreased from 13 mm to 7 mm
De Witte, 2013, n= 23 Part of an RCT-study	12 months; CMS, Radiology: size of deposit	CMS: 71 to 86 (> MCID); Radiology: decrease: 95%, Gone: 56%
Oudelaar, 2016, n= 431 Observational study	6 months; NRS, interview complete relief Y/N, PASS	Complete relief: 74% of 431 patients Decrease NRS: 4,3 points; PASS: 65%
Moosmayer, 2018, n= 52 Observational study	3 & 24 months; radiology ASES: > 17 points=success	3 months: Decrease: 52%; Gone: 27% 24 months: 62% success (= > MCID)
Darrieutort-L., 2019, n=65 Part of an RCT-study	3 months: VAS $_{activity}$ DASH; Radiology: size.	VAS $_{activity}$ 72 to 44 (2* MCID); DASH 51 to 32 (2* MCID); Gone (>90%): 46%
Louwerens, 2020, n= 41 Part of an RCT-study	6 months, CMS, VAS $_{average}$ Radiology: size of deposit	CMS: 66 to 88 (> 2*MCID); VAS: 6 to 3 (2*MCID), Gone: 68%
Oudelaar, 2021, n=39 Part of an RCT-study	12 months: NRS, CMS, Radiology: size deposit	NRS: 55 to 20 (>2* MCID); CMS 62 to 78 (1,5* MCID); Gone: 66%
Moosmayer, 2023, n= 73 Part of an RCT-study	4 months; OSS, VAS $_{activity}$ Radiology: size of deposit	OSS: 29 to 33 (< 1* MCID), VAS: 6 to 4 (1,5* MCID); Gone: 45%

Table 1: Results of barbotage/ lavage with corticosteroid injection in ten clinical studies.
Legenda: *ROM: Range Of Motion; CMS: Constant Murley score (0-100; higher = better); SPADI: Shoulder Pain And Disability Inventory (0-100; higher = worse); MCID: Minimal Clinical Important Difference; Gone: complete disappearance calcific deposits; PASS: Patient Acceptable Symptomatic State (NRS lower than 3 was considered as PASS); NRS: Numeric (Pain) Rating Scale; ASES: American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; VAS: Visual Analogue Scale (average pain score last week); DASH: Disabilities Arm Shoulder Hand (0-100; higher = worse);*
>: larger than; <: smaller than; OSS: Oxford Shoulder Score (0-48; higher = better).

We believe this difference can be explained by limitations in the in- and exclusion criteria. At baseline only a limited number of included patients had received proper conservative treatment: (shoulder?) physiotherapy (30%), steroid injection (11%) and physiotherapy with injection or ESWT (18%). This is important to note because the first step in the treatment of calcific tendinopathy is treating the present dysfunctions (for example pain, motor control, self-efficacy, health perceptions and ADL-functioning) in first line health care. Missing inclusion criteria were a positive isometric resistance test to justify the diagnosis tendinopathy, no attention for the interpretation about signs validating that the calcification in the tendon was symptomatic and not mentioning possible relevant non-somatic dysfunctions in this population with mean symptom duration of 32 months. Some non-somatic dysfunctions should lead to a, non-mentioned, exclusion criterium.

Ogon et al (11) showed that 73% of CT patients (n=420) are successfully treated conservatively. In the 'Dutch' clinical setting we respect these stricter inclusion criteria and find ultrasound guided needling to be a safe and effective treatment to help patients with refractory symptoms due to CT after proper first line healthcare focussed upon dysfunctions (5,6,9,10,12). These findings are supported by recent reviews (13-14). Furthermore, we consider short-term (<6 months) clinical improvement relevant for CT patients who are often of working age and deal with sick leave and a limited ability to work due to their shoulder complaints (15).

Thanks to the comprehensive KALK study by Moosmayer et al (1) we are even more aware of the fact that ultrasound guided lavage is not the proper treatment for all CT patients and that the majority of patients should be treated with conservative treatment options. But to conclude that there is no indication for ultrasound guided lavage in the treatment of patients with refractory CT is, we believe, not correct. Ultrasound guided lavage should however be reserved for patients who have persistent symptoms despite a proper conservative treatment, without signs of resorption of the calcific deposit. We believe future studies should focus on identifying patient prognostic factors that influence the course of CT. If the KALK trial teaches us anything, it is that determining the right treatment indication for the right CT patients remains a big challenge.

A response from:

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Hengelo, the Netherlands, 30th December 2023

References.

1. **Stefan Moosmayer, Ole Marius Ekeberg, Hanna Björnsson Hallgren, Ingar Heier, Synnøve Kvalheim, Niels Gunnar Juel, Jesper Blomquist, Are Hugo Pripp, Jens Ivar Brox. 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.**
2. Del Cura JL, Torre I, Zabala R, Legórburu A. Sonographically guided percutaneous needle lavage in calcific tendinitis of the shoulder: short- and long-term results. AJR Am J Roentgenol; 2007; 189: W12834.
3. De Conti G, Marchioro U, Dorigo A, et al. Percutaneous ultrasound-guided treatment of shoulder tendon calcifications: Clinical and radiological follow-up at 6 months. J Ultrasound; 2010; 13:188-98.
4. Yoo JC, Koh KH, Park WH, Park JC, Kim SM, Yoon YC. The outcome of ultrasound-guided needle decompression and steroid injection in calcific tendinitis. J Shoulder Elbow Surg; 2010; 19:596-600.
5. De Witte PB, Selten JW, Navas A, Nagels J, Visser CPJ, Nelissen RGHH, e.a. Calcific tendinitis of the rotator cuff: a randomized controlled trial of ultrasound-guided needling and lavage versus subacromial corticosteroids. Am J Sports Med. juli 2013;41(7):1665-73.
6. Oudelaar BW, Schepers-Bok R, Ooms EM, Huis In 't Veld R, Vochteloo AJH. Needle aspiration of calcific deposits (NACD) for calcific tendinitis is safe and effective: Six months follow-up of clinical results and complications in a series of 431 patients. Eur J Radiol. April 2016;85(4):689-94.
7. Moosmayer S, Aasen IB. Ultrasound Guided Percutaneous Needle Treatment and Steroid Injection for Calcific Tendinopathy of the Shoulder: Can the Orthopedic Surgeon, do it? Matthews J Orth2018; 3:1-8.
8. Darrieutort-Laffite C, Varin S, Coiffier G, Albert JD, Planche L, Maugars Y, e.a. Are corticosteroid injections needed after needling and lavage of calcific tendinitis? Randomised, double-blind, non-inferiority trial. Ann Rheum Dis. June 2019;78(6):837-43.
9. Louwerens JKG, Sierevelt IN, Kramer ET, Boonstra R, van den Bekerom MPJ, van Royen BJ, et al. Comparing Ultrasound-Guided Needling Combined with a Subacromial Corticosteroid Injection Versus High-Energy Extracorporeal Shockwave Therapy for Calcific Tendinitis of the Rotator Cuff: A Randomized Controlled Trial. Arthroscopy. Juli 2020;36(7):1823-1833.e1.
10. Oudelaar BW, Huis In 't Veld R, Ooms EM, Schepers-Bok R, Nelissen RGHH, Vochteloo AJH. Efficacy of Adjuvant Application of Platelet-Rich Plasma After Needle Aspiration of Calcific Deposits for the Treatment of Rotator Cuff Calcific Tendinitis: A Double-Blinded, Randomized Controlled Trial With 2-Year Follow-up. Am J Sports Med. maart 2021;49(4):873-82.
11. Ogon P, Suedkamp NP, Jaeger M, Izadpanah, K, Koestler W, Maier D. (2009). Prognostic factors in nonoperative therapy for chronic symptomatic calcific tendinitis of the shoulder. Arthritis & Rheumatism, 60 (10), 2978-2984.
12. Koel G, Louwerens JKG, Niemeijer – Blokvoort J (Dutch Article). Fysiotherapie bij SAPS-patiënten met een calcificerende tendinopathie. Physios, December 2022, 4:49-60.
13. 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 Apr;27(3):381-390.
14. Lafrance S, Doiron-Cadrin P, Saulnier M, Lamontagne M, Bureau NJ, Dyer JO, Roy JR, Desmueles F. 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-2018-000506:1-8.
15. Louwerens JKG, Kuijer PPFM, Sierevelt IN, Van den Bekerom MPJ, Van Royen BJ, Eygendaal D, Van Noort A. The impact of minimally invasive treatment for rotator cuff calcific tendinitis on self-reported work ability and sick leave. Artroscopy, Sports Medicine and Rehabilitation, vol2, 6 (December), 2020:821-827.