

Specific Question:

What is the clinical effectiveness of extracorporeal Shock Wave Therapy or barbotage in the management of rotator cuff calcific tendinopathy?

Clinical bottom line

There is moderate evidence that shock wave therapy and barbotage are safe procedures. There is limited evidence to suggest it is effective for rotator cuff calcific tendinopathy. Of the two interventions, available limited evidence suggests barbotage may be more effective than shockwave.

Why is this important?

Calcific tendonopathy commonly affects supraspinatus and infraspinatus muscles of the rotator cuff in adults aged 30 to 60 years, with females more commonly affected (Oliva et al., 2011; Louwerens et al., 2015). Calcific deposits (Hydroxyapatite) have been reported to exist in 43% of patients with sub-acromial pain syndrome (Louwerens et al., 2015). Calcific deposits also exist in patients without shoulder pain, but the prevalence of this is much lower (8%) (Louwerens et al., 2015). It is unclear why the calcification occurs, and why in some cases it causes little to no problem and or spontaneously resolves while in other instances, leads to ongoing pain and limited function. It has been reported that intrinsic factors (location of calcific deposits in supraspinatus, multiple tendon involvement, size of the deposit) and extrinsic factors (age, diabetes and high body mass index) are factors that correlate with pain and chronicity (Olva et al., 2011; Sansone et al., 2016).

In cases where calcific tendinopathy of the shoulder is persistent it can be a disabling condition affecting an individual's function and wellbeing. In these instances, options for interventions generally include activity modification, anti-inflammatory medication, physiotherapy, injections of steroid and anaesthetic, extracorporeal shock-wave therapy (ESWT), barbotage (ultrasound guided dry needling with or without lavage) or surgery. Surgery is indicated if other non-surgical options have failed (Funk, 2018).

Historically, the consultant radiologist at Queen's Hospital, provided barbotage. With his departure from the Trust, it was recognised that to continue the service provision, musculoskeletal physiotherapists and/ or radiographers would need to be trained to provide this intervention. It was also of interest to evaluate whether ESWT could be considered a preferred alternative to manage this condition. It was understood that there was a need to evaluate the evidence to support whether barbotage or ESWT were clinically effective and safe interventions for patients with rotator cuff calcific tendinopathy to justify the additional training costs and costs associated with either service provision.

Getting Evidence into Clinical Practice: Barbotage for calcific cuff tendinopathy
Musculoskeletal Research Facilitation Group (CAT Group)

Date: 25.7.18

Search timeframe (e.g. January 2009- September 2017)

Inclusion Criteria

	Description	Search terms (In the final document this should be a combination of your clinical and librarian search terms)
Population and Setting	Adults (18 years or over)	Calcific tend*, shoulder, rotator cuff
Intervention or Exposure	Extracorporeal shock wave therapy; barbotage.	Barbotage, ultrasound guided lavage, extracorporeal shockwave therapy; barbotage, ESWT.
Comparison, if any	Placebo, control, comparative intervention	<i>(no search terms used for this category)</i>
Outcomes of interest	Pain Function Cost Risk	<i>(no search terms used for this category)</i>
Types of studies	RCT, SLR, Cohort	Randomi* controlled trial, RCT, Randomi* trial, systematic literature review, SLR.

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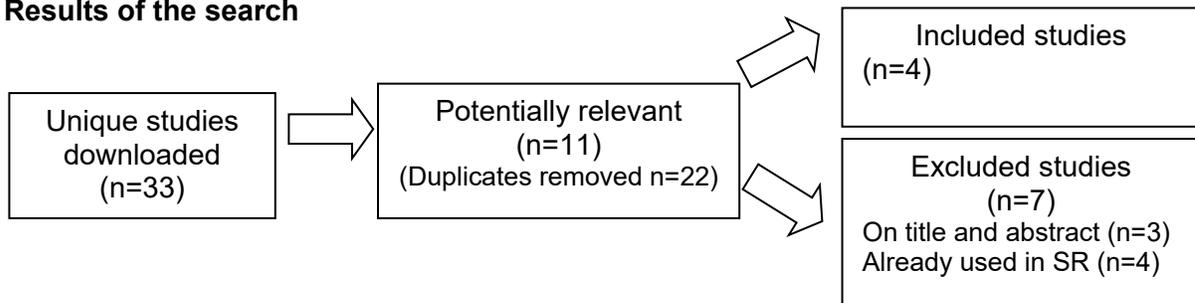
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Routine Databases Searched

Medline (n=7), Cinahl (n=6), Embase (n=20), AMED (n=0). Total papers found n=33. Of these 22 were duplicates. Of the 11 remaining, 3 were excluded on title and abstract: protocol only (n=1), conference abstract (n=1), study of case series (n=1). Four of the papers were systematic reviews (SR) and two included network meta-analyses. The remaining four RCTs were included in at least one of the SLRs and therefore not included in this review to avoid duplication.

Date of search- 25th September 2017

Results of the search



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Table 1- Detail of included studies

First Author, year and type of study	Population	Intervention or exposure tested	Study results	Assessment of quality and comments
Gatt et al. (2014) SR	Studies (n=13) Patients (n=908) Mean age 40-63 years	Experimental group: Barbotage The majority of the studies did not use a comparator intervention, placebo or control. One study compared barbotage to needling without aspiration.	Pain (VAS, NRS, verbal descriptions): 'marked improvement in nearly all the scores'. Pain and function (Constant, SPADI, L'Insalata): 'marked improvement in nearly all the scores'. Cost: No reports on cost-effectiveness Risk: Complications were reported in 5 papers. Overall complication rate was 7%, however all were minor. The two most consistently complications were mild vagal reactions (fainting) and the development of sub-acromial bursitis	Positive comments: Non-English language papers included (translated). Complications were reported. Negative comments: Heterogeneity in chronic and acute presentations (one week to 3 years). None of the studies included were RCTs (all were observational studies). Inconsistent follow-up points used making between-study comparison difficult. Mixed technique used for barbotage between studies. Dose of barbotage was not consistent e.g. once to three times depending on study. No meta-analyses possible.
Lanza et al. (2015) SR	Studies (n=15) Patients (n= 1,403) Mean age 40-63 years Unresponsive to previous interventions to the shoulder	Experimental group: Barbotage The SR did not compare any outcomes to placebo, control or comparative intervention.	Pain and function (Constant, SPADI, ASESS, DASH, Shoulder and hand questionnaire, WORC, Western Ontario rotator cuff index, L'Insalata, VAS): Mean weighted pain/disability improvement in 80% of treated patients was 55% (1223 of the patients). There was a trend for reduce treatment effect over time, but details regarding this were not clear. Cost: No reports on cost-effectiveness	Positive comments: Complications were reported Negative comments: Mixed technique used for barbotage between studies. Majority of studies included were not RCTs. No meta-analyses possible.

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	Calcification larger than 3mm		<p>Risk: Complications were reported in 10 papers. Overall complication rate was 10%. Most consistently reported were sub-acromial bursitis (7%) and mild vagal reactions (2%). Two patients were reported to have seizures (0.2%) and one patient to have lost consciousness (0.1%).</p>	
Arirachakaran et al. (2017) SR with Network meta-analyses	<p>Studies RCTs (n=7)</p> <p>Patients (n= unknown)</p> <p>Mean age unknown</p>	<p>Experimental group:</p> <p>Barbotage v</p> <p>ESWT v</p> <p>Sub acromial injection or placebo</p>	<p>Pain (VAS)- pooled data on 5 studies:</p> <ul style="list-style-type: none"> • ESWT reduced pain more than placebo by mean difference -4.4 (95%CI -6.3,-2.3) • ESWT alone reduced pain less than ESWT with barbotage by mean difference 1.3 (95%CI 0.9,1.7) <p>Pain and function (Constant)- pooled data on 5 studies:</p> <ul style="list-style-type: none"> • ESWT improved pain and function more than placebo by mean difference 23.3 (95%CI 9.8, 17.6) • ESWT with barbotage improved pain and function more compared to SWT alone- mean difference - 9.4 (95%CI -18.5,-0.5). • Barbotage improved pain and function more than SAI mean difference -12.1 (95% CI -20.6, - 3.6) <p>Re-absorption rate: ESWT was reported to reduce the size of the calcium deposits compared to placebo but this did not</p>	<p>Positive comments:</p> <p>Good systematic review procedures were followed (PRISMA method used) Follow-up period between 4 months to 2 years. Most followed up at one year. Network meta-analyses.</p> <ul style="list-style-type: none"> • Results for ESWT compared to placebo reached a positive statistical and clinically meaningful difference for pain and function. • Results for barbotage compared to SAI reached a positive statistical and clinically meaningful difference for pain and function. <p>Negative comments:</p> <p>Mixed technique used for barbotage between studies.</p> <ul style="list-style-type: none"> • The results for ESWT with barbotage for pain and function compared to ESWT alone may have been statistically significant (in favour of the barbotage) but did not meet a clinically meaningful difference.

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			<p>reach a statistically significant difference.</p> <p>Cost: No reports on cost-effectiveness</p> <p>Risk- pooled data from 7 studies:</p> <ul style="list-style-type: none"> • Barbotage and SAI had lower occurrences of adverse effects than placebo ($p < 0.05$). • ESWT had the highest reports of adverse effects compared to placebo (18%), but this did not reach a statistically significant level ($p > 0.05$). 	
<p>Yi-Cheng et al. (2017) SR with Network meta-analyses</p>	<p>Studies RCTs (n=14)</p> <p>Patients (n= 1105)</p> <p>Mean age unknown however all patients were aged 18 years or over</p>	<p>Experimental group:</p> <p>Barbotage (dry needling) v</p> <p>ESWT v</p> <p>US, TENS v</p> <p>control (defined as sham treatment or physiotherapy alone)</p>	<p>Pain (VAS)- pooled data on 8 studies:</p> <ul style="list-style-type: none"> • The greatest improvement reported for reduction in pain of all interventions compared to control was Barbotage which reduced pain more than control by mean difference 8.0 (95%CI 5.0,11.1). • The modality that was ranked the best in terms of pain reduction was barbotage (94.2%) followed by ESWT. <p>Pain and function (Constant)- 0 studies:</p> <p>Barbotage was not included in the network meta-analyses for function</p> <ul style="list-style-type: none"> • The modality that was ranked the best in terms of pain reduction was ESWT (93.9%). <p>Re-absorption rate from 14 studies:</p> <ul style="list-style-type: none"> • Barbotage had a higher odds 	<p>Positive comments:</p> <p>Good systematic review procedures were followed (PRISMA method used)</p> <p>Follow-up period 6 months after treatment (or the closest point to 6 months available- range 3-7 months).</p> <p>Barbotage was specific to dry needling only to avoid heterogeneity.</p> <p>The Egger test found no evidence of small study bias. Network meta-analyses.</p> <ul style="list-style-type: none"> • Barbotage ranked the highest in terms of reducing pain. • Barbotage was better for reabsorption compared to comparators. <p>Negative comments (recognised by the authors):</p> <p>Barbotage was not included in the meta-analyses for shoulder function.</p> <p>There was no true 'no treatment' group. Most patients involved in the RCTs were likely to have received either physiotherapy or medication for their</p>

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			<p>ration compared to the control group 6.84 (95% CI 3.78,9.90)</p> <ul style="list-style-type: none"> The modality that was ranked the best in terms of re-absorption was barbotage. <p>Cost: No reports on cost-effectiveness</p> <p>Risk: Risk was not included in a meta-analysis. One of the RCTs on barbotage reported a 5% risk of minor vagal reaction.</p>	<p>problem that could not be accounted for. There was possible heterogeneity in the amount and grade of calcification in patients. No long term outcomes (>6 months) analysed.</p> <ul style="list-style-type: none"> Although results for barbotage were statistically better than control, this did not reach a clinically meaningful difference.
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Key: ASESS= American Shoulder and Elbow Surgeons Score; DASH= Disability of arm shoulder and hand questionnaire; ESWT= Extracorporeal shock wave therapy; NRS= numerical rating score; SAI= sub-acromial injection; SR=systematic review; PT= physiotherapy; US= Ultrasound; VAS= visual analogue scale; WORC= Western Ontario rotator cuff index).

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Summary

There have been consistent reports from low quality studies that the use of barbotage is effective in reducing pain and improving function with a low level of risk for minor complications (<10%) and very low risk of moderate complications (0.3%).

The network meta-analyses reported findings to support effectiveness for ESWT and barbotage. However it is important to note that there were significant limitations in the methodologies of the network meta-analyses studies and, when provided, confidence intervals were wide and in some instances, not clinically significant. It appears that the high estimates of effects from one or two RCTs (potentially biased) were driving the network meta-analyses and could have resulted in potential bias in the ranking of effective interventions. The cost of both barbotage and ESWT need to be carefully considered. They involve expensive equipment and training resources. The administration costs have yet to be determined. The risk from barbotage and ESWT are reported to be low however data is limited. Patient preference and acceptability for one intervention over another also needs to be investigated.

Implications for Practice/research

From current evidence, barbotage and ESWT are generally safe procedures, but not completely without risk. Overall there is moderate evidence that these interventions can reduce pain, improve function and aid re-absorption of calcification, Clinical decision making will need to consider the available evidence, patient preference and clinical expertise. Both barbotage and ESWT are likely to be less costly than surgical alternatives. Future research on cost-effectiveness is required to determine overall feasibility of using barbotage or ESWT in conservative management. It is not known which stage of the condition or category of calcification (in terms of density level) barbotage or ESWT are most useful for. It is unknown how acceptable barbotage or ESWT are to patients compared to other treatment modalities.

What would you tweet? (140 characters)

@theCSP There is moderate evidence that #Barbotage and ESWT are safe, reduce pain & improve function for rot cuff #calcific #tendinopathy. Further research is needed to ascertain efficacy and cost-effectiveness for different stages of the condition and patient preference.

****Footnote:** Clinically meaningful differences have been reported as 20mm (Michener et al., 2011) on a VAS pain score for shoulder pain and 11 points for the constant score (Høytrup et al., 2015).

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Levels of Evidence

1	Strong evidence	Consistent findings in multiple high-quality RCTs
2	Moderate evidence	Consistent findings in one high-quality RCT and in one or more low-quality RCTs, or consistent findings in multiple low-quality RCTs
3	Limited evidence	Only one RCT (of high or low quality)
4	Conflicting evidence	Inconsistent findings in multiple RCTs

Source: After Van Tulder *et al.* (2000), cited in Rozen *et al.* (2004)