Getting Evidence into Clinical Practice:
Musculoskeletal Research Facilitation Group (CAT Group)
Date: February 2017

Specific Question:
'In adults with adhesive capsulitis (frozen shoulder) does the use of distension injections improve pain, function and range of movement when compared to lower volume, steroid injections?'

Clinical bottom line

There is a lack of high quality evidence to inform a change in current practice. The evidence available does not demonstrate a superiority of distension type injections over low-volume steroid injections. The available studies vary methodologically and often the processes and procedures studied do not reflect clinical practice, limiting applicability of results. The available evidence should be used clinically with caution.

Why is this important?

It is widely known that the NHS is, and shall remain under significant pressure in terms of maintaining and improving current levels of care in a background of financial restriction with increasing patient demand. All possible avenues to improve clinical effectiveness need to be explored, whilst exploiting cost savings, without compromising the quality of patient care delivered.

There is moderate evidence that arthrographic distension with saline and steroid provides short-term benefits in pain, range of movement and function in patients with adhesive capsulitis. See previous CAT:
https://www.keele.ac.uk/media/keeleuniversity/group/evidencebasedpractice/catbank/Distention.pdf

What is less clear is if there is a significant difference between this intervention and that of a standard, intra-articular (into the joint, and lower total volume) steroid injection.

A distension- type injection is typically done under ultrasound guidance, by a radiographer trained in injection therapy. Guided injections are more costly than that of a clinically guided injection, so this also has financial implications to the NHS. There exists national variance on the wait times for guided injections (locally upwards of 3 months) which ultimately prolongs the patient journey, implicating upon the wider economy and importantly patient experience.

Should there not be a significant difference between a distension and normal injection for the treatment of frozen shoulder it would be appropriate to offer a clinically guided, standard steroid injection first, before referring for a guided distension injection, on a stepped care approach. This would ultimately mean patients could be treated more quickly, reducing the pressure on radiology referrals and have a cost saving impact, which would be of a wider benefit to the NHS and other NHS users.

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Search timeframe 2006-2016

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 with frozen shoulder***	Adult, frozen shoulder, adhesive capsulitis, stiffness
Intervention or Exposure	High-volume-guided intra-articular injection	Steroid, intra- articular, local anaesthetic, high volume, hydrodilatation, arthrographic distension
Comparison, if any	Clinically guided standard steroid injection.	Steroid injection, intra-articular injection, clinician guided, blind, local anaesthetic
Outcomes of interest	**Pain, range of motion, function**	Visual/ Verbal analogue scale Function SPADI DASH
Types of studies	RCTs, systematic reviews.	

Exclusion:

Shoulder (gleno-humeral joint) osteo-arthritis (OA),fractures, malignancy. Sub-acrimial injections. Children (under age 18)

Routine Databases Searched

Clinical Knowledge Summaries, PEDro, BMJ Updates, Clinical Evidence, TRIP, Database, NICE, HTA, Bandolier, The Cochrane Library, Medline, Cinahl, Embase, PsycInfo, Professional websites. Joanna Briggs Institute, Web of Science, Sports Discus and Pub Med

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Results of the search

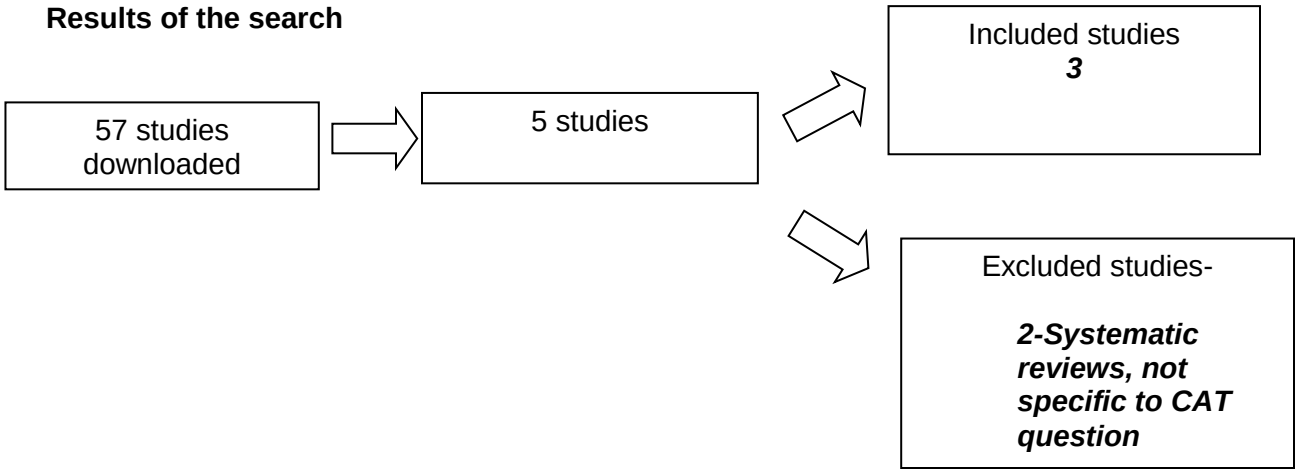

Table 1- Detail of included studies

First Author, year and type of study	Population and setting	Intervention or exposure tested	Study results	Assessment of quality and comments
Sharma (2016) RCT with 3 arms. 2 intervention, 1 control	**Adults, over 18 of age, no diabetes. No imaging pre-intervention. !06 participants (35 inject, 34 inject and distension, 36 treatment- as-usual)**	**Steroid and local anaesthetic (LA) Vs Steroid and saline Vs Treatment As Usual (TAU- no injections, advice). Injections were clinically guided. 33% of TAU group had injections after 8-week. Inject given day 1, after 7, 17 and 31**	**At 12/12 F/U no difference between all 3 groups. No statistically significance between steroid and distension at 4-8 weeks for ROM or SPADI**	**No between group baseline differences** **Block randomisation** **Excellent retention at 95% for 1-yr follow up** **Intervention does not reflect clinical practice of repeat distension injections (4- with 8-20ml volume)** **Non-image guided distension**

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				injections **No ROM for 1 yr F/U**
Tveita (2008) RCT	**Norway- 76 participants (39 in dilation (DIL), 3 excluded, 37 in steroid (ST) group, 4 excluded)**	**High volume 20ml total Vs low-volume steroid injection 8-10ml volume** **20mg triamcinolone each group** **3 injections 2 weeks apart for each group**	**No significant difference between DIL or ST** **Authors state cannot conclude that DIL is of no benefit stating an RX effect of DIL cannot be excluded due to CI not excluding a minimally clinical difference** **6 did not need intervention as condition improved- reflection of inclusion criteria** **In ST group with the volume used ? some distension achieved- rupture occurred in 4 participants. Whilst exclusion criteria state reduced ROM for reasons including RC tear, methodology does not state if excluded in all participants. XR for humeral up-slip only, NO USS**	**Low quality method for randomisation and Open trial- no blinding for injections- introduces bias** **Underpowered study** **Additional wait before initial intervention** **Robust inclusion/ exclusion criteria** **Variable time frame of condition – impact on expected outcome?** **All injections guided** **Capsular rupture achieved in 35/36 in DIL group and 4 in ST group** **Analysis using ITT** **Short 6-week follow up** **? reasoning for serial distension injections- not reflected clinically**

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Yoon (2016) RCT	**164 patients identified. 74 excluded, 30 allocated to each group.** **Clear inclusion criteria, 6/12-1 year of symptoms.** **OA, RC tear, calcification. DM included.**	**High volume (45ml) (DIL) vs low volume (10ml) intra-articular (IA) Vs sub-acromial injection (10ml) (SA)** **All 40mg Triamcinolone**	**Early improvements in DIL vs IA and SA group, but no difference at 6 months between all groups.** **No difference between SA and IA injection**	**Power calculations met- BUT low numbers generally** **No between group-baseline differences.** **Block computer randomisation** **Assessor but not patients blinded.** **Compliance to rehab programme not verified**

Summary

There is a lack of high quality evidence to inform a change in current practice. The available studies vary in what volume, dosages and frequency of injections are utilised. The methodology often does not reflect clinical practice further limiting the utility of the findings. This is in a background of methodological issues ranging from poor randomisation, under-powered studies due to small participant numbers and lack of blinding.

The available evidence should be used clinically with caution due to the above mentioned methodological limitations.

The available evidence does not demonstrate a superiority of distension type injections over low-volume steroid injections, however there is a clear need to corroborate these findings with higher quality evidence.

Implications for Practice/research

There exists variability in the inclusion and exclusion criteria utilised in the included studies, limiting comparability. Often these criteria do not reflect clinical practice. In addition, studies exclude diabetic patients, which as an attempt to control confounders is justifiable, however, this does not reflect clinical practice for which this patient sub-group comprises a significant proportion of patients encountered with adhesive capsulitis.

Furthermore, studies often use serial injections for both low volume and distension injections, again in contrast to clinical practice. This potentially dilutes the research findings in the respective studies and limits extrapolation of results into clinical practice.

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Additional well-designed research studies are required, to absolutely determine if arthrographic distension is, or is not more effective than steroid alone. In addition the design of future studies need to explore if treatment affects are due to the volume injected or steroid, given that steroid is often used across intervention groups.

Furthermore, there may exist a time-sensitivity for high volume or steroid alone when considering the natural progression of adhesive capsulitis, of which there is a paucity in the current literature exploring this notion specifically.

What would you tweet? (140 characters)

More high quality research required to explore outcomes of high Vs low vol. inj for frozen shoulder. Is it steroid or volume??

References

Buchbinder R, Green S, Youd J M, Johnston R V, Cumpston M. (2008) Arthrographic distension for adhesive capsulitis (frozen shoulder). Cochrane Database of Systematic Reviews. Issue 1.

Sharma S P, Bærheim A, Moe-Nilssen R, Kvåle A. (2016) Adhesive capsulitis of the shoulder, treatment with corticosteroid, corticosteroid with distension or treatment-as-usual; a randomised controlled trial in primary care. 17: 232 https://www.ncbi.nlm.nih.gov/pubmed/27229470

Tveita E K, Tariq R, Sesseng S, Juel N G, Bautz-Holter E. (2008) Hydrodilatation, corticosteroids and adhesive capsulitis: a randomized controlled trial. BMC Musculoskeletal Disorders.;9:53 https://www.ncbi.nlm.nih.gov/pubmed/18423042

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Yoon J P, Chung S W, Kim J E[1], Kim H S, Lee H J, Jeong W J, Oh K S, Lee D O, Seo A, Kim Y. (2016) Intra-articular injection, subacromial injection, and hydrodilatation for primary frozen shoulder: a randomized clinical trial. Journal of shoulder and Elbow Surgery. 25(3):376-83 https://www.ncbi.nlm.nih.gov/pubmed/26927433

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