Centre for Reviews and Dissemination

Frozen shoulder

The management of frozen shoulder: a systematic review and cost-effectiveness analysis

- Frozen shoulder is a painful condition in which movement of the shoulder can become severely restricted, usually taking one to three years to resolve.
- There are several treatment options available but no current consensus about the overall management of the condition.
- There was limited evidence on the effectiveness of treatments for primary frozen shoulder.
- Based on data from two RCTs, there may be short-term benefit from adding a single intra-articular steroid injection to home exercise, for patients with primary frozen shoulder of less than six months duration.
- There may also be benefit, in the same population, from adding physiotherapy to a single steroid injection.
- There are large gaps in the evidence for the effectiveness and cost-effectiveness of all the interventions investigated.

BACKGROUND

Frozen shoulder is a painful condition in which movement of the shoulder can become severely restricted, usually taking one to three years to resolve. The condition can impact on working life, leisure and general quality of life. It is estimated that frozen shoulder affects between 2% and 5% of the general UK population at some time and is most common amongst people in their 50's.

Frozen shoulder is typically characterised as having three overlapping phases:[1] a painful phase, where there is progressive stiffening and loss of motion in the shoulder with increasing pain on movement; a stiffening or 'freezing' phase, where there is a decrease in pain but range of movement remains restricted; and a resolution phase where range of movement improves. However, there is a lack of precise diagnostic criteria for the condition and a lack of consensus about the stages and what the condition should be called.

There are several treatments available; however there is uncertainty about which are the most effective and when they should be provided. The less invasive options are generally tried first (see Box 1).

The aims of treatment, depending on stage of condition, are pain relief, increasing arm movement, reducing the duration of symptoms and return to normal activities for the patient. Management of the condition commonly takes place in the primary care setting, though there is little information on referral patterns.[2] An estimated 22% of patients with shoulder complaints are referred to secondary care, most within three months.[3]

There is no current consensus about the overall management of the condition.[4]

Box 1: Current treatment options

- Watchful waiting
- Physiotherapy
- Acupuncture
- Steroid injection
- Arthrographic distension (injection of saline or other solution to expand the shoulder capsule and free up the joint)
- Mobilisation of the shoulder joint while under general anaesthesia
- Capsular release (surgical procedure to release contracted tissue).

NATURE OF THE EVIDENCE

This short report is based on a systematic review and cost-effectiveness analysis funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) programme.5 The main focus of the review was on comparing the treatment options for frozen shoulder and identifying the most appropriate treatment by stage of frozen shoulder. Full methodological details are given in the HTA report.[5]

FINDINGS

Thirty-two studies were included in the review, 28 were RCTs, one of which included a cost-utility analysis. Five of the studies were undertaken in the UK. There was considerable variability between studies within each of the interventions of interest e.g. injection dose, duration and intensity of treatment, and especially in terms of physiotherapy and home exercise programmes. Overall the quality of the studies was poor.

Watchful waiting

A single non-randomised controlled study of "watchful waiting" found a significant improvement in function and disability with watchful waiting compared to physiotherapy at three months and up to 24 months.[6] Several factors could have biased this result in particular the use of a two successive cohorts rather than an RCT, and differences in the pain threshold for exercises.

Physical therapy

Twelve studies investigated a physical therapy, 11 were forms of physiotherapy. The comparators were either another form of physiotherapy and/or a control group.

Based on single studies with some risk of bias, there was evidence of benefit with laser therapy compared to placebo;[7] short wave diathermy compared to home exercise;[8] and physiotherapy compared to home exercise for more than one outcome.[9] The majority of studies comparing two active interventions reported no significant difference in outcome between therapies. For the two studies that did report a benefit with one intervention over another, this was not consistent across outcomes.[8, 10]

Acupuncture

Three studies compared acupuncture to another treatment.[11-13] All had a high risk of bias. Based on the only study with a time horizon of >4 weeks, there was no statistically significant difference between electroacupuncture and inferential electrotherapy in pain or function and disability at short, medium or long-term follow-up.[12]

Steroid injection

Six RCTs evaluated steroid injection, but the majority of the usable data was from two multi-arm studies of satisfactory quality.[14-15] Both studies evaluated a single intra-articular steroid injection in patients with frozen shoulder of less than six months duration. The comparators were home exercise alone, physiotherapy alone (both with placebo injection) and steroid injection followed by physiotherapy.

For pain there was a short-term benefit with steroid injection compared to placebo (pooled SMD -1.15, 95% CI -1.62 to -0.67) but no evidence of benefit when compared to physiotherapy (pooled SMD -0.22, 95% CI -0.65 to 0.20). The results for function and disability and range of movement were broadly consistent with the results for pain from these two studies. When steroid injection was provided in conjunction with physiotherapy,

there was an added benefit for pain over physiotherapy alone (pooled SMD -0.98, 95% CI -1.43 to -0.52) and over steroid injection alone (pooled SMD -0.75, 95% CI -1.20 to -0.29). There was substantial heterogeneity for the latter analysis but the results of both studies were in the same direction. These statistically significant changes are also probably clinically significant, though data from a different population was used to estimate clinical significance. The results for other outcomes were broadly consistent with the results for pain.

Sodium hyaluronate

Three RCTs investigating sodium hyaluronate were all at high risk of bias and provided insufficient evidence to support any conclusions about effectiveness.[9, 16-17] One study reported a benefit with two injections of sodium hyaluronate compared to home exercise across more than one outcome; the same study reported there was no difference between sodium hyaluronate and physiotherapy or steroid injection across more than one outcome.[9] There was conflicting evidence from two other studies.

Distension

Three RCTs investigated distension with steroid injection.[18-20] One study of satisfactory quality reported a significant improvement with arthographic distension including steroid compared to placebo arthrography in one of two function and disability measures.[18] However, there was no evidence of benefit for range of movement or pain. A second study, with some risk of bias, compared arthrographic distension including steroid to steroid alone. There was benefit with distension for a single range of movement measure at six weeks. There was no evidence of benefit for other outcomes.[20] The third study, which had a high risk of bias, reported no differences between groups for a single outcome.[19]

Manipulation under anaesthesia

Four RCTs investigated manipulation under anaesthesia (MUA) in the treatment of primary frozen shoulder.[21-24] The MUA procedure was described in three of the RCTs[21-23] and was performed by a physician[22] or, in the two UK studies, by an orthopaedic surgeon.[21, 23] In two studies participants received a steroid injection in conjunction with MUA; one of 30mg[21] and one of 80mg.[24] Each of the studies had a different comparator. The inclusion criteria varied between studies in terms of extent of restriction of movement.[21-22, 24] A single, satisfactory quality study compared MUA to home exercise alone. There was no significant difference between groups in pain, function and disability, range of movement or working ability at short, medium or long-term follow-up.[22] A study with some risk of bias, compared MUA to arthrographic distension. There was greater improvement in pain and function and disability at six months with arthrographic distension than with MUA in participants with 'adhesive' stage primary frozen shoulder.[21]

Capsular release

Two case series of more than 50 participants were identified that investigated capsular release.[25-26] There was evidence of benefit in function and disability and range of movement from both studies. However, the lack of a control group presents particular problems in assessing the effectiveness of an intervention in a condition such as frozen shoulder where the condition normally resolves within a one to three year period.

Cost-utility study of mobilisation techniques

A cost-utility analysis[27] conducted as part of a clinical study compared high-grade mobilisation techniques (HGMT) (passive manipulation within the stiffness zone) with low-grade mobilisation techniques (LGMT) (passive manipulation within the pain-free zone), in a Dutch frozen shoulder population.[10] The measure of benefit used in the economic analysis was quality adjusted life years (QALYS); these were based on the SF-6D utility index values which were estimated using SF-36 data collected alongside the study. The average estimated QALYs were 0.695 for HGMT and 0.702 for LGMT. The difference of 0.007 in favour of LGMT was reported to be not statistically significant (p=0.71: 95% CI: -0.32 to 0.049). The total reported average annual societal costs were €8,809 for HGMT and €6,911 for LGMT (a cost difference of €1,898 in favour of low-grade mobilisation). The difference in costs was also reported to be not statistically significant (p=0.37: 95% CI: €-2551 to €5711). The authors concluded that the economic analysis does not allow for evidence based recommendation regarding the preferred treatment.

Whilst there were limitations in the analysis, there is an indication that LGMT may be a more cost-effective option than HGMT. Overall, despite the limitations the analysis was of reasonable quality and the results, whilst uncertain, provide an indication that LGMT may be a more cost-effective option than HGMT. A full assessment of this economic evaluation is available in the HTA report.[5]

Due to evidence limitations no economic modelling was undertaken as part of the HTA.

IMPLICATIONS FOR PRACTICE

Based on data from two RCTs, there may be short-term benefit from adding a single intra-articular steroid injection to home exercise, for patients with primary frozen shoulder of less than six months duration. There may also be benefit, in the same population, from adding physiotherapy (including mobilisation in eight to 10 sessions over four weeks) to a single steroid injection.

IMPLICATIONS FOR FUTURE RESEARCH

There are large gaps in the evidence for the effectiveness and cost-effectiveness of all the interventions investigated. The lack of high quality research on watchful waiting is surprising given it is a commonly used treatment in frozen shoulder.[4]

The large number of treatment options for frozen shoulder and the limited evidence for their effectiveness and cost-effectiveness makes prioritisation of areas for future research challenging. We suggest that an appropriate starting point would be a multi-arm trial that compares the effectiveness and cost-effectiveness of interventions of differing intensity and costs: high quality conservative management, steroid injection (possibly in conjunction with arthrographic distension) and surgical management (manipulation under anaesthesia and capsular release).

Any future trials should give more serious attention to the control group used. Home exercise (with or without a placebo) was the most commonly reported control in the included studies. However, in general the content of this control intervention was poorly reported. There is a large gap in the evidence about the effectiveness of a high quality conservative intervention of education, home exercise and self-management of pain with support and monitoring. Any future trial should pay careful attention to the control condition to clearly establish what additional benefit other interventions provide. We suggest it should involve a structured protocol of high quality education, advice, home exercise and monitoring. In addition, the maximum length of follow-up in most studies was three months. Future trials should therefore have follow up periods that are of sufficient length to allow determination of whether interventions are effective in the medium and long term. The inclusion of preference-based quality of life measures alongside clinical trials in frozen shoulder populations is a necessity as is a more thorough assessment of adverse events.

REFERENCES

1. Dias R, Cutts S, Massoud S. Frozen shoulder. *BMJ* 2005;331:1453-6.
2. Dawson J, Shepperd S, Carr A. An overview of factors relevant to undertaking research and reviews on the effectiveness of treatment for frozen shoulder. *Shoulder & Elbow* 2010;2:232–37.
3. Linsell L, Dawson J, Zondervan K, Rose P, Randall T, Fitzpatrick R, et al. Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. *Rheumatology* 2006;45:215-21.
4. Dennis L, Brealey S, Rangan A, Rookmoneea M, Watson J. Managing idiopathic frozen shoulder: a survey of health professionals' current practice and research priorities. *Shoulder & Elbow* 2010;2:294-300.
5. Maund E, Craig D, Suekarran S, Neilson AR, Wright K, Brealey S, et al. Management of frozen shoulder: a systematic review and cost-effectiveness analysis. *Health Technology Assessment* 2012;16(11):1-243.
6. Diercks RL, Stevens M. Gentle thawing of the frozen shoulder: a prospective study of supervised neglect versus intensive physical therapy in seventy-seven patients with frozen shoulder syndrome followed up for two years. *Journal of Shoulder & Elbow Surgery* 2004;13:499-502.
7. Stergioulas A. Low-power laser treatment in patients with frozen shoulder: preliminary results. *Photomedicine and Laser Surgery* 2008;26:99-105.
8. Leung MSF, Cheing GLY. Effects of deep and superficial heating in the management of frozen shoulder. *Journal of Rehabilitation Medicine* 2008;40:145-50.
9. Calis M, Demir H, Ulker S, Kirnap M, Duygulu F, Calis HT. Is intraarticular sodium hyaluronate injection an alternative treatment in patients with adhesive capsulitis? *Rheumatology International* 2006;26:536-40.
10. Vermeulen HM, Rozing PM, Obermann WR, le Cessie S, Vliet Vlieland TPM. Comparison of high-grade and low-grade mobilization techniques in the management of adhesive capsulitis of the shoulder: randomized controlled trial. *Physical Therapy* 2006;86:355-68.
11. Fang J-Q, Zhang Y, Xuan L-H, Liu K-Z, Chen L. [Observation on clinical therapeutic effect of transcutaneous point electric stimulation on periarthritis of shoulder at different stages]. *Zhongguo Zhenjiu* 2006;26:11-4.
12. Cheing GLY, So EML, Chao CYL. Effectiveness of electroacupuncture and interferential eloctrotherapy in the management of frozen shoulder. *Journal of Rehabilitation Medicine* 2008;40:166-70.
13. Ma T, Kao MJ, Lin IH, Chiu YL, Chien C, Ho TJ, et al. A study on the clinical effects of physical therapy and acupuncture to treat spontaneous frozen shoulder. *American Journal of Chinese Medicine* 2006;34:759-75.
14. Carette S, Moffet H, Tardif J, Bessette L, Morin F, Fremont P, et al. Intraarticular corticosteroids, supervised physiotherapy, or a combination of the two in the treatment of adhesive capsulitis of the shoulder: a placebo-controlled trial. *Arthritis & Rheumatism* 2003;48:829-38.
15. Ryans I, Montgomery A, Galway R, Kernohan WG, McKane R. A randomized controlled trial of intra-articular triamcinolone and/or physiotherapy in shoulder capsulitis. *Rheumatology* 2005;44:529-35.
16. Rovetta G, Monteforte P. Intraarticular injection of sodium hyaluronate plus steroid versus steroid in adhesive capsulitis of the shoulder. *International Journal of Tissue Reactions* 1998;20:125-30.
17. Takagishi K, Saito A, Segawa K, Takahira N, Itomitu S. Evaluation of intra-articular injection in patients with so-called Gojyukata: comparison hyaluronate and steroid. *Japanese Journal of Medicine & Pharmaceutical Science* 1996;35:377-81.
18. Buchbinder R, Green S, Forbes A, Hall S, Lawler G. Arthrographic joint distension with saline and steroid improves function and reduces pain in patients with painful stiff shoulder: results of a randomised, double blind, placebo controlled trial. *Annals of the Rheumatic Diseases* 2004;63:302-9.
19. Gam AN, Schydlowsky P, Rossel I, Remvig L, Jensen EM. Treatment of "frozen shoulder" with distension and glucorticoid compared with glucorticoid alone. A randomised controlled trial. *Scandinavian Journal of Rheumatology* 1998;27:425-30.
20. Tveita EK, Tariq R, Sesseng S, Juel NG, Bautz-Holter E. Hydrodilatation, corticosteroids and adhesive capsulitis: a randomized controlled trial. *BMC Musculoskeletal Disorders* 2008;9:53.
21. Quraishi NA, Johnston P, Bayer J, Crowe M, Chakrabarti AJ. Thawing the frozen shoulder. A randomised trial comparing manipulation under anaesthesia with hydrodilatation. *Journal of Bone & Joint Surgery - British Volume* 2007;89:1197-200.
22. Kivimaki J, Pohjolainen T, Malmivaara A, Kannisto M, Guillaume J, Seitsalo S, et al. Manipulation under anesthesia with home exercises versus home exercises alone in the treatment of frozen shoulder: a randomized, controlled trial with 125 patients. *Journal of Shoulder & Elbow Surgery* 2007;16:722-6.
23. Jacobs LG, Smith MG, Khan SA, Smith K, Joshi M. Manipulation or intra-articular steroids in the management of adhesive capsulitis of the shoulder? A prospective randomized trial. *Journal of Shoulder & Elbow Surgery* 2009;18:348-53.
24. Amir-Us-Saqlain H, Zubairi A, Taufiq I. Functional outcome of frozen shoulder after manipulation under anaesthesia. *Journal of the Pakistan Medical Association* 2007;57:181-5.
25. Austgulen OK, Oyen J, Hegna J, Solheim E. [Arthroscopic capsular release in treatment of primary frozen shoulder]. *Tidsskrift For Den Norske Laegeforening* 2007;127:1356-8.
26. Chen S-K, Chien S-H, Fu Y-C, Huang P-J, Chou P-H. Idiopathic frozen shoulder treated by arthroscopic brisement. *Kaohsiung Journal of Medical Sciences* 2002;18:289-94.
27. van den Hout WB, Vermeulen HM, Rozing PM, Vliet Vlieland TPM. Impact of adhesive capsulitis and economic evaluation of high-grade and low-grade mobilisation techniques. *Australian Journal of Physiotherapy* 2005;51:141-9.

This short report is based on a systematic review commissioned by the NIHR HTA programme as project number HTA 09/13/02. The systematic review is published in full as Health Technology Assessment 16(11) and can be downloaded free of charge from the HTA website at http://www.hta.ac.uk/2160.