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ORIGINAL STUDY

Frozen shoulder : long-term outcome following arthrographic distension

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Arthrographic distension of the glenohumeral joint was adopted as a mainstream treatment for frozen shoulder before any randomised controlled trials were performed. Interpretation of the effectiveness of this procedure rests mostly on data from cohort studies of which there are few of high quality. Papers reporting long-term results have either excluded diabetic patients or failed to report patient orientated outcomes. The authors present a long-term prospective cohort study of 51 patients (12 diabetics and 39 non-diabetics), with 53 frozen shoulders, who had an arthrographic distension performed by a single radiologist as a primary intervention. Oxford shoulder score (OSS), visual analogue pain score (VAS), and range of movement (ROM) were recorded pre-distension, at 2 days and 1 month post-distension. OSS and VAS were recorded again at a mean of 14 months post distension (range : 8-26 months). OSS improved from a pre-distension mean of 22.3 by 16.9 points at final follow-up ($p < 0.001$, 2 tailed paired samples t-test) whilst VAS improved from a mean pre-distension value of 7.1 by -3.5 ($p < 0.001$). ROM improved by a mean of 39.3 degrees in flexion, 55.2 degrees in abduction and 19.5 degrees in external rotation at one month ($p < 0.001$ for all). The outcome in diabetic patients was the same as in non-diabetic patients. Arthrographic distension is a safe and effective treatment for frozen shoulder ; it is also effective in diabetic patients. It gives long-term improvement. The authors believe that the low number of patients requiring a secondary procedure makes arthrographic distension preferable to manipulation under anaesthesia.

Keywords : frozen shoulder ; adhesive capsulitis ; arthrographic distension ; hydrodilatation ; diabetes mellitus.

INTRODUCTION

Spontaneous shoulder pain characterised by restricted active and passive shoulder movements in the absence of a pathological cause is extremely common in orthopaedic practice. Despite this there is little consensus regarding the pathophysiology, classification, optimal treatment or even nomenclature of this condition which we will call frozen shoulder.

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The diagnosis of frozen shoulder is based on the clinical history and examination after other causes of shoulder pain have been excluded (*15*). Frozen shoulder has an incidence of 3-5% in the general population (*2*) and up to 20% in diabetics (*18*). Although early studies suggested that it is a self limiting condition lasting for an average of 2-3 years (*14*), later studies have found that up to 40% of patients have persistent symptoms and restricted movement beyond 3 years, with 15% left with permanent disability (*11,16*).

Multiple treatments have been utilised for frozen shoulder, including analgesics, rest, physiotherapy, manipulation under anaesthesia, corticosteroid injections, oral steroids, arthrographic distension of the capsule and arthroscopic or open surgical release (*8*). Patients who do not improve after initial conservative measures are generally treated with intra-articular corticosteroid injections, arthrographic distension or manipulation under anaesthesia.

Arthrographic distension of the glenohumeral joint capsule leading to capsular rupture was first described as a treatment of the painful, stiff shoulder by Andren and Lundberg in 1965 (*1*). It is perhaps surprising that a procedure described over 50 years ago is widely considered to be an acceptable first line intervention for frozen shoulder despite having such a small evidence base to support it. One of the major problems with studying distension procedures is that the treatment gained widespread acceptance prior to full validation, and it is now both controversial and difficult to recruit patients into placebo controlled trials. A recent Cochrane review (*4*) found only five randomised controlled trials which looked at the outcome of arthrographic distension for frozen shoulder and only one of these trials compared arthrographic distension to placebo. This placebo controlled trial reported improved range of motion, pain scores and patient orientated outcomes, but follow-up stopped after 3 months (*3*). The other 4 randomised controlled trials were deemed to be at high risk of bias with a limited ability to draw conclusions from their data (*6,9,11,13*). The Cochrane review (*4*) concluded that there is only "silver" level evidence that arthrographic distension with saline and steroid provides short-term benefits in pain, range of movement and function in frozen shoulder and that no conclusions from the existing RCT's can be made on the long-term outcome.

The null hypothesis of the current study was that arthrographic distension of the glenohumeral joint does not provide a sustained benefit in shoulder function and pain scores in patients with a diagnosis of frozen shoulder.

MATERIALS AND METHODS

Patient selection

The authors conducted a prospective cohort study of patients undergoing arthrographic distension by a consultant musculoskeletal radiologist (FP) for treatment of frozen shoulder over an 18-month period, from June 2009 to January 2011. Each patient had initially been referred by one of 3 orthopaedic specialists with extensive experience treating patients with glenohumeral joint problems. The diagnosis was made from the clinical picture of shoulder pain lasting over six weeks with associated nocturnal pain and loss of active and passive motion in at least two planes with particular loss of external rotation. Each patient was reassessed by a specialist musculoskeletal physiotherapist (CD) who confirmed their eligibility for the study using the criteria shown in Table I.

Distension procedure

The patient was placed in the supine position on the screening table, and the affected shoulder was cleaned with antiseptic solution (Tisept : 0.015% weight/volume chlorhexidine gluconate BP and 0.15% weight/volume centrimide Ph). The arm was held in external rotation to clear the biceps tendon from the needle path, and a suitable skin entry site was marked using fluoroscopy. Local anaesthetic was injected into the skin and down the anticipated needle pathway (Xylocaine with epinephrine 1:200,000). A 19G needle was then inserted, and intra-articular needle placement was confirmed with iodinated contrast material injection (Fig. 1).

Ten ml of lidocaine 1% and 40 mg (diabetic patients) or 80 mg (non-diabetic patients) of Kenalog (triamcinolone) were then injected into the joint. Subsequently, the joint capsule was distended with up to 40 ml of warmed saline, until the plunger became difficult to depress or the patient complained of pain. From this point a few more millilitres of saline were injected and the pressure was

Table I. — Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Pain for over 6 weeks • Nocturnal pain • Restriction of active and passive motion in two or more planes, > 30° • Age over 18 • Able to attend local follow-up	• Previous arthrographic distension • Systemic inflammatory joint disease • Radiological evidence of osteoarthritis, fracture or tumour • Calcification about the shoulder joint • Confirmed or suspected rotator cuff tear • Contraindications to arthrography and /or distension including allergy to local anaesthetic or iodinated contrast • Pregnancy

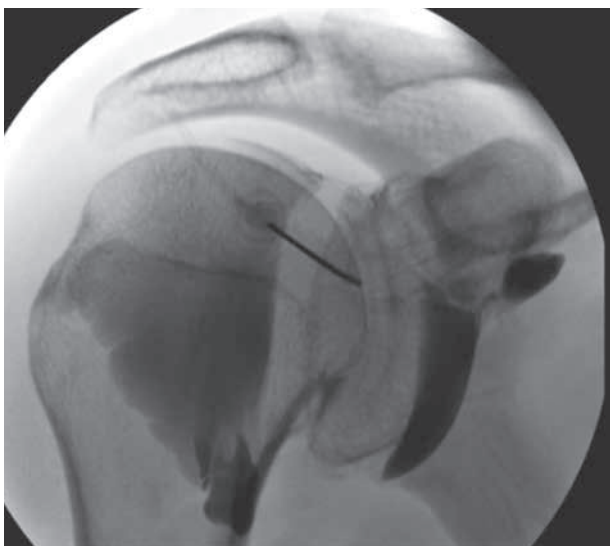

Fig. 1. — The characteristic arthrographic appearance of frozen shoulder showing reduced joint volume and no filling of the inferior capsular recess.

then released to allow backflow into the syringe. This process was repeated until all the saline was injected to a total capacity of 52 ml or until capsular rupture was felt with a sudden loss of capsular pressure and with relief of discomfort.

Post-distension procedure

Each patient had one dedicated session with a trained physiotherapist (CD), who told him/her how to perform a standardised set of stretches consisting of 4 different movements. These stretches were to be repeated 5 times daily, each stretch lasting 30 seconds. An information leaflet was handed over. It gave explicit instructions on how and when to perform each activity, and it stressed the importance of adhering to the physiotherapy regime.

Outcome Measures

Outcome measures were recorded immediately pre-distension, 2 days post-distension, 1 month post-distension and finally in September 2011 at a mean of 14 months post-distension (range, 8-26 months). Exception : final range of motion was evaluated at one month.

Functional capacity was considered to be the most important outcome and as such the Oxford shoulder score (OSS) formed the primary outcome measure. The OSS is a self administered, shoulder-specific, fixed-item index consisting of 12 questions, each graded from 0 to 4. The final score is graded 0-48 with a lower score indicating increased pain and disability. The OSS has high internal consistency, is reproducible and has acceptable test-retest reliability (*7*).

As far as pain was concerned, a visual analogue score (VAS) was used (0-10, with 10 the most severe pain imaginable). The visual analogue pain score has been validated as an accurate tool to distinguish moderate and severe pain (5).

Abduction, forward flexion and external rotation were assessed by a single physiotherapist (CD). Visual estimation was used to measure the range of movement as this method has been shown to be as accurate as goniometry when used by an experienced clinician (*10*).

Disturbance of sleep was ascertained via a questionnaire. A positive disturbance was documented only if sleep was disturbed at least one night in the past week as a direct result of shoulder pain. For inclusion the patient had to report difficulty getting to sleep, interruption of sleep or additional analgesics to aid sleep. Other causes of insomnia were excluded.

Adverse effects and complications were recorded from direct questioning and a review of the patient notes, in duplicate (RC, AR), on the final day of assessment in September 2011. Possible adverse events were : allergic reaction, aborted procedure due to pain, local cellulitis, septic arthritis and hypoglycemia.

Statistical Analysis

The data were compiled onto a secure database (Microsoft Excel 2008) and analyzed using SPSS 19.0 (SPSS Inc., Chicago, Illinois). Oxford shoulder scores, visual analogue pain scores, and range of movement were analyzed using a 2-tailed paired samples t-test for comparison of means which did not assume equal variances. Sleep disturbance was evaluated with the McNemar's test. The p value for rejection of the null hypothesis was set at 0.05.

RESULTS

A total of 51 consecutive patients with frozen shoulder underwent a distension arthrogram performed by one consultant musculoskeletal radiologist (FP). Bilateral procedures were performed on one male and one female giving a total of 53 procedures. There were 22 females and 29 males with a mean age of 52 (range : 34-75). The left shoulder was affected in 31 cases and the right in 22. In 23 patients the dominant limb was affected. Onset of frozen shoulder was secondary to trauma in 5 patients, following surgery in 2 and insidious in the remainder. A total of 12 patients (24%) were diabetic, of whom 6 (50%) were insulin dependent. The one-month follow-up was attended by all 51 patients, and 39 patients (41 shoulders, 82%) received further assessment. Indeed, 3 non-diabetic patients were excluded from the final analysis in September 2011. One patient had died from an unrelated cause, one had undergone a second distention procedure, and one had received an arthroscopic capsular release after the 1-month follow up. Nine other patients (including one diabetic) were not contactable during final follow-up in September 2011 and were considered lost to follow-up.

There was a strongly significant improvement in all outcome measures at each time point when compared with pre-distension values (Table II). The mean OSS recorded immediately pre-distension

Table II. — Outcome measures before and after arthrographic distension

Outcome and timing	Number of participants (number of shoulders)	Mean (95% CI)	Mean change from baseline values (95% CI)	Significance of difference from baseline (2 tailed)
OSS pre	51 (53)	22.3 (20.1-24.4)	/	/
OSS 2d	51 (53)	31.1 (28.2-33.9)	+8.8 (6.4-11.3)	p < 0.001
OSS 1m	51 (53)	36.5 (33.5-39.4)	+14.2 (11.7-16.8)	p < 0.001
OSS latest	39 (41)	39.2 (36.1-42.3)	+16.9 (13.2-18.9)	p < 0.001
VAS pre	51 (53)	7.1 (6.5-7.7)	/	/
VAS 2d	51 (53)	5.3 (4.6-6.0)	-1.8 (-1.2 / -2.4)	p < 0.001
VAS 1m	51 (53)	3.1 (2.4-3.9)	-4.0 (-3.1 / -4.9)	p < 0.001
VAS latest	39 (41)	3.6 (2.6-4.6)	-3.5 (-2.5 / -4.6)	p < 0.001
Flex pre	51 (53)	110.1° (103.6°-116.6°)	/	/
Flex 2d	51 (53)	130.8° (122.9°-138.7°)	+20.7° (14.1-27.2)	p < 0.001
Flex 1m	51 (53)	149.4° (142.6°-156.2°)	+39.3° (32.7-46.0)	p < 0.001
Abd pre	51 (53)	79.3° (70.6°-88.1°)	/	/
Abd 2d	51 (53)	115.9° (105.1° - 126.6°)	+36.5° (27.8-45.3)	p < 0.001
Abd 1m	51 (53)	134.5° (124.9°-144.1°)	+55.2° (45.2-65.2)	p < 0.001
ER pre	51 (53)	11.5° (8.4°-14.7°)	/	/
ER 2d	51 (53)	22.6° (18.7°-26.5°)	+11.1° (7.6-14.5)	p < 0.001
ER 1m	51 (53)	31.0° (26.8°-35.4°)	+19.5° (15.9-23.1)	p < 0.001

(OSS = Oxford shoulder score ; VAS = visual analogue pain score ; Flex = flexion ; Abd = abduction ; ER = external rotation).

was 22.3 with a mean improvement of 8.8 points at day 2, 14.2 points at 1 month and 16.9 points at final follow-up (2 tailed paired samples t-test, $p < 0.001$ in each case). Before arthrographic distension there were no patients with a normal or near normal OSS (OSS 40-48) ; 22 of 51 patients (43%) reported severe symptoms (OSS 0-19). At one month post-distension 28 of 51 patients (55%) had regained a normal or near normal condition, with 6 having severe complaints. The improvement in OSS was maintained long-term (mean 14 months) with 26 of 41 (63.4%) reporting a normal or near normal condition and 4 having severe complaints.

The mean visual analogue pain score pre-distension was 7.1 (indicating severe pain). Two days post-distension there was a statistically significant reduction of 1.8 points giving a mean score of 5.3 (moderate pain). By 1 month the mean score had significantly improved to 3.1 (mild pain) and this was maintained over the long-term (mean 14 months) with a final follow-up visual analogue pain score of 3.6 (2 tailed paired samples t-test, $p < 0.001$).

The improvement in ROM was highly significant (2 tailed paired samples t-test, $p < 0.001$) for all movements at 2 days and at 1 month. Flexion improved from a mean of 110.1 degrees pre-distension with 20.7 degrees at day 2 and with 39.3 degrees at 1 month. Abduction improved from a mean of 79.3 degrees pre-distension with 36.5 degrees at day 2 and with 55.2 degrees at 1 month. External rotation improved from 11.5 degrees pre-distension with 11.1 degrees at day 2 and 19.5 degrees at 1 month.

There was a significant reduction in the number of patients reporting disturbed sleep from 39 pre-distension to 6 at 1 month ($p < 0.001$).

Outcome in diabetic patients was comparable to non-diabetic patients (table III), but diabetics had significantly higher pain scores at presentation ($p = 0.048$) and significantly reduced external rotation ($p = 0.049$) one month post-distension.

One patient developed septic arthritis after the distension procedure. This required an emergent arthroscopic washout and an extended course of antibiotics. One distension procedure was aborted because the patient was unable to tolerate the procedure due to pain. Both patients were included in the final analysis. No other complications or adverse effects were reported.

DISCUSSION

Rarity of long-term studies

The only randomised controlled trial comparing arthrographic distension to placebo has been performed by Buchbinder *et al* (*3*). Although they concluded that there was a benefit of arthrographic distension with normal saline and corticosteroid over placebo in the short term (12 weeks), they had no long-term results. They noted that it was extremely difficult to recruit patients to their trial and that 4 of the 24 patients in the placebo arm withdrew early due to ongoing pain. The results of cohort studies with short-term follow-up appear to suggest that the results of arthrographic distension are more favourable than the natural history of the disease, but a large number of these studies are of poor methodology and it is difficult to draw conclusions from them.

The current study is only the second study which has evaluated long-term functional outcome following arthrographic distension. Given the inherent problems setting up placebo controlled randomised controlled trials to study arthrographic distension it seems unlikely that there will be any studies which report on the benefits of the procedure over the long term and therefore outcome data from cohort studies like this are valuable.

This study confirms the long term results reported by Watson *et al* (*19*) who performed a prospective cohort study investigating the long-term results of arthrographic distension in 53 non-diabetic patients with frozen shoulder. They reported statistically significant improvement in functional outcomes and range of movement over a 2-year period, but found that the majority of improvement had occurred within the initial 12 months.

Diabetics

A major strength of the current study has been the inclusion of diabetic patients as no other papers

Table III. — Diabetics versus non-diabetics

Outcome and timing	Mean (95% CI)		Significance of difference between diabetic and non-diabetic patients (2 tailed)
	Diabetic	Non-Diabetic	
OSS pre	19.2 (13.9-24.5)	23.3 (21.0-25.6)	p = 0.182
OSS latest	33.9 (26.9-40.9)	41.1 (37.9-44.3)	p = 0.090
VAS pre	8.1 (7.1-9.1)	6.8 (6.2-7.5)	p = 0.048
VAS latest	5.4 (3.3-7.5)	3.0 (1.9-4.1)	p = 0.065
Flex pre	117.1° (104.8°-129.4°)	108.8° (101.3°-116.3°)	p = 0.273
Flex 1m	154.1° (142.7°-165.4°)	148.2° (140.1°-156.3°)	p = 0.415
Abd pre	81.3° (60.6°-101.9°)	80.0° (70.2°-89.8°)	p = 0.916
Abd 1m	141.8° (124.8°-158.9°)	132.6° (121.2°-143.9°)	p = 0.386
ER pre	11.7° (4.2°-19.1°)	12.2° (8.6°-15.8°)	p = 0.902
ER 1m	22.3° (13.2°-31.4°)	33.4° (28.7°-38.1°)	p = 0.049

(OSS = Oxford shoulder score ; VAS = visual analogue pain score ; Flex = flexion ; Abd = abduction ; ER = external rotation).

have reported on the long-term outcome in this patient group. It shows that the functional outcome is equivalent in diabetic patients and that the benefits are maintained for over one year.

Manipulation under anaesthesia (MUA)

A widely used alternative to arthrographic distension as a primary procedure in the treatment of frozen shoulder is manipulation under general anaesthesia. A procedure under general anaesthetic is more costly, takes up theatre time and carries higher risk than injection alone. Thomas *et al* (*17*) reported the outcome of manipulation under anaesthesia (MUA) and injection of corticosteroid combined with local anaesthetic in 246 patients. They reported that patients experienced an average improvement of 16 points on their Oxford shoulder score at 26 days with 99% follow-up ; this is comparable to the 14.2 points improvement seen in the current study at one month. One major disadvantage of MUA is the number of patients requiring a secondary procedure, as 19% of those in Thomas' study required a further MUA. The outcome following MUA also appeared to be worse in diabetic patients with 40% of the 30 diabetic patients requiring a second procedure due to poor response. In the current study only two patients required additional procedures, and none of these was diabetic.

Weaknesses and strengths

The current study is prospective and presents the work of a single radiologist, whose results may not be readily transferable to the wider orthopaedic community. As a case series, there was no randomisation and no blinding of the patients, surgeon, radiologist or assessors. However, the set-up with a single radiologist in a single institution eliminated inter-observer error and reduced intra-observer error. Two independent reviews of the case notes (RC, AR) reduced the effect of data collection error. The number of diabetic patients within this series was small and it is possible that, with a larger group, differences between the diabetic and non-diabetic patients would become apparent. It is also important to note that the diabetic condition (such as HbA1c) was not evaluated in the diabetic patients : this condition might have had an influence on the outcome.

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