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The effectiveness of ultrasound guided hydrodistension and physiotherapy in the treatment of frozen shoulder/adhesive capsulitis in primary care: a single centre service evaluation

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Abstract

Background: Evidence for optimal non-operative treatment of frozen shoulder is lacking. The present study aimed to evaluate a treatment strategy for stage II to III frozen shoulder provided by the current primary care musculoskeletal service.

Methods: General practioner referrals of shoulder pain to the musculoskeletal service diagnosed with stage II to III frozen shoulder and who opted for a treatment strategy of hydrodistension and guided physiotherapy exercise programme over a 12-month period were evaluated for 6 months. Thirty-three patients were diagnosed with stage II to III frozen shoulder by specialist physiotherapists and opted for the treatment strategy. Outcome measures included Shoulder Pain Disability Index (SPADI) and Shortened Disabilities of the Arm, Shoulder and Hand (QuickDASH), pain score and range of movement. Data were collected at baseline, as well as at 6 weeks, 12 weeks and 6 months.

Results: All patients significantly improved in shoulder symptoms on the SPADI and QuickDASH scores ($p < 0.001$). Pain scores and range of shoulder movement flexion, abduction, external rotation showed significant improvement at all time points ($p < 0.001$).

Conclusions: This service evaluation demonstrates that management of frozen shoulder stage II to III, as conducted by physiotherapists in a primary care setting utilizing hydrodistension and a guided exercise programme, represents an effective non-operative treatment strategy.

Keywords

adhesive capsulitis, cost, frozen shoulder, hydrodistension, physiotherapy, primary care, QuickDASH, SPADI

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Introduction

Frozen shoulder or adhesive capsulitis is a common clinical condition that presents to both primary and secondary care services. It has been extensively discussed and debated in the literature and is proposed to affect 8.2% of men and 10% of women of working age in the UK.[1] The exact cause is unknown, although it is characterized by pain and progressive restriction of movement.[2,3] It is often classified into three stages: stage I, freezing (pain dominant); stage II, frozen (pain and restriction); and stage III, thawing

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(restriction dominant).[4,5] Debate regarding pathophysiology persists and, ultimately, contracture of the anterior capsule, coracohumeral and middle glenohumeral ligament occurs.[3,6,7]

The aim of treatment is to alleviate pain and restore shoulder movement. To meet this end, a number of treatment options are available, including medication, physiotherapy, corticosteroid injection, manipulation under anaesthetic (MUA), capsular release (arthroscopic and open) and hydrodistension. The efficiency of these interventions in relation to the frozen shoulder stage has yet to be established in clinical trials that would permit an evidence-based pathway.[8,9]

Hydrodistension was first described by Andren and Lundberg[10] who described the injection into the glenohumeral joint under X-ray guidance. A Cochrane review[11] on the effectiveness and safety of hydrodistension based on five trials ($n = 196$), involving only one of high quality,[12] found that the procedure may improve pain at 3 weeks and disability up to 12 weeks. It was concluded that there was evidence for distension with saline and steroid providing short-term benefits in pain and range of movement in frozen shoulder. It is uncertain, however, as to whether it is better than alternative treatments.

Hydrodistension is predominantly a secondary care procedure performed in radiology and estimated to cost up to £475.56.[13] A recent health economic analysis found primary care hydrodistension cost £121.00 compared to £250.68 via radiology, producing a saving of £135.68 per patient when performed by a physiotherapist trained sonographer.[14] Such cost benefits are enhanced compared to MUA and capsular release, which are estimated to cost £1446 and £2204, respectively.[13] Hydrodistension may therefore provide a treatment option for frozen shoulder patients that is relatively cheap and quick and, if delivered in primary care, easily accessible, reducing the need to progress to surgery. This primary care delivered treatment could have a significant impact on healthcare costs, patient's management and experiences.

This service evaluation assessed the feasibility and effectiveness of an ultrasound guided hydrodistension and directed exercise programme for patients with frozen shoulder delivered by physiotherapists in a primary care setting. The study also considered the cost effectiveness of this procedure delivered in primary care with respoect to other published treatment costs.

Materials and methods

This 10-year prospective evaluation study was registered with the Research and Ethics Department in line with our institutional policy (reference SE0456). Patients aged over 18 years, who were diagnosed with frozen shoulder and received a hydrodistension procedure and a directed physiotherapy exercise programme as their treatment pathway between December 2014 and January 2016, were included. Hydrodistension was offered as a treatment option to all patients at time of diagnosis together with three other treatment options: a physiotherapy exercise programme, standard intra-articular injection and a guided physiotherapy exercise programme, or referral to secondary care for possible MUA or shoulder capsular release. Patients who chose one of the other treatment pathways were excluded from the study.

Diagnosis of frozen shoulder stage II to III was made following detailed history, clinical examination that demonstrated global movement restriction (both active and passive), particularly external rotation with or without pain, and a normal glenohumeral joint X-ray, aiming to exclude other pathologies mimicking capsular restriction. This is consistent with the diagnostic criteria of previous studies.[15–17] Patients who opted for hydrodistension were counselled on the procedure and about what to expect, including their active role in the postprocedure exercise programme. Consent was also sought from the patients for their outcome data to be used in this service evaluation at this point.

Outcome measures

Data were recorded prior to the hydrodistension procedure and at 6 weeks, 12 weeks and 6 months postprocedure. The primary outcome measures were the Patient Reported Outcome Measures (PROMs), Shortened Disabilities of the Arm, Shoulder and Hand (QuickDASH) score and Shoulder Pain Disability Index (SPADI), which have been shown to be valid and reliable tools to measure pain and disability in primary care settings with good construct validity for a variety of shoulder conditions including frozen shoulder,[18–21] The QuickDASH is an 18-question self-reported measure of a patient's perceived difficulty to complete functional tasks using a numerical scale from 1 to 5, followed by calculations that produce a score out of 100 points. The Minimal Clinically Important Difference (MCID) is the smallest change in score that patients perceive as a beneficial change in their condition giving rise to a change in the clinical management of the patient's condition and is reported to be 14 for the QuickDASH.[22]

The SPADI is a self-reported questionnaire consisting of 13 items on two subscales: pain 5 items and disability 8 items, using an 11-point numerical rating scale of difficulty form 0 to 10. The scale produces a total score out of 130 and is subdivided into pain out of 50

and disability out of 80. The MCID for the SPADI is reported to be between 8 and 13.[23]

It is standard practice for all patients receiving treatment in the service to complete two Clinical Recorded Outcome Measures (CROMs): (1) pain score rated on a numerical scale from 0 to 10 (0 = no pain; 10 = severe pain) and (2) active shoulder movements of flexion, abduction and external rotation in degrees, measured using a goniometer (Sammons Preston Roylan 1-800-323-5547 #7514 30-cm axis; Patterson Medical, Warrenville, IL, USA).

Technique

Following patient consent, a routine ultrasound examination in sitting was performed to assess for a rotator cuff tear. The patient was then moved to the lateral decubitus for the guided hydrodistension.

All injections were performed under image guidance using a GE Logic e Ultrasound Scanner (GE Healthcare, Little Chalfont, UK) with a 6 MHz to 12 MHz linear array transducer by the consultant physiotherapist musculoskeletal service sonographer. An aseptic no-touch technique was used with sterile ultrasound gel following skin cleansing. The procedure was administered to the glenohumeral joint via the posterior approach. The posterior approach is often used with ultrasound to perform injections because it allows good needle and target visualisation.[24–26]

The patient was positioned in lateral decubitus position with the shoulder and elbow semi-flexed resting on a pillow for comfort. Lidocaine (10 mL 1%) was administered in real time as a hypoechoic volume within the glenohumeral joint, followed by 1 mL of 40 mg triamcinolone acetonide and, finally, 20 mL of 0.9% sodium chloride, slowly, to allow acceptance of the volume into the capsule. Rupture of the capsule can occur with this procedure and is felt as a sudden loss of resistance to injection and, visually on ultrasound, the hypoechoic enlarged capsule deflates. Any adverse reactions that occurred during the procedure were recorded.

Following the procedure passive stretching of the shoulder into external rotation, flexion and abduction was performed. Patients were then encouraged to exercise as much as possible with the stretching programme that had been given prior to this procedure. Patients were given a telephone number and instructed to call the department after 10 days. If they felt no improvement in movement or pain had been made, a repeat procedure was undertaken. If there was improvement, patients were reviewed by a specialist physiotherapist at 6 weeks, 12 weeks and 6 months, when data were collected.

Statistical analysis

A repeated measures analysis of variance (RM-ANOVA) with pairwise comparison plus Bonferroni correction was conducted at the pre-determined time points with an intention-to-treat analysis. Statistical analysis was performed using SPSS, version 22.0 (IBM Corp., Armonk, NY, USA).

Results

Table 1 shows the demographics of the patients.

In total, 33 patients were included in the present study. Interestingly, 12 patients had received previous unguided corticosteroid injections from various clinicians (and not the current service) at various time points, which failed to improve symptoms, and 22 had previously received physiotherapy input from public and private physiotherapists. We did not differentiate the results of the 12 previously injected patients from the other patients who had not had undergone

Table 1. Patient demographics.

			Percentage
Age, mean (range)	54.5	(44 months to 78 months)	
Male	15		45%
Female	18		55%
Type II diabetic	8		24.2%
Duration of symptom, mean (range)	8.6	(3 months to 20 months)	–
Previous injection	12		36.3%
Previous physiotherapy	22		66.6%

Table 2. Mean results of outcome measures and (SD) pre and post.

	Pre-treatment, mean (SD)	6 weeks post, mean (SD)	3 months post, mean (SD)	6 months post, mean (SD)	RM-ANOVA	Partial eta squared (ηp^2)
QuickDASH	46.1 (17.6)	17.8 (15.5)	11.3 (12.1)	8.2 (10.4)	$p < 0.001$	0.75
SPADI	61.1 (21.3)	25.1 (23.2)	14.9 (17.5)	11.5 (15.5)	$p < 0.001$	0.74
Pain VAS score 0 to 10	8.0 (1.1)	2.9 (2.3)	1.9 (1.7)	1.3 (1.4)	$p < 0.001$	0.84
External rotation (°)	7.3 (8.3)	31.8 (20.8)	42.7 (18.7)	54.5 (27.5)	$p < 0.001$	0.66
Abduction range (°)	56.4 (19.4)	98.5 (39.1)	123.5 (37.7)	149.5 (36.5)	$p < 0.001$	0.76
Flexion range (°)	80.7 (18.9)	119.2 (36.2)	141.2 (27.2)	157.6 (23.5)	$p < 0.001$	0.76

RM-ANOVA, repeated measures analysis of variance.
QuickDASH, Shortened Disabilities of the Arm, Shoulder and Hand; SPADI, Shoulder Pain Disability Index; VAS, Visual Analogue Score.

previous injections because their outcome measures were no different.

All 33 patients received hydrodistension and two patients received a repeat hydrodistension procedure at 2 weeks following the initial distension after the standard telephone consultation at 10 days. The indication to repeat was poor improvement in pain and movement from the initial procedure from the patient's perspective and agreed on consultation with the clinician; no set improvement was quantified to be achieved following the first procedure. None of the repeat distension patients were diabetics. Capsular rupture occurred in three patients but no alterations to treatment regimen were made and they followed standard postdistension protocol. All patients completed the data collection at the designated follow-up appointments.

The RM-ANOVA shows significant differences ($p < 0.001$) and a large effect size ($\eta p^2 > 0.6$) between the time points (Table 2). Pairwise comparisons with Bonferroni corrections show significant improvements between pre-treatment and 6 weeks, 3 months and 6 months for QuickDASH, SPADI and Pain ($p < 0.001$). No significant difference was seen between 3 months and 6 months; however, significant differences were seen between all other time points for QuickDASH ($p = 0.04$ to $p < 0.001$), SPADI ($p < 0.01$) and Pain ($p < 0.01$). In addition, significant improvements were seen between all-time points for range of motion in external rotation, abduction and flexion ($p < 0.001$) (Table 3).

Discussion

The patient demographics in this service evaluation are reflective of those previously reported in the literature.[1] We concluded that all diagnoses of frozen shoulder were correct and there were no adverse incidents or complications in the evaluation. Although this is not a randomized controlled trial and only a small number of participants were studied, the results suggest ultrasound guided hydrodistension and physiotherapy guided exercise for patients with frozen shoulder stage II to III in a primary care setting is effective at improving pain, disability and movement. This improvement was maintained for 6 months for all outcome measures. In addition, no patients were unhappy with the outcome of treatment and none required onward referral to secondary care, and were happy to be discharged.

The results of the present study clearly demonstrated a large clinically significant change in the SPADI at all three time points from baseline. Clinically, an effective treatment should result in a significant change in the first 6 weeks; the MCID for the SPADI is reported to be an 8 to 13 point change.[23] We clearly surpassed the recommended level of change. Similarly, the MCID for the Quick DASH is reported to be a 14-point change;[22] our Quick DASH results demonstrated a clinically significant sustained change at all three time points (Table 2).

Clinically recorded outcome measures of external rotation, abduction and flexion movements continued to show statistically significant improvements ($p < 0.001$) and clinically important changes at all time points from baseline and between all-time points, indicating a continued functional recovery of movement.

The pain mean score significantly reduced from 8.0 (pre) to 2.9 (6 weeks) ($p < 0.001$), showing a 64% reduction in pain after 6 weeks. This reducing trend continued at 12 weeks to 1.9 ($p < 0.001$), giving a 77% reduction, and also continued at 24 weeks, reducing to 1.0 ($p < 0.001$), giving an 84% reduction in pain, all of

Table 3. Mean differences and pairwise comparisons with Bonferroni correction.

	QuickDASH	SPADI	Pain	ROM: external rotation	ROM: abduction	ROM: flexion
Pre to 6 weeks	28.2 ($p < 0.001$)	35.9 ($p < 0.001$)	5.1 ($p < 0.001$)	–24.5 ($p < 0.001$)	–42.1 ($p < 0.001$)	38.5 ($p < 0.001$)
Pre to 3 months	34.7 ($p < 0.001$)	46.1 ($p < 0.001$)	6.1 ($p < 0.001$)	–35.5 ($p < 0.001$)	–67.1 ($p < 0.001$)	–60.5 ($p < 0.001$)
Pre to 6 months	37.8 ($p < 0.001$)	49.5 ($p < 0.001$)	6.7 ($p < 0.001$)	–47.3 ($p < 0.001$)	–93.2 ($p < 0.001$)	–76.8 ($p < 0.001$)
6 weeks to 3 months	6.5 ($p = 0.042$)	10.2 ($p < 0.01$)	1.0 ($p < 0.01$)	–10.9 ($p < 0.001$)	–25.0 ($p < 0.001$)	–22.0 ($p < 0.001$)
6 weeks to 6 months	9.6 ($p < 0.001$)	13.6 ($p < 0.01$)	1.6 ($p < 0.01$)	–22.7 ($p < 0.001$)	–51.1 ($p < 0.001$)	–38.3 ($p < 0.001$)
3 months to 6 months	3.1 ($p = 0.16$)	3.4 ($p = 0.73$)	0.6 ($p = 0.13$)	–11.8 ($p < 0.01$)	–26.1 ($p < 0.001$)	–16.4 ($p < 0.001$)

QuickDASH, Shortened Disabilities of the Arm, Shoulder and Hand; SPADI, Shoulder Pain Disability Index; ROM, range of motion.

Table 4. Cost comparison with other published data.

	Current service evaluation	Hydrodistension Primary care O'Conaire et al.[14]	Secondary care guided injection Maund et al.[13]	Surgery Maund et al.[13]	Physio & injection Bateman et al.[16]
Physiotherapy cost 4 appointments	(£25.07 per hour) 4 appointments = 1 × 40 minutes 3 × 20 minutes = £41.78	Total staff cost =£121.00	NA	NA	(£75.00 per hour) 5 appointments= 2 hours= = £135
Consultant physiotherapy cost × 1 appointment	(£37.01 per hour) 1 × 30 minutes =£18.50	NA	NA	NA	NA
Drugs and injection equipment	=£10.00	included	NA	NA	Included
Ultrasound equipment and facilities	=£50.00	£10	NA	NA	Included
Total	£120.28	£131.00	£299 to £475	£2204	£135

NA, not available.

which are significant ($p < 0.001$). Pain was high on the priority list in a study exploring perceptions and priorities when living with primary frozen shoulder,[27] and a main complaint in a recent paper looking at guided injection treatment for frozen shoulder.[28] Addressing the pain element as priority would reduce patient's disability and improve their quality of life.

These changes from baseline score were statistically significant and clinically important; however, there was no further change between time points. This indicates that the most significant improvements in patient reported outcomes occurred early in the treatment pathway after the hydrodistension procedure.

Short-term improvements in pain and function have been demonstrated in previous hydrodistension studies.[12,17] These short-term improvements on pain and disability have also been documented with intra-articular cortisone injection[29–32] and enhanced if physiotherapy is used in conjunction with injection.[13] A 2014 National Health Service (NHS) study[16]

retrospectively investigating cortisone injection and physiotherapy for frozen shoulder provided in secondary care over a 12-month period highlighted statistically significant improvements in pain scores, although it failed to document short- or medium-term pain outcomes, and failed to use a validated outcome measure. It was reported that patients were seen on average for five appointments, which is the same as the present study; however, 22% ($n = 12$) patients were referred for surgical opinion, unlike the present study, which referred none. This improvement could have occurred in the early or later stages of treatment but, without the data collection stages being identified, it is unclear at what time point this occurred. The present study demonstrates continued improvements at 6 weeks, 12 weeks and 6 months.

We did not separate the results from the 12 patients that had previously received a cortisone injection because they all had clinical symptoms and were actively seeking treatment. Their outcomes did not differ from those who had not previously received a cortisone injection before entering the treatment pathway.

Previous cost analysis has estimated costs of up to £475.56 for guided injection in secondary care and up to £2204 for surgical release.[13] In comparison, our treatment costs for frozen shoulder stage II to III in primary care are comparable with data published by O'Conaire et al.[14] (hydrodistension) and Bateman et al.[16] (nondistension injection) (see Table 4). This treatment approach offers a significant saving to the NHS compared to secondary care guided injection and surgical costs of £475.56 and £2204,[13] respectively.

Conclusions

The results of this small prospective service evaluation demonstrate that ultrasound guided hydrodistension with guided exercise provided by physiotherapists in primary care is clinically effective for patients with frozen shoulder II to III. It also highlights the cost effectiveness of providing hydrodistension in a primary care setting and, by doing so, has potential significant financial benefit to the NHS if it is embedded in a national recommended treatment pathway for frozen shoulder.

Although these findings do not provide new evidence on treatment efficacy, they are in keeping with the previous findings of hydrodistension treatment provided in secondary care. We have demonstrated that hydrodistension can be feasibly provided in a primary care setting by physiotherapists, easing the demand on secondary care services and potentially reducing the need for surgery for this condition. What is not clear is the efficacy of hydrodistension over nondistension injection and guided physiotherapy.

Further research should be conducted in the form of a randomised controlled trial aiming to compare ultrasound guided hydrodistension with physiotherapy guided exercise versus nondistension ultrasound guided injection and physiotherapy guided exercise in the primary care setting.

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Ethical Review and Patient Consent

Ethical approval was not required for the service evaluation of standard treatment but the project was registered with the Research and Ethics Department.

Level of evidence

Level III (Service evaluation)

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