

## The effectiveness of Ultrasound guided Hydrodistension and physiotherapy in the treatment of Frozen shoulder/Adhesive Capsulitis in Primary Care – a single centre service evaluation

Michael Bryant, MSc, MCSP<sup>a</sup>, Andrew Gough, BSc MCSP<sup>a</sup>, James Selfe, PhD<sup>b</sup>, Jim Richards, PhD<sup>b</sup>, Elizabeth Burgess, MChOrth, FRCS (Tr&Orth)<sup>a</sup>

<sup>a</sup>*Blackpool Teaching Hospitals Foundation Trust, Community Musculoskeletal Service, Lytham Primary Care Centre, Lytham, Lancashire UK.*

<sup>b</sup>*University of Central Lancashire, Preston, Lancashire, UK*

Abstract

**Background:** Evidence for optimal non-operative treatment of frozen shoulder is lacking. The aim of this study is to evaluate a treatment strategy for stage II-III Frozen shoulder provided by the current primary care Musculoskeletal Service.

**Methods:** GP referrals of shoulder pain to the musculoskeletal service diagnosed with stage II-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-III frozen shoulder by specialist physiotherapists and opted for the treatment strategy. Outcome measures included SPADI and QuickDASH, pain score and range of movement. Data was collected at baseline, 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-III, by physiotherapists in a primary care setting utilizing hydrodistension and guided exercise programme is an effective non-operative treatment strategy.

**Level of evidence:** Level III, Service evaluation.

**Keywords:** Frozen shoulder; adhesive capsulitis; Hydrodistension; Primary Care; Physiotherapy; Cost; SPADI; QuickDASH.

## Background

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<sup>1</sup>. The exact cause is unknown but is characterised by pain and progressive restriction of movement<sup>2,3</sup>. It is often classified into three stages stage I freezing (pain dominant), stage II frozen (pain & restriction), stage III thawing (restriction dominant)<sup>4,5</sup>. Debate regarding pathophysiology persists and ultimately contracture of the anterior capsule, coracohumeral and middle glenohumeral ligament occurs<sup>3,6,7</sup>.

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<sup>8,9</sup>.

Hydrodistension was first described by Andren and Lundberg (1965)<sup>10</sup> who described the injection into the glenohumeral joint under x-ray guidance. A Cochrane review<sup>11</sup> on the effectiveness and safety of hydrodistension based on five trials (n=196), involving only one of high quality<sup>12</sup>, found that the procedure may improve pain at 3 weeks and disability up to 12 weeks. The authors concluded that there was evidence that distension with saline and steroid provided 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<sup>13</sup>. 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<sup>14</sup>. Such cost benefits are enhanced when compared with MUA and capsular release which are estimated to cost £1446 and £2204 respectively<sup>13</sup>. Hydrodistension may therefore provide a treatment option for frozen shoulder patients which is relatively cheap, 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 health care 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 other published treatment costs.

## Method and Materials

This one year prospective evaluation study was registered with the research & ethics department in line with our institutional policy, reference SE0456. Patients aged over 18 years, diagnosed with frozen shoulder who received hydrodistension procedure and 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; physiotherapy exercise programme, standard intra-articular injection and guided physiotherapy exercise programme, or referral to secondary care for possible manipulation under anaesthesia (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-III was made following detailed history, clinical examination that demonstrating global movement restriction (both active and passive) particularly external rotation with or without pain and a normal glenohumeral joint x-ray, to exclude other pathology mimicking capsular restriction. This is consistent with previous studies diagnostic criteria<sup>15 16, 17</sup>. Patients who opted for hydrodistension were counselled on the procedure and what to expect including their active role in the post procedure 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 was recorded prior to the hydrodistension procedure and at week 6, 12 weeks and 6 months' post procedure. The primary outcome measures were the Patient Reported Outcome Measures (PROMs), Disability Arm Shoulder Hand (QuickDASH) 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,<sup>18,19, 20,21</sup>. The QuickDASH is an 18 question self-reported measure of the patients' perceived difficulty to complete functional tasks using a numerical scale 1-5 then calculated to 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<sup>22</sup>.

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 0-10. 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 8-13<sup>23</sup>.

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 0-10 (0=no pain, 10=severe pain), (2) Active shoulder movements of flexion, abduction and external rotation in degrees, measured using a goniometer. (Sammons Preston Roylan 1-800-323-5547 #7514 30cm axis).

### 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 UK) with a 6-12 MHz linear array transducer by the Consultant Physiotherapist MSK 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 as it allows good needle and target visualisation<sup>30 31 32</sup>.

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 40mg Triamcinolone Acetonide, finally 20ml 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 phone 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 was collected as previously described.

### Statistical Analyses

A repeated measures analysis of variance (RM-ANOVA) with pairwise comparison plus a 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 (SPSS Inc, Chicago, IL, USA).

## Results

Table 1 shows the demographics of the patients. A total of 33 patients were included in the study. Interestingly 12 patients had received previous unguided corticosteroid injections from various clinicians not the current service at various time points, which failed to improve symptoms, and 22 had previously received physiotherapy input by public and private physiotherapists. We did not differentiate the results of the 12 previously injected patients from the other patients who had not had previous injections because their outcome measures were no different.

**Table 1. Patient demographics**

	Mean	Range	Percentage
<b>Age</b>	54.5 (mean)	44-78	
<b>Male</b>	15		45%
<b>Female</b>	18		55%
<b>Type II diabetic</b>	8		24.2%
<b>Duration of symptom</b>	8.6	3–20 months	-
<b>Previous injection</b>	12		36.3%
<b>Previous Physiotherapy</b>	22		66.6%

All 33 patients received hydrodistension and 2 patients received a repeat hydrodistension procedure at 2 weeks post the initial distension after the standard telephone consultation at ten days. The indication to repeat was poor improvement in pain and movement from 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 3 patients but no alterations to treatment regimen were made and they followed standard post distension 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 ( $\eta^2 > 0.6$ ) between the time points (see table 2). Pairwise comparisons with Bonferroni corrections show significant improvements between pre-treatment and 6 weeks, 3 months and 6 months for Q-DASH, 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 Q-DASH ( $p = 0.04$  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 ( $p < 0.001$ ), (see table 3).

**Table 2. Mean and standard deviations**

	Pre treatment mean (sd)	6 weeks Post mean (sd)	3 Months post mean(sd)	6 Months Post mean (sd)	RM ANOVA	Partial Eta Squared ( $\eta^2$ )
<b>Q-DASH</b>	46.1 (17.6)	17.8 (15.5)	11.3 (12.1)	8.2 (10.4)	<b>P&lt;0.001</b>	0.75
<b>SPADI</b>	61.1 (21.3)	25.1 (23.2)	14.9 (17.5)	11.5 (15.5)	<b>P&lt;0.001</b>	0.74
<b>Pain</b> VAS score 0-10	8.0 (1.1)	2.9 (2.3)	1.9 (1.7)	1.3 (1.4)	<b>P&lt;0.001</b>	0.84
<b>External rotation degrees</b>	7.3° (8.3)	31.8° (20.8)	42.7° (18.7)	54.5° (27.5)	<b>P&lt;0.001</b>	0.66
<b>Abduction range degrees</b>	56.4° (19.4)	98.5° (39.1)	123.5° (37.7)	149.5° (36.5)	<b>P&lt;0.001</b>	0.76
<b>Flexion range degrees</b>	80.7° (18.9)	119.2° (36.2)	141.2° (27.2)	157.6° (23.5)	<b>P&lt;0.001</b>	0.76

**Table 3. Mean differences and Pairwise comparisons with Bonferroni correction**

	Q-DASH	SPADI	Pain	ROM External rotation	ROM Abduction	ROM Flexion
<b>Pre to 6 weeks</b>	<b>28.2</b>	<b>35.9</b>	<b>5.1</b>	<b>-24.5</b>	<b>-42.1</b>	<b>38.5</b>

	(p<0.001)	(p<0.001)	(p<0.001)	(p<0.001)	(p<0.001)	(p<0.001)
<b>Pre</b>	<b>34.7</b>	<b>46.1</b>	<b>6.1</b>	<b>-35.5</b>	<b>-67.1</b>	<b>-60.5</b>
<b>to 3 months</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>
<b>Pre</b>	<b>37.8</b>	<b>49.5</b>	<b>6.7</b>	<b>-47.3</b>	<b>-93.2</b>	<b>-76.8</b>
<b>to 6 months</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>
<b>6 weeks</b>	<b>6.5</b>	<b>10.2</b>	<b>1.0</b>	<b>-10.9</b>	<b>-25.0</b>	<b>-22.0</b>
<b>to 3 months</b>	<b>(p=0.042)</b>	<b>(p&lt;0.01)</b>	<b>(p&lt;0.01)</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>
<b>6 weeks</b>	<b>9.6</b>	<b>13.6</b>	<b>1.6</b>	<b>-22.7</b>	<b>-51.1</b>	<b>-38.3</b>
<b>to 6 months</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.01)</b>	<b>(p&lt;0.01)</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>
<b>3 months</b>	<b>3.1</b>	<b>3.4</b>	<b>0.6</b>	<b>-11.8</b>	<b>-26.1</b>	<b>-16.4</b>
<b>to 6 months</b>	<b>(p=0.16)</b>	<b>(p=0.73)</b>	<b>(p=0.13)</b>	<b>(p&lt;0.01)</b>	<b>(p&lt;0.001)</b>	<b>(p&lt;0.001)</b>

## Discussion

The patient demographics in this service evaluation are reflective of those previously reported in the literature <sup>1</sup>. 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 randomised 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-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.

Our results clearly demonstrated a large clinically significant change in the SPADI at all 3 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 8-13 point change <sup>23</sup>. We clearly surpassed the recommended level of change. Similarly, the MCID for the Quick DASH is reported to be a 14-point change <sup>22</sup>; our Quick DASH results demonstrated a clinically significant sustained change at all 3 time points, (see 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 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<sup>24</sup>, and a main complaint in a recent paper looking at guided injection treatment for frozen shoulder<sup>25</sup>. 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<sup>12, 17</sup>. These short term improvements on pain and disability have also been documented with intra-articular cortisone injection<sup>27, 28, 29</sup> and enhanced if physiotherapy is used in conjunction with injection<sup>13</sup>. A 2014 NHS study<sup>16</sup> 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, but failed to document short or medium term pain outcomes, and failed to use a validated outcome measure. They report patients were seen on average for five appointments, this is the same as our study, however 22% ( $n=12$ ) patients were referred for surgical opinion, unlike our 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. Our 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<sup>13</sup>. In comparison our treatment costs for frozen shoulder stage II-III in primary care are comparable with data published by O'Conaire (2012) hydrodistension, and Bateman et al (2014) non distension injection. This treatment



approach offers significant saving to the NHS when comparing to secondary care guided injection and surgical costs at £475.56, £2204<sup>13</sup> respectively.

**Table 4. Cost comparison with other published data.**

	Current service evaluation	Hydrodistension Primary care O' Conaire et al (2012)	Secondary care guided injection Maund et al (2012)	Surgery Maund et al (2012)	Physio & injection Bateman et al (2014)
<b>Physio cost</b>	(£25.07hr)	Total staff cost			(£75.00hr)
<b>4 appts</b>	4 appts = 1x40mins 3x 20mins = £41.78	=£121.00	n/a	n/a	5 appts = 2 hrs = =£135
<b>Consultant Physio cost x 1 appt</b>	(£37.01hr) 1x 30 min =£18.50	n/a	n/a	n/a	n/a
<b>Drugs &amp; injection equipment</b>	=£10.00	included	n/a	n/a	Included
<b>US equipment and facilities</b>	=£50.00	£10	n/a	n/a	Included
<b>Total</b>	<b>£120.28</b>	<b>£131.00</b>	<b>£299- 475</b>	<b>£2204</b>	<b>£135</b>

## Conclusions

The results of this small prospective service evaluation demonstrate ultrasound guided hydrodistension with guided exercise provided by physiotherapists in primary care is clinically effective for patients with frozen shoulder II-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.

Whilst these findings do not provide new evidence on treatment efficacy they are in keeping with the previous findings of secondary care provided hydrodistension treatment. 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 non distension injection and guided physiotherapy.

Further research should be conducted in the form of a randomised controlled trial to compare ultrasound guided hydrodistension with physiotherapy guided exercise, vs non distension ultrasound guided injection and physiotherapy guided exercise in the primary care setting.

#### Ethics

Ethical approval was not required for the service evaluation of standard treatment but the project was registered with the research and ethics department.

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#### Disclosures

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