

RESEARCH ARTICLE

The effectiveness of hydrodistension and physiotherapy following previously failed conservative management of frozen shoulder in a UK primary care centre

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Abstract

Background: There is a lack of evidence on the clinical effectiveness of hydrodistension for frozen shoulder following failed conservative management.

Methods: A total of 90 patients opted for hydrodistension following failed initial treatment which included physiotherapy and at least one corticosteroid injection. Shoulder pain and function were assessed at baseline, and 6, 12 and 24 weeks using the Shoulder Pain Disability Index (SPADI), The Upper Extremity Functional Index (UEFI) and a visual analogue scale (VAS) for pain. Active ranges of motion were assessed at baseline, post-24 hr and discharge.

Results: We observed clinically important improvements in pain (VAS −5.5; 90% confidence interval [CI] −6.0 to −5.0; SPADI pain, −20; 90% CI −23 to −17) and function (UEFI 23; 90% CI 19 to 26; SPADI disability, −32; 90% CI −36 to −28) at 6 weeks. These improvements remained clearly substantial at 24 weeks. Active range of motion improved substantially post-24 hr (flexion 20, 90% CI 18 to 23; lateral rotation 14, 90% CI 12 to 16; abduction 22, 90% CI 19 to 25) and at discharge (flexion 37, 90% CI 33 to 41; lateral rotation 24, 90% CI 21 to 27; abduction 44, 90% CI 38 to 50).

Discussion: This single-arm observational study suggests that hydrodistension is an effective treatment of frozen shoulder within a UK primary care setting when standard treatment has failed.

KEYWORDS

frozen shoulder, hydrodistension, injection, rehabilitation

1 | INTRODUCTION

Frozen shoulder is a commonly diagnosed condition within primary care, with an estimated incidence of between 2% and 5% in the general population, costing the National Health Service in the UK up to £110.3 million annually (Jones, Hanchard, Hamilton, & Rangan, 2013; Ogilvie-Harris, Biggs, Fitsialos, & MacKay, 1995). The aetiology and pathogenesis of primary frozen shoulder are not known but is more frequent in females, during the 6th decade of life (Hamdan & Al-Essa, 2003) and in patients with comorbidities such as hemiplegia, ischaemic heart disease

and diabetes (Boyle-Walker, Gabard, Bietsch, Masek-VanArsdale, & Robinson, 1997). Up to 20% of patients with diabetes will be affected at some time with frozen shoulder (Favejee, Huisstede, & Koes, 2011).

Frozen shoulder is characterized by a painful global restriction in movement, resulting in a significant impact upon daily activities. Despite frozen shoulder being considered a self-limiting condition, only approximately 50% of people affected have full resolution of symptoms after 4 years (Favejee et al., 2011; Hand, Clipsham, Rees, & Carr, 2008). Despite most remaining symptoms being considered mild, loss of function is still experienced, and 6% of all sufferers have

long-term severe symptoms, with symptom duration related to their severity at onset (Hand et al., 2008).

A range of treatment options exist, ranging from exercise-led physiotherapy and steroid injection, to surgical intervention, all with the aim of increasing the functional capacity of the individual (Watson et al., 2007). Unfortunately, it is universally accepted that no one therapeutic intervention restores range of motion and relieves pain in all (Favejee et al., 2011). Insufficient evidence exists for the management of frozen shoulder. One systematic review found no agreement or consensus from effective management through physiotherapy, corticosteroid injections or steroid use (Rookmonee et al., 2010). Substantial gaps in the evidence continue to remain for the non-surgical treatment of patients with frozen shoulder (Lowe, Barrett, McCreesh, De Burca, & Lewis, 2019).

Therefore, high-quality, evidence-based effective treatment options are still required to improve clinical outcomes in nonsurgical patients. One possible such treatment is hydrodistension, first described in (Andr n, L. & Lundberg, 1965). The nomenclature varies from "hydrodilatation", "hydrodistension" and "distension arthrography", where it is considered a therapeutic intervention for glenohumeral capsule contracture (Watson et al., 2007). The distension involves the intra-articular injection of a large volume of normal saline, with the exact mechanism not being fully understood. Theories for hydrodistension mechanisms include the rupturing of capsular adhesions (Quraishi, Johnston, Bayer, Crowe, & Chakrabarti, 2007), capsular distension, rupture of the subscapularis bursa, and stretching of pain receptors in the joint and at the periosteal attachments (Jacobs et al., 1991), thereby reducing pain and enabling an improved range of movement (Favejee et al., 2011).

Hydrodistension may provide superior outcomes compared with some conservative management methods, including medication and physical therapy (Wu et al., 2017). Hydrodistension has shown greater improvements in external rotation range of motion in the short term (Park, Nam, Lee, Kim, & Park, 2013; Yoon et al., 2016). Additionally, increased range of motion has been reported, compared with a single steroid injection (Mun & Baek, 2016). The latter single-centre service evaluation in primary care ($n = 33$) reported that hydrodistension and guided exercise represents an effective non-operative treatment strategy. It is widely considered that further research is warranted to understand further the value of hydrodistension (Lewis, 2015), as a first-line treatment or within a community outpatient primary care clinic (Mun & Baek, 2016).

Therefore, the aim of the present study was to investigate the clinical effectiveness of hydrodistension treatment on patient-reported outcome measures and range of motion in failed initial physiotherapy rehabilitation for patients diagnosed with frozen shoulder.

2 | MATERIALS AND METHODS

2.1 | Design

Our study employed a single-arm retrospective observational design.

2.2 | Participants

All patients included in the study were aged 16 years or above and had been diagnosed with frozen shoulder. All participants ($n = 90$, 59 males and 31 females, mean age 58 ± 9.4 years) were referred from primary care general practitioners (GPs) into the Sunderland Integrated Musculoskeletal Service, Sunderland, UK between October 2015 and September 2016. All patients were referred with an initial diagnosis of frozen shoulder; this was subsequently confirmed by a sports and exercise medicine consultant (***)Blinded for review purposes***) within the service. The diagnosis of frozen shoulder was made, consistent with the same diagnostic criteria as those used in other studies (Bateman, McClymont, & Hinchliffe, 2014; Bryant, Gough, Selfe, Richards, & Burgess, 2017; Yoong et al., 2015), following a detailed history, a clinical examination showing loss of both passive and active range of movement of at least 50%, in at least two directions out of abduction, internal or external rotation and flexion in a sagittal plane. All patients had a normal anteroposterior and axillary lateral shoulder X-ray (Quraishi et al., 2007).

All patients received a previously directed physiotherapy exercise programme plus at least one intra-articular steroid injection as their treatment. Each directed physiotherapy programme varied, depending on patient need, but included varying dosage of active and active-assisted range of movement exercises, appropriate advice and education on symptom management. Hydrodistension was offered to all patients within this group, as was referral to secondary care for possible manipulation under anaesthetic (MUA) or shoulder capsular release. Patients who chose surgical intervention or no further treatment were excluded from the study.

Patients with other shoulder pathologies, such as subacromial pain syndrome, previous ipsilateral humeral fractures, rotator cuff pathology, osteoarthritis of the glenohumeral joint or rheumatoid arthritis, were excluded from the study. Written informed consent, along with consent to use outcome data in this service, was gained from all patients. The trial was registered with the ****Foundation Trust Research and Development Department, UK, October 2014.

2.3 | Outcome measures

Key patient-reported outcome measures were utilized. The Shoulder Pain Disability Index (SPADI) is a validated tool to measure disability and pain for shoulder pathology, including frozen shoulder (Breckenridge & McAuley, 2011; Hill, Lester, Taylor, Shanahan, & Gill, 2011; Paul et al., 2004a). The questionnaire contains 13 items assessing two subscales—pain and disability. Responses are indicated on a visual analogue scale (VAS), where 0 equals no pain/no disability and 10 equals the worst pain imaginable/so difficult that it requires help. Each item is summed, with a total score out of 100. The minimal clinically important difference (MCID) has been identified in several studies, and ranges broadly from 8 units to 21 units (Dabija & Jain, 2019). We chose an MCID of 13 units, as this has been anchored to a change in the global disability rating of 1 unit in a population similar to

that investigated in the present study (Schmitt & Di Fabio, 2004). This is more conservative than the 8-unit MCID suggested by Paul et al. (2004), which may be too liberal, given that the patients in this study could achieve an 8-unit change in SPADI but rated no global self-rated change. Indeed, Paul et al (2004) suggest a threshold of 32 units to constitute "improved" global self-rated change, which was the mean change associated with a moderate improvement in this scale. As such, we used this threshold to evaluate moderate, as well as minimal clinical, differences.

The Upper Extremity Functional Index (UEFI) consists of 20 prescribed upper limb activities which are self-rated by the patient on a five-point Likert scale, where 0 is extreme difficulty or unable to perform the activity; 1 represents quite a bit of difficulty; 2 represents moderate difficulty; 3 represents a little bit of difficulty; and 4 represents no difficulty (Hamilton & Chesworth, 2013; Hefford, Abbott, Arnold, & Baxter, 2012). These items are total to constitute a maximal score of 80 units. The UEFI has high construct validity ($p < 0.001$), with moderate to good reliability (0.85) (Hill et al., 2011). MCIDs of between 8.5 units and 9.4 units have been suggested in the literature. However, a value of 10 units would represent a more practical MCID, as this relates to half a unit for each question, the minimal value that would guarantee a change from one point to the next on the Likert scale (e.g., from a little bit of difficulty to no difficulty) (Hopkins, 2010).

The VAS is a unidimensional measure of pain intensity, and is a common methodology for evaluating a patient's pain severity and relief (McCormack, David, & Sheather, 1988). It is an easy-to-use, practical and sensitive tool to measure treatment effects (Dexter & Chestnut, 1995; Kelly, 2001). The tool uses a 10-point scale, with 10 indicating the highest intensity or severity of pain. The reliability of the VAS has been reported as good (Boonstra, Preuper, Reneman, Posthumus, & Stewart, 2008). The MCID has been suggested to be 3 points in patients treated in muscle-related shoulder pain (Tashjian, Deloach, Porucznik, & Powell, 2009).

As many patients present with painful restriction of shoulder motion (Uppal, Evans, & Smith, 2015), participants' active range of flexion, abduction, and combined extension and internal rotation in standing were recorded.

2.4 | Intervention

Patients taking anticoagulant medication were managed as per South Tyneside Foundation Trust, UK, departmental guidelines. All patients were given an information leaflet more than 24 hr prior to the procedure. All injections were performed with the patient positioned in the lateral decubitus position, with the affected shoulder and elbow semiflexed (Rutten et al., 2009). Under ultrasound image guidance (using a Phillips HD7 Ultrasound Machine HD7XE, Phillips, Yorba Linda, USA with a 12 Hz linear array transducer), an aseptic no-touch technique was employed, using sterile ultrasound gel following skin cleansing. The probe was placed transversely across the posterior aspect of the affected shoulder, and the glenohumeral joint was visualized with the

glenoid in the middle of the screen. Under real-time ultrasound guidance, using a 21G green needle, via a postero-oblique approach (Fareed & Gallivan, 1989), 40 mg triamcinolone acetonide and 4 ml 1% lidocaine was injected immediately, followed by 25 ml 0.9% sodium chloride slowly into the glenohumeral joint.

All procedures were carried out by a consultant in sports and exercise medicine, with postgraduate qualifications in musculoskeletal ultrasound and 19 years of injection experience.

2.5 | Protocol

VAS, UEFS, SPADI and EuroQol-5 Dimensions-5 Levels (EQ-5D-5 L) data were collected immediately prior to hydrodistension, and subsequently at 6, 12 and 24 weeks after injection. Participants' active range of flexion, abduction, and combined extension and internal rotation in standing were assessed before and 24 hr after the hydrodistension procedure by the same physiotherapist. Active ranges were measured using a standard goniometer (Sammons Preston Rolyan, Bolingbrook, USA), except combined extension and medial rotation in standing, which was measured by thumb position, and all were reported to have good reliability (Hayes, Walton, Szomor, & Murrell, 2001). Following the injection, all patients followed the same protocol. They were permitted to undertake their normal activities, and encouraged to use simple analgesia of paracetamol 1 g four times a day. All participants had been educated prior to the injection to undertake a range-of-motion self-exercise programme at home, to start 5–6 hr following the injection. They then returned to see a musculoskeletal physiotherapist within 24 hr of the injection, to continue with active and active assisted range-of-movement exercises. Additional passive joint mobilizations could be undertaken if patients were struggling with movement. Supervised physiotherapy continued as required, based upon the benefit gained, with patients advised to exercise as appropriate by their physiotherapist (Robinson, Norris, & Roberts, 2017). The range of motion from their final visit was recorded as their 'overall post hydrodistension' measure.

2.6 | Statistical analysis

We inspected the histograms and Q-Q plots of the raw data for normal distribution. All were approximately normal, with the exception of VAS pain, which was highly skewed and reflective of our sample—that is, patients experiencing high levels of pain prior to treatment. As such, these data are presented as the median and interquartile range (Figure 1) and were rank-transformed prior to analysis. We assessed changes in pain from pre-hydrodistension using the Wilcoxon test, as recommended for such data (Heller, Manuguerra, & Chow, 2016). These analyses were performed in R (version 3.4.1, R Foundation for Statistical Computing, Vienna, Austria). Paired-samples *t*-tests were performed using the Statistical Package for the Social Sciences (SPSS; SPSS, Inc., Chicago, IL, USA) to evaluate the change between visits, which allowed for direct comparisons between individuals without

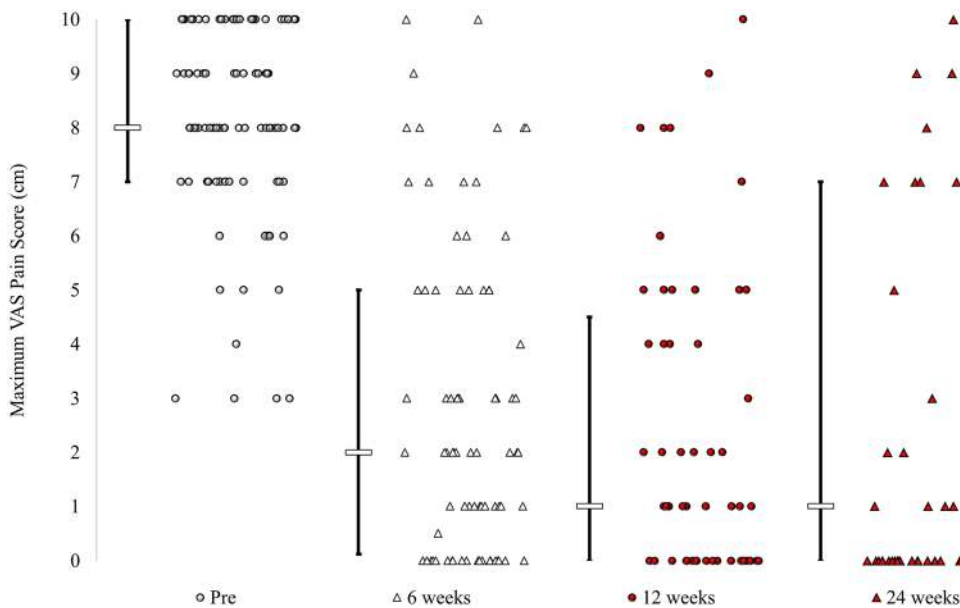


FIGURE 1 Individual distribution of visual analogue scale (VAS) pain score data, with medians and interquartile ranges

the need to account for missing data. The number of participants included for each comparison are identified in Tables 1–3.

Uncertainty in all estimates were expressed as 90% confidence intervals (CIs). We subsequently applied a calibrated Bayesian approach with a least-informative prior (i.e., clinical magnitude-based decisions) (Batterham & Hopkins, 2006; Hopkins & Batterham, 2019) to describe the size and precision of these changes. Here, the disposition of the effect distribution in relation to thresholds for our MCID (stated above) were evaluated as probabilities (percentage chances). For flexibility measures, we were not aware of a robust clinical anchor from which to specify our target difference, and thus defaulted to 0.2 of the between-subject standard deviations, as this represents a small effect size (Hopkins, Marshall, Batterham, & Hanin, 2009). Probabilities of effects being greater than these thresholds were qualified as: 0.5–5.0% very unlikely; 5.0–24.9% unlikely; 25.0–74.9% possibly; 75.0–94.9% likely; 95.0–99.5% very likely; >99.5% most likely (Hopkins et al., 2009).

3 | RESULTS

We observed clinically important improvements in pain and shoulder function (VAS, UEFS, SPADI) at 6, 12 and 24 weeks after hydrodistension (Tables 1 and 2). Patients were in substantially less pain

(VAS) from pre-injection at week 24, despite a likely increase of 2 VAS points from week 12. Substantial improvements in active range of motion were observed when the patients first visited the hospital post-injection, and these were maintained throughout (Table 3, Figures 2 and 3).

4 | DISCUSSION

We aimed to investigate the clinical effectiveness of hydrodistension treatment in patients diagnosed with frozen shoulder and with failed initial physiotherapy rehabilitation, in a UK primary care setting. Our study demonstrated that pain and disability were substantially reduced beyond our MCIDs. Subjective functional assessment of pain (SPADI and UEFS) displayed clear reductions post-hydrodistension. Additionally, our results demonstrated “most likely” improvements in active range of movement in all directions measured 24 hr post-injection and at discharge, supporting previous research (Buchbinder, Green, Forbes, Hall, & Lawler, 2004; Sharma, Bajekal, & Bhan, 1993).

Reductions in pain and disability measures were maintained at the 12-week post-injection review; however, although the improvement was shown to be maintained by week 24, there was a small increase, by 2 points, in the VAS score between weeks 12 and 24. Although the reason for this increase is unknown, it may potentially

TABLE 1 Comparisons of the visual analogue scale pain score between time periods, showing number of pairwise comparisons (n), mean difference and clinical inference

		n	Mean difference (90% confidence interval)	Practical inference (% probability of more/trivial/less pain)
Pre	6 weeks	78	−5.5 (−6.0 to −5.0)	Most likely in less pain (0/0/100)
	12 weeks	51	−5.5 (−6.2 to −4.7)	Most likely in less pain (0/0/100)
	24 weeks	32	−5.5 (−7.0 to −4.5)	Most likely in less pain (0/0/100)
6 weeks	12 weeks	51	0 (1.0 to −0.5)	Unclear (21/51/28)
12 weeks	24 weeks	21	2.0 (0 to 3.0)	Likely in more pain (84/13/3)

TABLE 2 Comparisons between the Shoulder Pain Disability Index (SPADI) and Upper Extremity Functional Index (UEFI) scores between time periods, showing the number of pairwise comparisons (*n*), mean difference and clinical inference

	SPADI disability			SPADI pain			UEFI		
	<i>n</i>	Raw units (90% CI)	Clinical inference probability (%)	<i>n</i>	Raw units (90% CI)	Clinical inference probability (%)	<i>n</i>	Raw units (90% CI)	Clinical inference probability (%)
Pre									
6 weeks	77	-32 (-36 to -28)	Most likely less disability 0/0/100	76	-20 (-23 to -17)	Most likely less pain 0/0/100	78	23 (19 to 26)	Most likely less difficult 0/0/100
12 weeks									
12 weeks	56	-35 (-40 to -30)	Most likely less disability 0/0/100	55	-22 (-25 to -18)	Most likely less pain 0/0/100	56	23 (19 to 28)	Most likely less difficult 0/0/100
24 weeks									
24 weeks	43	-38-44 to -32)	Most likely less disability 0/0/100	42	-38 (-46 to -18)	Most likely less pain 0/0/100	48	23 (18 to 27)	Most likely less difficult 0/0/100
6 weeks									
12 weeks	56	-1 (-4 to 3)	Most likely trivial 0/100/0	56	-1 (-2 to 2)	Most likely trivial 0/100/0	57	-1 (-3 to 6)	Most likely difficult 0/100/0
12 weeks									
24 weeks	37	1 (-4 to 3)	Most likely trivial 0/100/0	37	-2 (-4 to 0)	Most likely trivial 0/100/0	40	1 (-6 to 4)	Most likely difficult 0/100/0

Probability refers to the chances (as a percentage) that the change in outcome measure represents less/trivial/more disability or pain beyond the minimal threshold of 13 units. Bold text refers to inferences that were at least likely (75% chance) beyond the threshold of 32 units constituting a "moderate" improvement (Paul et al., 2004b). CI: confidence interval.

have been due to unrelated shoulder pathology or as a result of the persistent rotator cuff pathology that initially triggered the frozen shoulder (Linsell et al., 2005).

Despite all patients being informed verbally and in writing that they were able to self-refer to the service up until 24 weeks if they had any ongoing problems, no patients felt it necessary to do so between weeks 12 and 24, despite this increase in VAS. This may demonstrate the lack of actual clinical effect of this small rise in the patients involved.

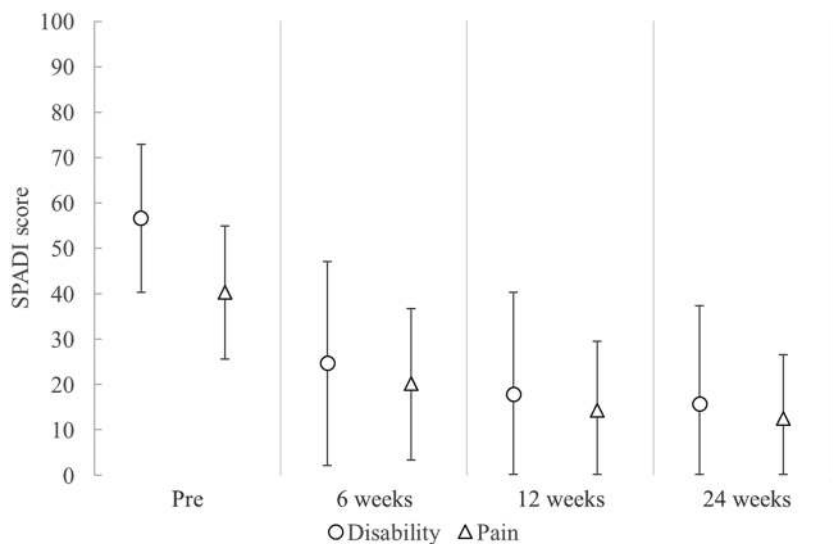
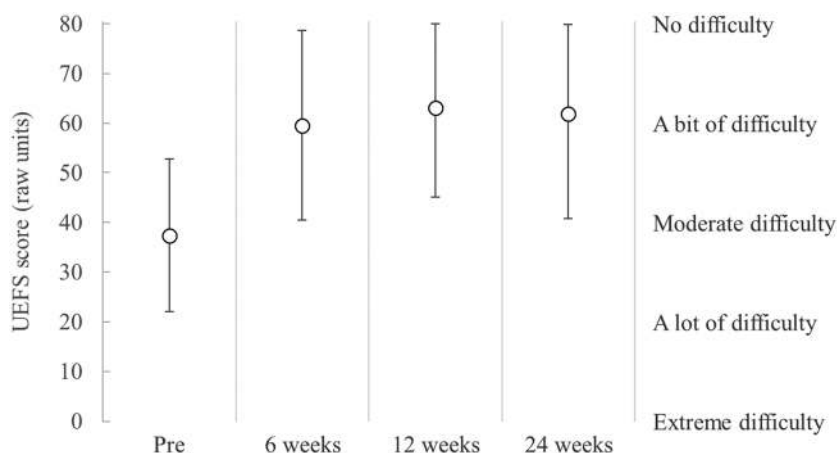
Hydrodistension is only one of the current treatment methods used to treat the symptoms of frozen shoulder (Rookmoneea et al., 2010). Steroid injections are widely accepted as a variable treatment option for frozen shoulder, but a lack of high-quality evidence exists regarding clinical effectiveness. A Cochrane systematic review identified one placebo-controlled trial of intra-articular steroid injection for "painful and stiff shoulders", which reported that corticosteroid injections gave no greater improvement in pain or range of movement than analgesia alone at 6 weeks (Rizk, Pinals, & Talaiver, 1991). Other studies have shown varying benefit; for example, Carette et al., 2003) compared steroid injections with placebo to treat frozen shoulder, and found a statistically significant reduction in pain but no associated improvement in the range of movement post-injection. A steroid injection plus distension was found to result in a statistically significant decrease in pain and an improvement in range of movement compared with steroid alone (Gam, Schydlowsky, Rossel, Remvig, & Jensen, 1998; Jacobs et al., 1991). Jacobs et al. (1991) further concluded that that distension in combination with steroid is superior to distension alone in improving range of movement but not significantly better than steroid alone. A combination of physiotherapy and intra-articular steroid injection displayed a greater benefit on range of movement than either modality independently (Carette et al., 2003). Our study cohort contained patients in whom a combination of a steroid injections and physiotherapy had already failed to give sufficient resolution to their pain, range of motion or disability levels.

The results of the present study suggest that hydrodistension can decrease the debilitating symptoms of frozen shoulder when initial frontline physiotherapy and steroid injection have failed. Importantly, hydrodistension may therefore prove to be a useful clinical tool for reducing the number of referrals for surgical intervention, and therefore give rise to significant financial savings. Bryant et al. (2017) quoted a cost of £131 for a primary care hydrodistension procedure, which correlated closely with other published figures (O'Connaire & Lewis, 2011). Savings per patient, based on published evidence, suggested a saving of £2,073 per patient if undergoing hydrodistension within a primary care clinic compared with surgery (Maund et al., 2012; O'Connaire & Lewis, 2011), with evidence suggesting similar, if not improved, outcomes from hydrodistension compared with those post-surgery (Quraishi et al., 2007). Furthermore, no significant complications or infections were reported in our study, consistent with other published work (Bell, Coghlan, & Richardson, 2003; Buchbinder et al., 2004). The only side effects reported within the literature are related to the steroid component of the procedure and are not attributed to the saline or the volume injected (Halverson & Rich,

TABLE 3 Mean active range-of-motion pre-hydrodistension, post-24 hr and at discharge, and pairwise comparisons between time periods, showing number of observations (*n*), mean difference and clinical inference

Active range of motion test	Pre-hydrodistension	24 hr post-hydrodistension	Final discharge	Differences at 24 hr post-hydrodistension (<i>n</i> = 87)		Differences at discharge (<i>n</i> = 88)	
	Raw mean $\pm$ SD (degrees)		Practical inference	Degrees (90% CI)	Practical inference	Degrees (90% CI)	Practical inference
Flexion	93 $\pm$ 22	113 $\pm$ 21	130 $\pm$ 21	20 (18 to 23)	Most likely improved 0/0/100	37 (33 to 41)	Most likely improved 0/0/100
Lateral rotation	26 $\pm$ 15	40 $\pm$ 15	50 $\pm$ 17	14 (12 to 16)	Most likely improved 0/0/100	24 (21 to 27)	Most likely improved 0/0/100
Abduction	70 $\pm$ 21	92 $\pm$ 25	115 $\pm$ 32	22 (19 to 25)	Most likely improved 0/0/100	44 (38 to 50)	Most likely improved 0/0/100

CI: confidence interval; SD: standard deviation.

**FIGURE 2** Mean Shoulder Pain Disability Index (SPADI) scores pre-hydrodistension ("Pre") and after 6, 12 and 24 weeks. Error bars represent standard deviations**FIGURE 3** Mean Upper Extremity Functional Index (UEFI) scores pre-hydrodistension ("Pre") and after 6, 12 and 24 weeks. Error bars represent standard deviations

2002; Jacobs et al., 1991). It has been suggested, however, that hydrodistension is more painful than steroid injection alone (Gam et al., 1998).

4.1 | Limitations

We conducted a single-arm, retrospective, observational study which had no randomized control group, given that this was a service evaluation of normal clinical practice. In addition, as all participants continued to receive physiotherapy post-injection, it is not known to what extent the rehabilitation programme had an effect on the outcome measures used within the study. However, all patients had previously failed on the same guided exercise programme, so it is likely that the benefits demonstrated were as a result of the hydrodistension injection, either in its entirety or in its ability to improve the rehabilitation offered. An experienced injection clinician, within the service, administered all hydrodistension injections. The skill and experience of the operator may affect the accuracy and efficiency of shoulder joint injections (Dogu, Yucel, Sag, Bankaoglu, & Kuran, 2012) but the extent of this is not known. In addition, research has indicated that ultrasound-guided injections have demonstrated higher accuracy compared with landmark procedures (Aly, Rajasekaran, & Ashworth, 2015). The latter systematic review and meta-analysis concluded that the use of ultrasound-guided injections into the shoulder resulted in improved accuracy. A more recent randomized controlled trial also reported greater injection accuracy, although the improvements in pain, range of movement and functional outcomes were not significant compared with landmark injections (Raeissadat, Rayegani, Langroudi, & Khoiniha, 2017).

5 | CONCLUSIONS

Hydrodistension substantially reduced pain and disability associated with frozen shoulder, in a UK primary care setting. The study suggests that the treatment of frozen shoulder can be undertaken within the community when standard treatment options of analgesia, physiotherapy and steroid injections fail to give sufficient benefit.

ACKNOWLEDGEMENTS

The authors would like to recognize the contribution of Catherine Grebby and Alex Plummer for their work in devising and implementing a rehabilitation programme. The authors would also like to thank Andy Richardson for supporting the data collection process.

CONFLICTS OF INTEREST

Both G.R. and J.C. work at South Tyneside and Sunderland Trust.

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How to cite this article: Rae GC, Clark J, Wright M, Chesterton P. The effectiveness of hydrodistension and physiotherapy following previously failed conservative management of frozen shoulder in a UK primary care centre. *Musculoskeletal Care*. 2019;1–9. <https://doi.org/10.1002/msc.1438>