

Predictors of reintervention following hydrodistension as a treatment for adhesive capsulitis

a multicentre retrospective study

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Aims

The primary outcome was to determine the proportion of patients with adhesive capsulitis who required reintervention following a treatment of hydrodistension. The secondary outcome was to identify predictors of reintervention.

Methods

A total of 712 hydrodistension procedures from six NHS trusts were included for statistical analysis. Minimum follow-up was 18 months. The primary outcome was the reintervention rate. Reintervention was defined as a subsequent steroid injection, arthroscopic capsular release, or repeat hydrodistension. The secondary outcome was to determine predictors of reintervention. Patient demographic characteristics, duration of symptoms, previous treatment, diabetic status, insulin usage, and glycated haemoglobin (HbA1c) were recorded. Logistic regression models were run for the primary and secondary outcomes.

Results

In total, 176/712 patients (24.7%) required further treatment. We found the following factors to be predictors of repeat intervention: female sex ($p = 0.036$), diabetics ($p = 0.003$), patients with a HbA1c ≥ 48 mmol/mol ($p = 0.011$), and patients who had received previous steroid injections ($p = 0.002$). Age and duration of symptoms did not correlate with increased risk of reintervention.

Conclusion

Hydrodistension may be considered an effective treatment for adhesive capsulitis, with the majority of patients in our cohort not requiring further intervention. We identified predictors of reintervention, which may assist in patient counselling and treatment planning. Although the optimal first-line management for adhesive capsulitis remains uncertain, hydrodistension represents a cost-effective, widely accessible, and minimally invasive option. Further comparative studies are warranted to establish its place in the treatment algorithm.

Take home message

- To the authors' knowledge, this is the largest multicentre UK study of its type. It supports previous studies suggesting that

hydrodistension is an effective treatment for adhesive capsulitis with reasonably low reintervention rates (24.7% in our cohort).

- Female sex, patients with diabetes, patients with an HbA1c ≥ 48 mmol/mol, and patients who have had previous steroid injection have higher rates of reintervention.
- Age and duration of symptoms did not predict reintervention rates.

Introduction

Adhesive capsulitis (AC) is a common cause of shoulder pain and stiffness. There is a lifetime prevalence of 3% to 5% in the general population, most commonly affecting females in their fifth to sixth decade of life.¹ Diabetes mellitus (DM) is frequently quoted as a risk factor. A 2016 meta-analysis involving 13 studies identified the prevalence of DM in patients with AC was 30% as opposed to a prevalence of 8% in the general UK population.² Not only is AC more common in DM patients, but it is also frequently more resistant to treatment.³ The condition is characterized by both histological changes in the glenohumeral joint capsule and a reduction of volume of the joint from 28 to 35 ml in healthy individuals to 5 to 10 ml in the diseased state. This capsular contraction is a hallmark of the 'frozen' stage of the condition.⁴

AC is often managed expectantly with pain management and physiotherapy, as it is frequently viewed as a self-limiting condition.⁵ However, the duration of the condition can be lengthy, varying between one and four years.⁶ Additionally, while resolution may be complete, some individuals are left with persistent pain and stiffness.² Both these factors may result in significant morbidity. As such, there has been a focus on identifying treatment methods that can either expedite and/or optimize recovery. Interventions include intra-articular steroid injections, hydrodistension (distension arthrography), or surgical options such as arthroscopic arthrolysis. These management options are often performed with simultaneous physiotherapy regimes. For many of these treatment methods there remains significant controversy in terms of both their suitability and efficacy. This is highlighted by the largest randomized control trial of the disease, UK primary frozen shoulder in secondary care (FROST), which found no differences between manipulation under anaesthesia, arthroscopic capsular release, and physiotherapy.⁷ Of note, hydrodistension (HD) was not used as a treatment arm in this study.

HD treatment has been identified as an area to concentrate further research. The proposed mechanism is that of immediate capsular expansion, maintained with supplementary physiotherapy.^{8,9} While differences in technique do exist, the procedure commonly involves the introduction of local anaesthesia to the skin, followed by a radiology-guided injection of 20 to 40 ml saline into the joint capsule and an intra-articular steroid injection at the end of the procedure. Proponents of HD point to the fact the procedure is less invasive than surgical intervention, is cost-effective,¹⁰ and does not require a general anaesthetic or theatre resources. Critics highlight studies that have demonstrated clinically insignificant outcomes.¹¹

This study aims to evaluate the effectiveness of HD by identifying the number of individuals who need no further intervention following their HD treatment. This was taken as a marker of treatment success. Our secondary aim was to identify any predictors of re-intervention in those patients requiring further treatment.

Methods

This study involved patients who underwent a primary HD procedure for suspected AC between January 2018 and June 2022 from six NHS trusts in the UK. In cases where the diagnosis was in question, further investigations were performed to rule out an alternative diagnosis. Our inclusion criteria also included patients aged 18 years or over with a minimum follow-up of 18 months. Patients were excluded if further investigation revealed an alternative diagnosis (e.g. radiography showing glenohumeral osteoarthritis), if arthrography was done for a different indication (e.g. MRI arthrogram to investigate rotator cuff pathology), if patients failed to attend follow-up, or if the HD procedure was abandoned (e.g. the patient did not tolerate it). We did not exclude any patients who had an incidental finding of rotator cuff pathology on imaging. This was because the clinical presentation was thought to be caused by capsulitis rather than a cuff tear. Patients were referred for HD treatment if they had clinical signs of AC such as stiffness and pain.

Data collected included basic demographic characteristics such as age and sex. These were prospectively recorded locally in each trust and retrospectively gathered by the authors to be amalgamated into a final anonymized database. We considered a patient having bilateral HD therapy as separate events. Referral letters were scrutinized to collect the duration of the patient's symptoms prior to HD therapy. Preceding interventions such as prior physiotherapy, injections, and capsular release were also recorded. Diabetic status, insulin use, and glycated haemoglobin (HbA1c) levels were gathered from medical notes. A HbA1c level of ≥ 48 mmol/mol was chosen to be significant as this may indicate diabetes as per the National Institute of Health and Care Excellence (NICE).¹² These data were collected as we thought there may be a possibility of patients with raised HbA1c levels with levels of ≥ 48 mmol/mol (typically diagnostic of diabetes in many demographic groups) but no formal diagnosis of diabetes recorded in the medical notes.

HD therapy was performed by trained musculoskeletal radiologists in each of the six NHS trusts. Patients were positioned supine or prone and the skin injected with 1% lidocaine local anaesthetic over the upper medial quadrant of the humeral head. A fluoroscopic-guided injection of dye using a 22-gauge spinal needle confirmed intra-articular position. This was followed by the injection of between 20 ml to 30 ml of saline into the joint with 1% lidocaine. A dose of 40 mg steroid (triamcinolone or depomedrone) was injected into the joint at the end of the procedure. Physiotherapy was requested to occur within 48 hours of HD therapy.

We recorded 753 episodes of HD appropriate for inclusion across the data collection period. A total of 41 treatments were excluded as these were the same patients having repeat procedures on the same shoulder. This gave a total of primary 712 HD treatments available for statistical analysis.

The primary outcome was to determine the reintervention rate which the authors feel reflected a suitable marker for overall 'success' of treatment. Reintervention was defined as a patient having one or more episodes of the following treatments after a HD therapy: subsequent steroid injection, repeat HD, or surgery. This information was gathered from medical notes as well as radiological records. The

Table I. Descriptive statistics.

Variable	Freq. (%)	Miss. (%)	Mean (range, SD)
Age, yrs		0 (0)	54.62 (22 to 87, 9.96)
Bilateral disease			
Yes	34 (95.23)	0 (0)	
No	678 (4.48)		
Sex			
Male	271 (38.06)	0 (0)	
Female	441 (61.94)		
Location of treatment			
Trust A	210 (29.49)	0 (0)	
Trust B	92 (12.92)		
Trust C	75 (10.53)		
Trust D	168 (23.60)		
Trust E	75 (10.53)		
Trust F	92 (12.92)		
Diagnosis of diabetes			
Yes	176 (24.72)	5 (0.70)	
No	531 (74.58)		
HbA1C recorded			
Yes	436 (61.24)	0 (0)	
No	276 (38.76)		
			48.17
HbA1C value	276 (38.76)		(29 to 124, 16.62)
HbA1C value ($\geq$ 48 mmol/mol)			
Yes	153 (21.49)	276 (38.76)	
No	283 (39.75)		
Insulin user			
Yes	63 (8.85)	5 (0.70)	
No	644 (90.45)		
			12
Duration of symptoms, mths		67 (9.41)	(1 to 240, 14.57)
Previous capsular release			
Yes	31 (4.35)	32 (4.49)	
No	649 (91.15)		
Previous injections			
Yes	294 (41.29)	32 (4.49)	
No	386 (54.21)		
Previous physiotherapy			
Yes	582 (81.74)	32 (4.49)	
No	98 (13.76)		

(Continued)

(Continued)

Variable	Freq. (%)	Miss. (%)	Mean (range, SD)
Had any reintervention post initial HD			
Yes	176 (24.72)	6 (0.84)	
No	530 (74.44)		
Had further HD post initial HD			
Yes	61 (8.57)	6 (0.84)	
No	645 (90.59)		
Had injection post initial HD			
Yes	91 (12.78)	6 (0.84)	
No	615 (86.38)		
Had surgery post initial HD			
Yes	94 (13.20)	6 (0.84)	
No	612 (85.96)		

HbA1C, glycated haemoglobin; HD, hydrodistension.

secondary outcome was to determine predictors for reintervention. Age, sex, duration of symptoms, diabetes status, insulin usage, serum HbA1c level, bilateral symptoms, and previous treatments were recorded and analyzed for potential predictors of reintervention.

Patient characteristics

A total of 712 patients underwent a primary HD procedure across six different trusts in our region between January 2018 and June 2022. There were 441 females and 271 males. A diagnosis of diabetes was recorded in 176 patients (24.7%). Of these patients, 63 (8.8%) were prescribed insulin. A HbA1c was recorded in 436 patients and a value of ≥ 48 mmol/mol was recorded in 153 patients.

Patients had a mean duration of 12.0 months of symptoms prior to a HD treatment (1 to 240, SD 14.6). Prior to HD treatment, some patients had alternative treatments. This was in the form of a capsular release ($n = 31$, 4.4%), a steroid injection ($n = 294$, 41.3%), and/or physiotherapy ($n = 582$, 81.7%). A total of 17 patients (34 shoulders) had bilateral disease. Summary descriptive statistics are shown in [Table I](#).

Statistical analysis

Analyses were conducted by a medical statistician (LB) using R version 4.2.0 (R Foundation for Statistical Computing, Austria). Descriptive statistics were calculated for all variables, including means and SDs for continuous variables, and frequencies and percentages for categorical variables. Missing data patterns were examined and reported ([Table I](#)). We examined predictors of reintervention using logistic regression models, first conducting univariable analyses to examine associations between each predictor and reintervention outcomes; and second, running multivariable models adjusted for the

Coefficient plot

Model —●— Multivariable —●— Univariable

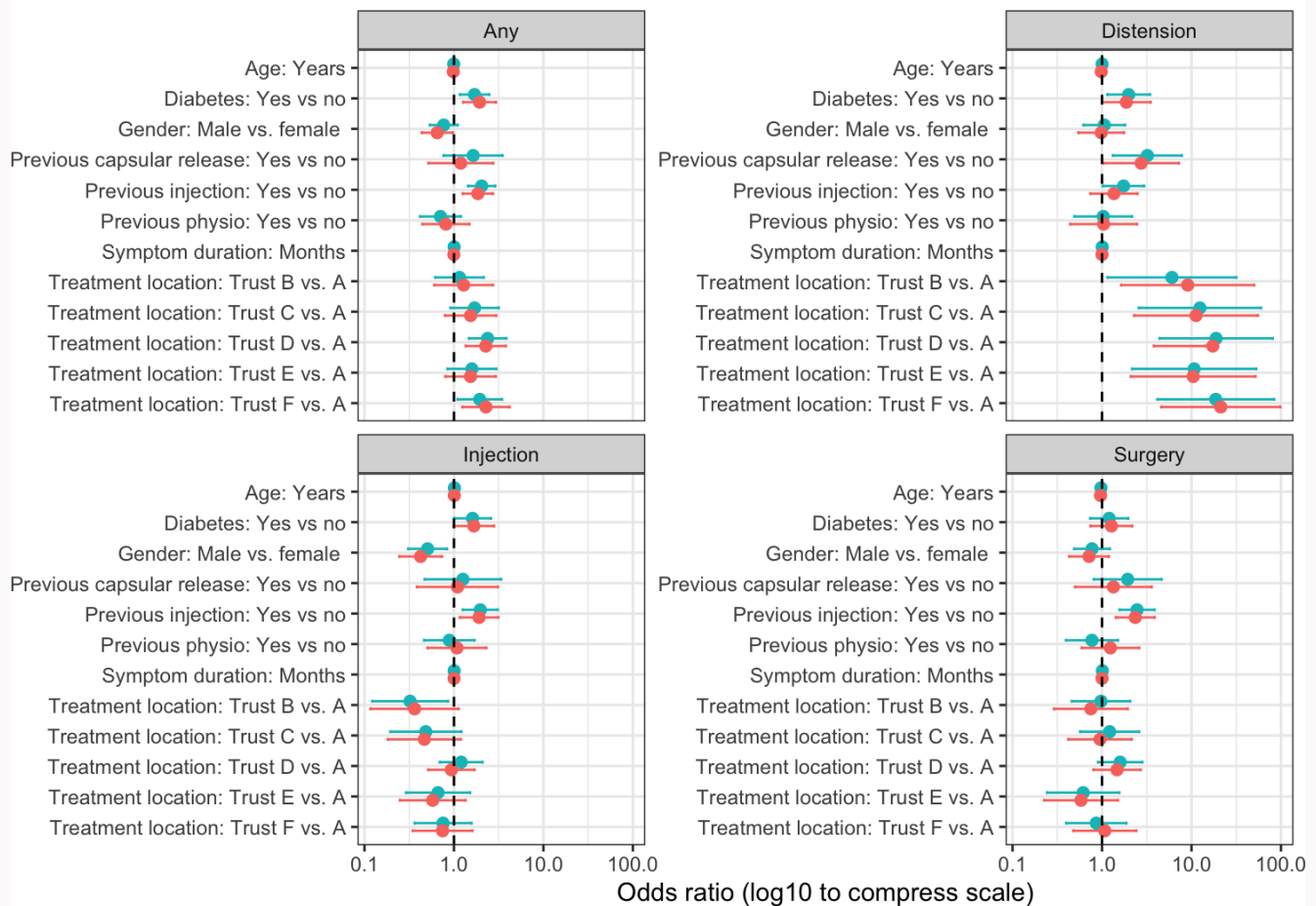


Fig. 1
Univariable and multivariable regression odds ratios (95% CI).

following variables: bilateral disease status; diabetes status; age; sex; trust location; self-reported duration of symptoms (months); previous physiotherapy; previous injections; and previous capsular release.

Variables highly collinear with diabetes status (insulin use and HbA1c values) were excluded from adjusted models in order to avoid multicollinearity. Univariable and multivariable models were run for each binary (yes/no) outcome, namely any of the following interventions: surgery, injection, and repeat distension.

For repeat patients, we assessed the impact of within-patient clustering using mixed-effects logistic regression models. The intraclass correlation coefficient (ICC) was negligible (< 0.01), indicating minimal within-patient dependency, so standard logistic regression was used for the final analyses.

Model performance was assessed using McFadden's pseudo- R^2 and Bayesian Information Criterion (BIC). For model comparison, we quantified differences in BIC values (Δ BIC), where lower values > 10 indicate strong evidence for the better-fitting model. Model coefficients are presented as odds ratios (ORs) with 95% CIs. Given the exploratory nature of the analyses and multiple tests performed, we recommend

focusing more on these effect size intervals as opposed to p-values, though we did pre-specify an alpha of two-tailed 0.05.

Results

Primary outcome

In total, 530 patients (74.4%) had no further intervention after their HD treatment; 176 patients required further intervention. There were missing datasets for further intervention for six patients. Overall, 61 patients required a further HD treatment, 91 required a steroid injection, and 94 went on to have surgery (Table I).

There is overlap between the three groups, as some patients may have had one more than one further intervention. In those patients who had a further steroid injection, this was in the glenohumeral joint in 47.3% ($n = 43$), the subacromial region in 42.8% ($n = 39$), and the acromioclavicular joint in 9.9% ($n = 9$).

Secondary outcomes

Pertinent summary statistics for the 176 patients undergoing further intervention are shown in Table II while Supplementary Table I details the complete results and statistical analysis.

Table II. Clinical factors predicting the rate of any reintervention following primary hydrodistension (summary statistics following multivariable logistic regression unless otherwise specified, model performance using McFadden's pseudo-R² and Bayesian Information Criterion).

Parameter	Reintervention	No reintervention	OR	95% CI	p-value
Mean age, yrs (SD)	54.18 (9.61)	54.775 (10.08)	0.981	0.962 to 1.000	0.053
Symptom duration, mths (SD)	12.77 (10.68)	11.75 (15.72)	0.997	0.984 to 1.011	0.716
Bilateral disease (Y:N)	13:163	21:509	1.868	0.882 to 3.956	0.103
Sex (Male:Female)	59:117	210:320	0.652	0.437 to 0.973	0.036*
Diabetes (Y:N:unknown)	57:119	116:411:3	1.919	1.257 to 2.929	0.003
Previous physio (Y:N)	155:20	427:78	0.830	0.453 to 1.522	0.547
Previous injection (Y:N)	98:76	196:310	1.860	1.260 to 2.746	0.002
Previous capsular release (Y:N)	11:163	20:486	1.219	0.530 to 2.799	0.641
HbA1c $\geq$ 48 mmol/mol (Y:N)†	49:127	102:428	2.208	1.185 to 3.649	0.011†

Complete analysis and model details demonstrated in Supplementary Table i.

*Univariable analysis due to collinearity with diabetic status.

†In favour of female sex predicting need for reintervention.

HbA1c, glycated haemoglobin; OR, odds ratio.

We found the following factors to be predictors of patients requiring further treatment following their HD: female sex ($p = 0.036$), diabetics ($p = 0.003$), patients with a HbA1c ≥ 48 ($p = 0.011$), and patients that had received previous steroid injections ($p = 0.002$) (Table II and Figure 1).

In total, 57 patients requiring further intervention were identified as diabetic. Reviewing the specific nature of the further intervention undertaken in diabetic patients, it was identified that, while these individuals were more likely to have a subsequent injection and/or a repeat HD after their index procedure, there were no differences in the frequency of those going ahead to surgery between diabetic and non-diabetic patients (Table II).

Discussion

We found a reintervention rate of 24.7% in patients undergoing primary HD for adhesive capsulitis over a six-year period with a minimum follow-up of 18 months. Reintervention rates were higher in female patients, diabetic patients, patients with a serum HbA1c level of ≥ 48 mmol/mol, and patients who had previously received a steroid injection.

These results show some similarities to previous studies in the literature. In the largest comparable study of 2,432 HDs over a ten-year period, Nicholson et al¹³ revealed that HD was less effective in diabetic patients and patients with bilateral disease. Like our study, they also found no differences in reintervention rates in age. However, they did reveal a much lower overall reintervention rate of 7.6%. They had a similar number of diabetic patients in their cohort. In a separate smaller study of 107 patients by Haughton et al,¹⁴ only two patients required further intervention. The differences in methodology between our studies and others in the literature may explain some of the discrepancy in reintervention rates. Our study identified an injection as a further intervention, whereas the other studies did not. If we removed an injection as a further intervention, our study revealed a reintervention rate of 19.8%, which does slightly decrease the discrepancy.

Our multivariate regression model demonstrated that females were more likely to undergo a repeat intervention compared to males. This finding has not been encountered elsewhere in the literature.¹³ The explanation for this is unclear, and any interpretation should be made with caution. We recommend further studies to investigate this potential relationship.

Our study suggests that diabetic patients were over twice as likely to undergo further treatment. However, it is interesting to note that, while they were more likely to require further injections or HD, they were not more likely to have surgery compared to non-diabetic patients. The treating surgeons in this study may have been hesitant to offer surgery to diabetic patients who had failed initial HD treatment because of the previous poor outcomes reported in the literature,^{15,16} or due to local restrictions on elective surgery in diabetic patients with elevated HbA1c results.

In a prospective study of 51 patients undergoing HD, Clement et al¹⁷ found no differences in patient-reported outcome measures (PROMs) or range of motion (ROM) between diabetic and non-diabetic patients. While this study involved small numbers and had different outcome measures, it contradicts our conclusion that diabetic patients appear to have a less favourable prognosis. However, a more recent study of 135 patients by Dimitri-Pinheiro et al¹⁸ revealed that diabetic patients had worse pain and function than non-diabetic patients.

In our statistical analysis, the R² values (McFadden analogues) were generally low, which could indicate that there are other important variables that predict outcomes which were not included in this study. One of these variables could be that the diagnosis of AC may not always have been correct – we relied on mainly upper limb specialists (and sometimes primary care clinicians) making a clinical diagnosis. This did not always include cross-sectional imaging with MRI, which may aid clinical diagnosis and rule out alternatives. The uncertainty in diagnosis may be further highlighted by the fact that while 91 patients were given a further

steroid injection, we found that this was administered to the glenohumeral joint in only 47.3% of patients (n = 43). The remainder were given the injection into either the subacromial space or acromioclavicular joint, which could suggest an alternate pathology. This highlights a weakness of the study, but also reflects the challenges in making the diagnosis in clinical practice.

Another variable that could have affected the results is the method of performing the HD procedure. While all radiologists performed the procedure similarly overall, there are some small interoperator differences. We did not assess the total volume injected into the joint and/or content of the fluid used to facilitate HD. We also did not record whether there was a capsular rupture, or which approach was used (anterior, posterior, or posterolateral).

We found variations in reintervention rates across the six NHS trusts. Predominantly, this was due to lower reintervention figures in 'Trust A'. Possible explanations for this include differences in threshold to intervene, access to theatres/radiology, or perhaps the subtle differences in the technique of delivering HD.

It is still unclear what the best treatment is when managing AC. In a systematic review of 65 studies with 4,097 participants, Challoumas et al¹⁹ revealed that HD with intra-articular steroid had the highest probability (96%) of being the most effective treatment in reducing pain when given within eight to 12 weeks of onset of symptoms. It became less effective in the four to six months post onset of symptoms. Our study did not support this, as we found no difference in reintervention rate with increased duration of symptoms. We found a wide variation in the timing of the initial HD treatment. This ranged from between one month to two years and may be due to patient, clinician, or system factors.

Multiple studies have shown no differences in HD and steroid compared with steroid alone.^{20–22} Gallacher et al²³ revealed that patients undergoing an arthroscopic capsular release had higher Oxford Shoulder Scores compared to those having HD. Another study compared manipulation under anaesthesia and HD, with the latter having significantly higher satisfaction scores.²⁴ The ideal treatment of AC therefore remains elusive.

This is, to our knowledge, the largest multicentre UK study that has investigated the efficacy of HD for AC. Despite this, our study is not without its limitations. This is a retrospective study and prone to selection bias. The primary outcome was the overall reintervention rate, which we took as a surrogate marker for the overall 'success' of the treatment. This will not be wholly accurate as we acknowledge that some patients may remain symptomatic after their HD, however they refuse/do not seek further treatment. This would imply either those that have had diabetes, are female, and/or have had previous injections may be less likely to ask for further treatment purely because of that characteristic, rather than the effectiveness of HD.

It is also difficult to ascertain whether it is the HD treatment that helps patients, or whether it is the natural course of the disease, as AC usually resolves with time, with or without treatment. Further areas for research would be the cost-effectiveness of HD compared with other AC treatments,

complications of HD, differences in the method of giving HD, and subsequent effects on PROMs and ROM.

Supplementary material

Table of univariable and adjusted logistic regression results for each reintervention type outcome.

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Ethical review statement

This project was registered with the audit departments in each NHS trust to allow access to patient notes and as such did not require an application to the NHS Research Ethics Committee.

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