Title: Analysis of hydrodilatation as part of a combined service for stiff shoulder.

Sinha R[a], Patel P[b], Rose N[c], Tuckett J[a], Banerjee Anurag N[d], Williams J[e], Aldridge S[e], Stuart P[e].

a- Consultant Musculoskeletal Radiologist, Newcastle Hospitals NHS Trust
b- Specialist Registrar, Department of Radiology, Newcastle Hospitals NHS Trust
c- Specialist physiotherapist, Newcastle Hospitals NHS Trust
d- Lecturer, Durham Business School, Durham University
e- Consultant upper limb surgeon, Newcastle Hospitals NHS Trust.

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Abstract

Objectives: Adhesive capsulitis is a common cause of stiff shoulder and may result in pain and restriction of movement. The aim of this study was to investigate the role of hydrodilatation of the glenohumeral joint in the management of adhesive capsulitis.

Methods: Patients referred from the shoulder clinic underwent hydrodilatation under ultrasound guidance. Of 209 referred for hydrodilatation, 163 underwent the procedure and attended follow-up physiotherapy. Outcome measures were available on 118 patients (58 men, 60 women). Mean age of the study group was 52.6 years.

Results: There was a statistically significant improvement in both Oxford Shoulder Score (OSS) and Disability Arm Shoulder Hand Scores (Quick DASH) in the first four weeks after the procedure, which was maintained, but not improved to the end of the study period. Patients presenting with pain, those who had a history of steroid injections and older patients had worse functional scores at presentation. Diabetes (both Type I and II), previous physiotherapy, length of history and whether pain or stiffness or both were the predominant symptom did not have any statistical significance at presentation. These factors were not predictors of statistically significant improvement in functional scores.

Conclusion: Hydrodilatation results in significant improvement of symptoms in patients with adhesive capsulitis.

Article focus

A combined service for managing the stiff shoulder using orthopaedics, physiotherapy and radiology was analysed using patient scoring systems.

Key messages

1. Hydrodilatation under ultrasound guidance is an effective treatment for the stiff shoulder.

Strengths and limitations

1. Hydrodilatation is a minimally invasive procedure for the management of the non-arthritic stiff shoulder.
2. The procedure well tolerated.
3. The multi-disciplinary team, (MDT), of orthopaedic surgeons, physiotherapists and radiologists functioned well in our institution
4. Loss to follow-up limited the size of our trial cohort.

Introduction

Stiff shoulder is a common presentation to the shoulder clinic; adhesive capsulitis, (commonly referred to as frozen shoulder), is the most common cause, affecting approximately 2-5%of the population[1, 2]. However later studies surmise that the real incidence of capsular contracture is about 0.75% of the population as described by Bunker[3]. The condition is characterised by a thickening and contracture of the capsule akin to Dupuytren's contracture of the hand[3].

Night pain with a reduced range of movement, particularly external rotation is one of the cardinal symptoms[4]. Frozen shoulder may be idiopathic or secondary to preceding trauma. Although older studies suggested a significant female preponderance[5] more recent arthroscopic studies demonstrate a 1:1 male to female ratio and go on to suggest female preponderance if any is very small[3]. There is a strong association with diabetes mellitus[6]. The condition is usually self-limiting, typically lasting between 12-36 months[7], with spontaneous resolution usually demonstrated, though some studies demonstrate up to 41% of patients had persisting symptoms associated with pain and functional loss[8, 9].

Three stages have been described in the past[4] but it is accepted that the course of the disease can be variable[3]. Multiple treatment strategies have been suggested for the management of adhesive capsulitis, including manipulation under anaesthesia, surgical capsular release, physiotherapy regimens, intra-articular steroid injections , hydrodilatation of the gleno-humeral joint (either using fluoroscopy[10] or ultrasound[11] guidance), or a combination of the above. Hydrodilation has been demonstrated to be more effective than physiotherapy[12] and is also effective when compared with manipulation under anaesthesia[13]. Arthroscopic capsular release[14] is an effective method of improving symptoms but is more invasive and expensive. Recent evidence suggests steroid injection into the rotator interval may be of benefit in this group of people[15]. Studies have suggested an improvement following hydrodilatation, usually with steroid in the injectate[16-24].

Hydrodilatation distends the gleno-humeral joint capsule with capsular rupture as the desired end-point. This study illustrates our strategy for managing stiff shoulder.

Materials and methods

Patient recruitment

Our stiff shoulder service is a multi-disciplinary team (MDT) approach between orthopaedics, physiotherapy and radiology. Ethical approval was deemed unnecessary by our institutional review board. The aim of this study was to assess the efficacy of hydrodilatation of the gleno-humeral joint combined with intra-articular steroid injection and followed by a prescribed course of physiotherapy.

An initial pilot study of twenty patients with primary stiff shoulder was performed. Successful clinical outcomes were noted. Our institution's "New Procedures Committee" approved the technique for clinical use as part of a prospective clinical study. Appropriate consent procedures were established.

209 patients with primary or secondary (but not post-operative), stiff shoulder were referred to the study from the shoulder clinics of the Newcastle upon Tyne teaching hospitals. After the procedure, subjects were followed up in those clinics. Six patients who failed to improve with hydrodilatation were considered for other procedures where appropriate.

Patients were recruited from 2011-14. Four patients with a proven full thickness rotator cuff tear were excluded as hydrodilatation is not effective in this group.

Technique

All procedures were carried out by one of two consultant musculoskeletal radiologists with the first author performing all the procedures in the initial pilot study.

Patients were requested to bring a family member/friend as an escort after the procedure and were also recommended not to drive post-procedure. If any patient was on anticoagulant usual departmental policy for interventional procedures was followed.

Radiographs of the shoulder were assessed to exclude osteoarthritis of the shoulder. History obtained included duration of symptoms, history of diabetes, previous steroid injections, physiotherapy, any co-existing medical condition was recorded, whether symptoms were worsening or plateaued prior to procedure and whether pain, stiffness or both were the predominant symptom.

OSS (Oxford shoulder score) [and] Quick DASH (Disabilities of the arm, shoulder and hand) scores were also obtained immediately prior to the procedure. A diagnostic ultrasound of the shoulder was performed with a 9MHz curvilinear or 12.5MHz linear array ultrasound transducer (Phillips IU22 or Epiq 5) to confirm cuff integrity and exclude other cause of shoulder pain relating to the cuff, long head of biceps tendon, subacromial bursa or acromioclavicular joint. In the absence of contra-indications the patient was consented including discussion of potential complications.

The procedure was performed in the lateral position lying on the un-affected side. The probe was placed transversely across the posterior aspect of the glenohumeral joint such that the glenoid labrum was in the middle of the screen. An appropriate site of puncture was marked. Using aseptic technique, 1% lidocaine was infiltrated into the skin and subcutaneous tissues. Under ultrasound guidance a 21G needle was placed into the glenohumeral joint via a postero-oblique approach.

Approximately 8-10ml Lignocaine 1% was then injected into the joint followed by a mixed injectate of 80mg triamcinolone, 15ml of 0.25% bupivacaine and 40-60mls of normal saline with phasic distension to the point of rupture. If capsular rupture had not been achieved after instillation of 60mls of normal saline the procedure was terminated.

Five simple exercises aimed at increasing shoulder joint ranges of movement (flexion, abduction and rotations) were demonstrated to the patient, these were to be performed three times a day. Physiotherapy started the day after the procedure and continued as required and advised by the physiotherapist.

Patients completed the Quick DASH and the OSS scores at four weeks, three, six and twelve months post-procedure.

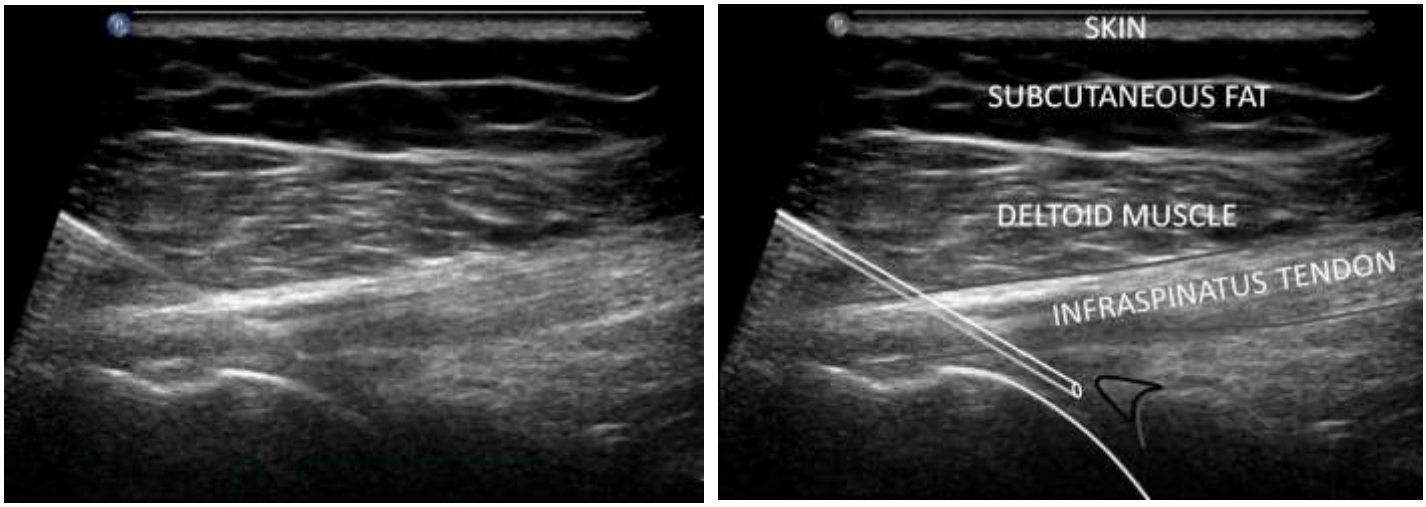

Figure 1. Ultrasound image on left showing needle tip position into the gleno-humeral joint with corresponding image on the right annotating various structures (humeral head outlined, glenoid outline in grey and posterior labrum in black).

Results

209 patients were referred for hydrodilatation during the study period. On presentation for the procedure 19 had improved and declined treatment, 11 patients did not attend the procedure; seven did not attend their initial physiotherapy appointment. Nine procedures were abandoned for various reasons, (Table 1). Six patients had subsequent procedures following failed hydrodilatation (Table 7).

163 patients underwent hydrodilatation, with adequate post-procedure rehabilitation and data scores (at least 2 sets) available in 118.

Mean age was 52.6 years (range 28-73 years; Table- 2), 60 were female and 58 male and 26 suffered from diabetes mellitus.

Extremely tight capsule	1
Breast carcinoma and radiotherapy	1
Cuff tear	4
Syncope prior to procedure	1
Cerebral bleed prior to procedure	1
Withdrawn consent	1

Table 1: Indication for abandoning / not performing procedure.

Age group in years	Number of patients
Less than 20	0
21-30	2
31-40	2
41-50	31
51-60	59
61-70	21
71-80	3

Table 2: Age distribution of study group.

Regression analysis of the pre-procedure OSS and Quick (QDASH) scores demonstrated that older patients, those who had undergone steroid injection/s and those who considered themselves to be in the worsening phase rather than in the plateau phase were functionally worse at the time of presentation. No statistical difference in pre-procedure scores was noted between the diabetics and non-diabetics. Patients who had received prior physiotherapy did not have a statistically different score from those who had not; the duration of symptoms pre-procedure did not correlate with the scores at time of hydrodilatation.

	Estimates		**std_errors**		**t_stats**		**p_values**	
	OSS	**QDASH**	**OSS**	**QDASH**	**OSS**	**QDASH**	**OSS**	**QDASH**
Const	38.66	16.46	6.57	12.68	5.89	1.30	0.00	0.20
Diabetes(y=1)	1.77	-1.48	2.38	4.59	0.74	-0.32	0.46	0.75
Physio(y=1)	-1.33	2.37	2.41	4.65	-0.55	0.51	0.58	0.61

Pain/stiffness/both(p=1)	0.42	-3.83	1.74	3.34	0.24	-1.15	0.81	0.25
Plateau/worse(w=1)	-5.74	13.50	2.30	4.43	-2.50	3.05	0.01	0.00
Steroid>0	-4.41	9.26	2.16	4.17	-2.04	2.22	0.04	0.03
Age(yrs)	-0.22	0.50	0.11	0.22	-1.97	2.30	0.05	0.02
Symptom duration(mth	-0.02	0.05	0.07	0.13	-0.31	0.39	0.76	0.70
ADj R2:	0.10	0.14						

Table 3: Regression analysis of pre-procedure scores.

A significant improvement in functional scores was demonstrated at four weeks post- procedure, OSS score increasing by 14.99 (p=0.00) and the QDASH reducing by 26.82 (p=0.00).

No statistical difference was observed in either score between four weeks and subsequent follow-up, (Table 4).

There has been a reduction in datasets available especially in the latter stages of patient follow-up with the largest set of scores (df) being available for the time period from procedure to 4 weeks i.e. 79(OSS) and 80(QDASH) which reduced for the subsequent periods.

	Mean		**t_stats**		**df**		**p_values**	
	OSS	**QDASH**	**OSS**	**QDASH**	**OSS**	**QDASH**	**OSS**	**QDASH**
Between procedure and 4 weeks	***14.99***	***-26.82***	***15.75***	***-15.20***	***79***	***80***	***0.00***	***0.00***
Between 4 weeks and 3 months	1.02	**-3.34**	1.36	**-2.28**	52	**53**	0.18	**0.03**
Between 3 and 6 months	-0.54	1.91	-0.56	0.95	34	34	0.58	0.35
Between 6 months and 1 year	0.79	-4.97	0.44	-1.46	42	42	0.66	0.15

Table 4: Demonstrates that the only significant consistent improvement occurs between the procedure and four weeks when using both OSS and QDASH scores.

Regression analysis of the functional scores between the procedure and four weeks (table 5), demonstrated significant, (p=0.04), improvement in the QDASH scores of younger patients vs older patients, with a similar but not as significant (p=0.07) trend with the OSS scores. The other patient factors did not correlate with post-procedure scores.

	Estimates		std_errors		t_stats		p_values	
	OSS	QDASH	OSS	QDASH	OSS	QDASH	OSS	QDASH

Const	4.31	0.10	7.44	13.90	0.58	0.01	0.56	0.99
Diabetic	-2.99	1.85	2.71	5.05	-1.10	0.37	0.27	0.72
Prior physiotherapy	-0.01	-1.73	2.74	5.11	0.00	-0.34	1.00	0.74
Type of symptoms (pain/stiffness/both)	0.19	3.73	2.02	3.73	0.10	1.00	0.92	0.32
Stage of disease (plateau/worse)	4.07	-7.82	2.65	4.95	1.53	-1.58	0.13	0.12
Prior steroid injections	-1.10	2.99	2.41	4.49	-0.46	0.67	0.65	0.51
Age(years)	0.24	-0.51	0.13	0.24	1.87	-2.11	0.07	**0.04**
Symptom duration (months)	-0.11	-0.14	0.14	0.26	-0.76	-0.53	0.45	0.60
ADJ R2:	0.01	0.01						

Table 5: analysis of patient factors - QDASH and OSS scores procedure to four weeks..

Discussion

Stiff shoulder, with or without pain, is a common presenting symptom[25]. It represents a socioeconomic burden leading to significant work absence.[26]

Incidence of stiff shoulder in General Practice is about 2.4 per 1000 head of population per year[27]. Referral to secondary care varies but UK data suggest only 22% patients were referred during the three years from initial presentation[28].

Many strategies have been described to reduce the level of pain or the duration of symptoms. We feel management of these patients within the current NHS primary care and secondary / tertiary musculo-skeletal services is often fragmented. We believe that composite MDT approach improves and hastens the treatment of the condition.

Gleno-humeral osteoarthritis can mimic frozen shoulder. All stiff shoulders should therefore be x-rayed.

Referral from primary care to specialist clinics is often delayed, (table 6).

Duration of symptoms to hydrodilatation	Number of patients
0-6months	18
7-12 months	63
13-24 months	28
>24 months	9

Table 6 Referral delays for hydrodilatation.

Regression analysis of scores at presentation suggest patients in the worsening stage were on average 13.5 points worse off on Quick DASH and 5.74 points worse off on OSS compared to the plateau stage. Patients who had at least one prior steroid injection had Quick DASH scores and OSS scores which were worse off by 9.26 and 4.41 points respectively. The scores also reveal that for every additional year age the Quick DASH and OSS scores were worse by a factor of 0.5 and 0.22 respectively.

Our experience suggests that ultrasound guidance is superior to fluoroscopy as it allows confirmation of cuff integrity, (allowing sufficient pressure for capsular rupture if achievable), and to exclude alternate local pathologies.

Our results demonstrate a statistically significant improvement in shoulder function and symptoms within four weeks of the procedure. This improvement was maintained to the end of the study period.

Given the initial results we observed on the patients with primary stiff shoulders, we subsequently performed the procedure in the later part of the study on some patients with secondary stiff shoulders. However we do not have adequate data and consider this aspect to be part of a future study.

The authors believe that it is vitally important to start exercising on the day of hydrodilatation and have a physiotherapy appointment the day after. However we will be assessing the role of physiotherapy in a future study.

Age does not appear to be a significant predictor of response to hydrodilatation. Results demonstrated (Table 5) that although there was some statistical significance on QDASH scores (p= 0.04), but this was not mirrored in the OSS scores (p= 0.07). However, there might be an underlying trend here.

There is a higher incidence of adhesive capsulitis in the diabetic population[6], our study had 22% patients who were diabetics. There was no difference in outcome between the diabetics to the non-diabetics in our study group - this concurs with a previous study by Clement et al[29].

There was also no statistical significance to the functional outcome in hydrodilatation patients who had previous physiotherapy, whether they recorded pain or stiffness or both as the predominant symptom and whether patients felt they were in the plateau or worsening stage.

Six patients required surgery post hydrodilatation. These patients are regarded as ‘failure of the procedure’. Three patients underwent an arthroscopic capsular release, two had manipulation under anaesthetic and one went on to have cervical spinal surgery. No common factors were demonstrated in this small sub-group of patients. All three participating surgeons saw a large reduction in the number of ‘stiff shoulder ‘procedures performed during the study period.

Arthroscopic capsular release	2
Manipulation under anesthesia	2
Subacromial decompression and capsular release	1
Cervical decompression for disc prolapse	1

Table 7: Post hydrodilatation surgery

The procedure was well tolerated by all patients. Our patient group experienced few adverse events / complications of the procedure. One patient developed transient suprascapular nerve palsy because of leakage of anaesthetic into the supraglenoid notch region. Patients often feel some discomfort and sometimes feel dizzy in the first few minutes of / after the procedure. We advised our patients to be accompanied for the procedure and not to drive for the rest of the day.

Table 8 demonstrates the reduction in surgical procedures (manipulation under anaesthesia or arthroscopic capsular release) for stiff shoulder in the four years after the start of the study period. This represents a 78.5% reduction in surgical treatment.

The procedure takes an hour to perform in our ultrasound department, with the patient free to leave once the procedure is completed. This compares favourably to surgical procedures.

Before		After	
2007	14	2011	3
2008	18	2012	2
2009	10	2013	3
2010	14	2014	4
Total	56	Total	12

Table 8: Surgical rates pre / post study. Our current management follows the algorithm below:

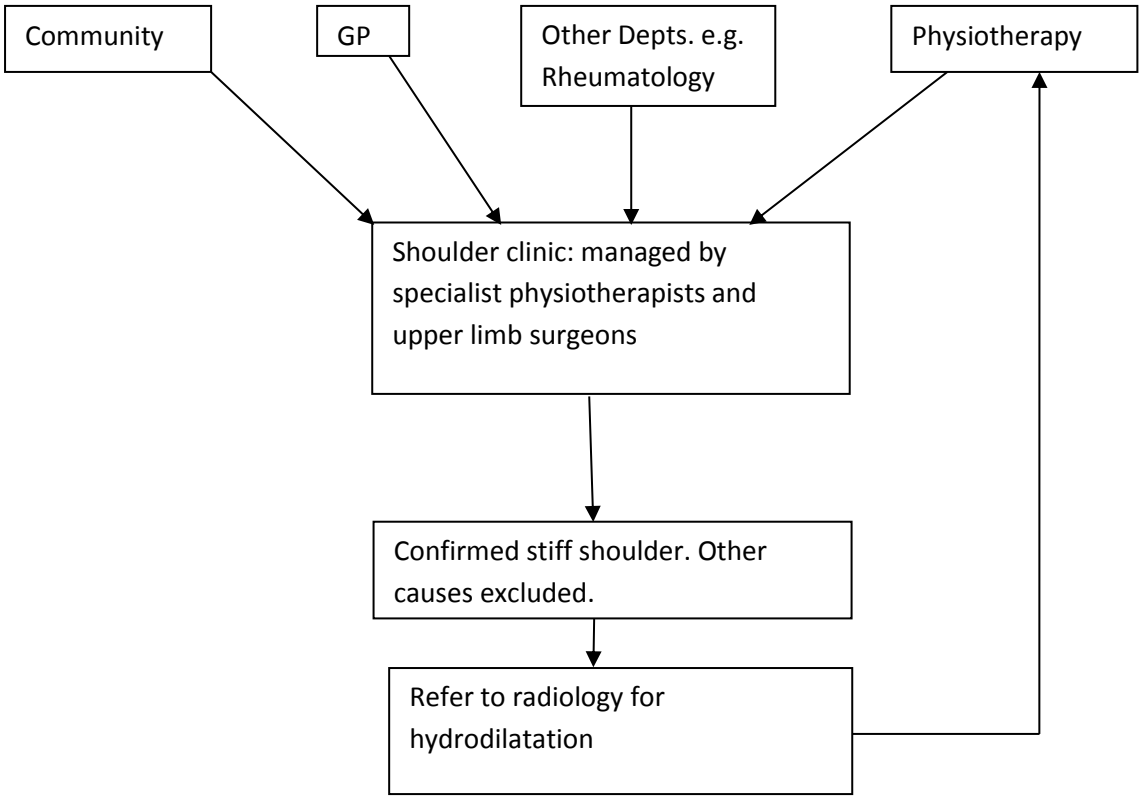

Figure 2: Flow pattern for management of frozen shoulder

A review in 2012 concluded there was limited clinical evidence on the effectiveness of treatments for primary frozen shoulder and that the studies which have been published in this area have all suffered from small participant numbers[30]. This study demonstrates with statistical significance, the

effectiveness of hydrodilatation in a large cohort. At our institution, the estimated cost of a surgical release is £1015 whilst for hydrodilatation is £282 as per currently priced coding guidelines, which represents a saving to the trust of £733 per case.

Conclusion

We have demonstrated that hydrodilatation under ultrasound guidance followed by physiotherapy is an effective management option for the stiff shoulder.

We have found that the MDT approach to the stiff shoulder has improved our management of this group of patients and markedly reduced our requirement for surgical procedures.

We propose that the establishment of a 'stiff shoulder clinic' run by specialist physiotherapists within the consultant led shoulder clinic with rapid access to hydrodilatation could hasten the resolution of patient's symptoms, facilitate an early return to work and sport. The reduction in surgical procedure will lead to considerable financial savings for the NHS and at the same time create a non-operative pathway for the management of this condition.

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