



Intra-articular steroid for adhesive capsulitis: does hydrodilatation give any additional benefit? A randomized control trial

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Abstract

Objectives To assess the benefit offered by capsular hydrodilatation in addition to intra-articular steroid injections in cases of adhesive capsulitis, assess outcomes in diabetic patients with capsular hydrodilatation as compared to non-diabetics and correlate duration of symptoms with outcome based on the type of intervention given.

Materials and methods This prospective double-blinded randomized control trial included patients presenting with clinical features of adhesive capsulitis with no evidence of rotator cuff pathology and randomized them into two groups—intra-articular steroid with hydrodilatation (distension group) and only intra-articular steroid (non-distension group) with intervention being performed as per the group allotted. Primary outcome measure was Shoulder Pain and Disability Index (SPADI) scores which were taken pre-intervention, at 1.5, 3 and 6 months post-intervention, which were assessed by generalized linear model statistics and Pearson correlation.

Results Although there was statistically significant drop in SPADI in both groups over time [$F(1.9, 137.6) = 112.2$; $p < 0.001$], mean difference in SPADI between the 2 groups was not statistically significant (1.53; CI:-3.7 to 6.8; $p = 0.56$). There was no significant difference between both groups among diabetics [$F(1,38) = 0.04$; $p = 0.95$] and no significant difference between diabetic and non-diabetic patients who received hydrodilatation [$F(1.8, 60) = 2.26$; $p = 0.12$]. There was no significant correlation between the reduction in SPADI scores and duration of symptoms in any subset of the study population.

Conclusion Shoulder joint hydrodilatation offered no additional benefit compared to intra-articular steroid injections for shoulder adhesive capsulitis. Outcome for diabetics and non-diabetics were similar and there was no correlation between duration of symptoms and outcome.

Keywords Shoulder joint · Adhesive capsulitis · Prospective studies · Injections, intra-articular · Diabetes mellitus

Abbreviations

ANOVA	Analysis of variance
CI	Confidence interval
CONSORT	Consolidated Standards of Reporting Trials
ITT	Intention to treat
RCT	Randomized control trial

SD	Standard deviation
SPADI	Shoulder Pain and Disability Index
VAS	Visual analog scale

Introduction

Adhesive capsulitis of shoulder, also called frozen shoulder, is a condition resulting in pain and global motion restriction at glenohumeral joint, resulting in joint stiffness, pain and dysfunction [1, 2]. Histopathological evaluation shows inflamed glenohumeral synovium, hypertrophy of coracohumeral ligament and fibrosis of joint capsule [3]. Frozen shoulder may be primary (idiopathic) or secondary to previous trauma, painful rotator cuff disorders, post-shoulder surgery, post-

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cerebrovascular accident or cardiovascular disease [2]. Although three stages have been described in the past [4], it is accepted that the course of the disease can be variable [5]. The natural history of this condition is controversial, with studies showing complete resolution of symptoms in 39–94% of patients on long-term follow-up of 2 years or more, irrespective of whether treatment was given or not [6–8].

Several treatment strategies have been advocated for treatment of this condition such as rest and analgesia, active and passive mobilization, physiotherapy, oral and intra-articular injectable corticosteroids, capsular distension, manipulation under anesthesia and arthroscopic capsular release [9]. Studies have shown that intra-articular steroid injections, under fluoroscopy or ultrasound-guidance are beneficial in cases of adhesive capsulitis [10, 11]. Distension of shoulder joint capsule with fluid, called as hydrodilatation, was first performed by Andr en and Lundberg [12]. Since then, multiple studies have shown equivocal results. One systematic review was inconclusive if this procedure was better than alternative treatments [13], while two recent meta-analyses concluded that joint distension with intra-articular steroid had similar efficacy as that of intra-articular steroid injection alone [14, 15]. However, one of these meta-analyses also mentioned that the cases enrolled in all previous randomized controlled trials were multi-factorial and recommended further studies for assessing the benefits of hydrodilatation in specific patient groups [15]. There is a strong association of this primary or idiopathic frozen shoulder with diabetes in both sexes [16]. Also, limited data is available on the efficacy of hydrodilatation in diabetic frozen shoulder. No previous study has assessed the relation between duration of symptoms and response to intra-articular steroids with or without hydrodilatation of shoulder, which may be significant considering the natural history of the disease.

Through this trial, we assessed the additional benefit offered by capsular hydrodilatation over and above isolated intra-articular steroid injections in cases of adhesive capsulitis. We also assessed if there was any additional benefit provided by capsular hydrodilatation of shoulder joint in diabetic patients as compared to non-diabetics; and if the duration of symptoms had any correlation with the outcome based on type of intervention given.

Materials and methods

This was a prospective, single-center, double-armed, randomized control trial (RCT) conducted in a tertiary care hospital from September 2016 to August 2018 using a parallel-intervention group type of design. The intervention period lasted for a period of 1.5 years with follow-up period lasted for 2 years, extending 6 months beyond the intervention period to ensure adequate follow-up of all patients. Institutional Ethical Committee approval was obtained prior to start of the

trial and the trial was registered prospectively on the National Clinical Trials Registry. Informed consent was obtained from all individual participants included in the study.

All consenting patients who were aged 18 years and above, who presented with clinical features suggestive of adhesive capsulitis and were referred for intra-articular steroid injection were included in the study. Diagnosis of adhesive capsulitis was made through a consensus decision of the shoulder clinic team of the department of orthopedics under the guidance of a senior orthopedic surgeon (VP), after taking into consideration the clinical history, physical examination, radiographs and relevant laboratory reports. All patients presenting with pain and global loss of shoulder movement within 6 months to a maximum of 12 months of onset of complaints were included in the study. The subjects were identified and selected based upon the clinical history and examination and were diagnosed as frozen shoulder/adhesive capsulitis as per current definition provided by ISAKOS shoulder consensus group [17]. All patients were given a preliminary course of analgesics for 3 weeks for pain relief. Only those who did not respond to the analgesics and continued to have severe pain or those who had recurrence of severe pain after a course of analgesics were included to be given intra-articular injection. Patients with history of rotator cuff pathologies like tendinopathy (calcific or non-calcific) and tears, history of trauma, bleeding diathesis, suspected infection of shoulder (osteomyelitis/septic arthritis), uncontrolled diabetes, prior cerebrovascular accident, cardiac disease or any contraindication to injection of intra-articular corticosteroids were excluded from the study. We excluded patients with history of trauma and intrinsic pathologies of rotator cuff since pain and disability arising from these conditions may confound the benefit offered by intra-articular steroid injection. Diabetics were included in the study as long as patients were under medical management and random blood sugar was less than 200 mg/dl on the day of procedure.

Upon referral for intra-articular injection, the patient's shoulder pain and disability were assessed using the Shoulder Pain and Disability Index (SPADI) by the data collector. Informed consent was obtained from all patients, after explaining the trial in detail. A radiologist with over 5 years' experience (SMP) in musculoskeletal imaging performed a preliminary ultrasound prior to intervention. Any patients with evidence of rotator cuff tendinopathy or tear were excluded from study. The supervisor (RK) was responsible for randomizing the patients into two groups—distension and non-distension groups using block randomization (blocks of 4) by preparing closed envelopes with a serial number on them. We were not able to maintain a 'control' group of patients who did not get injected since the standard of care for all patients having adhesive capsulitis was intra-articular steroid injections in this institute and it would be ethically inappropriate to deny such care to a group of patients. The clinical details

and treatment provided was printed and enclosed in the envelope with patient serial number on the outside by the injecting radiologist, which were later provided to the data analyzer (PS). Patients were not informed as to which treatment was given to them. Hence the data analyzer and patients were blinded to treatment allocation at the point of patient inclusion, while the injecting radiologist was not blinded.

Intervention

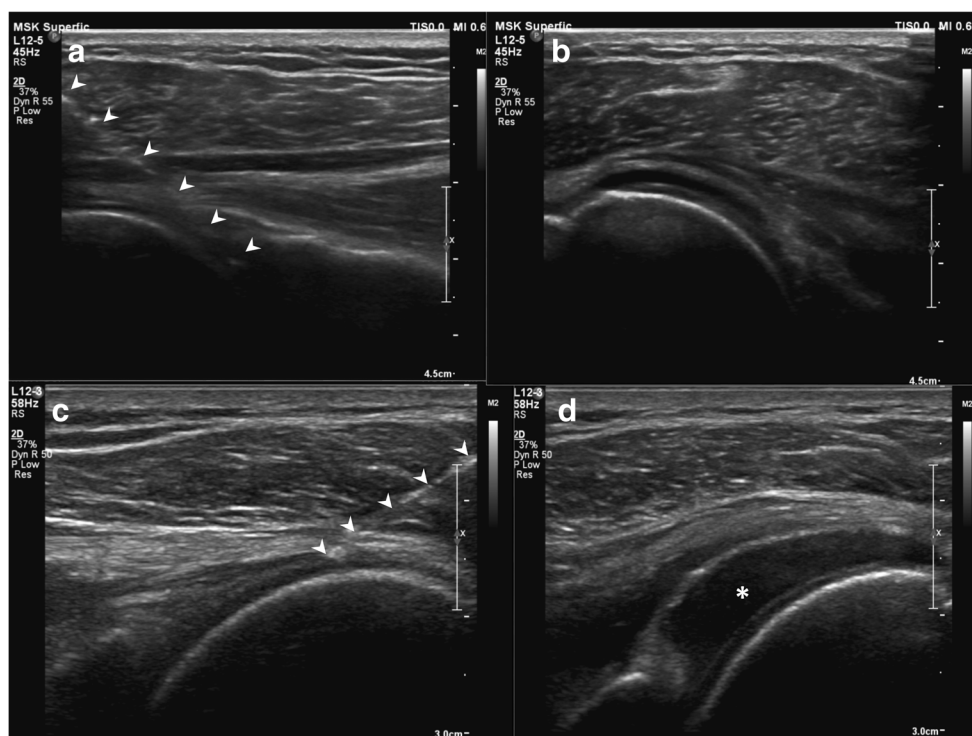
Following randomization, the radiologist (SMP) injected 2 ml of 0.25% bupivacaine plus 2 ml (80 mg) of methylprednisolone acetate into the affected shoulder joint in the non-distension group and 12–18 ml of 0.25% bupivacaine plus 2 ml (80 mg) of methylprednisolone acetate in the distension group under ultrasound guidance. A 20G lumbar puncture needle was used for the injection. The approach for intra-articular injection was via posterior aspect of the shoulder, which prevented the patient from viewing the syringe size and volume of injectate. The end-point for injection in the distension group was either (1) resistance to distension, or (2) severe unbearable pain while distending the joint (Fig. 1). Pain experienced by the patient during injection was measured on a visual analog scale (VAS). Following injection, all patients were given a standard dose of NSAIDs (slow-release diclofenac 100 mg once in the night before sleep for a week) to cover for ‘flare’ phenomenon and were further referred for physiotherapy exercises. We believed questioning the patient regarding the type of intervention given may have

led to introduction of bias in the results of the follow-up questionnaires. Hence, we did not question the patients regarding what treatment group they thought they were a part of. The procedure is not known to have any significant side-effects, apart from pain, and hence this procedure was performed on an out-patient basis with no active monitoring of the patient after injection. However, the patients were asked to report back in case they developed severe pain or fever.

Outcome measures

The primary outcome measure was SPADI, which is a composite index to measure pain and functional disability of a patient due to shoulder joint pathology. SPADI is a highly reliable, reproducible and consistent questionnaire-based indicator to discriminate adequately between patients with improving and deteriorating conditions of the shoulder [18]. It is scored between 0 and 100, which is calculated as a weighted mean of two subsets—pain index (scored out of 50: 5 questions of 10 points each) and disability index (scored out of 80: 8 questions of 10 points each). Both subsets are converted to a percentage score and averaged to give the final SPADI score. Baseline SPADI score was obtained from each patient prior to intervention and repeat SPADI scores were taken at intervals of 1.5, 3 and 6 months post-intervention by the data analyzer (PS). Repeat SPADI scores were taken either in person or telephonically if patient was not able to visit the hospital at the time of desired follow-up.

Fig. 1 Images **a** and **b** are posterior oblique axial ultrasound images of the shoulder of a 65-year-old female patient which was randomized to the non-distension group, while images **c** and **d** are of a 54-year-old male patient which was randomized to the distension group. Note the path of the needle to reach the joint cavity (white arrow heads in images **a** and **c**). 2 ml fluid was injected just to confirm the location of the needle tip in non-distension group (image **b**), while maximum tolerable distension was achieved in the distension group without rupturing the capsule (asterisk in image **d**)



Patients were further categorized as diabetics or non-diabetics on the basis of history of diabetes prior to the intervention. Additionally, duration of shoulder symptoms for each of the patients in months was also noted prior to intervention.

Sample size

As per a previous trial [19] a drop of 20% in the SPADI score was considered as clinically significant improvement in a patient's symptoms. The same trial assumed a mean SPADI score at presentation as 70, making a clinically significant drop in the score to be 14. We considered the same cut-off of 20% as clinically significant improvement in the pain and disability of the affected shoulder to calculate the sample size of our study.

The standard deviation of the study population in the previous trials was also found to be varying between 9.6 and 20 [19–21]. By considering an alpha of 5%, power of 80% and an average standard deviation of 15, in order to detect a drop of 20% in the mean SPADI score, we required a sample size of 20 in each group. Assuming an attrition rate of 10%, the total number of patients required in each group was 22; hence the minimum number of patients in the distension and non-distension groups as well as in the diabetic and non-diabetic groups was considered as 22 and the study was continued till this target was achieved in all the groups.

Statistical analysis

The difference in outcome between both groups was analyzed by performing 2-way repeated measures ANOVA assuming a normal distribution of outcome, considering 'time' as the within-subject factor, 'intervention groups' as the between-subjects factor and SPADI scores as the dependent variable. F-statistics for the Greenhouse-Geisser correction were included, since assumption of sphericity was violated.

Similarly, 2-way repeated measures ANOVA was also performed for the subsets of diabetic and non-diabetic patients to look for any difference in outcome. We performed an intention-to-treat (ITT) analysis, and hence kept the patient in the same group as originally allocated during randomization, irrespective of the final distension achieved. Software used for statistical analysis was IBM SPSS Statistics version 25 for Windows.

Results

Patient flow

Our study followed the 2010 CONSORT (Consolidated Standards of Reporting Trials) 2010 guidelines for reporting. Out of 151 potential cases referred, 109 met our inclusion

criteria, whereas the remaining 42 patients were excluded, including 12 patients with full thickness rotator cuff tears, 25 patients with partial rotator cuff tears and 5 patients with calcific rotator cuff tendinopathy. From the included 109, 21 patients declined to take part in the study, whereby the main reason offered by patients to decline participation was fear of pain during distension of shoulder. The remaining 88 patients were included and randomized for participation in the study, with 44 patients being allotted in each of the 2 groups.

We were successful in contacting all 88 patients per telephone or in person at the stipulated dates of follow-up, and hence we had no drop-outs or patients who were lost to follow-up. The 6 month follow-up for all patients ended by August 2018. We did not perform any interim analysis during the period of the trial. Figure 2 is the CONSORT Flow Diagram for our trial.

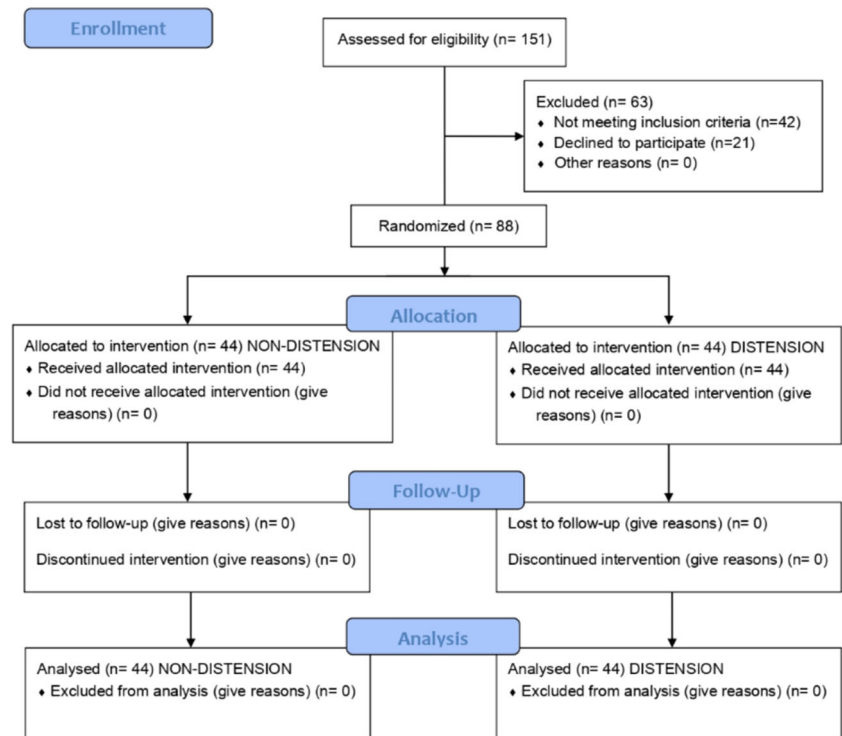
Baseline patient characteristics

Baseline patient characteristics are as shown in Table 1. The distension group had a higher percentage of males (54.5%), while females were more in number in non-distension group (54.5%). More patients in distension group had involvement of right shoulder (65.9%), while majority of patients in non-distension group had involvement of left shoulder (59.1%). A total of 46 out of 88 patients (52.3%) were diabetics. Half of the patients in distension group were diabetics, while 54.5% of the patients in non-distension group were diabetics. Both groups were comparable in characteristics of age, previous history of frozen shoulder on the opposite side, duration of symptoms and baseline mean SPADI scores at presentation.

Effect of intervention

Table 2 describes mean SPADI in both groups at presentation, 1.5 months, 3 months and 6 months after intervention. There was statistically significant drop in SPADI scores in both groups at all three time points of assessment [$F(1.9, 137.6) = 112.2; p < 0.001$]. There was no interaction seen over time with respect to effect of distension of shoulder joint [$F(1.9, 137.6) = 3.0; p = 0.052$]. As compared to non-distension group, there was no significant difference in SPADI scores in distension group [$F(1, 70) = 0.342; p = 0.56$]. On pair-wise comparison, the mean difference in the SPADI scores between the 2 groups over the period of 6 months was 1.53 (95% CI: -3.7 to 6.8), which was not statistically significant ($p = 0.56$). Figure 3 shows the trend of average SPADI scores in both groups at presentation, 1.5, 3 and 6 months duration, while Fig. 4 shows the same trend for each individual patient separately.

The mean SPADI scores of diabetic and non-diabetic patients are shown in Table 3. There was no statistically significant interaction over time with respect to the effect of

Fig. 2 CONSORT flow diagram for the trial

distension in diabetic population [$F(1.7, 65.7) = 2.843$; $p = 0.07$] and no significant difference on comparison with non-distension diabetic group [$F(1,38) = 0.04$; $p = 0.95$]. There was no significant difference between the diabetic and non-diabetic patients who received hydrodilatation as the mode of intervention [$F(1.8, 60) = 2.26$; $p = 0.12$].

There was no significant correlation between the reduction in the SPADI scores and duration of the symptoms at any point of time, either in the overall study population, the distension or diabetic groups (Table 4).

Complications pertaining to intervention

Other than intra-procedural pain, there were no other significant complications. The average VAS pain score for the non-

distension group was 7.4(SD: 1.1) while that in the distension group was significantly higher—8.6(SD:1.0); $p < 0.001$. Four patients from the distension group and 3 patients from the non-distension group had very severe post-injection pain on the night following the intervention, which were controlled by analgesics. None of the patients had any features of septic arthritis post-intervention.

Discussion

Our study showed that intra-articular steroid injection, irrespective of hydrodilatation, caused significant improvement in pain and disability of patients suffering from adhesive capsulitis in the short and medium-term durations. We found

Table 1 Baseline characteristics of the study group

Characteristics	Intervention group: distension (n = 44)	Intervention group: non-distension (n = 44)	p value
Mean age (years)	56.5 (range: 40–77)	54.9 (range: 39–68)	0.45
Female/male	20/24	24/20	0.39
Average duration (months)	5.0 (range: 1–12 months)	5.1 (range: 2–12 months)	0.96
Right/left	29/15	18/26	0.46
Diabetes	22	24	0.34
Previous frozen shoulder on opposite side	2	3	0.64
Baseline SPADI mean	68.6 (SD: 9.0)	63.9 (SD: 11.1)	0.06
Mean volume injected (ml)	15.8 (SD: 3.4)	4	<0.001

Table 2 Mean SPADI scores in distension and non-distension intervention groups

Time	SPADI in distension group (<i>n</i> = 44) mean (SD)	SPADI in non-distension group (<i>n</i> = 44) mean (SD)
Presentation	68.6 (9.0)	63.9 (11.1)
At 1.5 months	42.5 (11.5)	43.5 (14.9)
At 3 months	45.9 (12)	48.4 (14.6)
At 6 months	25.7 (21.0)	33.1 (22.9)

that although hydrodilatation of the shoulder joint marginally improves the mean pain and disability scores in short-term, this improvement did not bear any statistical significance. Even at the end of 6 months, there was no significant improvement in the outcomes of distension group of our trial. In the past, there have been conflicting studies, with few studies finding no additional benefit of hydrodilatation [19–22], while others [23, 24] have shown significant benefit with hydrodilatation. Our trial with its strong study design, large sample size and specific study groups provides definitive data for clinical decision-making.

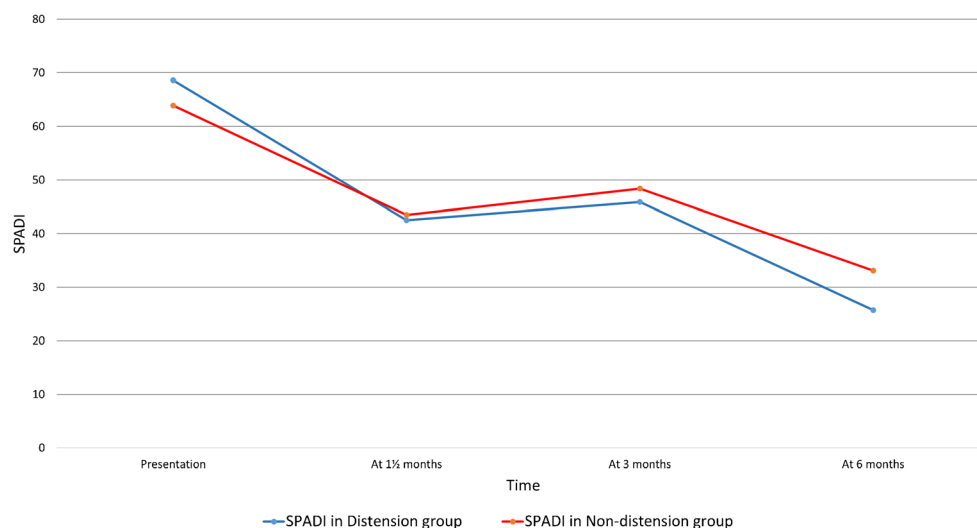
Two studies concluded that intra-articular steroid injections as well as hydrodilatation was less beneficial in diabetics [11, 25]. However, our study found no significant difference between diabetics and non-diabetics with respect to the outcome; neither did distension make any significant difference in outcomes in diabetics. It has to be noted that our study was pertaining to the subjective relief of pain and disability after injection with/without hydrodilatation in medium-term, while the study performed by Marx et al. dealt only with intra-articular steroid injections (without hydrodilatation) and measured its outcome in the form of recovery of restricted movements [11]. Another study by Bell et al. assessed the benefit of

hydrodilatation till rupture in patients having adhesive capsulitis, and found better improvement in the non-diabetics as compared to diabetics [25]. This study, however, had only 15 diabetics in a total study population of 109; hence, statistical significance of this conclusion is debatable.

Marx et al. had classified these patients into stages 1 and 2 of adhesive capsulitis in his study and concluded that stage 1 patients improved faster than stage 2 [11]. However, we believe that classifying these patients into stages is somewhat arbitrary, bearing in mind the variability in onset and duration of these phases. Hence, we used duration since onset of symptoms in months instead of classifying the disease into phases. We found no correlation between duration of onset of symptoms and improvement in pain and disability scores.

In previous studies, the volume of injectate in distension group varied from 9 to 45 ml in previous studies [14, 15, 19, 23, 24, 26–28], while in the comparative non-distension group it varied from 1 to 10 ml. During the course of natural history of adhesive capsulitis there is contracture of joint capsule in the second phase which reduces the overall volume of shoulder joint cavity [2]. However, this phase is variable in onset and severity; thereby, we believed that a ‘one-size-fits-all’ approach may not be appropriate, since a given volume of injectate may not be adequate to distend the joint in certain cases, while in others the same amount may lead to rupture of the joint capsule. Therefore, we set definite end-points for injections in distension group as a part of our protocol.

It is postulated that the positive effect of hydrodilatation is supposedly by improving glenohumeral mobility via stretching or rupturing of the joint capsule [20]. A few studies performed high volume injections which would invariably lead to rupture of the capsule [22, 24, 25, 27, 28]. However, we felt that such large amounts of fluid injected would only lead to expulsion of the injectate (including the steroid) out of the shoulder joint cavity, leading to probable reduced efficacy

Fig. 3 Line chart showing trend of SPADI scores in both intervention groups over the duration of the trial

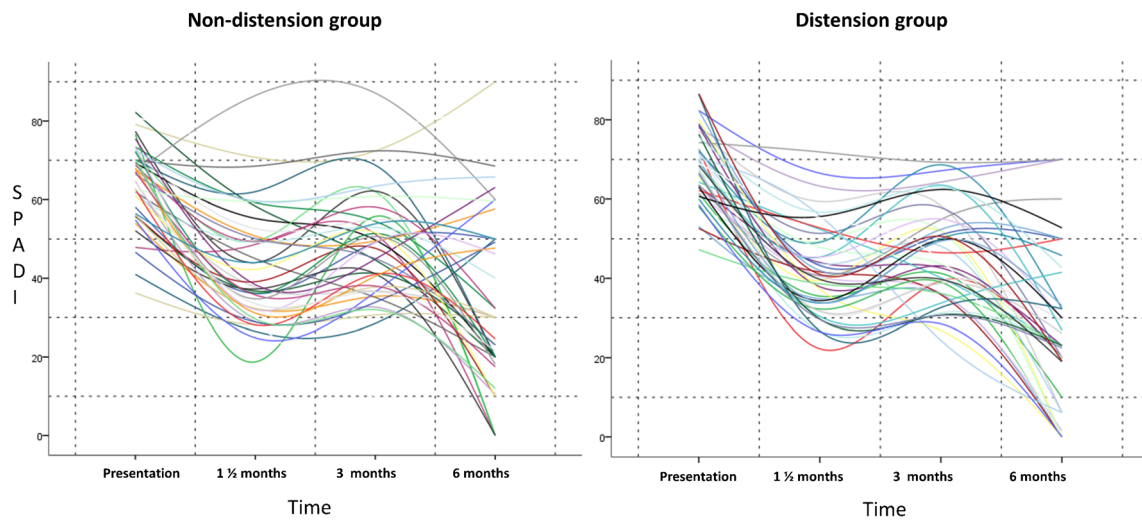


Fig. 4 Spaghetti chart showing trend of SPADI scores in individual patients of both treatment arms

of the steroid in distension group, creating a confounding bias as compared to non-distension group. Although capsule rupture is known to occur anteriorly, indirect signs of rupture such as sudden collapse of the distended shoulder joint capsule on ultrasound while performing hydrodilatation is a reliable sign to confirm a rupture. On the basis of this sign, none of the patients in our trial developed a capsule rupture.

For intra-articular injections, we used methylprednisolone as the steroid of choice for our study. Both methylprednisolone as well as triamcinolone are recommended for medium and large joints by the National Institute for Health and Care Excellence [29]. With respect to the amount of steroid injected, previous studies used 20 mg [19, 20, 23], 40 mg [21, 22, 24, 27] as well as 80 mg [11, 30] of steroid injections to treat adhesive capsulitis; however, no study or meta-analysis has definitively concluded on the ideal amount of steroid to be injected into shoulder joint. We injected 80 mg as a standard dose for all patients, since that was the standard of care in our hospital.

The strength of our study is the fact that the diagnosis and exclusion of cases was done after considering the ultrasound

findings and also that the intervention was performed under ultrasound guidance. Although adhesive capsulitis is a clinical diagnosis, rotator cuff tears and tendinosis could be confirmed with ultrasound and such cases could be excluded confidently from the study group. In addition, unlike blind injection, ultrasound-guided injections gave definitive proof of intra-articular injection, while avoiding the radiation exposure of fluoroscopy guidance.

A limitation of our trial was the subjective nature of the outcome measure used by us. SPADI as an outcome measure is more functional than objective. Since our hospital is a tertiary care hospital, a significant number of patients referred to us came from neighboring states and districts, making it difficult for them to stick to a schedule to visit the hospital at specific dates and times. Also, patients who have significant improvement would be less inclined to visit as compared to the ones who did not show improvement. Due to these limitations, we could not include objective outcome measures like active and passive range of movements for follow-up. In addition, although all patients claimed to have followed the physiotherapy regimen, we could not monitor the adequacy

Table 3 Mean SPADI scores in diabetic and non-diabetic sub-groups

Time	Diabetics		Non-diabetics	
	SPADI distension group (n = 22) mean (SD)	SPADI non-distension group (n = 24) mean (SD)	SPADI distension group (n = 22) mean (SD)	SPADI non-distension group (n = 20) mean (SD)
Presentation	67.9 (10.5)	60.2 (12.1)	69.4 (7.4)	69.5 (6.3)
At 1.5 months	43.7 (12.5)	43.8 (15.4)	41.3 (10.7)	43.0 (14.6)
At 3 months	48.3 (12.9)	46.8 (14.5)	43.5 (10.8)	51 (14.8)
At 6 months	27.5 (26.2)	35.5 (21.1)	24 (14.5)	29.4 (25.9)

Table 4 Correlation of duration of symptoms with drop in SPADI

Parameter	Overall study group vs duration of symptoms Pearson correlation (<i>p</i> value)	Distension group vs duration of symptoms Pearson correlation (<i>p</i> value)	Diabetics vs duration of symptoms Pearson correlation (<i>p</i> value)
Drop in SPADI at 1.5 months ^a	0.088 (0.46)	0.002 (0.99)	0.039 (0.81)
Drop in SPADI at 3 months ^a	0.055 (0.65)	-0.015 (0.93)	0.49 (0.76)
Drop in SPADI at 6 months ^a	0.028 (0.82)	0.239 (0.16)	0.075 (0.64)

^aDrop in SPADI scores as compared to baseline score

and frequency of the exercises since many of the patients stayed far away from the hospital and were unable to come for follow-up.

In conclusion, although intra-articular injection resulted in significant improvement in the pain and disability of patients with adhesive capsulitis, **shoulder joint hydrodilatation offered no additional benefit**. The diabetics showed similar outcomes as the non-diabetics in both study groups with hydrodilatation offering no additional benefit in diabetic patients. There was no correlation between the duration of symptoms before intervention and improvement in pain and disability in study population.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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