



ORIGINAL ARTICLE

## Comparison of intra-articular steroid injection versus hydrodilatation with saline and corticosteroid for the treatment of refractory adhesive capsulitis of the shoulder.

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**Article Citation:** Rasool A, Khan KA, Gillani H, Rashid M, Umair M, Israr H. Comparison of intra-articular steroid injection versus hydrodilatation with saline and corticosteroid for the treatment of refractory adhesive capsulitis of the shoulder. Professional Med J 2023; 30(08):971-976. <https://doi.org/10.29309/TPMJ/2023.30.08.7611>

**ABSTRACT... Objective:** To compare the outcome of intra-articular steroid injection versus hydrodilatation with saline and corticosteroid for the treatment of refractory adhesive capsulitis of the shoulder. **Study Design:** Randomized Controlled Trial. **Setting:** Department of Orthopaedic Surgery, Sahiwal Teaching Hospital Sahiwal. **Period:** February 2021 to January 2022. **Material & Methods:** A total of 156 patients with refractory adhesive capsulitis were randomized. In Group-A, patients were treated with intra articular steroid injection alone and in Group-B, patients were treated with hydrodilatation using corticosteroid and saline. The patients were followed up at 3<sup>rd</sup>, 6<sup>th</sup> and 12<sup>th</sup> week and their functional outcomes was assessed in terms of pain and range of motion (disability) using “Shoulder Pain and Disability Index (SPADI)” scoring system. **Results:** In a total of 156 patients, 81 (51.9%) were females. The mean age was 51.4±10.6 years (ranged between 33 to 68 years). History of steroid intake was reported in 30 (19%) patients. The mean pain scores on the basis of SPADI scoring at 3-week (p=0.0001), 6-week (p=0.0001) and 12-week (p<0.0001) were significantly less in Group-B when compared to Group-A. The disability scores on the basis of SPADI scoring at 3-week (p<0.0001), 6-week (p<0.0001) and 12-week (p<0.0001) were significantly less in Group-B when compared to Group-A. In comparison to Group-A, functional outcomes were significantly better among patients of Group-B at 6-week (p<0.0001) and 12-week (p<0.0001) intervals. **Conclusion:** Hydrodilatation along with corticosteroid injection were better treatment options when compared to intra-articular steroid injection alone for reduction in pain and improvement in range of motion among patients with refractory frozen shoulder.

**Key words:** Adhesive Capsulitis, Corticosteroid, Disability, Frozen Shoulder, Intra-articular, Pain.

### INTRODUCTION

Adhesive capsulitis is known to cause significant morbidity in people prone to it.<sup>1</sup> The term adhesive capsulitis can be used interchangeably with frozen shoulder.<sup>2</sup> Duplay was the first to describe adhesive capsulitis as “peri-arthritis scapulohumeral”, though the term frozen shoulder was first coined in 1934 by Codman.<sup>3,4</sup> The characteristics of adhesive capsulitis include a typically spontaneous start of shoulder discomfort and a gradual impairment of both active and passive glenohumeral motion.<sup>5</sup> Over the course of months or years, both stiffness and discomfort often go away on their own. Adhesive capsulitis’ primary pathology is the thickening and constriction of the joint capsule, which causes it to become stuck to the humeral head

and decrease patients’ joint mobility.<sup>6</sup> Adhesive capsulitis is mostly idiopathic, but it can also be secondary to other intrinsic causes, trauma or systemic causes.<sup>7,8</sup>

Adhesive capsulitis has a number of potential treatments, including manipulation under anaesthesia, surgical capsular release, physical therapy routines, intra-articular steroid injections, glenohumeral joint hydrodilatation, or a combination of the aforementioned. According to recent research, hydrodilatation is just as effective as anaesthetic manipulation and has less side effects.<sup>9</sup> Quraishi et al analyzed patients in stage 2 of frozen shoulder who were either given manipulation under anaesthesia or hydrodilatation with curative intent, and the results were more

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**Article received on:** 05/04/2023

**Accepted for publication:** 20/06/2023

in favour of hydro-dilatation than manipulation under anaesthesia.<sup>10</sup> The objective of this study was to compare the outcomes of patients with adhesive capsulitis treated with either intra-articular steroid injection versus hydrodilatation with saline and corticosteroid in terms of pain and range of motion.

## MATERIAL & METHODS

This randomized controlled trial was carried out at the department of orthopaedics, District Headquarter Teaching Hospital, Sahiwal, Pakistan, from February 2021 to January 2022 after approval from ethical committee (54-/IRB/SLMC/SWL). A total of 138 was calculated considering the anticipated proportion of improvement in ROM as 63% with corticosteroid injection and 84% with hydro-dilatation<sup>11</sup>, level of confidence ( $\alpha$ )=5%, and the power of the study ( $1-\beta$ )=80%. Since some patients could be lost to follow-up and some could leave the study at later stages, it was decided to increase the sample size to 156, with 78 participants in each group. Simple random sampling technique was applied and randomization was done using the lottery method.

Patients of both gender aged between 18-70 years, having symptoms for more than 2 months that were refractory to treatment with “non-steroidal anti-inflammatory drugs (NSAIDs)” and other painkillers, and patients in their fourth to sixth decades that were presented with shoulder pain or stiffness without features of osteoarthritis were analyzed. Patients with pain and disability, limiting their daily activities as indicated by the SPADI scoring index, were also included. Exclusion criteria were patients with haemophilia, thrombocytopenia, a history of cardiac arrhythmias or drug abuse, or who were mentally challenged. Patients who presented with shoulder pain after trauma or had any other bony or soft tissue pathology were also excluded. Informed and written consents were obtained from the patients. Approval from the “Institutional Ethical Committee” was also obtained.

Patients were enrolled in the study from orthopaedic wards or outpatient department

of orthopaedics, and then socio-demographic characteristics were noted. Two groups (with 78 patients in each group) were formed. Group-A patients received intra-articular steroid injection alone, and Group-B patients received hydrodilatation with corticosteroid. Hydrodilatation, or hydrodistension, is the injection of fluid into the joint under pressure with the motive of dilating the joint and hence breaking the adhesions.

In Group-A, aseptic technique was employed in patients with adhesive capsulitis to inject 40 mg of methylprednisolone and 3 ml of 2% lignocaine into the shoulder joint using a posterior subacromial approach with the patient in a seated position. This was followed by counselling the patient to practise simple exercises aimed at increasing ROM. The exercises were demonstrated to the patient. These included Codman exercises, finger wall sliding to increase flexion and abduction, towel exercises, door closing and opening for external and internal rotation. Patients were advised to practice these exercises as a set of 25 twice a day. In Group-B, patients were injected with 40 mg of methylprednisolone, 3 ml of 2% lignocaine, and about 20 ml of normal saline. Similar posterior subacromial approaches and aseptic techniques using a wide-bore needle were carried out for insertion into the glenohumeral joint. This was followed by counselling the patient to practise simple exercises aimed at increasing ROM as advised in Group-A.

The pain and ROM in both groups were assessed before any intervention using the SPADI scoring index and then reassessed at 3<sup>rd</sup>, 6<sup>th</sup>, and 12<sup>th</sup> weeks. Functional outcome in terms of pain and ROM was estimated using the SPADI scoring system. A post procedure score of 0-40% was graded as excellent, 41-50 % as good, 51-60% as fair and 61% or above as poor for both pain and disability and for both treatment Groups. All the required data was collected on a customized proforma.

Data was analyzed utilizing “Statistical Package for Social Sciences (SPSS)”, version 26.0. Means and standard deviation (SD) were calculated

for the representation of quantitative variables. Proportions and percentages were calculated for qualitative data. Comorbidities among the patients, like hypertension and diabetes, were noted. Effect modifiers like BMI and the steroid intake history of patients were controlled by making stratified tables. Comparisons of quantitative data were made using t-test while chi-square test was used for comparing qualitative data. P-value  $\leq 0.05$  was taken as significant.

## RESULTS

In a total of 156 patients, 81 (51.9%) were females. The mean age was  $51.4 \pm 10.6$  years (ranged between 33 to 68 years). History of steroid intake was reported in 30 (19%) patients. Diabetes mellitus and hypertension were present in 28 (17.9%) and 57 (36.5%) patients respectively. Table-I is showing the comparison of baseline characteristics of patients in both study groups.

The mean pain scores on the basis of SPADI scoring at 3-week ( $p=0.0001$ ), 6-week ( $p=0.0001$ ) and 12-week ( $p<0.0001$ ) were significantly less

in Group-B when compared to Group-A. The disability scores on the basis of SPADI scoring at 3-week ( $p<0.0001$ ), 6-week ( $p<0.0001$ ) and 12-week ( $p<0.0001$ ) were significantly less in Group-B when compared to Group-A (Table-II).

In comparison to Group-A, functional outcomes were significantly better among patients of Group-B at 6-week ( $p<0.0001$ ) and 12-week ( $p<0.0001$ ) intervals as shown in Table-III.

## DISCUSSION

In the present study, the mean pain scores on the basis of SPADI scoring at 3-week ( $p=0.0001$ ), 6-week ( $p=0.0001$ ) and 12-week ( $p<0.0001$ ) were significantly less in patients who were administered hydrodilataion with steroid injections when compared to intra-articular injection alone. The disability scores on the basis of SPADI scoring at 3-week ( $p<0.0001$ ), 6-week ( $p<0.0001$ ) and 12-week ( $p<0.0001$ ) were also significantly less in patients who were administered hydrodilataion with steroid injections when compared to intra-articular injection alone.

Characteristics		Total (n=156)	Group-A (n=78)	Group-B (n=78)	P-Value
Gender	Male	75 (48.1%)	39 (50.0%)	36 (46.2%)	0.6307
	Female	81 (51.9%)	39 (50.0%)	42 (53.2%)	
Age, years (mean $\pm$ SD)		51.4 $\pm$ 10.6	50.3 $\pm$ 10.1	52.7 $\pm$ 10.8	0.1538
BMI, kg/m <sup>2</sup>	<18.5	28 (17.9%)	14 (17.9%)	14 (17.9%)	0.6893
	18.5-25	69 (44.2%)	31 (39.7%)	38 (48.7%)	
	25-30	43 (27.5%)	23 (29.5%)	18 (23.1%)	
	30-35	15 (9.6%)	9 (11.5%)	6 (7.7%)	
	35-40	3 (1.9%)	1 (1.3%)	2 (2.6%)	
History of steroid intake		30 (19%)	15 (19.2%)	15 (19.2%)	-
Diabetes mellitus		28 (17.9%)	28 (35.9%)	30 (38.5%)	0.7404
Hypertension		57 (36.5%)	25 (32.1%)	32 (41%)	0.2448

**Table-I. Comparison of baseline characteristics of patients in both study groups (N=156)**

Group-A received intra-articular steroid injection alone; Group-B received hydrodilataion with corticosteroid

Outcomes	Groups	SPADI Score			
		Pre-procedure	3-weeks	6-weeks	12-weeks
Pain	A (n=78)	80.1 $\pm$ 8.1	77.9 $\pm$ 8.3	68.1 $\pm$ 7.1	59.7 $\pm$ 6.4
	B (n=78)	81.6 $\pm$ 7.5	72.5 $\pm$ 8.1	63.2 $\pm$ 8.4	53.2 $\pm$ 7.6
	P-value	0.2198	0.0001	0.0001	<0.0001
Disability	A (n=78)	79.0 $\pm$ 7.4	75.8 $\pm$ 7.6	68.9 $\pm$ 7.9	58.6 $\pm$ 7.2
	B (n=78)	80.6 $\pm$ 6.8	69.4 $\pm$ 8.3	59.6 $\pm$ 7.4	48.6 $\pm$ 6.1
	P-value	0.1617	<0.0001	<0.0001	<0.0001

**Table-II. Comparison of pain and disability mean SPADI score comparison (Pre- and Post-Procedure) (n=156)**

Group-A received intra-articular steroid injection alone; Group-B received hydrodilataion with corticosteroid

Outcomes	Weeks	Groups	Poor (61-100)	Fair (51-60)	Good (41-50)	Excellent (0-40)	P-Value
Pain	0	A	78 (100%)				-
		B	78 (100%)				
	3	A	78 (100%)				-
		B	78 (100%)				
	6	A	68 (87.2%)	10 (12.8%)			<0.0001
		B	44 (56.4%)	31 (39.8%)	3 (3.9%)		
	12	A	37 (47.4%)	31 (39.8%)	8 (10.2%)	2 (2.5%)	<0.0001
		B	12 (15.3%)	28 (35.9%)	34 (43.5%)	4 (5.1%)	
Disability	0	A	78 (100%)				-
		B	78 (100%)				
	3	A	78 (100%)				-
		B	78 (100%)				
	6	A	68 (87.2%)	8 (10.2%)	2 (2.5%)		<0.0001
		B	28 (35.9%)	40 (51.3%)	10 (12.8%)		
	12	A	37 (47.4%)	25 (32.1%)	11 (14.1%)	5 (6.4%)	<0.0001
		B	11 (14.1%)	17 (21.8%)	33 (42.3%)	17 (21.8%)	

**Table-III. Functional outcomes (Shoulder Pain and Disability) of patients on the Basis of SPADI Scores (n=156)**

Group-A received intra-articular steroid injection alone; Group-B received hydrodilatation with corticosteroid

Dai et al from China analyzing patients of primary frozen shoulders revealed that combination of corticosteroid hydrodilatation was more effective than any of these alone ( $p < 0.01$ ).<sup>12</sup> Some other researchers have shown that hydrodilatation with corticosteroids is most efficient conservative mode of management for managing adhesive capsulitis.<sup>13,14</sup>

Corticosteroid with hydrodilatation could be preferred over any of these alone as the high-pressure delivery enhances spread throughout articular cavities specifically along biceps tendon sheath for broader anti-inflammatory effects.<sup>12</sup> A meta-analysis done by Saltychev et al found that hydrodilatation alone in adhesive capsulitis did not yield any significant improvements in functional outcomes.<sup>15</sup> A study done by Oh et al from Korea comparing corticosteroid versus hyaluronic acid versus corticosteroid plus hyaluronic acid in patients with adhesive capsulitis revealed that simultaneous injection of corticosteroid and hyaluronic acid were better in improving SPADi scores.<sup>16</sup> The study by Jacobs demonstrated no statistically significant differences between manipulation of shoulder joint under anesthesia and hydrodilatation with saline and corticosteroid.<sup>17</sup>

The present study adds to what little international

literature exists regarding the comparison of corticosteroid injection along versus corticosteroid injection along with hydrodilatation. To the best of knowledge, no comparative study exists comparing current study approaches so the findings of the present study shed important light for the management of refractory adhesive capsulitis. No adverse or unwanted event occurred during the study period while the studied approaches could be performed in the outpatient department. Being a single center study with a relatively moderate follow-up period were some of the limitations of this study. Further similar studies could be conducted in the light of this research like different strengths of corticosteroid injections could be compared. A comparison between different corticosteroids like methyl prednisolone and triamcinolone could be made. A comparison of functional outcome between single corticosteroid injection and multiple corticosteroid injections could be done. A comparison between corticosteroid injection and platelet-rich plasma or hyaluronic acid may also be planned.

## CONCLUSION

This study concluded that hydrodilatation along with corticosteroid injection were better treatment options when compared to intra-articular steroid injection alone for reduction in pain and






improvement in range of motion among patients with refractory frozen shoulder.

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3	Haroon-ur-Rehman Gillani	Study concept, Data analysis, Proof reading.	
4	Majid Rashid	Data collection, Literature review.	
5	Muhammad Umair	Data collection.	
6	Humayun Israr	Data collection.	