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Comparison of functional outcome of intra-articular steroid injection versus steroid injection in rotator interval in the treatment of early frozen shoulder

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***Abstract*---**Adhesive capsulitis (AC) is a painful frozen shoulder disease that continues for more than 3 months, is also known as frozen shoulder. The glenohumeral joint capsule fibrosis that results from this inflammatory disease is accompanied by substantial range of motion limitation and gradually advancing stiffness (typically external rotation). The findings of this study will support better outcomes for adhesive capsulitis patients in our local population in terms of pain reduction and a decline in SPADI score. Objective: To compare functional outcome of steroid injection vs intra-articular

steroid injection in rotator interval in the treatment of early frozen shoulder. Place and Duration of study: Department of Orthopedic Surgery, MTI-HMC, Peshawar from 27 Feb, 2021 to 27 Aug, 2021. Study Design: Randomized Control Trial. Methods: Patients were randomly allocated to both groups through blocked randomization. Patients in Group A was subjected to intra-articular steroid injections whereas patients in Group B were subjected to steroid Injection in rotator interval. Results: As per functional outcome in both groups, in Group A, 51 (85.0%) patients were showed effective results while in Group B, 42 (70.0%) patients showed effective results. Conclusion: Patients in Group A (intra-articular steroid injection) yielded better effects and superior results in terms of improvement in pain, range of movement assessed through SPADI Score as compared to patients in Group B (steroid injection in rotator interval).

***Keywords*---**Adhesive capsulitis (AC), Intra-Articular Steroid Injection, Steroid Injection

Introduction

Adhesive capsulitis (AC) is a frozen painful shoulder disease that lasts more than three months, is also known as frozen shoulder[1-2]. The glenohumeral joint capsule fibrosis that results from this inflammatory -disease is accompanied by substantial range of motion limitation and gradually advancing stiffness (typically external rotation)[3]. However, the patients can have a fast onset of symptoms and a protracted healing process. Even though it could take up to two or three years, most of the time, the recovery is satisfying[4-5]. It occurs in up to five percent of adhesive capsulitis cases. The shoulder which is non-dominant is more predisposed to injury as compared to shoulder which is dominant, and females suffer from it four folds more often than males[6-7]. The coracohumeral ligament covering the roof of the rotator cuff is usually the first structure to be damaged. External rotation of the arm is usually limited in early AC by contraction of the coracohumeral ligament that first affects it. The shoulder joint capsule contracts and thickens in advanced stages, greatly decreasing range of motion in all directions. A clinical diagnosis of frozen shoulder is done using the medical history, physical examination, and imaging techniques (ruling out another condition, rather than confirming the diagnosis of AC)[8-9]. No one laboratory or imaging test can provide the complete confirmation of the AC diagnosis on its own. Despite the abundance of AC-related research that has been published, there is no universally accepted approach to managing AC. The majority of AC treatments are non-surgical and involve medication management and physical therapy[10].

In one study, men made up the majority (60.62%). Patients in group A (Steroid Injection in Rotator Interval) had mean pre-procedure scores of 9.87, 4.44, and 22.8, 5.14, while patients in group B (Intra-articular Steroid Injection) had mean pre-procedure scores of 9.78, 4.49, and 21.49, 5.56. Out of 80 patients in group A, functional outcome (effectiveness) was seen in 92.50% of cases, compared to 73.75% of patients in group B.

More study was required to compare the functional outcomes of intra-articular steroid injection against steroid injection in the rotator interval in the treatment of early frozen shoulder in our local population due to the dearth of related studies[11]. The findings of this study will demonstrate better outcomes in terms of pain relief and a reduction in SPADI scores to be taken into consideration in patients with adhesive capsulitis in our local population, and will subsequently show the correct site of corticosteroid injection for the treatment of FS in our local population.

Methods

Setting: This Randomized controlled trial study was conducted at the Department of Orthopedic Surgery, MTI-HMC, Peshawar from 27 Feb, 2021 to 27 Aug, 2021.

The sample size was 120, selected by nonprobability consecutive sampling technique (60 in each group) with 92.50%10 effectiveness in Group A (Steroid Injection in Rotator Interval) and 73.75%10 in Group B (Intra-articular Steroid Injection), with 95% confidence level, 80% power of test and level of significance 5% under WHO software for sample size determination.

Inclusion Criteria:

1. All patients with frozen shoulders for minimum of 4 weeks as per operational definition.

2. Either gender.

3. Age group 30-65.

Exclusion Criteria:

1. Stiff shoulders with other causes like arthritis, fractures, post Injection.

2. Previous surgical intervention on same shoulder.

3. Local skin Injection.

4. Abnormal coagulation and blood sugar levels (diabetics).

The aforementioned factors are confounders and, if present, will bias the study's findings.

Patients matching the criteria of inclusion were included from the orthopedics department's OPD after receiving approval from the hospital's research and ethics committee. To exclude any other potential causes of shoulder pain and stiffness, all patients had their shoulders radiographed. The study's benefits and goal were explained to all participants, who also provided written and informed consent. This research study was conducted only for the purpose of research and data

publishing. Through blocked randomization, patients were distributed in the two groups randomly. Patients in Group A received intra-articular steroid injections, while patients in Group B received rotator interval steroid injections. A posterior approach was used to inject a solution containing 40 mg of methylprednisolone acetate and 4 mL of 1% lidocaine into the glenohumeral joint in Group A using a 21 G × 50 mm needle. Up to three doses were administered by repeating the injections.

Patients in Group B underwent steroid injection into the rotator interval (a 21 G 50 mm needle was used to administer a combination of 40 mg methylprednisolone acetate and 5 mL 1% lidocaine). The injection point was about 2 cm cephaloid to the midpoint of the scapula spine). The C-reactive protein, Sedimentation rate, rheumatoid factor, thyroid hormone and blood glucose levels were obtained as part of routine laboratory examinations. All patients were given written and verbal instructions for a home exercise routine of self-mobilization and joint-stretching after each session. Additionally, the patient was instructed to just use paracetamol for pain relief. Moreover, functional outcomes were assessed in both groups 45 days following the follow-up visit. Age, gender, BMI, socioeconomic position, occupation, educational attainment, diabetes mellitus, hypertension, family history of frozen shoulder, smoking status, and functional outcome were all documented in a specifically created proforma.

Software SPSS Version 20.0 was used to enter the data. Age, baseline and follow-up VAS Pain Score, baseline and follow-up SPADI Score, disease duration, and BMI are examples of numerical variables for which mean + SDs were determined.

For categorical variables like gender and functional outcome, frequencies and percentages were computed. Age, gender, BMI, socioeconomic status, profession status, educational status, diabetes mellitus, hypertension, family history of frozen shoulder, and smoking status were stratified according to the functional result to examine how the influence changed. The post-stratification chi square test was applied with a P value less than 0.05.

Results

This study was carried out on 120 (60 patients in each group) at the Department of Orthopedic Surgery, MTI-HMC Peshawar. Following are the results of this study

In Group A, mean and SDs for age was 49.52+9.166. Mean and SDs for baseline VAS pain score was 8.70+0.766. Mean and SDs for follow up VAS pain score was 3.75+1.800. Mean and SDs baseline SPADI Score was 49.48+4.707. Mean and SDs for follow up SPADI Score was 19.92+9.708. Mean and SDs for duration of disease was 6.95+1.799. Mean and SDs for BMI was 26.02+1.632. In Group B, mean and SDs for age was 50.55+8.280. Mean and SDs for baseline VAS pain score was 8.75+0.795. Mean and SDs for follow up VAS pain score was 4.50+2.311. Mean and SDs baseline SPADI Score was 51.07+4.606. Mean and SDs for follow up SPADI Score was 23.80+12.226. Mean and SDs for duration of disease was 7.12+1.757. Mean and SDs for BMI was 26.06+1.618. (Table No. 1).

Table-I shows the demographic features of the patients

Treatment Group		Minimum	Maximum	Mean	Std. Deviation
Group A (n=60)	Age	34	62	49.52	9.166
	Baseline VAS Pain Score	8	10	8.70	.766
	Follow up VAS Pain Score	3	8	3.75	1.800
	Baseline SPADI Score	43	58	49.48	4.707
	Follow up SPADI Score	11	45	19.92	9.708
	Duration of Disease	4	9	6.95	1.799
	BMI	23	29	26.02	1.632
Group B (n=60)	Age	34	62	50.55	8.280
	Baseline VAS Pain Score	8	10	8.75	.795
	Follow up VAS Pain Score	3	8	4.50	2.311
	Baseline SPADI Score	43	58	51.07	4.606
	Follow up SPADI Score	4	46	23.80	12.226
	Duration of Disease	4	9	7.12	1.757
	BMI	23	29	26.06	1.618

In Group A, 22 (36.7%) patients were recorded in 30-45 years age group while 38 (63.3%) patients were recorded in 45-65 years age group. In Group B, 18 (30.0%) patients were recorded in 30-45 years age group while 42 (70.0%) patients were recorded in 46-65 years age group. (Table No. 2).

Table-II shows the Gender wise and age-group distribution of patients

Treatment Group	Age Groups	Frequency	Percent
Group A (n=60)	30-45 Years	22	36.7%
	46-65 Years	38	63.3%
	Total	60	100.0%
Group B (n=60)	30-45 Years	18	30.0%
	46-65 Years	42	70.0%
	Total	60	100.0%
Treatment Group	**Gender**	**Frequency**	**Percent**

Group A (n=60)	Male	39	65.0%
	Female	21	35.0%
	Total	60	100.0%
Group B (n=60)	Male	41	68.3%
	Female	19	31.7%

In Group A, 39 (65.0%) male patients and 21 (35.0%) female patients were recorded. In Group B, 41 (68.3%) male patients and 19 (31.7%) female patients were recorded.

In Group A, 35 (58.3%) patients were from poor families, 16 (26.7%) patients were from middle class families, 09 (15.0%) patients were from rich families. In Group B, 35 (58.3%) patients were from poor families, 13 (21.7%) patients were from middle class families and 13 (21.7%) patients were from rich families. (Table No. 3).

Table-III shows the social class, education status and occupation of the patients

Treatment Group	**Social Class**	**Frequency**	**Percent**
Group A (n=60)	Poor	35	58.3%
	Middle Class	16	26.7%
	Rich	9	15.0%
	Total	60	100.0%
Group B (n=60)	Poor	35	58.3%
	Middle Class	13	21.7%
	Rich	12	20.0%
	Total	60	100.0%
Treatment Group	**Educational Status**	**Frequency**	**Percent**
Group A (n=60)	Primary & Above	46	76.7%
	Secondary & Above	14	23.3%
	Total	60	100.0%
Group B (n=60)	Primary & Above	47	78.3%
	Secondary & Above	13	21.7%
Treatment Group	**Occupation Status**	**Frequency**	**Percent**
Group A (n=60)	Office Worker	33	55.0%
	Laborer	18	30.0%

	Farmer	9	15.0%
	Total	60	100.0%
Group B (n=60)	Office Worker	39	65.0%
	Laborer	9	15.0%

In Group A, 46 (76.7%) patients had primary and above education whereas 14 (23.0%) patients had secondary & above education. In Group B, 47 (78.3%) patients had primary & above education while 13 (21.7%) patients had secondary & above education. In Group A, 33 (55.0%) patients were office workers, 18 (30.0%) patients were farmers, 18 (30.0%) patients were laborers 09 (15.0%) patients were farmers. In Group B, 39 (65.0%) patients were office workers, 09 (15.0%) patients were laborers while, 12 (20.0%) patients were farmers.

In Group A, 44 (73.3%) patients were diabetic while in Group B, 44 (73.3%) patients were diabetic. (Table No. 7).

Table-IV shows the Diabetic status, Hypertension status and smoking status of the patients

Treatment Group	**Diabetes Mellitus**	**Frequency**	**Percent**
Group A (n=60)	Yes	44	73.3%
	No	16	26.7%
	Total	60	100.0%
Group B (n=60)	Yes	44	73.3%
	No	16	26.7%
	Total	60	100.0%
Treatment Group	**Hypertension**	**Frequency**	**Percent**
Group A (n=60)	Yes	43	71.7%
	No	17	28.3%
	Total	60	100.0%
Group B (n=60)	Yes	48	80.0%
	No	12	20.0%
Treatment Group	**Smoking Status**	**Frequency**	**Percent**
Group A (n=60)	Yes	38	63.3%
	No	22	36.7%
	Total	60	100.0%
Group B (n=60)	Yes	42	70.0%
	No	18	30.0%

In Group A, 43 (71.7%) patients were recorded with hypertension while 48 (80.0%) patients were recorded with hypertension. In Group A, 38 (63.3%) patients were smokers while in Group B, 42 (70.0%) patients were recorded with smoking history. As per frequencies and percentages for functional outcome in both groups, in Group A, 51 (85.0%) patients were showed effective results while in Group B, 42 (70.0%) patients showed effective results. (Table No. 5).

Table-V shows the Functional outcome of the patients

Treatment Group	Functional Outcome	Frequency	Percent
Group A (n=60)	Effective	51	85.0%
	Not Effective	9	15.0%
	Total	60	100.0%
Group B (n=60)	Effective	42	70.0%
	Not Effective	18	30.0%
	Total	60	100.0%

Functional outcome in both groups was stratified with age, Occupation status, diabetes mellitus, hypertension family history of frozen shoulder status are given respectively.

Table-VI shows the functional outcome with reference to the age-groups

Age Groups			Functional Outcome		Total	P Value
			Effective	Not Effective		
30-45 Years	Treatment Group	Group A	19	3	22	0.067
			63.3%	30.0%	55.0%	
		Group B	11	7	18	
			36.7%	70.0%	45.0%	
	Total		30	10	40	
			100.0%	100.0%	100.0 %	
46-65 Years	Treatment Group	Group A	32	6	38	0.256
			50.8%	35.3%	47.5%	
		Group B	31	11	42	
			49.2%	64.7%	52.5%	
	Total		63	17	80	
			100.0%	100.0%	100.0 %	

Table-VI shows the functional outcome with reference to the Occupation status

Occupation Status			Functional Outcome		Total	P Value
			Effective	Not Effective		
Office Worker	Treatment Group	Group A	28	5	33	0.028
			53.8%	25.0%	45.8%	
		Group B	24	15	39	
			46.2%	75.0%	54.2%	
	Total		52	20	72	
			100.0%	100.0%	100.0%	
Laborer	Treatment Group	Group A	14	4	18	0.484
			63.6%	80.0%	66.7%	
		Group B	8	1	9	
			36.4%	20.0%	33.3%	
	Total		22	5	27	
			100.0%	100.0%	100.0%	
Farmer	Treatment Group	Group A	9	0	9	0.198
			47.4%	0.0%	42.9%	
		Group B	10	2	12	
			52.6%	100.0%	57.1%	
	Total		19	2	21	
			100.0%	100.0%	100.0%	

Table-VII shows the functional outcome with reference to the Diabetes Mellitus

Diabetes Mellitus			Functional Outcome		Total	P Value
			Effective	Not Effective		
Yes	Treatment Group	Group A	39	5	44	0.020
			56.5%	26.3%	50.0%	
		Group B	30	14	44	
			43.5%	73.7%	50.0%	
	Total		69	19	88	
			100.0%	100.0%	100.0%	
No	Treatment Group	Group A	12	4	16	1.000
			50.0%	50.0%	50.0%	
		Group B	12	4	16	
			50.0%	50.0%	50.0%	
	Total		24	8	32	
			100.0%	100.0%	100.0%	

Table-VIII shows the functional outcome with reference to the Hypertension

Hypertension			Functional Outcome		Total	P Value
			Effective	Not Effective		
Yes	Treatment Group	Group A	35	8	43	0.338
			50.0%	38.1%	47.3%	
		Group B	35	13	48	
			50.0%	61.9%	52.7%	
	Total		70	21	91	
			100.0%	100.0%	100.0%	
No	Treatment Group	Group A	16	1	17	0.019
			69.6%	16.7%	58.6%	
		Group B	7	5	12	
			30.4%	83.3%	41.4%	
	Total		23	6	29	
			100.0%	100.0%	100.0%	

Table-IX shows the functional outcome with reference to the Family History of Frozen Shoulder

Family History of FS			Functional Outcome		Total	P Value
			Effective	Not Effective		
Yes	Treatment Group	Group A	42	4	46	0.018
			55.3%	23.5%	49.5%	
		Group B	34	13	47	
			44.7%	76.5%	50.5%	
	Total		76	17	93	
			100.0%	100.0%	100.0%	
No	Treatment Group	Group A	9	5	14	0.883
			52.9%	50.0%	51.9%	
		Group B	8	5	13	
			47.1%	50.0%	48.1%	
	Total		17	10	27	
			100.0%	100.0%	100.0%	

Discussion

Adhesive capsulitis (AC) is a frozen painful shoulder disease that lasts more than three months, is also known as frozen shoulder. The glenohumeral joint capsule fibrosis that results from this inflammatory disease is accompanied by substantial range of motion limitation and gradually advancing stiffness (typically external rotation)[11]. However, the patients can have a fast onset of symptoms and

a protracted healing process. Even though it could take up to two or three years, most of the time, the recovery is satisfying[12]. It occurs in up to five percent of adhesive capsulitis cases. The shoulder which is non-dominant is more predisposed to injury as compared to shoulder which is dominant, and females suffer from it four folds more often than males. In Group A, mean and SDs for age was 49.52+9.166. Mean and SDs for baseline VAS pain score was 8.70+0.766.

Mean and SDs for follow up VAS pain score was 3.75+1.800. Mean and SDs baseline SPADI Score was 49.48+4.707. Mean and SDs for follow up SPADI Score was 19.92+9.708. Mean and SDs for duration of disease was 6.95+1.799. Mean and SDs for BMI was 26.02+1.632. In Group B, mean and SDs for age was 50.55+8.280. Mean and SDs for baseline VAS pain score was 8.75+0.795. Mean and SDs for follow up VAS pain score was 4.50+2.311. Mean and SDs baseline SPADI Score was 51.07+4.606. Mean and SDs for follow up SPADI Score was 23.80+12.226. Mean and SDs for duration of disease was 7.12+1.757. Mean and SDs for BMI was 26.06+1.618. These findings were in consistent with the results concluded by Hubbard MJ.

The coracohumeral ligament covering the roof of the rotator cuff is usually the first structure to be damaged. External rotation of the arm is usually limited in early AC by contraction of the coracohumeral ligament that first affects it[13]. The shoulder joint capsule thickens and contracts in later stages, greatly reducing range of motion in all directions. In Group A, 38 (63.3%) patients in the 45-65-year-old age group and 22 (36.7%) patients in the 30-45-year-old age group were both documented. In Group B, 42 (70.0%) patients were documented in the 46-65-year age range, compared to 18 (30.0%) patients in the 30-45-year age range.

These findings agreed with the conclusions reached by Xiao RC[14]. A clinical diagnosis of frozen shoulder is done using the medical history, physical examination, and imaging techniques (ruling out another condition, rather than confirming the diagnosis of AC). No one laboratory or imaging test can provide the complete confirmation of the AC diagnosis on its own. There were 21 (35.0%) female patients and 39 (65.0%) male patients in Group A. There were 19 (31.7%) female patients and 41 (68.3%) male patients in Group B. These findings were in consistent with the results concluded by Murakami AM[15-16]. In Group A, 35 (58.3%) patients were from poor families, 16 (26.7%) patients were from middle class families, 09 (15.0%) patients were from rich families. In Group B, 35 (58.3%) patients were from poor families, 13 (21.7%) patients were from middle class families and 13 (21.7%) patients were from rich families. (Table No. 4). These findings were in consistent with the results concluded by Kingston K. In Group A, 46 (76.7%) patients had primary and above education whereas 14 (23.0%) patients had secondary & above education. In Group B, 47 (78.3%) patients had primary & above education while 13 (21.7%) patients had secondary & above education[17]. These findings were in consistent with the results concluded by Cho CH. In Group A, 33 (55.0%) patients were office workers, 18 (30.0%) patients were farmers, 18 (30.0%) patients were laborers 09 (15.0%) patients were farmers. In Group B, 39 (65.0%) patients were office workers, 09 (15.0%) patients were laborers while, 12 (20.0%) patients were farmers. These findings were in consistent with the results concluded by Wu F, Kachooei AR[18]. In Group A, 44 (73.3%) patients were diabetic while in Group B, 44 (73.3%) patients were

diabetic. These findings were in consistent with the results concluded by Oderuth E, Ali M. In Group A, 43 (71.7%) patients were recorded with hypertension while 48 (80.0%) patients were recorded with hypertension[19-20]. These findings were in consistent with the results concluded by Wong CK. In Group A, 38 (63.3%) patients were smokers while in Group B, 42 (70.0%) patients were recorded with smoking history. These findings were in consistent with the results concluded by Chen Y[21].

As per frequencies and percentages for functional outcome in both groups, in Group A, 51 (85.0%) patients were showed effective results while in Group B, 42 (70.0%) patients showed effective results. These findings were in consistent with the results concluded by Kamran A, Tahreen A[22].

Despite the abundance of AC-related research that has been published, there is no universally accepted approach to managing AC. The majority of AC treatments are non-surgical and involve medication management and physical therapy[23].

In one study, men made up the majority (60.62%). Patients in group A (Steroid Injection in Rotator Interval) had mean pre-procedure scores of 9.87, 4.44, and 22.8, 5.14, while patients in group B (Intra-articular Steroid Injection) had mean pre-procedure scores of 9.78, 4.49, and 21.49, 5.56. Out of 80 patients in group A, functional outcome (effectiveness) was seen in 92.50% of cases, compared to 73.75% of patients in group B. 10 These results were in line with the study's findings, which revealed that for functional outcome in both groups, 51 (85.0%) of the patients in Group A and 42 (70.0%) of the patients in Group B demonstrated successful outcomes.

This research has several restrictions. First, the topics might only apply to the local populace. As a result, the information from this study cannot be used in other contexts. Second, the findings of this study cannot be generalized due to the limited sample size of 120 (60 patients in each group). Despite these drawbacks, it is anticipated that this study will demonstrate the ideal location for corticosteroid injection for the treatment of FS in the local community.

Conclusion

Patients in Group A (intra-articular steroid injection) yielded better effects and superior results in terms of improvement in pain, range of movement assessed through SPADI Score as compared to patients in Group B (steroid injection in rotator interval).

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