



**A Randomized comparative study of various doses of intra-articular triamcinolone acetonide for clinically diagnosed adhesive capsulitis cases**

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**Abstract**

**Background:** In the present study, two different doses of a corticosteroid (20mg and 40mg triamcinolone acetonide) which are most widely used for patient with adhesive capsulitis and to compare the efficacy and find the optimal dose.

**Methods:** Randomized controlled study for adhesive capsulitis was conduct at patient suffering from adhesive capsulitis attending in the dept. of Physical Medicine and Rehabilitation, SMS Hospital, Jaipur.

**Results:** According to SPADI, There was no significant difference observed among the groups (P value varies category wise). It was more in SPADI Week 0 where the Mean  $\pm$ SD value was  $38.60 \pm 2.29$  followed by Week 1, Week 3, Week 12 and then Week 6. According to VAS, There was no significant difference observed among the groups (P value varies category wise). According to ROM: flex extension, abduction, Ex. Rotation Internal Rotation There was no significant

difference observed among the groups (P value varies category wise).

**Conclusion:** In our study, the group receiving low-dose corticosteroid injections showed no significant difference in efficacy compared with the high dose. Therefore, the use of 20 mg can be considered first in an initial trial to minimize its potential local and systemic complications. Intra articular injection of steroid were effective for adhesive capsulitis in terms of response Remarkable improvement in pain and range of motion was observed in both the groups.

**Keywords:** Adhesive capsulitis, VAS score, Corticosteroid

**Introduction**

Adhesive capsulitis is a common cause of shoulder pain which is estimated to affect between 2% and 5%<sup>4,38</sup> of the population. Adhesive capsulitis is a clinical diagnosis made from a history of the gradual onset of severe shoulder pain with the progressive limitation of

active and passive glenohumeral movement. Adhesive capsulitis is a self-limiting condition which can take up to two - three years for symptoms to resolve and some patients may never fully regain full range of motion. Recent cytogenetic analysis study has revealed elevated fibrogenic metalloproteinase (MMP 3) as well as inflammatory (IL-6) cytokines in patients with adhesive capsulitis.<sup>1</sup>

The definitive treatment for Ac remains unclear even though multiple interventions have been studied, But now use of intra-articular corticosteroid injection to treat adhesive has remained one of the most common procedure.

In corticosteroid triamcinolone acetonide is one of the most commonly used long acting corticosteroid 20mg (low dose) and 40mg (high dose)<sup>2,3</sup>.

A higher dose of corticosteroid may raise the incidence of local and general complication such as atrophy of subcutaneous fat tissue, local depigmentation of the skin, tendon rupture, lesion to local structure such as the nerve, disturbance of the menstrual pattern, hot flush like symptom, and hyperglycemia in diabetes mellitus.<sup>4</sup>

Intra-articular corticosteroid may alter the metabolism of articular cartilage, inhibiting chondrocyte proliferation and cartilage repair and inducing cartilage damage, the severity of such damage of dose depended. In the present study, two different doses of a corticosteroid (20mg and 40mg triamcinolone acetonide) which are most widely used for patient with adhesive capsulitis and to compare the efficacy and find the optimal dose.

## Material and Methods

**Study Area:** Patient suffering from adhesive capsulitis attending in the dept. of Physical Medicine and Rehabilitation, SMS Hospital, Jaipur.

**Study design:** Randomized controlled study for adhesive capsulitis.

**Duration:** From the approval of the Research Review Board till the desired sample size is obtained and their follow up completed

**Sample Size:** Sample size were calculated at 80% study power and alpha error of 0.05 assuming SD of 14 in spadiscore at 12 week in low dose group of corticosteroid as found in study of seung-hyun, hyun young lee, hyunjung lee and kyu-sung kwack investigation performed at ajou university medical center, suwon, south korea at al (the American journal of sports medicine) for minimum detectable mean difference of 9 in spadi score between low and high dose group 38 patient in each group are required as sample which is further enhanced and rounded off to 44 patient in each group as final sample size for present study expecting 15% dropout.

## Inclusion Criteria

- Eligible participants were men or women between the ages of 20 and 70 years who had adhesive capsulitis with a normal radiograph finding of the affected shoulder and restriction of passive motion of greater than 30 degree in 2 or more plane of movement stage 2 of adhesive capsulitis according hannaftin and chiaia
- At least 1month of pain duration, and average pain intensity during a day defined as a score of 3 point or more on a 10cm visual analogue scale rated from 0 (no pain) to 10cm (worst imaginable pain)
- Those willing to participate in study

## Exclusion Criteria

- They had any of the following –sec.adhesive capsulitis like causes inflammatory, metabolic, infectious arthritis, cerebrovascular accident tumor and fracture, rotator cuff lesion on both physical n

ultrasonographic examination, full thickness tear of the rotator cuff.

- Previous corticosteroid injection at the affected shoulder.
- Medication such as an antiplatelet agent or anticoagulant with the exception of those who agreed to stop for a minimum of 5 days before the injection.
- Participants undergoing any of these treatments (oral analgesic, acupuncture, physical modalities such as heat, cold and electricity) were excluded from this study only those who agreed to stop the treatment for min 1 week before the injection, were included.
- Participants non cooperative and severely ill.

#### Methodology

- The benefits, risk and alternative treatment s were explained to the patient and informed consent was obtained.
- The patient is then placed in sitting position with the forearm resting comfortably on the ipsilateral thigh. The skin overlying the glenohumeral joint is

then prepared with antiseptic solution (povidine iodine and spirit)

- The glenohumeral joint is then identified beneath supraspinatus tendon, after the joint space is identified, the needle is placed through the skin just lateral to the acromion below and directed 45 degree medially anteriorly. When the tip of needle is thought to be within the joint space, a desired amount of local anesthetics and steroid is injected
- The needle is then removed and a sterile pressure dressing and ice pack are placed at the injection site.

#### Statistical Analysis

- Continue variable were summarized as mean and standing deviation, whereas nominal variable were in percentage.
- Parametric test like unpaired T Test used for continuous variables and Medcalc 16.4 version software were used for all statistical analysis.
- For significance, P value of <0.05 were considered as significant.

#### Results

Table 1: Distribution of the cases according to socio-demographic variable

Variable	Group-A	Group-B	p-value
Age	53.25±8.787	54.18±11.117	0.664
Sex (M:F)	20:24	26:18	0.286
Site (Left: Right)	25:19	27:17	0.828

No significant difference was observed among the groups according to age ( $P=0.562$ NS) The Mean  $\pm$ SD of group A was  $53.25 \pm 8.787$  years and of the group B was  $54.18 \pm 11.117$  with P value  $0.664$ NS). There was no significant difference observed among the groups (P value=  $0.286$  NS). Also males were more as compared

to females across the groups but in Group A, females contributed more as compared to Group B where males contributed to 59.1%. There was no significant difference observed among the groups( $P = 0.828$  NS). Left shoulder (59.09%) was affected more than the right shoulder(40.91%) with no bilateral affection.

Table 2: Distribution of the cases according to spadi

Groups	Spadi	0 wk	1 wk	3 wk	6 wk	12 wk
Group A	N	44	44	44	44	44
	Mean	38.52	25.41	16.05	13.00	12.93
	Std. Deviation	2.38	3.49	2.07	1.75	1.90
Group B	N	44	44	44	44	44
	Mean	38.68	25.16	16.98	13.48	13.73
	Std. Deviation	2.22	2.78	2.56	1.77	2.18
Total	N	88	88	88	88	88
	Mean	38.60	25.28	16.51	13.24	13.33
	Std. Deviation	2.29	3.14	2.36	1.77	2.07
P Value LS		.746NS	.711NS	.064NS	.207NS	.072NS

The above table depicts the distribution of cases according to spadi. There was no significant difference observed among the groups (P value varies category

wise). It was more in SPADI Week 0 where the Mean  $\pm$ SD value was 38.60 $\pm$ 2.29 followed by Week 1, Week 3, Week 6 and then Week 12.

Table 3: Distribution of the cases according to VAS

Groups		0 wk	1 wk	3 wk	6 wk	12 wk
Group A	N	44	44	44	44	44
	Mean	5.91	4.14	2.84	1.77	1.34
	Std. Deviation	0.83	0.95	.680	1.031	.745
Group B	N	44	44	44	44	44
	Mean	5.77	3.84	2.66	2.00	1.43
	Std. Deviation	0.83	0.86	.713	.216	.587
Total	N	88	88	88	88	88
	Mean	5.84	3.99	2.75	1.89	1.39
	Std. Deviation	0.83	0.92	.699	.749	.668
P Value LS		.444NS	.131NS	0.224NS	0.15NS	0.53NS

The above table depicts the distribution of cases according to VAS. There was no significant difference observed among the groups (P value varies category wise). It was more in Week 0 where the Mean  $\pm$ SD

value was 5.84 $\pm$ 0.83 followed by Week 1, 3, 6 and 12. Mean VAS was decrease with the time in both the group. (P<0.001S)

Table 4: Distribution of the cases according to rom: flex

Groups		0 wk	1 wk	3 wk	6 wk	12 wk
Group A	N	44	44	44	44	44
	Mean	138.7	150.45	156.11	158.5	162.05
	Std. Deviation	7.87	6.04	4.95	4.87	3.44
Group B	N	44	44	44	44	44
	Mean	136.57	149.34	155.11	158.11	161.07
	Std. Deviation	6.49	5.07	4.22	2.73	3.05
Total	N	88	88	88	88	88
	Mean	137.64	149.9	155.61	158.31	161.56
	Std. Deviation	7.25	5.57	4.6	3.93	3.27
P Value LS		0.167NS	0.35NS	.121NS	.409NS	.163NS

The above table depicts the distribution of cases according to rom:flex. There was no significant difference observed among the groups (P value varies category wise). It was more in Week 12 where the

Mean  $\pm$ SD value was 161.56 $\pm$ 3.27 followed by 6, 3, 1 and 0. Mean ROM Flexion was increase with the time in both the group. (P<0.001S)

Table 5: Distribution of the cases according to abduction

Abduction		0 wk	1 wk	3 wk	6 wk	12 wk
Group A	N	44	44	44	44	44
	Mean	88	150.45	156.11	158.5	162.05
	Sd	6.14	6.04	4.95	4.87	3.44
Group B	N	44	44	44	44	44
	Mean	89.16	149.34	155.11	158.11	161.07
	Sd	7.75	5.07	4.22	2.73	3.05
P Value LS		0.439NS	0.351NS	0.311NS	0.647NS	0.163NS

The above table depicts the distribution of cases according to abduction. There was no significant difference observed among the groups for Week 0 to 12 (P value= 0.439) It was significantly increase upto

Week 12 where the Mean  $\pm$ SD value was 162.05 $\pm$ 3.44 in group A and 161.07  $\pm$  3.05 in group B. Mean ROM abduction was increase with the time in both the group. (P<0.001S)

Table 6: Extension among the groups

Groups		0 wk	1 wk	3 wk	6 wk	12 wk
Group A	N	44	44	44	44	44
	Mean	37.64	50.16	55.89	62.98	62.75
	Std. Deviation	3.43	3.81	3.04	3.21	2.29
Group B	N	44	44	44	44	44
	Mean	39.93	52	56.36	60.09	60.52
	Std. Deviation	4.2	4.75	2.48	2.98	2.74
P Value LS		0.67NS	0.34NS	0.422NS	0.45NS	0.23NS

The above table depicts the distribution of cases according to extension among the groups. There was no significant difference observed among the groups Week 0 to 12 (P value= 0.67). It was significantly increase

upto Week 12 where the Mean  $\pm$ SD value was  $62.75 \pm 2.29$  in group A and in group B  $60.52 \pm 2.74$ . Mean ROM Extension was increase with the time in both the group. (P<0.001S)

Table 7: External rotation among the groups

Groups		0 wk	1 wk	3 wk	6 wk	12 wk
Group A	N	44	44	44	44	44
	Mean	40.41	55.61	63.8	64.32	68.89
	SD	3.99	5.44	3.04	2.4	1.43
Group B	N	44	44	44	44	44
	Mean	39.3	53.7	62.09	63.5	67.89
	SD	4.28	4.61	3.72	2.64	2.81
P Value LS		0.21NS	0.079NS	0.45NS	0.46NS	0.64NS

The above table depicts the distribution of cases according to external rotation among the groups. There was no significant difference observed among the

groups at different follow up time from Week 0 to 12. Mean ROM External rotation was increase with the time in both the group. (P<0.001S).

Table 8: Internal rotation among the groups

Groups		0 wk	1 wk	3 wk	6 wk	12 wk
Group A	N	44	44	44	44	44
	Mean	40.98	55.89	61.32	63.34	67.75
	SD	4.45	5.7	3.72	3.27	2.34
Group B	N	44	44	44	44	44
	Mean	39.73	54	59.57	62.73	64.43
	SD	4.1	4.6	4.11	3.99	4
P Value LS		0.23NS	0.45NS	0.34NS	0.78NS	0.52NS

The above table depicts the distribution of cases according to internal rotation among the groups. There was no significant difference observed among the groups at different follow up time from Week 0 to 12. Mean ROM internal rotation was increase with the time in both the group. ( $P < 0.001$ S).

### Discussion

This hospital based study conducted in the department of PMR at SMS medical college and attached hospital in with the aim to find out Optimal Dose of Intra-articular Corticosteroids for Adhesive Capsulitis.

In the present study, there was no significant difference observed among the groups according to spadi. (P value varies category wise). It was more in SPADI Week 0 where the Mean  $\pm$ SD value was  $38.60 \pm 2.29$  followed by Week 1, Week 3, 6 week Week 12 similar with the study conducted by **Michael J. Griesse et al**<sup>5</sup> in 2011 to review of the effectiveness of intra-articular corticosteroid injections in adhesive capsulitis and concluded that systematic review of existing level-I and II evidence reveals that all treatments resulted in improved clinical out-come measures based on Constant-Murley and SPADI scores, **Seung –Hyun-Yoon et al** conducted a study in 2013 Test also showed improvement in SPADI scores especially for the low and high dose groups.<sup>6</sup>

**Gulzar Saeed Ahmed, Altaf Hussain, Muhammod Ali** conducted a study in 2011 about role of single intra articular corticosteroid injection and home exercise programme in frozen shoulder. Single intra articular injection of corticosteroid combined with simple home exercise program is effective in improving shoulder pain and disability. In newer studies SPADI score was considered, as it was developed by **Roach et al** (1991) for evaluation of pain and disability of the patient with

shoulder pain. Thus SPADI score improves with the follow up in both the groups.

In the present study, there was no significant difference observed among the groups (P value varies category wise). It was more in Week 0 where the Mean  $\pm$ SD value was  $5.84 \pm 0.83$  followed by Week 1, 3, 6 and 12. similar with the study conducted by **Gram AN et al**<sup>7</sup> conducted in 1998 where they were evaluated by pain VAS on function and at rest within the study period,. It is concluded that distension with steroid can seem to help in management of “Frozen Shoulder”.

**Michael J. Griesse et al** (2011)<sup>5</sup> also observed that these significant improvements appear to be transient as all treatments resulted in improved passive shoulder motion at the time of the latest follow-up, with no treatment reaching a significant difference, as compared with another.

In this study, there was no significant difference observed among the groups (P value varies category wise). It was more in Week 12 where the Mean  $\pm$ SD value was  $161.56 \pm 3.27$  followed by 6, 3, 1 and 0. Mean ROM Flexion was increase with the time in both the group. ( $P < 0.001$ S) this findings corresponded with the study **Gram AN et al**<sup>7</sup> conducted in 1998 they were evaluated by the different ranges of motion (ROM) were measured at inclusion time and subsequent afterwards at 3, 6, and 12 weeks. It is concluded that distension with steroid can seem to help in management of “Frozen Shoulder”. Other studies seems to support the conclusion **Michelj, Griesser et al**<sup>5</sup> conducted a study in 2011 about adhesive capsulitis of the shoulder about, intraarticular cortisone injection can lead to satisfactory results in the treatment of adhesive capsulitis with improved range of motion **Seung – Hyun-Yoon et al**<sup>6</sup> conducted a study in 2013 Test showed improvement in in flexion, abduction, and



internal rotation especially for the low and high dose groups.

There was no significant difference observed among the groups for Week 0 (P value= 0.439) It was significantly increase upto Week 12 where the Mean  $\pm$ SD value was  $162.05 \pm 3.44$  in group A and  $161.07 \pm 3.05$  in group B. Mean ROM abduction was increase with the time in both the group.( $P < 0.001S$ ) **Michael J. Griesse et al**<sup>5</sup> conducted a study in 2011 Most treatments resulted in improved passive shoulder motion at the time of early follow-up, with both intra-articular and oral corticosteroid treatment showing significantly greater improvements in shoulder abduction and forward elevation in comparison with intra-articular lidocaine and intra-articular saline solution.

In the present study, there was no significant difference observed among the groups Week 0 to 12 (P value= 0.67). It was significantly increase upto Week 12 where the Mean  $\pm$ SD value was  $62.75 \pm 2.29$  in group A and in group B  $60.52 \pm 2.74$ . Mean ROM Extension was increase with the time in both the group.( $P < 0.001S$ ).

In this study, there was no significant difference observed among the groups at different follow up time from Week 0 to 12. Mean ROM External rotation was increase with the time in both the group. ( $P < 0.001S$ ) There was no significant difference observed among the groups at different follow up time from Week 0 to 12. Mean ROM internal rotation was increase with the time in both the group. ( $P < 0.001S$ )

In this study, there was no significant difference observed among the groups for week 0, 1 and 6 (P value varies category wise) There was no significant difference observed among the groups at different follow up time from Week 0 to 12. Mean ROM internal rotation was increase with the time in both the

group.( $P < 0.001S$ ) similar with study conducted by **M.A. Taskaynatan et al**(2005) found in there study that after application of a single session steroid injection, a significant improvement was reported by patient in there range of motion till the follow up.<sup>8</sup>

### Conclusion

In our study, the group receiving low-dose corticosteroid injections showed no significant difference in efficacy compared with the high dose. Therefore, the use of 20 mg can be considered first in an initial trial to minimize its potential local and systemic complications. Intra articular injection of steroid was effective for adhesive capsulitis in terms of response Remarkable improvement in pain and range of motion was observed in both the groups.

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