A Comparative study of Disability and Pain Assessment by Shoulder Pain and Disability Index (SPADI) Score in Patients of Adhesive Capsulitis Treated by Hydrodilatation with and without Corticosteroids

Kunal K. Saoji\(^1\), Vasant Gawande\(^2\), Rajesh Dulani\(^3\)

\(^1\)Assistant Professor, Department of Orthopedics, Datta Meghe Medical College, ShalinitaiMeghe Hospital and Research Centre. (SMHRC), Wanadongri, Hingna. (Maharashtra); \(^2\)Associate Professor, Department of Orthopedics, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi, Wardha, Maharashtra-4422001; \(^3\)Professor, Department of Orthopedics, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi, Wardha, Maharashtra-4422001.

ABSTRACT

Background: Adhesive Capsulitis is a painful condition commonly occurring in the middle age group population causing disability in the population and hence we conducted the present study with the aim to describe the pain and disability assessment in patients of adhesive capsulitis treated with and without injectable corticosteroids (hydrodilatation).

Methodology: A prospective study was conducted from June 2018 to March 2020 for a period of 2 years, at a tertiary care hospital. The sample size included 40 patients with the diagnosis of adhesive capsulitis divided into 2 groups randomly. SPADI score was calculated and p<0.05 was considered significant.

Results: SPADI score was performed on pre-injection day and on 3\(^{rd}\), 6\(^{th}\), 12\(^{th}\) and 16\(^{th}\) week in the two groups. The mean pre-intervention score in the steroid group was (75.18) which improved on follow up weeks 3\(^{rd}\) wk (49), 6\(^{th}\) wk (40.45), 12\(^{th}\) (39.10), and 16\(^{th}\) wk (31). Similarly, the SPADI score for the saline group was (75.05) pre-intervention which also improved on the review weeks as on 3\(^{rd}\)wk (65), 6\(^{th}\) wk (64.95), 12\(^{th}\)wk (56.15), and 16\(^{th}\) week (40.40).

On comparing the mean score of saline and steroid group, there was more improvement in range of motion and pain in the patients of steroid group. The mean score observed on 16\(^{th}\) week post-intervention in steroid group was (31) and that in the saline group was (40.40).

Conclusion: Comparison between steroid hydrodilatation and saline hydrodilatation was suggestive of, as steroid hydrodilatation being a better modality of treatment for pain relief and improvement in shoulder mobility when compared on SPADI Score.

Key Words: Adhesive capsulitis, Saline, Steroid, Hydrodilatation, Disability, Pain

INTRODUCTION

Adhesive capsulitis is a clinical syndrome complicated by many synonyms and paucity of comprehension. The terminology used to characterize the glenohumeral joint’s painful steadiness is adhesive capsulitis, periarthritis, and frozen shoulder. It may represent final result of any of the preceding painful lesions of the shoulder. Its multifactorial etiology marks the adhesive capsulitis as a functional more than a pathological entity for its onset can be occasioned by almost any painful shoulder derangement as well as appearing as idiopathic adhesive capsulitis in absence of any recognizable cause.

The common denominator of this syndrome is generally a stiff painful shoulder, insufficient activity, and periarthritic unit or hyperirritable and passive personality in a patient with low pain tolerance. The true mechanism has been the grist of innumerable scholarly efforts. Diagnosis is usually not difficult although the precise cause may be elusive. It is characterized by insidious, starting of pain in the shoulder associated with progressive restrictions of active and passive glenohumeral joint range of motion.
Neviaser and Neviaser described the term “frozen shoulder” as a “waste-can diagnosis,” this was because frequently overused and misapplied in patients with a sore, painful neck. Conditions such as calcium tendonitis, bicipital tenosynovitis, glenohumeral and acromioclavicular arthritis, and rotator cuff tears may result in a stiff and painful shoulder. Causing obvious limitation of the active motion range, but lacking true capsular contracture and restriction of passive motion range, they should not be classified as adhesive capsulitis. Accurate diagnosis is important for those different groups due to dissimilar treatment strategies.

This ambiguity and uncertainty about the meaning and treatment of adhesive capsulitis reflected our limited understanding of this disorder and its etiology, treatment, and management. Our understanding of this disease has progressed gradually, and a variety of surgical and non-operative approaches to treatment have been established, this often-obstinate disease has been investigated. Hence we conducted this study, to study the disability and pain assessment by SPADI score in patients of adhesive capsulitis treated with and without corticosteroids hydrodilatation.

**METHODOLOGY**

The present study was conducted in the Dept. of Orthopaedics at Datta Meghe Medical College, Shalinitai Meghe Hospital and Research Centre in collaboration with Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi, Wardha, Maharashtra, India. It was a hospital-based prospective study carried for 2 years in a single centre in a tertiary care hospital in Central India. Patients were distributed randomized in two groups of 20 patients each

1. Group A-Injection of corticosteroid, local anesthetic, and saline,
2. Group B-Injection of normal saline and local anesthetic drug.

**Inclusion Criteria:**

1. Limitation of passive movement in the glenohumeral joint with respect to the unaffected side, reaching 30 degrees for at least two of these three motions: forward flexion, abduction, or lateral rotation.
2. Patients with prior adhesive capsulitis in the opposite shoulder were accepted even though the sides varied a little less than 30 degrees.
3. Patients with a history of diabetes on medication (controlled blood sugar levels) and limitation of range of motion.

All included patients were clinically assessed for restriction of active and passive range of motion. Plain radiographs of the shoulder joint to rule out other pathologies were done and ultrasonography of shoulder joint for confirming the diagnosis of adhesive capsulitis was carried out.

**Exclusion Criteria:**

1. Patients not willing to give consent for the study.
2. Patients contraindicated for steroid injection- bleeding disorders, known drug allergy.
3. Patients with a history of trauma to shoulder needing immobilization.
4. Patients with serious mental illness.
5. Patients with age under 18 or over 70.
6. Patients currently taking oral corticosteroid therapy.
7. Patients with decreased glenohumeral motion vary for causes other than adhesive capsulitis with glenohumeral arthritis suggestive X-ray, dislocation, or full-thickness rotator cuff tears with the movement of the humeral head.

**Technique:** The proper consent of the procedure was taken from the patient and the Xylocaine sensitivity test was performed 45 minutes before the procedure. The procedure was performed according to the Kaye-Schneider technique. The patients were placed supine under the opposite shoulder on a table with an overhead X-ray tube and a support pillow. A marker was positioned over the glenohumeral joint space at about the junction of its middle and lower third or just lateral to the coracoid process under image-intensified fluoroscopy, or ultrasonographically directed.

The point was then marked with a pen on the skin. An antiseptic was used to cleanse the skin. The needle was used to puncture the joint (18 or 22 Gauge intramuscular spinal needle) and its location during the procedure was frequently tested with fluoroscopy. The needle was connected to a 20 ml syringe. Up to 16 ml of sterile normal saline, 2 ml of local anesthetic (Bupivacaine hydrochloride, 5 mg/ml), and an injection of 2 ml Depomedrol (80 mg Methyl Prednisolone) as a total of 20 ml solution was injected slowly in group “A” patients.

A similar procedure was carried out for hydrodilatation in group “B” patients with 18ml of sterile normal saline and 2 ml of local anesthetic (Bupivacaine hydrochloride, 5 mg/ml).

In both the groups, following hydrodilatation, manipulation of the affected shoulder joint was done.

**Physiotherapy programme included:**

1. Active movement which allows a paced stretching within pain limits.
2. Gentle passive movements to provide maximum assistance during stretching.
3. Pendulum exercises to assist force such as gravity and pull of normal limb.
4. Wheel exercises.
5. Pulleys exercises.
6. Marking on the wall.
7. Assistance by towel
Disability assessment (SPADI)
SPADI 5 is a self-administered, shoulder-specific, fixed object index composed of 13 items divided into two subscales: pain (five items) and impairment (eight items). Responses to each item were recorded on a 10 point Likert scale, where 0 = “no pain” or “no difficulty” and 10 = “worst imaginable pain” or “so difficult it required help” for the pain and disability items, respectively.

The SPADI score is calculated by summing and then averaging the items of the two subscales to give a score out of 100 (higher scores reflect more pain/disability). The SPADI has acceptable test–retest reliability (intraclass correlation coefficients of 0.91 and 0.65 (95% CI, 0.42 to 0.8) in surgical and primary care populations respectively) and acceptable responsiveness.

STATISTICAL ANALYSIS
Data collected was entered Microsoft Excel Worksheet and statistically analyzed by using SPSS (Statistical Package for Social Sciences) version 20. For quantitative data mean, standard mean, standard deviation, t-test, and Chi square test were used. P value < 0.05 (0.01) will be considered as statistically significant (highly significant) at 95% confidence interval.

RESULT
On the basis of inclusion and exclusion criteria, 40 patients were selected for study which was then divided into 2 groups of 20 patients each.

The intra steroid group analysis with respect to pre-intervention and with post-intervention 3, 6, 12, and 16 weeks gave a significant p-value on comparison. Thus, an improvement was observed on hydrodilatation of steroid.

Table 1: Comparison of SPADI score in steroid group at pre intervention, post injection 3 wks, 6 wks, 12 wks and 16 wks

|                | Mean | N  | Std. Deviation | Std. Error Mean |
|----------------|------|----|----------------|-----------------|
| Pre Intervention | 75.18| 20 | 12.95          | 2.89            |
| 3 wks          | 49.00| 20 | 14.76          | 3.30            |
| 6 wks          | 40.45| 20 | 15.32          | 3.42            |
| 12 wks         | 39.10| 20 | 16.22          | 3.62            |
| 16 wks         | 31.00| 20 | 19.54          | 4.37            |

Figure 1: Comparison of SPADI score in steroid group at pre intervention, post injection 3 wks, 6 wks, 12 wks and 16 wks.

In the present study, a significant p-value was observed on the post injection 3, 6, 12, 16 weeks within the saline group. Thus an improvement in the SPADI score was observed after the injection of saline also, but not as compared to the steroid group.

Table 2: Student paired t test

|         | Mean | Std. Deviation | t  | df | p-value |
|---------|------|----------------|----|----|---------|
| Paired Differences | Std. Error Mean | 95% Confidence Interval of the Difference |     |     |
| 3 wks   | 26.18| 13.08          | 2.92|20.05|32.30|8.94|19|0.000|p<0.05|
| 6 wks   | 34.73| 14.27          | 3.19|28.04|41.41|10.87|19|0.000|p<0.05|
| 12 wks  | 36.08| 15.30          | 3.42|28.91|43.24|10.54|19|0.000|p<0.05|
| 16 wks  | 44.18| 21.66          | 4.84|34.04|54.31|9.12|19|0.000|p<0.05|

Table 2: Student paired t test

Figure 1: Comparison of SPADI score in steroid group at pre intervention, post injection 3 wks, 6 wks, 12 wks and 16 wks.
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The comparison between the saline and steroid group with respect to the SPADI score was done pre-intervention and on 3, 6, 12, 16 weeks follow up. The p-values derived on these assessment weeks were (pre-intervention) 0.9, 0.001, 0.000, 0.025, 0.313, respectively. This indicates that there was a significant difference in comparing the two groups on 3rd, 6th, 12th week.

But the follow up on 16th week resulted in a non-significant p-value. Thus an improvement in pain and movement on comparing the two groups using student’s unpaired t-test was similar (on 16th week post-injection).

Intermittent follow up findings on 6th and 12th week presented with the steroid group having better results than the saline group.

Table 3: Comparison of SPADI score in saline group at pre intervention, post injection 3 wks, 6 wks, 12 wks and 16 wks

|          | Mean | N  | Std. Deviation | Std. Error Mean |
|----------|------|----|----------------|-----------------|
| Pre Intervention | 75.05 | 20 | 14.67 | 3.28 |
| 3 wks     | 65.00 | 20 | 13.81 | 3.08 |
| 6 wks     | 64.95 | 20 | 14.53 | 3.25 |
| 12 wks    | 56.15 | 20 | 28.25 | 6.31 |
| 16 wks    | 40.40 | 20 | 36.16 | 8.08 |

Table 4: Student’s paired t test

|          | Paired Differences | t | df | p-value |
|----------|--------------------|---|----|---------|
| Mean     | Std. Deviation     | Std. Error Mean | 95% Confidence Interval of the Difference | Lower | Upper |       |
| 3 wks    | 10.05              | 8.94 | 2.00 | 5.86 | 14.23 | 5.02 | 19 | 0.000 p<0.05 |
| 6 wks    | 10.10              | 10.91 | 2.44 | 4.99 | 15.20 | 4.13 | 19 | 0.001 p<0.05 |
| 12 wks   | 18.90              | 31.48 | 7.03 | 4.16 | 33.63 | 2.68 | 19 | 0.015 p<0.05 |
| 16 wks   | 34.65              | 40.65 | 9.09 | 15.62 | 53.67 | 3.81 | 19 | 0.001 p<0.05 |

Table 5: Showing Comparison of SPADI score in both groups at pre intervention, post injection 3 wks, 6 wks, 12 wks and 16 wks

|          | Group     | N  | Mean | Std. Deviation | Std. Error Mean |
|----------|-----------|----|------|----------------|-----------------|
| Pre Intervention | Steroid   | 20 | 75.18 | 12.95 | 2.89 |
|           | Saline    | 20 | 75.05 | 14.67 | 3.28 |
| 3 wks    | Steroid   | 20 | 49.00 | 14.76 | 3.30 |
|           | Saline    | 20 | 65.00 | 13.81 | 3.08 |
Table 5: (Continued)

| Group     | N | Mean | Std. Deviation | Std. Error Mean |
|-----------|---|------|----------------|-----------------|
| 6 wks     |   |      |                |                 |
| Steroid   | 20| 40.45| 15.32          | 3.42            |
| Saline    | 20| 64.95| 14.53          | 3.25            |
| 12 wks    |   |      |                |                 |
| Steroid   | 20| 39.10| 16.22          | 3.62            |
| Saline    | 20| 56.15| 28.25          | 6.31            |
| 16 wks    |   |      |                |                 |
| Steroid   | 20| 31.00| 19.54          | 4.37            |
| Saline    | 20| 40.40| 36.16          | 8.08            |

Table 6: Student’s unpaired t test

|          | t  | df | p-value | Mean Difference | Std. Error Difference | 95% Confidence Interval of the Difference |
|----------|----|----|---------|-----------------|-----------------------|-----------------------------------------|
|          |    |    |         |                 |                       | Lower | Upper |
| Pre Intervention | 0.030 | 38 | 0.976 NS, p>0.05 | 0.13 | 4.37 | -8.72 | 8.98 |
| 3 wks    | 3.539 | 38 | 0.001 S, p<0.05 | -16.00 | 4.52 | -25.15 | -6.84 |
| 6 wks    | 5.188 | 38 | 0.000 S, p<0.05 | -24.50 | 4.72 | -34.06 | -14.93 |
| 12 wks   | 2.340 | 38 | 0.025 S, p<0.05 | -17.05 | 7.28 | -31.79 | -2.30 |
| 16 wks   | 1.023 | 38 | 0.313 NS, p>0.05 | -9.40 | 9.19 | -28.00 | 9.20 |

**DISCUSSION**

A total of 40 patients were studied which were divided into 2 groups of 20 each randomly. In our study volume used for hydrodilatation was 20 ml, in both the groups.

The study by Jacobs LG 7 (2009) included dilatation procedure of injecting a maximum of 10 ml which is less than most other investigations. It is unclear if this volume is sufficient to cause effective distension of the joint capsule.

Gam AN 8 (1998) stated whether hydrodilatation effects accumulate if injections are repeated is more unclear. It is possible that the specific effects of hydrodilatation might have been easier to identify if only one injection had been given.

Eklund A 9 (1992) reviewed two other studies were a volume of 20 ml was used in the distension group, but those studies were inconclusive due to the small sample size.

In the present study Group A (Steroid Hydrodilatation) when analysis with respect to pre-intervention and with post-intervention SPADI score gave a significant p-value on the comparison. Thus, stating an improvement on Hydrodilatation with steroid is better than Hydrodilatation with saline.

Bal A 10 (2008) found that intra-articular steroid injection was significantly associated with an improvement in range of motion and pain 2 weeks (but not for 12 weeks) after the conclusion of their study.

Ryans I 11 (2005) found that patients having intraarticular corticosteroid therapy had a better outcomes in disability scores but not in pain and range of motion in the 6th weeks. Van der Windt DA 12 (1983) in its fluoroscopically directed injection trial with and without physiotherapy, corticosteroid-injected patients were found to have less pain and a greater range of motion results at six weeks relative to physical therapy alone or placebo.

In present study, the comparison between saline and steroid group with respect to SPADI score was done pre intervention and on follow up. This indicates that there was a significant difference in comparing the two groups on 3rd, 6th, 12th week. But the follow up on 16th week resulted in a non-significant p-value. Thus an improvement in pain and movement on comparing the two groups using student’s unpaired t-test was similar (on 16th week post-injection). Intermittent follow up findings on 6th and 12th week presented with the steroid group having better results than the saline group.

Thus the results were consistent with the previous literature.

Buchbinder R 13 (2003) assessed the effectiveness of corticosteroid hydrodilatation for shoulder pain and found that corticosteroid hydrodilatation for adhesive capsulitis may be beneficial, although its effect may be small and not well-maintained; there were inconsistent short-term results and limited evidence for the long-term outcome.

Sakeni RA 14 (2007) stated that triamcinolone acetate has shown to be more effective than methylprednisolone in the management of diabetic adhesive capsulitis.

Shah N 15 (2007) showed that multiple steroid injections were more effective than single injection in relieving pain, improving function, and enabling a better range of motion in subjects with adhesive capsulitis.
But in the present study, we had subjected the patients to a single dose of hydrodistilation, in both the groups.

Marx R G16 (2007) advocated the use of steroid injections in the management of early adhesive capsulitis and suggested that patients treated with glenohumeral steroid injections in an acute phase of that disorder respond better than if they receive treatment in later phase presumably because there is more inflammation in early adhesive capsulitis.

Buchbinder R17 (2004) reported the short term efficacy of treatment with distention by steroid and normal saline solution in a cohort of 48 patients, in which shoulder abduction and pain scores improved after that therapy.

Buchbinder R18 (2008) in his recent Cochrane review analyzed the efficacy of hydrodistention in treating adhesive capsulitis in 5 clinical trials with a total of 196 patients and concluded that treatment consisting of repeated hydrodistention with steroid injection has been found to be more effective than a single hydrodistilation in reducing disability and pain.

**CONCLUSION**

Comparison between steroid hydrodistilation and saline hydrodistilation was suggestive of, steroid hydrodistilation being a better modality of treatment for pain relief and improvement in shoulder mobility when compared on SPADI Score.

**Limitations**

1. Small study sample.
2. Single dosage of hydrodistilation.
3. Multiple operators.
4. Lack of timely follow-up.
5. Lack of patient compliance for Physiotherapy.

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