



RESEARCH ARTICLE

COMPARATIVE STUDY OF TREATMENT WITH INTRA-ARTICULAR CORTICOSTEROID INJECTION AND NSAID IN ADHESIVE CAPSULITIS OF SHOULDER IN DIABETIC PATIENTS; A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Adhesive capsulitis commonly presents with pain and limitation of both active and passive shoulder movements. It involves the glenohumeral joint and is relatively more common condition encountered in elderly and among diabetic patients. The incidence among the diabetic group of patients is 10-20%. Diabetic patients with adhesive capsulitis present with severe stiffness and pain and should be treated actively. The treatment modalities include intra-articular corticosteroid injection, NSAIDs and physiotherapy. In this study we compare the efficacy of intra articular corticosteroid injection with NSAIDs in adhesive capsulitis of diabetic patients.

**Method:** The study was conducted during Feb 2016-Aug 2017 on diabetic patients with adhesive capsulitis in Department of orthopaedics, Sree Balaji medical college and hospital. Pain and the limitation of range of movements in all the directions were taken as our diagnostic criteria. The patients were divided into 2 groups, of which the first received NSAID and the second group undergone intra- articular corticosteroid injection. Exercises in the home were started after 1 week, for both the groups. Patients were evaluated in 2nd, 6th, 12th and 24th weeks. SPSS-15 software were used to compare and analyze the data.

**Results:** 57 patients of which 19 were males (33.3 %) and 38 were females (66.7 %) are included in the study. There is significant difference noted between sex ( $P = 0.4$ ) and age ( $P = 0.19$ ) of patients. No significant relation was seen between 2 groups after 24 weeks considering the range of motion in flexion ( $P = 0.51$ ), range of motion in abduction ( $P = 0.76$ ), range of motion in external rotation ( $P = 0.12$ ) and range of motion in internal rotation ( $P = 0.91$ ). There is also any significant difference in pain score was not detected ( $P = 0.91$ ).

**Conclusion:** Our study showed that there is no significant difference in efficacy in diabetic patients with adhesive capsulitis treated with both intraarticular corticosteroid and NSAID's.

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INTRODUCTION

Adhesive capsulitis commonly presents with pain and limitation (Frieman *et al.*, 1994) of both active and passive shoulder movements. It involves the glenohumeral joint and is relatively more common condition encountered in shoulder in elderly and among diabetic patients. The incidence among the diabetic group of patients is 10-20%. Diabetic patients with adhesive capsulitis present with severe stiffness and pain and should be treated actively. It is more prevalent among women aged in their fifth decade of life (Bjelle, 1989; Frieman *et al.*, 1994).

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The appearance of Pain and stiffness of shoulder joint might take few months to one year; however, the progression may be faster in some patients (Frieman *et al.*, 1994). Pre-disposing factors like diabetes can be a major cause of adhesive capsulitis of shoulder (Bjelle, 1989; Palmer *et al.*, 2001), However adhesive capsulitis of shoulder could be idiopathic. Adhesive capsulitis can be diagnosed with the patient complaining of pain and restricted range of movements in all directions (de Jong, 1998). Arthrography can be helpful in establishing the diagnosis. (Macforlane, 2001). There will be spontaneous resolution of symptoms within 1-3 years in most of patients, but restriction of movements may remain upto some degree (Macforlane, 2001). There is a 2 % Prevalence of adhesive capsulitis in normal population where as in diabetic patients it can increases to 10–20 %. The duration and the control of Diabetes can play a major role in treating adhesive capsulitis.

However, The mean age of adhesive capsulitis in diabetic patients is generally lower than normal population; The response to the treatment in diabetes patients is less when compared to normal population. Adhesive capsulitis can occur bilaterally in diabetic patients (Ryans *et al.*, 2005). Population with 4th–6th decades of life can be affected more often by adhesive capsulitis. There are 3 phases: First phase the ‘Painful Phase’ associated with pain and restricted range of movements. This generally lasts about 2–9 months. The second phase, ‘Freezing (Adhesive) Phase’ that lasts about 3–9 months. This phase is associated with fibrosis and patient sees decrease in the pain, while range of motion is even more restricted. Third phase, the ‘Throwing (Resolution) Phase’. In this phase pain subsides and lost motions are resolved. This phase lasts about 12–18 months (Macforlane *et al.*, 2001). Treatment modalities such as rest, physiotherapy, analgesics, acupuncture, mobilization exercises, oral and intraarticular corticosteroid along with capsular distension, manipulation under anaesthesia and surgical capsular release are advocated. However, effective treatment for such common condition hasn’t been described anywhere (Palmer *et al.*, 2001; Sharma, 2011). Diabetic patients often complain of restriction of movements and pain which can effect on performance of the individual and quality of life, and there is no definitive and effective treatment, we made this study to compare the efficacy of two of the most popular treatment modalities being used.

## MATERIALS AND METHODS

Our study was a randomized clinical trial study conducted only on diabetic patients with adhesive capsulitis. The following parameters:  $\alpha=0.05$ ,  $\beta=0.2$  and  $d=10$ , about 30 cases were needed for each group on basis of the previous study. We have prepared a questionnaire which included questions about sex, age, duration of diabetes, drug history, results of shoulder clinical examination with goniometer and pain score based on VAS (visual analogue score). All the diabetic patients who were admitted in our department of orthopaedics were taken up for the study. Diagnosis was confirmed by clinically examining the patient. Patients with more than 5 months of disease were excluded from the study as there is difference in response to treatment between acute and chronic form of disease. Patients with other associated conditions like degenerative diseases, infection, active peptic ulcer, history of GI bleeding, history of coagulopathies and renal failure, fractures and stroke were excluded from the study. Plain radiograph was taken for each patient to rule out other associated factors like osteopenia and osteoporosis. Routine laboratory tests like Complete Blood picture, Erythrocytes Sedimentation Rate, C Reactive Protein, urea, creatinine, uric acid, Liver function test and routine Urine Analysis were checked for all patients. The treatment modalities are thoroughly explained and a written consent was obtained from all the patients who participated in the study. We have divided the Patients into 2 groups randomly. First group were treated with analgesics the second group underwent intra-articular corticosteroid injection. All the patients were evaluated clinically and radiologically before initiating the treatment. VAS (Visual Analogue Score) and Pain Assessment Ruler (PAR) were used to assess the severity of pain. Pain is graded between no pain to severe pain (0-10). This is a subjective Evaluation which was done by patients and recorded in the questionnaire at each visit. Range of movements were evaluated in terms of flexion, abduction, Internal rotation and external rotation by using the goniometer.

Internal rotation is assessed by plus (0–4) by asking the patient to reach the dorsum of the hand to the inferior border of scapula and noted at each visit. All the group of patient were treated with NSAIDs with daily 500 mg Naproxen take twice. In second group patients underwent ultrasound-guided single intra articular injection of 40 mg depomedrol at the start of study. After 1 week, all patients were started on physiotherapy in the home. All the patients were initiated exercises in flexion (maximum range of 180 °), abduction (maximum range of 180°) and internal rotation. Three sessions a day and 15 times at each session were recommended for the patients. Patients were evaluated at 2nd, 6th, 12th and 24th weeks. SPSS-15 program was used to analyze by repeated measures, T-test and Chi-square tests.

## RESULTS

A Total of 75 patients were visited out of which 11 patients of intraarticular injection group and 7 patients of naproxen group were excluded as they have discontinued the follow-up. The remaining 57 patients were included in the analysis of which 28 patients in naproxen group and 29 patients in intraarticular injection group. In naproxen group, out of 28 patients, female constitute 17 (60.7 %) patients and male constitute 11(39.3 %) patients, while in intraarticular injection group 21 (72.4 %) are female and 8 (27.6 %) are male respectively ( $P=0.4$ ; Chi-square). Mean age of participants were  $52.78 \pm 6.72$  and  $55.31 \pm 7.7$  years for naproxen and intraarticular injection groups respectively ( $P=0.19$ ; T-test). Also there was no significant difference between groups according to HbA1C (0.25; Chi-square) and duration of diabetes ( $P=0.9$ ; T-test) ( $9.3 \pm 7$  years in naproxen group vs.  $9.5 \pm 5.8$  in injection group). Mean range of movements of flexion, abduction and external rotation were increased in fifth visit when compared with second visit significantly ( $P=0.001$ ; paired T-test). Data showed the improvement of mean of internal rotation and reduction in pain score ( $P=0.001$ ; paired T-test) Intraarticular injection group also showed similar ( $P=0.001$ ; paired T-test)

No significant difference was noted between both the groups according to flexion ( $P=0.51$ ; Repeated Measure), Abduction ( $P=0.76$ ; Repeated Measure), external rotation ( $P=0.12$ ; Repeated Measure), internal rotation and also the pain score ( $P=0.91$  and  $P=0.90$  respectively; repeated measure). Mean flexion and abduction scores were compared with the normal range of movements at the fifth visit. They were found to be closer to maximum score that hadno significant relation with maximum normal range. The group treated with naproxen showed a similar results, range of motion in abduction at fifth visit was 170 °.

## DISCUSSION

In Our study, we have compared diabetic patients with adhesive capsulitis treated with intra-articular injection of depomedrol with naproxen. This study was done exclusively in diabetic patients suffering with adhesive capsulitis. Any other underlying causes were excluded from the study. Goniometer was used in assessing the Range of movements. Intraarticular injections of depomedrol were done under the guidance of ultrasound. Patients were followed for five visits in a span of 6 months. There was no significant difference between 2 groups in flexion, abduction, external rotation, internal rotation and also pain score. Range of movements in patients of both groups almost returned to normal range.

There is only one study in the literature which compared intra-articular corticosteroid with oral NSAID in patients with adhesive capsulitis (Widiastuti-Samekto, 2004). There has been no study to compare these treatment modalities in diabetic patients specifically. In a study by Arslan *et al.* in 2001 (Arslan, 2001), on effect of corticosteroid, physiotherapy and NSAID on adhesive capsulitis. A group of 20 patients of which 10 men and 10 women allocated into 2 groups. Group A underwent 40 mg intraarticular methylprednisolone while in group B physiotherapy and NSAID was administered. Results showed significant improvement in pain and range of movements. However, the Sample size in this study was much lower than that of ours and was not just limited to diabetic patients. Buchbinder *et al.*, has compared the effect of oral corticosteroids to placebo which pointed out that a 3-week course of prednisolone 30 mg daily in patients is better than placebo which improved pain, function, and range of motion (Buchbinder, 2004). Russel *et al.* in his study in 2007, compared prednisolone and triamcinolone in a painful shoulder. After 2 weeks of follow-up, 92 % of patients got prednisolone and 50 % of patients got triamcinolone which showed improvement in pain and range of motions. Patients treated with prednisolone had faster recovery (Russell, 2007) when compared to patients treated with triamcinolone. However, duration of the follow-up lasted for 2 weeks and the study included the painful shoulder in any reason. In 2008 Isar Ahmad (2009), showed no significant difference between 2 groups comparing these 2 drugs in adhesive capsulitis. Both the diabetics and non-diabetics population were taken into account in this study, while our study has focused on diabetic patients. In 2011, Roh *et al.* the efficacy of corticosteroid injections for the treatment of adhesive capsulitis is studied in patients with diabetes mellitus. A group of patients underwent intraarticular injection and home exercise and another group only did home exercise. This study showed that a corticosteroid intraarticular injection in diabetic patients decreases the pain and improves the functional recovery in the early post-injection period (Roh *et al.*, 2011). The effect of corticosteroids with any oral drugs is not studied in this study.

Smith *et al.* in 2005, compared triamcinolone in adhesive capsulitis patients with fluoroscopy guided intra articular injection of triamcinolone following with 12 sessions of physiotherapy. Results showed that corticosteroid with physiotherapy have better results. Widiastuti-Samekto *et al.* in 2010 compared intraarticular injection of corticosteroid with oral corticosteroid in 26 patients with adhesive capsulitis. This study showed the cure rate of injection group was 5.8 times more than oral group and after a week remission is seen in 62 % of patients in injection group while only 14 % remission is seen in oral group. This study had smaller sample size and follow-up period was shorter than our study (Widiastuti-Samekto, 2004). Sakeni *et al.* in Turkey study proved during first week, that intra-articular corticosteroid has additive effect to exercise in acceleration of remission. No other treatment modality is compared in this study (Sakeni, 2007). A systematic review was done by Bruce Arroll (2005) indicated that sub acromial injection of corticosteroid is suitable for improvement of tendinitis and possibly is more appropriated than NSAID. But there is lack of evidence for determination of intra-articular injection of corticosteroids in adhesive capsulitis, A valuable Meta analysis in 2012 by Maund *et al.*, suggested that there may be benefit from adding a single intra-articular steroid injection to home exercise in patients with adhesive capsulitis of less than 6 months duration. This

concluded that there is limited clinical evidence on the effectiveness of treatments for primary adhesive capsulitis of the shoulder (Maund *et al.*, 2012). In our study, we didn't find any difference between intraarticular injection and NSAID. It seems that administration of 1 injection of Intraarticulardepomedrol had equal treatment effects with less side effects when compared to those treated with NSAIDs and can be suggested as the method of choice in diabetic patients.

### Conclusion:

Based on our study, Both the intra articular corticosteroid and NSAID are effective in treating the adhesive capsulitis of the shoulder in diabetic patients and there is no significant difference found between these 2 treatment modalities. Our study was the first one comparing the corticosteroid and NSAID in adhesive capsulitis of diabetic patients. Because diabetic patients have other associated conditions such as hypertension or nephropathy, administration of intra-articular injection of depomedrol may be more appropriated in comparison to receiving NSAID for 1 month.

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