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Original Research Article

The Effect of Intra-Articular Corticosteroid with Nsaid and Therapeutic Exercise in the Treatment of Adhesive Capsulitis: A Randomized Clinical Trial in Tertiary Level Hospital in Bangladesh

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Abstract: ***Background*:** Frozen shoulder or adhesive capsulitis is a moderately common musculoskeletal disorder that arises after soft tissue involvement of the glenohumeral joint and manifests as shoulder discomfort and limits of active and passive mobility. Local injections of glucocorticoids, nonsteroidal anti-inflammatory drugs, and physiotherapy may all alleviate the symptoms. The purpose of this research was to evaluate the effectiveness of glenohumeral injections of Glucocorticoid in conjunction with nonsteroidal anti-inflammatory drugs (NSAIDs) and therapeutic exercise in the treatment of adhesive capsulitis. ***Method*:** Randomization was used to assign 68 patients with primary adhesive capsulitis in the freezing stage to intra-articular injections of triamcinolone acetonide 80 mg and oral NSAIDs and therapeutic exercise. The abridged Disabilities of the Arm, Shoulder, and Hand (Quick DASH) score for function was used to record clinical outcomes at baseline and after 2, 4, 8, and 12 weeks. ***Statistical Analysis*:** Using the Student t test or the chi-square test, correlations between baseline demographic and clinical variables between the two therapy groups were evaluated. Using mixed-effect models with random patient effects, we estimated changes in the mean functional and ROM outcomes (1) between follow-up and baseline measures within each group and (2) between the 2 groups at each time point. Using SPSS 23, the analysis was conducted on patients with full data at all follow-up assessments. A P value <0.05 was regarded as statistically significant. ***Result*:** Female in both the group were prevalent than the male group. In terms of mean age and distribution of sex, shoulder dominance, duration of symptoms, diabetes mellitus, and hypothyroidism, there were no significant differences between the two groups based on demographic data and possible risk factors at baseline. Until week 8, there were substantial differences in favor of the intervention group (week 2 and 4, P .001; week 8, P =0.121), and by week 12, the function scores in both groups were relatively equal and the difference was no longer statistically significant. All ROM parameters improved considerably within each treatment group. Flexion, abduction, and external rotation were not only recovered much quicker in the intervention group than in the control group. At the conclusion of the trial, there was no difference in internal rotation across the groups. ***Conclusion*:** Intra-articular corticosteroid injection plus oral NSAIDs and physical therapy hastened function recovery in individuals with adhesive capsulitis compared to those who only receive oral NSAIDs and physical therapy.

Keywords: Intra-articular corticosteroid, NSAID, Adhesive Capsulitis, Frozen Shoulder.

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INTRODUCTION

It has been said that adhesive capsulitis is a self-limiting condition [1]; nevertheless, long-term follow-up studies using objective outcomes have revealed persistent discomfort in up to 50% of patients and shoulder mobility impairment in 60% of patients [2, 3]. Adhesive capsulitis is a somewhat frequent musculoskeletal symptom among outpatients, caused by soft tissue involvement of the glenohumeral joint, and is more prevalent in women over 50 years of age [4]. For adhesive capsulitis, several therapeutic options with acceptable clinical effects have been identified. Physical therapy [5], oral corticosteroids [6], glenohumeral intra-articular corticosteroid injection [7], hydraulic distension [8], suprascapular nerve inhibition [9], manipulation under anaesthesia [10], and arthroscopic [11] release are a few of the treatments available.

Adhesive capsulitis is often defined as occurring in three stages: Stage 1 (freezing stage) with growing pain and stiffness lasting 2–9 months; Stage 2 (frozen stage) with persistent stiffness lasting 4–12 months; and Stage 3 (thawing stage) with spontaneous healing lasting 12–42 months [12]. While typically defined as a self-limiting illness with spontaneous recovery after 2–3 years, up to 40% of individuals may endure chronic symptoms, and between 7% and 15% may incur lifelong functional loss [13].

It has been shown that intra-articular steroid injections give superior short-term pain relief, range of motion (ROM), and shoulder function when compared to alternative nonsurgical therapies [7]. The majority of patients may be treated non-operatively in general care [14]. Due to its cost-effectiveness and patient acceptability, intra-articular corticosteroid is often used as a conservative therapy for adhesive capsulitis. As adhesive capsulitis is hypothesised to be an inflammatory and fibrotic illness, early therapy with intra-articular corticosteroid injections may minimise synovitis, restrict the development of capsular fibrosis, and change the disease's natural course [15].

Despite the availability of several therapeutic options for adhesive capsulitis, the data supporting their effectiveness is insufficient, and it remains unclear if it is preferable to combine various approaches [13, 14]. Previous research on the use of corticosteroid in adhesive capsulitis mostly showed its short-term efficacy. In 2003, Buchbinder *et al.*, conducted a systematic review of randomised and pseudo-randomised trials on the use of corticosteroid injections (including 12 randomised controlled trials [RCTs] on adhesive capsulitis) in patients with shoulder pain; the authors concluded that the treatment may be beneficial, but its effect may be small and not well maintained [16, 17]. The idea that intra-articular injections should be performed under image control has been put up by many writers. The use of imaging does appear to increase accuracy, but not all clinical settings may have access to such technology, and it is not obvious if injections performed under image control lead to better patient-relevant results. In their systematic assessment of the literature, Bloom *et al.*, [18] found no evidence that ultrasound-guided glucocorticoid injections for shoulder problems were superior to landmark-guided injections in terms of pain, function, shoulder range of motion, or safety. Furthermore, prior randomised investigations evaluating the effectiveness of subacromial and gleno-humeral steroid injections under imaging control failed to detect any appreciable variations in clinical outcomes according to the injection site [19]. A prior study by Renatella demonstrated that, in comparison to oral NSAIDs, a single corticosteroid injection administered without imaging control gives quicker pain relief and an earlier recovery in shoulder function and motion [20].

Our goal was to see the efficacy of intra-articular corticosteroid injection with oral NSAIDs and therapeutic exercise of the patients with primary adhesive capsulitis.

METHOD

The ethical committee of Dhaka Medical College Hospital gave its approval to this study. Since parts of the inclusion and exclusion criteria were dependent on these diagnostic techniques, all patients underwent diagnostic shoulder radiography. A total of 75 consecutive patients with a diagnosis of frozen shoulder were admitted to our facility from November 2021 to November 2022 and were evaluated for eligibility and finally 68 who were included after giving their informed consent and were then randomly assigned.

The total pain perception at one week was the main end measure, which was decided before the research began. Based on a prior study by Buchbinder *et al.*, [8] on adhesive capsulitis, assumptions concerning primary outcome values and variation were made. A power of 90% (b =.10, a =.05), a mean difference of 2 points with a standard variation of 2 points between the treatment groups, and 34 patients per group were utilised to discover significant differences.

Study Design, Randomization and Intervention

A randomised, single-blind, controlled trial was used in this investigation. Randomization was carried out by allowing patients to select between two sealed and opaque envelopes; each of these envelopes housed the allocation to one of two treatment groups, so each patient had the same chance of being assigned to one of the groups. Patients in group 1 (case) had a single corticosteroid injection in the glenohumeral with NSAID (diclofenac 50 mg) twice a day for 10 days and therapeutic exercise (ROM without stretching of affected shoulder, pulley, pendulum ex. Wall climbing

5-10 repetition twice daily 5 days in a week) . Patients in group 2 (control group) were given an oral NSAID (diclofenac 50 mg) twice a day for 10 days and therapeutic exercise (ROM without stretching of affected shoulder, pulley, pendulum ex. Wall climbing 5-10 repetition twice daily 5 days in a week). The progression from one phase to the next was mostly determined by ROM improvement. The therapist's practise exercises were supplemented by a supervised home rehabilitation regimen that was explained to each patient on the initial session.

Before therapy and after 2, 4, 8, and 12 weeks of follow-up, clinical and functional data were recorded. The physician's assistant who gathered the data was blinded to the patients' treatments; her only role in the trial was data collecting. The primary outcome measures consisted of a shoulder function assessment form based on the Disabilities of the Arm, Shoulder, and Hand (Quick DASH) score.

Statistical Analysis

Using the Student t test or the chi-square test, correlations between baseline demographic and clinical variables between the two therapy groups were evaluated. Using mixed-effect models with random patient effects, we estimated changes in the mean functional and ROM outcomes (1) between follow-up and baseline measures within each group and (2) between the 2 groups at each time point. Using SPSS 23, the analysis was conducted on patients with full data at all follow-up assessments. A P value<0.05 was regarded as statistically significant.

RESULT

Table 1 shows the socio-demographic and clinical history of the 34 patients in the case group and the 34 patients in the control group with full follow-up data. Female in both the group were prevalent than the male group. In terms of mean age and distribution of sex, shoulder dominance, duration of symptoms there were no significant differences between the two groups based on demographic data and possible risk factors at baseline.

Table 1: Socio-demographic and clinical characteristic

Variables	Case (Group 1 =34)	Control (Group 2 =34)	P value
Age, year	61.3 ± 10.4	58.1 ± 8.9	0.190
Sex			
Female	20 (58.82)	24 (70.59)	0.219
Male	14 (41.20)	10 (29.41)	
Shoulder dominance			
Dominant	24 (70.59)	18 (52.94)	0.223
Non-dominant	10(29.41)	16 (47.06)	
Duration of symptoms, week	10 (9-16)	9(6-10)	0.089

Early in the trial in table 2, statistically significant differences were seen between the treatment groups. Until week 8, there were substantial differences in favor of the intervention group (week 2 and 4, P .001; week 8, P =0.121), and by week 12, the function scores in both groups were relatively equal and the difference was no longer statistically significant.

Table 2: Quick-dashFunctional Scale Scores Estimated by Time and Treatment of Case and Control Group

Outcome measure	Case (Group 1)		Control(Group 2)		P value
	Mean	Change	Mean	Change	
2 weeks	31.0± 12.0	7.9 ± 3.9	33.4 ± 11.1	30.0± 2.5	0.001
4 weeks	47.0 ± 9.8	12.4 ± 4.8	41.7 ± 14.1	31.8 ± 8.1	0.001
8 weeks	68.0 ± 19.0	35.2 ± 3.1	71.8 ± 19.5	39.9 ± 5.8	0.121
12 weeks	87.1 ± 10.4	44.6 ± 7.9	88.2 ± 0.9	45.6 ± 3.2	0.165

From the beginning through the completion of the follow-up period shown in table 2, all ROM parameters improved considerably within each treatment group. Flexion, abduction, and external rotation were not only recovered much quicker in the intervention group than in the control group, but they also remained superior until the conclusion of the trial. Initially, internal rotation improved more rapidly in the case group (2 weeks: P=0.001; week 4: P = 0.145). At the conclusion of the trial, there was no difference in internal rotation across the groups.

Table 3: Differences in Range of Motion Outcomes Estimated by Time and Treatment of Case and Control Group

ROM	Case Group Mean ± SD	Control Group Mean ± SD	P value
Flexion			
2 weeks	103.7±22.3	110 ± 19.4	0.001
4 weeks	127.3±15.7	136.3 ± 12.7	0.001
8 weeks	147.9±22.0	150.1± 18.2	0.001
12 weeks	167.4±24.2	169 ± 19.2	0.001
Abduction			
2 weeks	120.6±21.3	122.1 ± 19.0	0.141
4 weeks	129.2±21.6	130.2 ± 18.2	0.001
8 weeks	140±20.9	149.1 ± 20.1	0.001
12 weeks	152.9±21.6	162.4 ±19.4	0.001
External rotation			
2 weeks	28.2±9.5	30.1 ± 11.0	0.001
4 weeks	30.8±11.7	36.2 ± 13.1	0.001
8 weeks	45.7±9.8	51.7 ± 14	0.001
12 weeks	47.4±11.4	59.0 ± 17.2	0.001
Internal rotation			
2 weeks	32±16.4	41.2 ± 19.1	0.001
4 weeks	45±15.1	49.7 ± 16.9	0.145
8 weeks	50±18.7	51.5 ± 16.1	0.651
12 weeks	64±11.4	65.1 ± 14.9	0.124

DISCUSSION

Therapeutic exercise is nearly universally used because of its well-established advantages in the treatment of adhesive capsulitis [5, 23]. In contrast to physical therapy alone, many studies have found that intra-articular steroid injections offer considerable short-term advantages with regard to pain, ROM, and shoulder function.

In 2001, Arslan *et al.*, investigated the effects of NSAIDs, physical therapy, and corticosteroids on adhesive capsulitis. Ten men and ten women were divided into two groups. Group A received 40 mg of intra-articular methylprednisolone, whilst group B received physiotherapy and NSAIDs. Results revealed that improvements in active and passive range of motion and pain score were comparable between groups at the conclusion of the 12th week [24]. The result is very similar to our study. The effectiveness of oral corticosteroids was compared to a placebo in a research by Buchbinder *et al.,* They noted that a three week regimen of prednisolone 30 mg daily is superior to a placebo to improve pain, function, and range of motion in individuals with adhesive capsulitis [25]. Prednisolone and triamcinolone were tested in a 2007 study by Russel *et al.*, for a sore shoulder. 92% of patients who received prednisolone and 50% of those who received triamcinolone showed improvement in pain and range of motion after two weeks of follow-up. Prednisolone-treated patients recovered more quickly [26]. Patients in these studies experienced shoulder discomfort for any reason, and the follow-up period was just 2 weeks. Isar Ahmad compared these 2 medications in adhesive capsulitis in 2008, but the results did not demonstrate a difference between the two groups [27].

In a placebo-controlled trial, Carette *et al.*, [28] found that a single fluoroscopically guided injection of 40 mg of triamcinolone combined with closely monitored physical therapy resulted in significantly higher SPADI (Shoulder Pain and Disability Index) scores than either a placebo injection combined with physical therapy or a placebo injection alone. The first three months of this benefit were kept in place. These results were supported by Shin *et al.*, [29] Researchers found that, during the first 4 weeks, a single corticosteroid injection provided pain relief more quickly, increased patient satisfaction, and improved shoulder mobility and function earlier than did oral medicine. There were no discernible differences between groups 12 weeks following therapy. We had comparable outcomes. The effectiveness of corticosteroid injections for treating adhesive capsulitis in people was investigated by Roh *et al.*, in 2011 [30]. Patients were divided into two groups: one group received an injection and just performed exercises at home. A corticosteroid injection in diabetic patients reduces pain perception and speeds up functional recovery in the immediate post-injection period, according to the authors' findings. The effects of corticosteroids and any other oral medications were not contrasted in this paper.

CONCLUSION

Intra-articular corticosteroid injection plus oral NSAIDs and physical therapy hastened function recovery in individuals with adhesive capsulitis compared to those who only receive oral NSAIDs and physical therapy.

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