ISSN 2063-5346

COMPARISON OF THE EFFECTIVENESS OF EARLY INTRA-SHOULDER INJECTION WITH RECEIVING ONLY PHYSIOTHERAPY TREATMENT IN PATIENTS WITH CHRONIC SHOULDER PAIN REFERRED TO THE ORTHOPEDIC CLINIC OF IMAM KHOMEINI AND GOLESTAN EDUCATIONAL CENTERS IN AHVAZ IN 2021

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Article History: Received: 01.02.2023 **Revised:** 07.03.2023 **Accepted:** 10.04.2023

Abstract

Background & Aims: Objective to compare the effectiveness of corticosteroid injections with physiotherapy for the treatment of painful stiff shoulder.

Methods: This study was designed as a prospective randomized. Subjects 78 patient for shoulder pain were enrolled in the study. Interventions Patients were randomly allocated to 6 weeks of treatment either with corticosteroid injections or physiotherapy. Primary outcome measures were the success of treatment as measured by scores on scales measuring improvement in the main complaint and pain, and improvement in scores on a scale measuring shoulder disability.

Results: 18 (23 %) were male and 60 (67%) were female. The average age of the patients in this study also was 56.88 years. 73.1 % of subjects have an Adhesive capsulitis and 26.9% subacromial impingement (SI). The difference in improvement favored those treated with corticosteroids and physiotherapy in nearly all outcome measures; these differences were statistically significant. There was an improvement in overall shoulder disability and patient global assessment at 6 weeks in both groups treated with corticosteroid injection with physiotherapy and the group with physiotherapy treated; but we observed better results and significantly differences in corticosteroid injection with physiotherapy than physiotherapy group in all of variables except DASH Score (p=0. 171). The range of ROM improved at 6 weeks in those having injection with physiotherapy treatment was significant differences with who treated with physiotherapy (p=0.034). At 6- and 12-weeks differences between the groups were comparatively small.

Conclusion: The beneficial effects of corticosteroid injections with physiotherapy administered by general practitioners for treatment of chronic shoulder pain are superior to those of physiotherapy. The differences between the intervention groups were mainly the result of the comparatively faster relief of symptoms that occurred in patients treated with injections with physiotherapy.

Keywords: intra-shoulder injection, physiotherapy, chronic shoulder pain, corticosteroids.

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DOI: 10.31838/ecb/2023.12.s1.116

Background

Shoulder pain is the third most prevalent type of musculoskeletal disorder following spinal and knee pain and has a tremendous psychosocial impact when it progresses to the chronic stage (1). The origins of shoulder pain are multiple, and can include the muscles and tendons of the rotator cuff as well as the bony structures and ligaments of the glenohumeral, acromioclavicular, and sternoclavicular joints (2, 3). The presentations of shoulder pain pathology are also diverse, comprising tendon tears, tendinopathy, ligamentous instability, bursitis, and arthropathy (4). Also, Shoulder impingement is a clinical syndrome in which soft tissues become painfully entrapped in the area of the shoulder joint. Patients present with pain on elevating the arm or when lying on the affected side (5). Only 50% of shoulder injuries resolve within the first 6 months, with 40% of cases persisting for more than 12 months. Oral medication, physical therapy, and intra-articular corticosteroid injection are common approaches to treatment but the effectiveness of these interventions may be disappointing in cases with long standing shoulder pain (6). Shoulder injections are either performed in a blind fashion via anatomical landmarks to guide needle placement or via image guidance, such as ultrasonography (US) (7, 8). There has been considerable debate regarding the most efcacious method of injection in the treatment of shoulder diseases. The suprascapular nerve, stemming from the ventral rami of spinal nerves C4, C5, and C6 and emerging from the upper trunk of the brachial plexus, provides 70% of sensory innervations to the shoulder joint (9). Corticosteroid injections are a commonly used modality to treat shoulder pain irrespective of underlying aetiology (e.g., impingement syndrome, bursitis, adhesive capsulitis, and rotator cuf disease) (10). Corticosteroid may be injected into the glenohumeral joint via an anterior or posterior approach, into the subacromial space, tendon sheaths of specific tendons, or locally into trigger or tender points. It has been reported that CS injection improves functional outcomes and compliance with physical therapy (11).

On the other hands, the role of physical therapy in the treatment of chronic shoulder pain has not been clearly defined (12). There is insufficient evidence to support physical therapy over pharmacotherapy or steroid injections in patients with soft tissue disorders of the shoulder. Studies have shown that corticosteroid injections in the glenohumeral space and the subacromial joint reduce inflammation of the synovial membrane and capsule fibrosis, and as a result improve shoulder pain and movement. Although corticosteroid injections have had positive effects in reducing shoulder pain and improving range of motion, at least in the short term (13), but the results of using intra-articular steroid injections are still contradictory. In the study, it has been reported that intra-articular injection can be useful in the short term, but this effect may be slight or insignificant (14). In addition, a meta-analysis reported that glucocorticoid injection can be more useful than the combination of manual therapy and exercise (15).

The results of a meta-analysis and systematic review showed that corticosteroid injection is more effective and better than placebo and physiotherapy in improving range of motion and pain and disability scores of frozen shoulder patients in the short term (up to 12 weeks) (16). On the other hand, showed that corticosteroid injection is not significantly effective compared to physical therapy alone (17). Also, the superiority of adding corticosteroid injection to physiotherapy in improving ROM and functional limitations in the early stages of frozen shoulder has also been reported (18). In a meta-analysis, the beneficial effects of corticosteroid injection along with physical therapy were reported (19), but conclusive evidence to support this hypothesis is limited, which indicates the need for further studies. Nevertheless, previous reviews of randomized controlled trials investigating these treatments concluded that there was very little evidence to either support or refute the efficacy of interventions commonly used to treat shoulder pain. Furthermore, the interpretation of results of studies that have been performed is often hampered by the fact that these disorders are labelled and defined in diverse and often conflicting ways. However, the effects of this treatment vary in various study populations and in comparison, with different reference treatments. Since physical therapy and corticosteroid injection are two effective, low-cost and common treatment options for chronic

shoulder pain, but limited studies have been conducted in the field of adding corticosteroid injection at the beginning of treatment to physical therapy in pain reduction and functional improvement of the shoulder. Therefore, the present study conducted with the aim comparison of the effectiveness of early intra-shoulder injection with receiving only physiotherapy treatment in patients with chronic shoulder pain referred to the orthopedic clinic of Imam Khomeini and Golestan educational centers in Ahvaz in 2021.

Material and Methods

Participants, inclusion and exclusion criteria

A randomized and prospective study was conducted on patients with chronic shoulder pain who referred to the orthopedic clinic of Imam Khomeini and Golestan Ahvaz Medical Education Centers in 2021. The study included patients aged 18 yrs. or older with a painful shoulder, in the fifth cervical (C5) dermatome distribution, of more than 3 months duration, and with limitation of active and passive range of movement greater than 25% in abduction and external rotation compared with the other shoulder.

Patients with symptoms lasting longer than 3 months are not considered to be in the chronic phase of the disease and may require different treatments. Those who had received intra-articular injections or physical therapy for shoulder pain were also excluded. We also excluded plain radiographs with evidence of severe glenohumeral osteoarthritis, clinical evidence of complete rotator cuff tear in MRI (ie, positive signs of rotator cuff muscle decline or weakness), clinical evidence of overt cervical disease, and patient with history of severe cervical disease. History of shoulder trauma or inflammatory joint or cerebrovascular accident affecting the study shoulder. Patients with bilateral capsular adhesions were excluded because bilateral symptoms may suggest an underlying systemic cause, and we excluded patients with history of corticosteroid injection or physiotherapy in the last 6 months and history of shoulder surgery and unwillingness to participate in this study.

Informed consent

A consent form was signed by both the subject and the investigator, and a copy of both forms given to the patient. Ethical approval code (IR.AJUMS.HGOLESTAN.REC.1400.170) and IRCT code (IRCTID: IRCT20220221054084N1) were gained from the medical research ethics committee for Ahvaz Jundishapur University of Medical Sciences (AJUMS) and Iranian Registry of Clinical Trials.

Treatment groups

Subjects are randomly assigned to two treatment groups. Grouping is done by computer randomization software. The patient and the doctor evaluating the patients will not know about the grouping method. The first group with physiotherapy is given a corticosteroid injection (80 mg of methylprednisolone) in the shoulder at the first visit after diagnosis. Injections are performed in patients both intra-articularly and subacromially. The second group is only treated with shoulder physiotherapy. The number of physiotherapy sessions is 15, which are done in 6 weeks. Physiotherapy sessions are conducted by two experienced physiotherapists. Also, during the study, patients of both groups are treated with oral painkillers.

Injection technique

Injections were given by a combined approach to the shoulder: half the solution (40 mg of methylprednisolone) was injected by a posterior approach and half (40 mg of methylprednisolone) by a lateral approach. The combined approach of anterior glenohumeral and lateral subacromial injection was chosen as both are used in clinical practice and there is no research evidence to indicate a preferential approach.

Physiotherapy

Physiotherapy consisted of 15 sessions of standardized treatment over a period of 6 weeks by a two therapist. The treatment programme was based on local practice and expert opinion in the absence of clear consensus in the literature. It included proprioceptive neuromuscular facilitation, Maitland mobilizations which were progressed as condition improved, standardized interferential modality and active exercise therapy with gym equipment.

Blinding procedure

The injection in this study was done in such a way that one group was injected the drug and the other group did not receive the injection. The physical therapist and the one who analyzed the data and the Physician who checked the results after 6 and 12 weeks were blind. Obviously, it was not possible to blind subjects to physical therapy, but subjects were asked not to disclose whether they were receiving physical therapy.

Outcome comparison criteria of two intervention methods

Shoulder performance of patients at the beginning of treatment and after 6 weeks is evaluated based on DASH score, Constant score, shoulder range of motion (ROM) criteria. Also, pain intensity is evaluated using visual analog scale (VAS) from 0 (no pain) to 10 (maximum pain intensity). Patient satisfaction regarding change in shoulder function is assessed using a 5-point Likert scale (worsening, no change, unsatisfactory, satisfactory improvement, good or very good improvement). Evaluation of pain intensity of patients is based on visual pain scale (VAS). This scale is a standard method for measuring the amount of pain, in which the patient evaluates the intensity of his pain from 0 (complete painlessness) to 10 (the most pain experienced by the person). This scoring depends on the patient's statement. The number zero is defined as no pain, 1-3 as mild pain, 4-6 as moderate pain, and 7-10 as severe pain. ROM is measured using an inclinometer. To evaluate flexion and abduction movements, the person sits on a chair and the inclinometer is attached to the distal arm. It elevates the arm in the sagittal plane for flexion and in the coronal plane for abduction. External rotation is tested in the supine position and internal rotation is tested in the prone position; in which case the inclinometer is closed in the distal forearm. The Disability Arm, Shoulder and Hand (DASH) score is a 30-item self-report questionnaire that assesses the patient's health status during the past week. Each item has 5 response options (no problem, mild problem, moderate problem, severe problem, disability) which is scored from 1 to 5 and the total score is from 0 (no disability) to 100 (the most severe disability). The Constant score system (CS) includes four variables that are used to evaluate shoulder performance and the total test score is 100. Right and left shoulders are checked separately. Subjective variables include pain (15 points) and ADL (activities of daily living including sleep, work, recreation/exercise) (20 points) with a total score of 35 and objective variables of ROM (40 points) and strength (25 points) with a total score of 65.

Statistical analysis

Sample size was estimated based on data from a previous study of injection therapy in shoulder pain. A two-way analysis of variance was used to explore the relative contribution of the interventions to the outcome measures at 6 and 12 weeks. In order to measure the significance of differences and compare quantitative and qualitative variables between two groups, independent t-tests (non-parametric Mann-Whitney test) and chi-square are used, respectively. Paired t-test (or Wilcoxon test) is used to compare the average of variables within the group. SPSS v.22 statistical software was used for statistical calculations. A significant level is considered 0.05 in tests.

Results

Participants Information

Seventy-eight subjects were recruited from the orthopedic clinic of Imam Khomeini and Golestan Ahvaz Medical Education Centers in 2021. Thirty-nine subjects were enrolled in Group A (steroid injection and physiotherapy), 39 in Group B (physiotherapy). The basic characteristics of the patients are given in Table 1.

Based on Table 1, 18 (23 %) were male and 60 (67%) were female. The average age of the patients in this study also was 56.88 years. 73.1 % of subjects have an Adhesive capsulitis and 26.9% subacromial impingement (SI). Also, 79.5 % had pain in the right shoulder and 20.5% in the left.

Table 1: Baseline characteristics of patients in the two intervention groups (n=78[a])

Variables		Group A (n=39)	Group B (n=39)
Age (yr)		53.42 (3.27)	49.81 (4.18)
Sex	Male	9	9
	Female	30	30
Disease Type	AC	27	30
	SI	12	9
External rotation, Abrasion, Forward Flexion (FF)		53.80 (22.75)	49.82 (24.97)
VAS		7.62 (0.67)	7.58 (0.63)
Constant score		34.37 (3.96)	35.69 (5.89)
Pain side	Right	29	33
	Left	10	6
DASH Score		57.31 (7.12)	56.78 (6.94)

[a] Values, except were indicated otherwise, are mean with S.D. in brackets.

Table 2: Mean values of change from baseline in main outcome measures in group A and B at 6 weeks after randomization

Variables	Mean change from base line (S.D)		Treatment effect (95% CI)	
	Group A (n=39)	Group B (n=39)	Group A (n=39)	Group B (n=39)
Passive ROM—external rotation	85 (25.82) *	58.46 (23.79)	31.2 (20.82-25.12)	8.64 (19.79-23.34)
VAS	3.33 (1.30) *	4.84 (1.15) *	-4.29 (-0.25-1.30)	-2.74 (-1.15-1.65)
Constant score	57.25 (8.45) *	56.20 (11.25) *	22.88 (8.45-9.97)	20.51 (11.25-13.2)
DASH Score	30.17 (2.29) *	35.73 (3.94)	-27.14 (-2.29-3.17)	-21.05 (-3.94-4.66)

S.D. and 95% CI in brackets.

*P <0.05 versus Group B.

Table 3. Mean values of change from baseline in main outcome measures in group A and B at 12 weeks after randomization

Variables	Mean change from base line		Treatment effect (95% CI)	
	Group A (n=39)	Group B (n=39)	Group A (n=39)	Group B (n=39)
Passive ROM—external rotation	86.92 (22.68)	63.85 (23.52)	1.92 (1.45-3.12)	5.64 (0.19-0.74)
VAS	3.03 (1.39)	4.15 (1.37)	-0.30 (-0.25-1.30)	-0.69 (-0.35-0.69)
Constant score	61.72 (8.88)	61.51 (11.15)	4.33 (0.45-0.97)	5.51 (0.10-0.23)
DASH Score	27.38 (2.01)	32.74 (3.39)	-3.24 (-0.27-0.57)	-2.99 (-0.05-0.12)

S.D. and 95% CI in brackets.

Table 4: Analysis of effect of steroid injection and physiotherapy on change in outcome measures between 6 and 12 weeks by two-way ANOVA. Main effect of Corticosteroid injection is significant in mean improvement (F=8.7, P<0.005) and in mean improvement in Global VAS (F=4.5, P<0.05). Main effect of physiotherapy is significant in mean improvement in passive external rotation (F=5.7, P<0.05). Interaction effects are not significant[a]

Variables	Corticosteroid + Physio.	Physio.	P value
	Group A (n=39)	Group B (n=39)	
Passive ROM—external rotation	23.17 (2.43)	16.74 (3.79)	0.034
VAS	-1.03 (0.39)	-0.69 (-0.43)	0.057
Constant score	17.65 (3.56)	12.51 (2.11)	0.011
DASH Score	-6.97 (2.44)	-4.13 (-1.33)	0.171

[a] Values are mean (S.D.

Discussion

Our study showed positive findings. There was an improvement in overall shoulder disability and patient global assessment at 6 weeks in both groups treated with corticosteroid injection with physiotherapy and the group with physiotherapy treated; but we observed better results and significantly differences in corticosteroid injection with physiotherapy than physiotherapy group in all of variables except DASH Score (p=0. 171). The range of ROM improved at 6 weeks in those having injection with physiotherapy treatment was significant differences with who treated with physiotherapy (p=0.034). These results support the findings of previous studies showing improvement in early outcome after corticosteroid injection in shoulder capsulitis (20, 21). Previous trials have evaluated the treatment of shoulder pain with physiotherapy and corticosteroid injections both separately and together (5, 7, 22-25). One recent trial of fluoroscopically guided injection of triamcinolone 40 mg with and without physiotherapy (12) found that injection was superior to physiotherapy and placebo at 6 weeks in terms of pain and function. Injections were given under radiological guidance so it may not be appropriate to generalize these findings to usual clinical practice. Three other trials were unable to show significant differences between injections and physiotherapy treatments (9, 14, 18). In two trials in Dutch general practice, injection provided quicker relief of symptoms than physiotherapy (14, 26). One of these studies assessed patients defined as having painful stiff shoulder (14) similar to our criteria for adhesive capsulitis. They used a higher dosage and greater number of injections (up to three) than in our study. The second Dutch study assessed patients defined as having 'synovial disorders' of the shoulder, a definition that includes patients with disorders arising from the subacromial, glenohumeral and acromioclavicular impingement, a broader definition than used in the present study. Injection was better than physiotherapy or manipulation at 5 weeks. Their definition of physiotherapy excluded mobilization techniques which would not be comparable with the definition of physiotherapy used in our study or normal physiotherapy practice in the United Kingdom. In a recent trial in the United Kingdom, primary care community physiotherapy and local corticosteroid injections were found to be similarly effective (27). They used a broad definition of shoulder pain with no discrimination between capsulitis and other shoulder syndromes. Hay's group found no improvement in range of motion, whereas our study showed an increased range of motion with injection with physiotherapy and physiotherapy at 6 weeks although improvement in other measures of range of motion was not associated with physiotherapy. In our study, the effect of injection with physiotherapy and physiotherapy was detected in range of motion. Also, the positive effect of these treatments may therefore be seen in

different aspects of dysfunction associated with shoulder capsulitis.

Completion is difficult for patients in a study which involves an injection with uncertain results and an intensive physiotherapy programme. It was little surprise that failure of treatment was a significant reason for non-completion. The overall participation rates in our study are higher than another similar study (3) where completion rates were 77 out of 93 (83%) at 12 months. But it should be noted that our study was conducted in 12 weeks and the improvement results were observed after 6 weeks of treatment. Ryans et al. (21) recruited 80 patients of whom 57 (71%) completed the study at 16 weeks. The most common reason for dropping out was unwillingness of the subject to continue due to failure of treatment. Subjects were allowed, in keeping with ethical guidelines, to withdraw from the trial if they felt unable to cope with ongoing pain and expressed a desire for alternative treatment. Most missing data were from subjects who had failed treatment before 16 weeks. This is a potential source of bias as those subjects who felt their treatment had failed were missing from the analysis, particularly at week 16. No benefit was shown beyond 6 weeks, but missing data due to subjects lost to follow-up and dropping out due to failure of treatment makes interpretation at 16 weeks difficult. they addressed this by secondary analysis using imputed values, analysis of failure of treatment between groups and survival analysis. Analysis using imputed values demonstrated a significant effect of steroid injection at 16 weeks on pain outcome. their analysis of failure of treatment and survival analysis revealed that significantly fewer subjects dropped out due to failed treatment in the group having both physiotherapy and active injection. This could suggest the possibility of a more sustained treatment effect, although this should be interpreted with caution. It may be, however, that patients continued in this group for reasons other than treatment effectiveness. It should be stated that due to the success of the treatment methods in our study, none of the patients left the study and data analysis was done based on the results of subjects 6 and 12 weeks after the start of the treatment.

Further work is necessary to assess the long-term effectiveness of these treatments, but it may be difficult for subjects to adhere to a trial protocol when allocated to a placebo group. Injections were given by a combined approach to the shoulder: half the solution (40 mg of methylprednisolone) was injected by a posterior approach and half (40 mg of methylprednisolone) by a lateral approach. Other studies have used different approaches and dosages, and practice in clinical care varies considerably. Further research is required to ascertain the most effective dose and approach to shoulder injection in this condition. Previous work has suggested that accuracy of injection is important with regard to outcome of corticosteroid injection treatment (28), and it has also been shown that injection, particularly of the shoulder joint, is often inaccurate (29). All injections in the present study were performed by a single experienced clinician reducing potential bias from variation in injection accuracy. In this study, injections were performed without imaging guidance. Further studies could explore the effect of improving injection accuracy by the use of imaging such as ultrasonography. The physiotherapy approach used in this study was standardized and included proprioceptive neuromuscular facilitation, Maitland mobilizations, which were progressed as condition improved, standardized interferential modality and active exercises with gym equipment. There is little evidence on which to base decisions regarding physiotherapy treatment for capsulitis of the shoulder. Little work has been done to evaluate which of the many physiotherapeutic approaches to shoulder pain is most effective and which combinations of approaches are most appropriate (19). We are unsure which aspects of the physiotherapy treatment improved the range of movement in external rotation. Further work in this area is recommended. The findings of the trial presented here reinforce the evidence that corticosteroid injection is effective for capsulitis of the shoulder in the short term. The clinical relevance of the finding that physiotherapy improves the range of external rotation, which was not influenced by injection, is unclear. The finding that these interventions have positive effects on different aspects of shoulder related disability raises the possibility of benefit in combining the treatments. This is in keeping with a recent study comparing corticosteroid injection with and without physiotherapy, which suggested a

clinical but not statistically significant benefit of combination treatments (30).

Strengths and weaknesses

This study has some notable strengths. We took care to define subjects using strict selection criteria; we tried to applied rigorous blinding wherever possible. Overall, the only positive differences between treatments were at 6 weeks; Of course, the results showed improvement after 12 weeks. Also, Patients' satisfaction in this study 6 and 12 weeks after treatment that showed that patients were highly satisfied with their treatment process. This is very early in the treatment programme and the clinical relevance of treatment effects at this stage, if not maintained in the longer term, is uncertain.

Conclusions

In the treatment of chronic shoulder pain, corticosteroid injection with physiotherapy and physiotherapy observed effective in improving shoulder-related disability at 6- and 12-weeks following treatment. Also, we observed the significantly differences between the results of corticosteroid injection with physiotherapy and physiotherapy in satisfaction of patients. injection with physiotherapy and Physiotherapy treatment is effective in improving the range of motion at 6 weeks after commencement of treatment. For a more accurate evaluation of the treatment results, it is suggested to conduct studies with a longer period of time.

Acknowledgment

The present study was a part of the dissertation registered in Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran with the registration number of U-00290. It was financially supported by the Vice-Chancellor for Research of the AJUMS, Ahvaz, Iran.

Conflict of Interest

All authors of this study have equally contributed to designing, conducting, and preparing this manuscript and declare no conflict of interest in publishing this manuscript.

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