

THE RAPID EFFECT OF INTRAVENOUS PREDNISOLONE TO IMPROVE THE SHOULDER RANGE OF MOTION IN PATIENTS WITH FROZEN SHOULDER

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Abstract

Adhesive capsulitis is a disabling painful and often prolonged shoulder condition that requires careful clinical diagnosis and management. Patients recover usually, but they may never regain their full range of motion. In order to evaluate the beneficial effects of short-course IV Prednisolone in increasing shoulder range of motion, this comparative study was planned.

Two age-sex matched groups of thirty patients suffered from idiopathic adhesive capsulitis for more than four months from the onset were collected. The extreme range of shoulder active motions at external rotation and abduction were measured and the mean values were calculated. Patients' pain in external rotation was qualified via visual analog scale before and after the two weeks course of the treatment. The first group received oral Diclofenac (100mg/day), Omeprazole 20mg oral for two weeks associated with physiotherapy, but the second group received 500mg IV Prednisolone for three consecutive days at the beginning of the treatment in addition to the schedule for the first group.

Data obtained from before and after the treatment showed that mean improvement in shoulders external rotation in the first group was 30.7 degrees, while it was 51.4 degrees for the second group, this difference was significant at $p < 0.001$. Also, the mean value of shoulder abduction improvement for the first group was 34.1 degrees while it was 26.1 degrees for the second group. Patients from both groups reported a significant reduction in pain severity. It can be concluded that adding 500mg IV prednisolone for three consecutive days to the routine treatment may improve shoulder movements at shoulder external rotation and abduction which reduces disability caused by adhesive capsulitis.

Key words:

Shoulder motion, Frozen Shoulder, Prednisolone, Diclofenac.

Introduction

Shoulder pain and stiffness are common presenting symptoms in patients who seek evaluation from musculoskeletal physicians. Codman described a painful shoulder condition of insidious onset that

was associated with stiffness and difficulty in sleeping on the affected side in 1934(1, 2). Long before Codman, in 1872, the same condition had been labeled "peri-arthritis" by Duplay (3).

In 1945, Neviaser called the term adhesive capsulitis (4).

Although still in use, adhesive capsulitis is an unfortunate nomination. Because a frozen shoulder is associated with synovitis and capsular contracture, it is not associated with capsular adhesions. Frozen shoulder is a specific condition that has a natural history of spontaneous resolution, but it requires a management pathway to prevent any remain limitations and lead the patients to a complete recovery. So, frozen shoulder is completely different from other shoulder conditions such as the rotator cuff syndrome or osteoarthritis (1, 3).

Although the frozen shoulder naturally leads to spontaneous resolution, this may not be complete. Reeves in a prospective study of 41 patients with 5-10 years follow up found that 39% had full recovery, 54% had clinical limitation without functional disability, and 7% had functional limitation (3). Shaffer et al. showed that 50% of 61 patients with frozen shoulder had some degree of pain and stiffness, an average of seven years after onset of the disease (4).

There is no good consensus regarding the amount of range of motion loss to define frozen shoulder. External rotation, abduction, and internal rotation are the most affected and observed patterns of motion loss. The location of capsular contracture can be helpful in determining the etiology. A limitation of external rotation with the arm in abduction is typically associated with an antero-inferior capsular restriction⁵.

To decrease the time of recovery and improve the outcome of this condition, a carefully designed treatment plan including physiotherapy and pain medications e.g. anti-inflammatory drugs such as non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids are required. Symptomatic relief from adhesive capsulitis may be achieved using oral corticoids, intra-articular

corticosteroid injection and arthrographic distention of the constricted capsule. Manipulations under anesthesia or surgical release have been advocated when conservative treatments have failed (5, 6, 7, 8). Each of these treatment regimens had little long-term advantage, but steroid injections may improve the pain and range of motion in the early stage of this condition (9, 10).

On the other hand, frozen shoulder could lead to a chronic situation which may cause another process called neuronal plasticity in which increased pain sensitization may happen. As a result some behavioral changes may occur. Corticosteroids not only exert a positive effect on the mood but also have a significant pain-controlling effect involved in the inflammatory processes such as frozen shoulder while NSAIDs are not potent and reliable pain-alleviating drugs enough to elevate patients' mood in the chronic inflammatory musculoskeletal pain conditions. NSAIDs are effective pain medications in their own right (11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21). Although Glucocorticoids play a significant role in the treatment of arthritic conditions (6, 11, 12), only recently the usage of IV Prednisolone for the treatment of frozen shoulder was reported in medical literature (22). The present prospective study by comparing the results of the two methods of treatment, with and without IV Prednisolone, will evaluate the role of pulsed IV Prednisolone in improving shoulder range of motion in patients with adhesive capsulitis.

Materials and Methods

Based on the time of referral, patients of either sex were randomly divided into two groups. Each group consisted of fifteen men and fifteen women (n=30) who suffered from painful shoulder stiffness and referred to a musculoskeletal pain clinic during the period of September

2005 to September 2008. All of the patients were evaluated to assure that they had a normal complete blood count, cell differential and erythrocyte sedimentation rate in order to exclude the inflammatory joint diseases or serious infectious processes. Plain shoulder radiography was performed to preclude any tumor or gross anatomic abnormalities such as calcifications around the shoulder joint or fracture. Other exclusion criteria in this study were a history of diabetes mellitus, pregnancy, peptic ulceration and uncontrolled hypertension. The mean duration of the patients' awareness of their shoulder motion limitation, discomfort and pain was calculated and recorded. All the patients complained of pain on shoulder motion and difficulty during sleeping while lying over the involved shoulder. All of them were asked about their night sleep quality and quantity before and after the treatment.

The ranges of shoulders abduction was measured while patients' arms were placed at their sides with the palms toward the bodies. By this method of goniometry shoulder range of motion varies between 180 degrees or fully arm adducted to 90 degrees abduction, and up to 10 degrees or fully abducted-elevated (13). So by the clinical improvement of the shoulder abduction the numerical value of shoulders range of motions decreases (Fig. 1).

The ranges of shoulders external rotation were measured while the patients were lying in supine position and their arms were abducted as possible up to 90 degrees. Their elbows and forearms were positioned in pronation so that arms facing their feet. In this method shoulder ranges of external and internal rotation varies between 180 degrees or fully internal rotation to 0 degree or fully external rotation (13). In this method of goniometry by the clinical improvement of the shoulder external rotation, its numerical value decreases (Fig: 1). The ranges of these two motions were measured and recorded at the beginning and end of the two weeks treatment plan. The absolute amount of changes in patients' ranges of shoulders motion from the beginning to the end of the treatment plan were calculated in both groups and considered as the final treatment efficacy. The first group received oral Sodium Diclofenac 25mg four times a day (QID) for ten days associated with Omeprazole 20mg every twelve hours for two weeks to prevent gastrointestinal tract ulceration and physiotherapy including pulsed-ultrasound for 10 minutes, followed by a program of shoulder range of motion exercises including mobilization techniques and interferential therapy for 10 minutes daily.

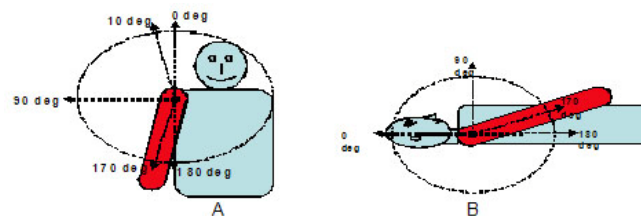


Fig.1: Techniques of shoulder joint goniometric measurements.
A- Shoulder abduction; B- Shoulder external rotation

The pain reported by the patients was quantified via self-reporting Visual Analog Scale using a 10cm baseline in the morning of starting and finishing days of the treatment (14). The patients were monitored for their blood pressure, blood sugar and electrolytes, gastrointestinal disturbances and any signs of bone pain on hip and ankle motions to secure about necrosis of bones during research period

Statistical analysis

First, Independent Sample Test was used to find whether the two groups were statistically matched and similar enough to be compared or not. If so, the researchers could compare the results in both groups. Secondly, paired sample test was performed to compare the changes of shoulders range of motions in both groups.

Ethical consideration

This study was performed under the ethical guidelines approved by the committee of ethics, Jundishapur University of Medical Sciences. According to that guidelines all the patients were informed about the research process and the drug side effects, and the possible complications of the treatment methods were explained to the patients, but they did not know on which treatment method they would be. They were made sure that they are under close medical and moral observation by the physician and medical staff during research period. Even they could refer to the researchers because of any unexpected complications related to the research after this period. All the patients were examined to find the evidences of bone pain or limitation of hip and ankle joint motion six months after the research. It was expected that the two treatment regimens will improve their condition, so all of them consented to participate in this research program.

Results

The patients' age varied from 46 to 67 years old and the mean age for the first and second groups were 57 and 59 years respectively.

The mean duration of reported awareness of the shoulder motion limitation and discomfort was five months for both.

Only 26 patients remembered a history of significant physical trauma at the onset of the disease.

The results of the independent sample test showed that the two treated groups were matched in shoulder external rotation.

The mean range of external rotation for the first group was 77.6 ± 1.62 degrees which improved to 46.9 ± 1.42 degrees after the treatment period while the range of external rotation for the second group was 73.26 ± 2.72 degrees which reached 11.86 ± 0.96 degrees after the treatment schedule. On the other hand, mean improvement in shoulders external rotation in the first group was 30.7 degrees, while it was 51.4 degrees for the second group. Statistically, the initial mean ranges of external rotation were similar in both groups. And the result of independent sample test showed the absolute improvement is much more in the second group ($p \leq 0.001$) (fig 1 & table 1). The mean range of abduction motion in the first group was 78.8 ± 1.61 degrees and for the second group was 66.93 ± 3.02 degrees and the maximum shoulder abduction in the first group was twelve degrees more at the beginning. After the treatment, the range of the shoulder abduction reached to 44.7 ± 2.5 while for the second group it reached to 40.76 ± 4.56 degrees. On the other hand the mean value of shoulder abduction improvement for the first group was 34.1 degrees while it was 26.1 degrees for the second group. But the results of independent sample test for the shoulder abduction motion revealed that the two groups were not statistically comparable (fig 1 & table 2).

Patients from both groups were satisfied from decrement of pain in shoulder motion and reported a significant reduction in pain severity.

None of the patients exhibit evidence of bone pain or hip or ankle motion limitation after six months.

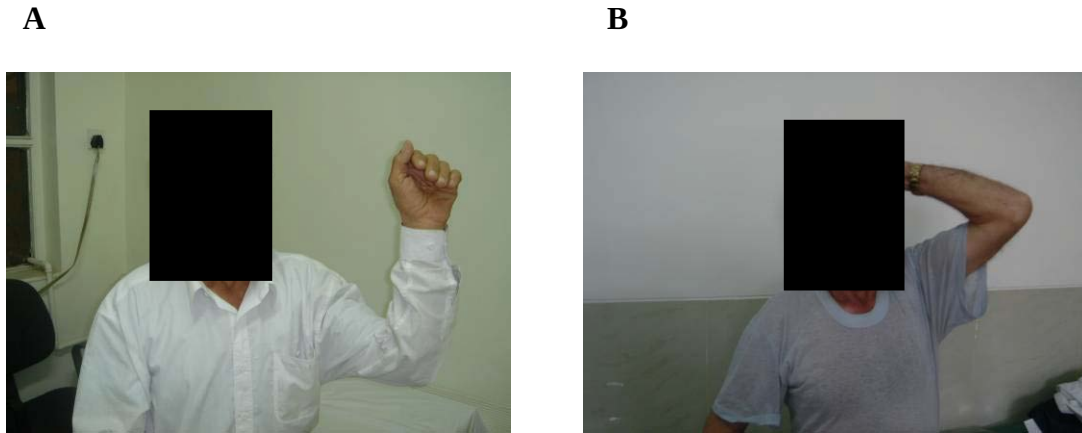


Fig 2: Representative photographs from patient with frozen shoulder A: before treatment that patient was not able to bring his hand behind his head, B: after treatment.

Table 1: Means and Standard Errors of the range of active assistive shoulder external rotation (degrees) before and after treatment.

	N	Before treatment Mean $\pm$ SE	After treatment Mean $\pm$ SE
Group I	30	77.6 $\pm$ 1.62	46.9 $\pm$ 1.42
Group II	30	73.26 $\pm$ 2.72	11.86 $\pm$ 0.96*

*Indicates significant difference with group I ($p < 0.001$).

Table 2: Means and Standard Errors of the range of active assistive shoulder abduction (degrees) before and after treatment .

	N	Before treatment Mean $\pm$ SE	After treatment Mean $\pm$ SE
Group I	30	78.8 $\pm$ 1.61	44.7 $\pm$ 2.5
Group II	30	66.9 $\pm$ 3.02	40.76 $\pm$ 4.56

Discussion

Shoulder pain and motion limitation has been the major patients' complains which drive them to the medical centers. "Frozen shoulder" was first described by Codman in 1934, as an idiopathic painful restriction in the range of shoulder movement in the presence of normal plain radiographs. Based on the chronic synovitis and a contracted, thickened capsule seen during open surgeries of the shoulder joints, it is also known as "adhesive capsulitis". Its natural clinical course includes an insidious initial painful phase followed by progressive stiffness associated with the gradual loss of joint movement and a gradual return of functional range of motion. Recovery is frequently prolonged despite multiple therapeutic maneuvers. Between 15 to 50 percent of patients have persisting severe refractory pain that is unresponsive to conservative management involving physiotherapy, NSAIDs and sub-acromial corticosteroid injections (5, 6, 7, 15). Hence, in spite of improving medical science, the pain and motion limitation still remain the main problems of patients suffering from frozen shoulder and seeking for a conservative management.

During the initial painful freezing stages, treatment should be directed to relieve the pain. Because the pain keep them to limit all activities require their shoulder motion activity, it has been a tradition to give patients the NSAIDs, if they tolerate them. Even sometimes it is necessary to add other analgesics. However, there are not enough randomized controlled trials that confirm the effectiveness of NSAIDs in the specific condition of adhesive capsulitis (1).

The use of adreno-corticoids has provided a great relief for patients with rheumatoid arthritis and some painful inflammatory diseases from the beginning of 1950. By reducing the production of cytokines and certain pro-inflammatory enzymes they induce anti-inflammatory effects. But they

were subsequently shown to frequently lead to complications such as myopathy, gastrointestinal bleeding, cataract, osteoporoses and other complications (2, 4, 10, 11, 16, 17, 18).

Because of their potent analgesia steroids are used in the treatment of radiculopathies, Complex Regional Pain Syndrome type II and other neuropathic pain conditions (19, 20). Because of strong anti-inflammatory action the beneficial effects of corticosteroids have been shown in certain rheumatic diseases such as ulcerative colitis, asthma and Sjogren's syndrome (21, 22, 23). Also they have been used for the treatment of frozen shoulder (5, 8, 24, 25). Recent studies suggest by including 30mg oral Prednisolone in the daily treatment schedule of adhesive capsulitis one can get significant short term benefit in reduction of pain severity and improving shoulder range of motion (5, 6, 12, 16). Some researchers suggested that shoulder intra-articular injections of steroids or injections into the subacromial bursa have advantageous effects to the routine treatment regimen of frozen shoulder by analgesics-oral steroids and physiotherapy. It would cause the shortening of disease natural history (2, 8, 26, 27). Another study which was done by our group indicated that use of IV prednisolone in the treatment of frozen shoulder had a significant advantage on NSAIDs in terms of pain relief (28). Because of the potential corticosteroids side effects, it is important to evaluate the patient's general conditions, the severity of the disease and weigh up the harms of high dose iv pulsed steroids versus the benefits that a patient may gain. Also it is suggested that using Corticosteroids should be cautiously considered and if necessary in the smallest possible dose for the briefest period (28, 29).

Diercks et al. described a prospective study of 77 patients which compared the effect of exercise within the limits of pain

with intensive physiotherapy in patients with frozen shoulder. They found better results with exercise performed within the limits of the pain (30). Hazelman performed a meta-analysis on the use of intra-articular gleno-humeral joint which may reduce the synovitis(24). De Jong et al. have reported that the response to steroid injection is dose-dependent. Those authors concluded that when used alone even supervised physiotherapy has a limited benefit, but that a single steroid injection in combination with physiotherapy dependent (27).

In a randomized placebo controlled trial, Carrette et al. compared the effectiveness of different treatment methods in the treatment of frozen shoulder such as: 1) physiotherapy alone 2) a single intra-articular steroid injection given under X-Ray control 3) patients treated by physiotherapy and steroid injection in combination and 4) a fourth placebo group treated with saline injections. They concluded that even supervised physiotherapy has a limited benefit when used without medication, but when they used supervised physiotherapy combined with a single intra articular steroid injection they got more benefit (31).

Conclusion

The results of this study indicates that adding 500mg IV prednisolone for three consecutive days to its routine treatment may improve shoulder external rotation which reduces disability caused by adhesive capsulitis. Although the thawing of shoulder motion limitation could be due to prompt anti-inflammatory action of corticosteroids, their analgesic effect may provide a proper ground for performing effective range of motion exercises. Thus another question may rise, whether pain or inflammation is the cause of frozen shoulder in different conditions? Because of this, another research to compare these two effects is suggested.

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