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Treatment of Frozen Shoulder: A Double Blind Study Ccomparing the Impact of Triamcinolone Injection Alone or In Association with Joint Distention

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ABSTRACT

A comparison between the impact of intra – articular triamcinolone injection alone and in association with a joint swelling technique in the treatment of frozen shoulder. A group of one hundred patients suffering from stiff- painful shoulder lasting more than 3 months were allocated in two sex and age matched groups. The first group was treated by intra- articular triamcinolone injection along with a program of active home exercises considering shoulder ranges of shoulder motions for one week. The second group received the treatment of the first group along with shoulder joint distention using normal saline. The outcome measures included active shoulder ranges of motions and patients' pain scales via visual analogue scale, which were assessed two days and twelve weeks after the treatment using proper statistical analysis. The data resulting from the two groups were then compared. Both the mean values of shoulders motions and pain scale decrement were significantly higher in the second group than the first at two days and twelve weeks after the treatment. This study revealed that incorporating shoulder joint distention could improve the effectiveness of intra – articular corticosteroids in the treatment of painful frozen shoulder.

Keywords: Frozen shoulder, triamcinolone, distention, pain, adhesive capsulitis

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INTRODUCTION

Shoulder pain with motion limitation is one of the common disabling musculoskeletal complains that affects about 2-5 percent of population in developed countries. This was first explained by Duplay in 1834. Because of capsular adhesions the disease was properly named ''frozen shoulder'' by Codman [1, 2].

Although the previous researchers have designated it as a three- phase disease which is self- limiting after 1-2 years, recent studies have shown that 40% of the involved individuals suffer from shoulder pain and motion limitations after 3 years [1, 3, and 4].

This disease tends to affect females between 50 to 6o years old. Arthrographic evidence of inflammation and adhesions inside the joint capsules support the idea that capsular inflammation causes abnormal union of collagen fibers inside the joint capsule, resulting in such clinical conditions. Adhesion bands at anterior and inferior parts of the joint capsules induce shoulder motions limitation and pain on its motion. Noticeably, about 15% of patients complain of persistent disability, thus an impressive treatment to decrease the duration of disease and its related morbidity need to be taken into consideration. Intravenous Corticosteroid drugs have shown to have a beneficial role in the treatment of stiff and painful shoulders [2, 4]. It has also been established that inrta- articular injection of these drugs helps to improve the movement of gleno-humeral joint and reduction of the symptoms in a frozen shoulder [2, 5, and 6].

Moreover, it has been observed that simple home exercises could reduce the symptoms of pain and disability better than placebo at six weeks. Furthermore, physiotherapy techniques, directed at mobilization of shoulder joint, provide a rapid progress in gleno-humeral joint motion [2].

Buchbinder et al. postulated a significant positive impact of intra- articular corticosteroid injection combined with arthrographic shoulder joint distention with normal saline in this condition [3, 7]. Further studies have revealed different aspects and effects of this treatment method such as the effects of repeated distention [8], the role of capsular preservation to improve the outcome of distention [9]. Another study has compared the impact of capsular distention with the rehabilitative management of the disease [10]. Although there have been case reports which reveal positive results from arthrographic swelling of gleno–humeral joint in the treatment of frozen shoulder, they do not reveal wether it is directly related to the effect of shoulder joint distention or the steroid [11, 12]. However, some studies fail to show any advantages of performing shoulder joint distention combined with steroid over corticosteroid alone [2, 13]. On the other hand, both the time for the joint distention and the amount of the injected fluid seem to be significant factors affecting the outcome of the treatment.

Both treatment methods of the frozen shoulder [shoulder capsule distention by normal saline along with steroid, and the intra- articular injection of corticosteroid alone] may prove advantageous in the treatment of the disease. The present study is directed at comparing the

effect of intra-articular corticosteroid injection alone with the impact of shoulder distention combined with the intra – articular injection of corticosteroid.

METHODS

One hundred [out of one hundred- four] patients suffering from painful stiff shoulder that had lasted more than 3 months, and were reluctant to perform arthroscopy, agreed to participate in this study. They were recruited from two academic musculoskeletal clinics in the cities of Ahvaz and Tehran, Iran [2007 – 2010]. In the study, the whole 100 patients consented to participate while the numbers of participants in similar researches were reportedly fewer [3, 7].

Based on the patients' sex, they were randomly allocated to two matched groups each consisting of 50 individuals on their arrivals. Because of their pain and the possibility of the patients' intolerance to bear the sufficient liquid volume needed for the joint swelling, we selected the patients suffering from frozen shoulder lasting for more than three months from the onset. At this phase of the disease, the severity of the pain is expected to decrease [1, 2].

A complete blood count [CBC] with erythroblast sedimentation rate [ESR] and shoulder and neck radiography were performed for all the patients. They were excluded from the study if they showed gross infections, inflammatory diseases, space occupying, and shoulder bone lesions or calcium deposits around the joints [14]. Also, the evidence of abnormal muscular mass around the arm or shoulder (suggestive of the rotator cuff tendon tearing), fever, pain on shoulder touch, history of pregnancy, diabetes mellitus, polyarthritis, or unwillingness to sign the consent form led to being excluded from the study.

For the control group, triamcinolone acetonide [40mg] was injected into the shoulder joint, followed by a program of active home exercises focusing on active shoulder ranges of motions for one week [15]. Foe the other group [active] arthrographic shoulder capsule distention was performed by a 50ml solution through an anterior- lateral method in addition to the treatment for the control group [16]. The solution contained 27ml normal saline, 20ml contrast material [Iohexol], 2ml xylocaine 2% with 1ml [40mg] Triamcinolone acetonide.

The degree of patients' pain was measured via visual analog scale from 0 to l0 using a baseline and the patients' reports.

Shoulder ranges of motions at flexion, extension, external rotation, internal rotation and abduction were measured before the treatment, two days and twelve weeks after the treatment [15]. The ''patient’s recruitment'' had already been reported as a research problem in previous similar studies [3, 17]. To manage the problem, the participants of this study were recruited from two referral community- based university clinics.

A biostatistician planned the study groups' allocation as well as the blindness of the study. Neither the participants nor the physicians were informed as to the type of the treatment before the research schedule.

In order to evaluate the study outcome measures, occupational therapists were assigned to evaluate the amount of patients' improvement using the same methods of goniometry and pain scale evaluation (4, 14, and 19). The assessing processes had been outlined to be performed at the beginning, two days and twelve weeks after the onset of the treatment. The assessors thus recorded the patients' addresses and followed them up individually during the study period to avoid the problem of ''dropouts''.

By means of repeated measurement tests (a derivative of ANOVA), the mean changes in patients' pain, ranges of motions, in both groups during the treatments' timetable were compared (18). Besides, independent t- tests were performed to compare the amount of changes which occurred from the starting point of the study to the second and fourteenth day after the treatments in both groups.

Two consultant physicians performed the joints injections and expansions. The patients' eyes and faces were covered to decrease their awareness and anxiety about the procedure, prior to each injection. The injections were performed under the direct supervision of radiologists. The use of fluoroscopy technique ensured the correct sites of needle insertion. Patients were requested to sit on a chair and their affected arms were put in a maximum possible external rotated position depending on their ability to move their shoulders.

The exact skin sites over their shoulders were marked before each insertion and the injection sites were infiltrated by l ml of xylocaine 2% as a local anesthetic agent. By intra-articular injection of 2ml of a water soluble radiologic contrast [iohexol] and the fluoroscopy, the researchers ensured the exact point of joint distention. Meanwhile, the procedure of joint distention was terminated where there were an evidence of the patients' intolerance, pain, or any incidences of allergic reactions. The radiographic image intensifiers were concentrated on the glono-humeral joints. The distance of image intensifiers from the table tops were 40 cm. Each fluoroscopic picture included the scapula, shoulder joint, and the upper part of the humorous bone.

This study was carried out taking into consideration the ethical guidelines approved by the ''Committee of Ethics, Jundishapur University of Medical Sciences Ahvaz, Iran''. According to the guidelines, all the patients were informed about the research process and the potential side effects of the drugs. Furthermore, the likely complications of the treatment methods were explained to them. They were convinced that they would be under close medical observation by the physician and medical staff throughout the research period, and they could refer to the researchers in case there were any unexpected complications related to the research after this period. Also, they had the option to leave the study at any time for any reason without jeopardizing their care.

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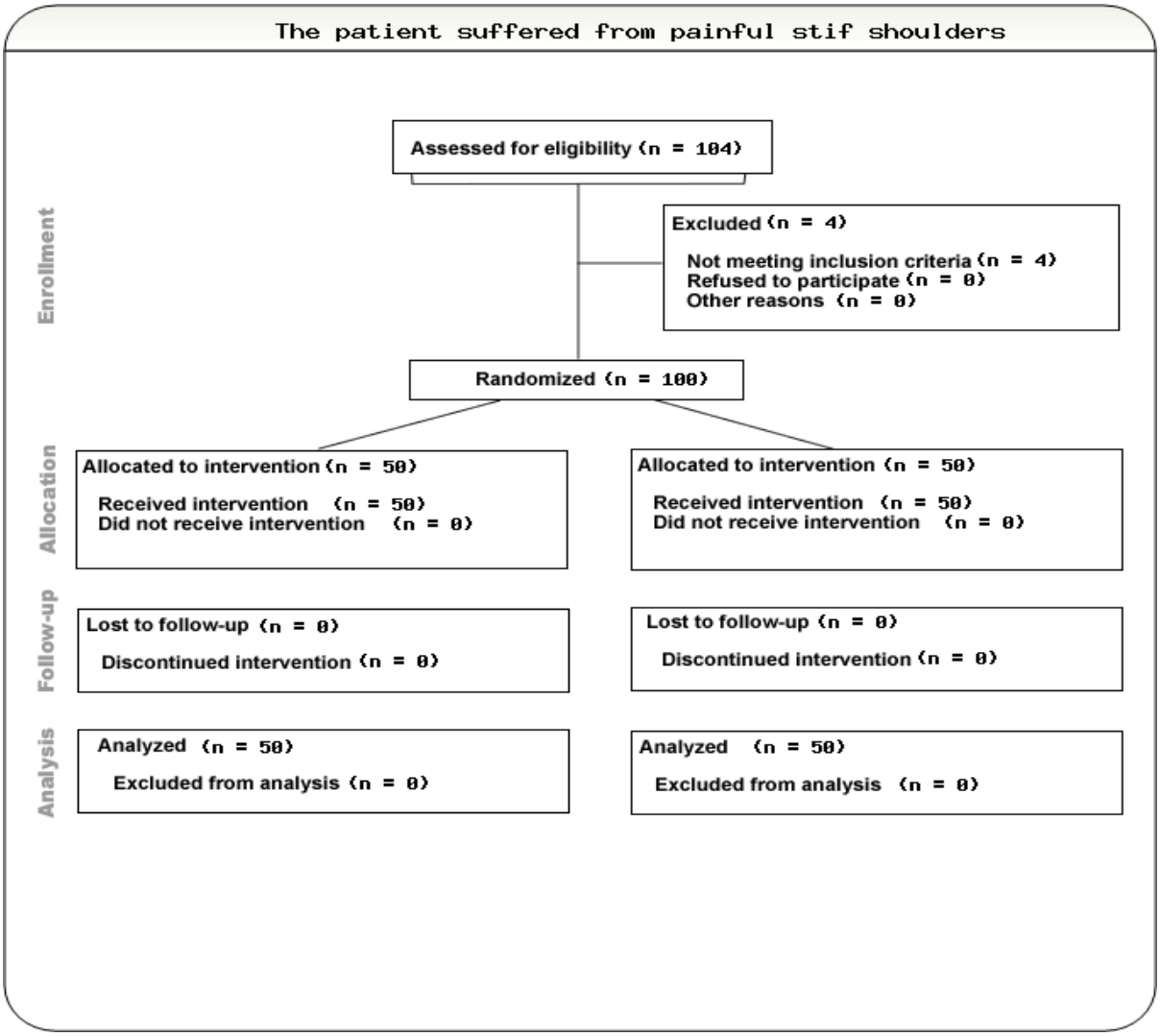
Diagram 1 shows the patients enrollment and study design of this research.

Diagram 1: The participants allocation to the study



RESULTS

There were no significant clinical or demographic differences between the case and the control group at the beginning. Both groups consisted of 25 males and 25 females. The mean patients' age in the case group was 61 ± 9, and for the control group 58 ±11, ($p \leq 0.001$). The mean duration from the onset of patients' awareness about their diseases for the case group was 112 ± 14 days, and for the control group it was 119 ± 11 ($p \leq 0.003$). The pain scale for the case group was 7.21± 1.2 and for the control group it was 7.18 ± 1.9, ($p \leq 0.001$). Table 1 shows the characteristics of shoulder ranges of motions in the both groups.

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Table 1: The comparison of mean changes and standard deviations of ranges of shoulders motions among groups before, two days and twelve weeks after the treatment

		Before			After 2 days			After 12 weeks			
Motion	**Group**	**X**	**SD**	**CI95%**	**X**	**SD**	**CI95%**	**X**	**SD**	**CI95%**	**P value**
Flexion	Case	66.6	29.5	54± 77.9	104.4	32	48 ± 117.3	110.8	33.3	97.3±124.3	0.009
	Control	63.3	24.2	53.47±73.06	75	21.7	66.2 ±83.7	84.8	21.3	76.24± 93.4	
Abduction	Case	63.8	25.6	53.5± 74.2	102.7	30.7	90. ±115.1	114.4	30.1	127.8± 102.7	0.005
	Control	65.4	24.1	55.6±75.1	72.6	24.9	62.5 ±82.6	82.7	22.6	73.5 ± 91.8	
External rotation	Case	20.4	12.5	15.3±25.4	40.9	17.5	33.8± 47.96	50.8	17.15	43.8 ±.57.7	0.027
	Control	22.7	11.06	18.2.± 27.1	28.1	10.9	23.7 ±32.5	36.3	12.2	31.4 ± 41.2	
Extension	Case	28.3	13.7	22.7.± 33.8	45.7	11.1	41.2± 50.2	52.8	11	48.3± 57.2	0.57
	Control	34.6	11.9	29.7.±39.4	38.6	11.04	35.15± 43.07	48.4	10.76	44.07 ± 52.7	
Internal rotation	Case	33.6	21	25.1.± 42.1	48.1	19.6	40.15 ± 56	55.4	18.2	48.07 ± 62. 7	0.10
	Control	31.5	11.8	26.7± 36.2.	36.9	11.5	32.2 ±41.5	48.4	10.76	44.07±52. 77	

The results of the repeated measure test for the pain revealed that there was a meaningful difference between the active and the control group at P= 0.002. The degree of improvement in the active group was significantly greater than the control group [table 2 and figure1].

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There were no ''dropouts' during the research period. The total intra-articular injected volume for each participant of the active group was 52ml and for the control group 5ml. Table 1 also shows the mean and the standard deviation changes of ranges of shoulders motions among the groups before, two days and twelve weeks after the treatment. Based on the data, there was a significant improvement in the active group in comparison with the control group at shoulders flexion, abduction and internal rotation motions at p= 0.009, 0.005 and 0.027, respectively. But the improvement differences between the groups at extension and internal rotation motions were not as significant.

Table 2: The comparison of mean changes and standard deviations of the pain scale among groups before, two days and twelve weeks after the treatment

		Before		After 2 days		After 2 days 12 weeks		p-value
Pain scale	n	X	SD	X	SD	X	SD	
Case	27	7.96	0.98	4.33	1	3.29	0.95	0.002
control	26	7.46	1.15	6.76	1.17	3.57	1.1	

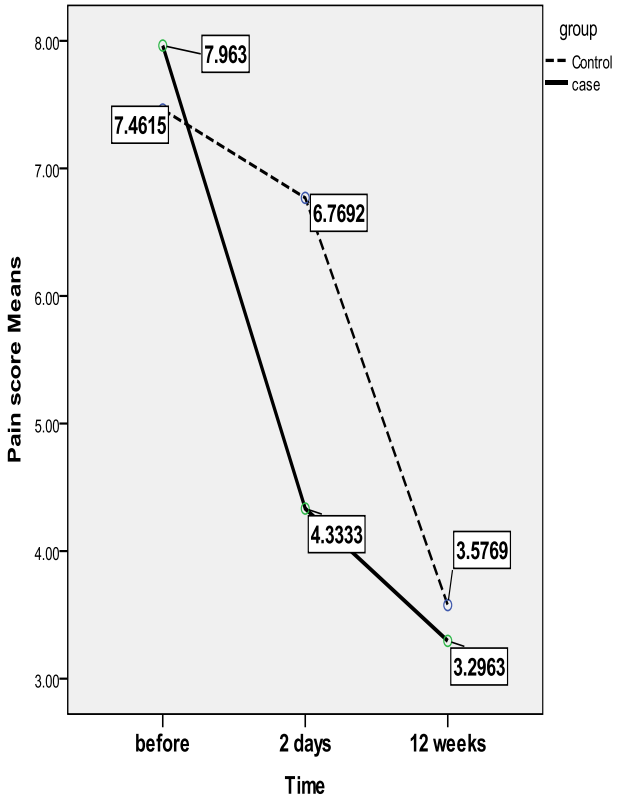

Fig 1: The graphic representation of the mean pain scale changes among the groups before, two days and twelve weeks after the treatment

An independent t-test was used to compare the degrees of changes in the two groups. The comparison of changes in the degree of patients' pain and shoulders' ranges of motion, in the second day with the changes occurred at the twelfth week after the treatment showed

there was a significant improvement at p= 0.001. In other words, the improvement of patients' condition mostly occurred at the first two days after the shoulders distension.

DISCUSSION

Motion limitation and pain have been shown to be responsible for the disability and change of the life style of the patients with frozen shoulders. Although different methods have been tried to improve the conditions for such patients, there is more to be done in this area. The present study revealed that arthrographic shoulder distention with normal saline and triamcinolone in patients suffering from frozen shoulders is more effective than with triamcinolone alone. Such an effect was sustained in the control group for twelve weeks after the beginning of the procedure.

Upon evaluating the trend of changes in shoulders ranges of motions and the patients pain scale in the study, it can be realized that the most visible improvement in the active group in comparison with the control group, occurred early after the procedure. Although we previously reported the beneficial effect of corticosteroids on shoulder ranges of motions within two weeks, this very rapid effect could be explained in terms of the impact of volume distention rather than analgesic and anti- inflammatory action of triamcinolone [19,20]. Some former and even new researches do confirm that there are no significant beneficial changes between the shoulder distention combined with intra-articular corticosteroid on corticosteroid injection alone [11, 12, 13, and 21]. However, Gam et al postulated that there was a meaningful shoulder motion improvement in patients treated by shoulder distention and corticosteroid compared with the group treated by intra–articular corticosteroid alone. However, they did not have any beneficial effects on the pain. In those studies only, a little amount of intra–articular liquid had been injected [9ml, 10ml and up to 20ml respectively] [13]. Their studies seem to have been influenced by the effect of low injected volumes and fewer numbers of participants. According to Buchbinder et al. a lack of correlation between ranges of motions and disability and the improvement in participants' disability was mainly due to the decrement of their pain suffering following their shoulders distention. The present study also confirmed that most improvement in the pain and shoulder motions occurred at the early days after the distention, whereas the patients' shoulders motions at external rotation, extension and internal rotation directions did not show a meaningful improvement. To look critically at the findings of the study reported here, one may say that in this research there was no control group to be compared with the two active groups. However, the purpose of this research was not to offer a new technique for treatment but it just aimed at comparing two well- known methods for the treatment of the frozen shoulders. Although this may be a correct criticism, one is expected to consider that the problem of lacking a control group could influence the results of the both studied groups. Nor did the present study show the causes of insignificant amounts of motions improvements in some shoulders motion directions, and further research is required to evaluate these aspects of the disease. Also, further researches to compare the effects of different sites of needle insertion for the shoulder distention procedure and the anatomical size and the compliance of the shoulders joints are necessary.

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