Comparative Study of Treatment of Adhesive Capsulitis of Shoulder: Corticosteroid Versus Corticosteroid with Hydro Distension

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ABSTRACT

Objective: To compare the effectiveness of Intra-articular corticosteroid versus intra-articular corticosteroid with hydro-distension.

Methods: This randomized control trial study was conducted January 2014 to December 2016. The primary outcome was percentage reduction in the Shoulder pain and disability index (SPADI).

Total one thousand patients diagnosed clinically were divided into two groups A and B. Group A received 40mg Triamcinolone injection, 4ml of contrast medium (ultravist), 3ml 2% Lidocaine and distension was done with 10 to 20ml of 0.9% normal saline. Group B was treated with intra articular 40mg Triamcinolone injection, 4ml of contrast medium (ultravist), 3ml 2% Lidocaine. SPADI was measured before and after giving of injections. Patients were followed up for three months and SPADI was measured at third week and sixth week.

Results: The Pretreatment mean SPADI score of Group A patients was noted as 79.99±3.54 whereas the mean SPADI score of Group B patients was 81.50±3.01. The mean SPADI score of patients at 6th week post treatment of Group A noted as 26.83±2.62 and mean SPADI score of Group B was 34.32±1.67. Statistically all follow up treatments are highly significant according to the study groups i.e. p-value=0.000*.

Conclusion: We concluded that as far as percentage reduction in SPADI is concerned a little difference between hydro-distension and intra-articular corticosteroid injection alone, which help to reduce the pain and disability in frozen shoulder. But Hydro-distention is slightly superior in reducing Pain and Disability.

Keywords: Adhesive capsulitis, Corticosteroid, Hydro distension, SPADI

INTRODUCTION

Adhesive capsulitis of shoulder joint is common musculoskeletal problem with incidence of 2 to 5 % of general population, commonly known as frozen shoulder, characterized by gradual limitation of movements at glenohumeral joint and shoulder pain, causing disability in middle age patients [1].

The patient presents with gradual onset of diffuse shoulder pain, aggravated by lying on affected side and worse at night. Sleepless night due to shoulder pain is a common happening in this condition. The disease cause marked disability and generalized stiffness of shoulder joint that disturbs the patient's daily routine activities of life, work and leisure. According to Adhesive capsulitis (idiopathic) in which there is no inciting event, secondary Adhesive capsulitis with some underlying pathology, i-e trauma, diabetes [2]. The primary adhesive capsulitis has three phases, first phase is painful phase lasting from 2 to 9 months, characterized by insidious onset of severe diffuse shoulder pain, worse at night, patient gradually learns to get relief of pain by restricting his movement at shoulder joint and the pain gradually decreases, in second phase of the disease restriction of movements and stiffness are the main symptoms, lasting from 4 to 12 months. The last phase is marked by the feeling of regain of near normal range of movements; it spans a period of 5 to 24 months [3].

The disease Etiology and pathophysiology are poorly understood, the inflammation and fibrosis following the hypervascular synovitis seems to be the main pathophysiologic events. The cytokines and growth factors concentrations were found to be raised

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in the synovial fluid and opposite to that, matrix metalloproteinase was absent [4]. In 1995, with the help of immunohistochemistry, fibroblast and myofibroblast cells were identified as the main cells causing extensive fibrosis. Accordingly, the primary pathology was found to be fibrosis and not the inflammation [5].

Many treatment options are available for the adhesive capsulitis, NSAIDs, supervised physical therapy, oral corticosteroid, and intra articular corticosteroid injection, manipulation under anesthesia, hydro dilatation, open surgical release, arthroscopic capsular release, or combination of above mentioned treatment options. Which treatment is best is still a controversial issue, intra articular corticosteroids are best at early stage of the disease [3].

There is need of further research in this field. One study found the percentage reduction in SPADI after 6 weeks treatment in hydro-dilatation group was 66.1% and in intra-articular injection group was 58.7%. The difference was insignificant (p-value= 0.2813) [6].

This study was designed to compare hydro dilatation with intra-articular Corticosteroid injections for management of primary frozen shoulder. Literature is available but without valid and conclusive evidence to support treatment modality as better. Through this study we want to confirm the better treatment method. A fore mentioned study was done only in 76 patients. We want to conduct this study with large sample size to generate more valid results. This would help in decision-making and choice of better treatment option; this would minimize morbidity and burden of multiple procedures.

METHODS

This was a Randomized Controlled Trial **from** January 2014 to December 2016. The primary outcome was percentage reduction in the Shoulder pain and disability index (SPADI) [17], which measures a combination of pain and functional disability on a score from 0 to 100. Sample size of 1000 cases; 500 cases in each group, was calculated with 80% power of study, 6% level of significance and taking expected percentage reduction in SPADI i.e. 66.1% with hydrodilatation and 58.7% with intra-articular corticosteroid injection for management of primary frozen shoulder.

It was a non-probability purposive sampling

Data Collection Procedure

After approval from hospital ethical committee, 1000 patients, fulfilling the criteria of selection, were selected from orthopedic Outpatient Department. Pregnant women were not included. Demographic information (name, age and gender) was obtained after taking written Informed consent. Then patients were randomly allocated in two equal groups by lottery method. Group "A" patients received Hydro dilatation under radiographic (fluoroscopic) control, followed by physiotherapy as an outpatient. The injection, consisting of 40 mg of Triamcinolone (in 1ml), 4ml of contrast medium (ultravist), 3mL of 2% Lidocaine and 10-20ml of Normal saline was injected through the posterior route. The affected shoulder was held between the middle finger on the coracoid process and thumb on the posterior border of the acromion. The needle was then inserted 1-2cm below the posterior border of the acromion into the "soft spot" and directed towards the index finger, thereby entering the glenohumeral joint, where the injections were given.

Group "B" patients received intra-articular corticosteroid injection without dilatation and followed by physiotherapy as an outpatient, the injection in this group consisted of 40mg of Triamcinolone (in 1ml), 4ml of contrast medium (ultravist) and 3ml of 2% Lidocaine. The technique was same as for the group "A". All patients were reviewed at 3rd and 6th weeks. At 1st visit and then on each subsequent visit, percentage reduction after treatment was assessed. This data was recorded on specially designed Performa. The person doing the assessment was blinded about the two groups. Patients lost to follow-up were excluded from the study.

Data analysis:

Data was entered and analyzed through SPSS version 11. Quantitative variables like age, baseline SPADI and post treatment SPADI were presented as mean and standard deviation. Qualitative variables like gender were presented as frequency and percentages. Chi-square test was used to compare the percentage reduction in both treatment groups. (*P*-value <0.05 is considered as statistically significant).

RESULTS

Total one thousand patients presented in orthopedic Outdoor Lahore General hospital Lahore. The mean age of group A patients was noted as 58.10±9.26 years with range of 25 years, whereas the mean ages of group B

patients was noted as 54.70±11.18 years with range of 40 years.

In this study 550(55%) patients were male while 450(45%) were female. The male to female ratio was noted as 1.2:1.

The mean SPADI score at pretreatment of group A patients was noted as 79.99±3.54 whereas the mean difference SPADI score of group B patients was 81.50±3.01. Mean SPADI score at 6th week post treatment of group A patients was 26.83±2.62 and group B was 34.42 ± 1.67. The total mean difference SPADI score of patients at 6th week post treatment of group A was noted as 53.16±4.63 and mean difference SPADI score of group B was noted as 47.07±1.76. Statistically all follow up treatments were highly significant according to the study groups i.e. p-value=0.000*. **Table#3**

The percentage reduction of SPADI scores of group A patients was noted as 66.46% whereas the percentage reduction of group B patients was 57.75%. Statistically there was insignificant difference between the study groups i.e. p-value= 0.1023 (p-value>0.05). **Table#4**

Table 1: Descriptive Statistics of Total pain score with respect to study group at different follow-up visits

			Study Groups		p-value
			Group A	Group B	
Total pain score	Pre-treatment	Mean	87.20	83.60	0.000
		SD	3.13	4.46	
	Post-treatment at week 3	Mean	47.80	43.60	0.000
		SD	9.87	6.87	
	Post-treatment at week 6	Mean	25.20	27.40	0.000
		SD	2.40	1.81	

Table 2: Descriptive Statistics of Total disability score with respect to study group at different follow-up visits

			Study Groups		p-value
			Group A	Group B	
Total disability score	Pre-treatment	Mean	75.50	80.09	0.000
		SD	4.27	3.59	
	Post-treatment at week 3	Mean	55.86	61.92	0.000
		SD	7.32	4.06	
	Post-treatment at week 6	Mean	27.87	39.31	0.000
		SD	3.68	3.08	

Table 3: Descriptive Statistics of difference in pre- and post treatment SPADI score with respect to study group

			Study Groups		p-value
			Group A	Group B	
Difference	Pre-treatment	Mean	79.99	81.50	0.000
		SD	3.54	3.01	
	Post-treatment at week 6	Mean	26.83	34.42	0.000
		SD	2.62	1.67	
	Difference	Mean	53.16	47.07	0.000
		SD	4.63	1.76	

Table 4: Comparison of percentage reduction in SPADI score with respect to study group

	Study Groups	
	Group A	**Group B**
Pre-treatment Mean SPADI	79.99	81.50
Difference Mean SPADI	53.16	47.07
Reduction	(53.16/79.99) * 100	(47.07/81.50) * 100
Percentage	66.46%	57.75%

(Note: Percentage reduction = difference in SPADI score / pre-treatment SPADI score * 100)
p-value = 0.1023 (Insignificant)

DISCUSSION

Frozen shoulder is a painful, debilitating disorder affecting 2–5% of the general adult population and 10–20% of people with diabetes mellitus. Most cases resolve over the course of 18–30 months. However, a small number of patients had a prolonged, recurrent course with continued disability [7,10,11].

it is a common cause of shoulder pain in people aged between 40 and 60. In 1945, Nevasier was the first who introduced the term Adhesive Capsulitis and described the pathology as being characterized by adhesions and contractures of the fibrous capsule that surrounds the shoulder joint. To date the cause of this contracted capsule has not been worked out, although this disease is associated with other medical problems such as diabetes, thyroid problems and previous history of ischemic heart disease [8,9].

We included one thousand patients with frozen shoulder with the mean age of 54.70±11.18 years. There were more male patients with Frozen Shoulder as compared to females with male-to-female ratio of 1.2:1. Other studies have also showed that the presentation of this disease is more common in males (55%) as compared to females (45%) [12].

In hydro-dilatation group, the mean pain score was 87.20±3.13 which was reduced to 47.80±9.87 after 3 weeks and 25.20±2.40 after 6 weeks treatment. Similarly, in intra-articular injection group, the mean pain score was83.60±4.46 which was reduced to 43.60 ± 6.87 after 3 weeks and 27.40±1.81 after 6 weeks treatment. Statistically all follow up treatments are highly significant according to the study groups i.e. p-value=0.000*. The baseline pain score was higher in hydro-dilatation group but after 6 weeks there was more reduction in hydro-dilatation group.

In hydro-dilatation group, the mean SPADI score was 79.99±3.54 which was reduced to 52.77±6.80 after 3 weeks and 26.83±2.62 after 6 weeks of treatment. Similarly, in intra-articular injection group, the mean SPADI score was81.50±3.01 which was reduced to 54.51 ± 3.87 after 3 weeks and 34.32±1.67 after 6 weeks of injection. Statistically all follow up treatments are highly significant according to the study groups i.e. p-value=0.000*.

The baseline SPADI score was higher in hydro-dilatation group but after 6 weeks there was more reduction in hydro-dilatation group and difference was also significant but when percentage reduction was calculated, it was revealed that although the there was more reduction in SPADI score with hydro-dilatation but there was insignificant difference in both groups. Results of a Later studies agreed with results of our study Siraj 2012 reported that Using SPADI the baseline subscale pain was 81±7.2 which improved to 14.5±7.4 at 4th week of intra-articular corticosteroid injection in affected glenohumeral joint. When compared statistically a significant p-value of 0.000 was obtained [12].

Iqbal MJ et al found significant improvement in SPADI score in his study. The mean baseline SPADI was 70.9±6.8, which improved to 24.6±5.6 at 4 weeks of treatment [13].

Tveita reported the percentage reduction in SPADI after 6 weeks treatment with hydro-dilatation as 66.1% and with intra-articular injection as 58.7%. The difference was insignificant (p-value= 0.2813) [6]. The results of this study match with results of our study.

Since the SPADI function test is based on shoulder pain with functional activities, it makes sense that interventions resulting in pain reduction would also result in an improved SPADI score[14].

Treatments options for Frozen Shoulder reported in the literature range from program of rest, analgesia and motion exercises to open surgical release. The available literature is not helpful in assisting clinical decision making with regards to superior treatment.

Cochrane Data research determined that no conclusion can be drawn regarding the efficacy of the intervention for adhesive capsulitis [15].

It is worth nothing, however that Buchbinder 2008, have published a randomized double-blind placebo controlled trial which supports the use of hydro dilatation for frozen shoulder [1]. Using hydro-dilation can reduce Frozen Shoulder pain immediately and reduces disability from periods of months to periods of weeks [16].

CONCLUSION

The conclusion of our study is that, statistically there is insignificant difference between hydro-dilatation and intra-articular injection, which help to reduce the pain in frozen shoulder as far as percentage reduction in SPADI is concerned. Hydro dilatation is slightly superior in reducing the Pain and Disability in the management of Frozen Shoulder as compared to intra-articular steroid injection.

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