ORIGINAL ARTICLE

Comparison of efficacy of intra articular steroid injection versus hydrostatic shoulder distention in idiopathic frozen shoulder

Aimal Sattar, Muhammad Ayaz Khan, Mahmood Ul Hassan, Muhammad Shabbir, Zeeshan Faisal

Abstract

Received: 29th September, 2018 Accepted: 21st March, 2019 Introduction: The term frozen shoulder was first used in 1934 by Codman, who described the common features of a slow onset of pain felt near the insertion of the deltoid muscle, inability to sleep on the affected side, and restriction in both active and passive elevation and external rotation, yet with a normal radiological appearance. This study will also provide local statistics for efficacy of the intra-articular steroid injection and hydrostatic distension and if any modality found to be significantly high, we will disseminate the results with other local orthopedic surgeons and will suggest its routine use in the treatment of idiopathic frozen shoulder. The study will also form a basis for further research.

Objective: To compare the efficacy of intra articular steroid injection versus hydrostatic shoulder distention in idiopathic frozen shoulder.

Setting: Department of Orthopedic Surgery, Khyber Teaching Hospital, Peshawar.

Study design: Randomized Control Trail

Duration of study: 6 months 2nd February, 2018 to 2nd August, 2018.

Material and Methods: In this study a total sample size is 142. (71 in each group) were observed. Patients in group-A were injected this solution (steroid+Lignocaine) intra-articularly and in patients in Group B with 10ml Distilled water, by anterior approach (with the needle passing through the deltopectoral groove and then below and medial to the tip of the coracoid process, through the coracobrachialis – biceps origin and subscapularis) (with a 21 gauge x 1.5" needle). All patients of both groups then would have active and assisted range of motion exercises under supervision of a physiotherapist for 3-days and once the exercises are learnt by the patient, then the patient was allowed to do these exercises at home. Patients were reassessed at 6-weeks follow up to determine intervention effectiveness in terms of decrease in at least one grade of pain on Visual Analouge Scale and increase in range of motion of shoulder joint more than 20 degrees on gonometer.

Results: In this study mean age in group-A was 38 years with SD \pm 10.53 while mean age in group-B was 40 years with SD \pm 9.48. In Group A 42% patients were male and 58% patients were female. While in group-B 40% patients were male and 60% patients were female. More over group-A (Intra articular steroid infection) was effective in 93% patients while group-B (Hydrostatic Distention) was effective in 87% patients.

Conclusion: Our study concludes that Intra-articular steroid is more effective than hydrostatic distention for idiopathic frozen shoulder.

Keywords: efficacy, intra articular steroid injection, hydrostatic shoulder distention, idiopathic frozen shoulder.

Correspondence:

Hamdard University

Hospital, Karachi

Dr. Muhammad Shabbir, Department of Orthopedics & Trauma Lady Reading Hospital, Peshawar Cell: +92-300-5932039 Email: draimalsattar@gmail.com

Lady Reading Hospital,

Peshawar

MA Khan

M ul Hassan M Shabbir

A Sattar

Z Faisal

Introduction:

The term frozen shoulder was first used in 1934 by Codman, who described the common fea-

tures of a slow onset of pain felt near the insertion of the deltoid muscle, inability to sleep on the affected side, and restriction in both active and passive elevation and external rotation, yet with a normal radiological appearance.¹ The pathology of frozen shoulder involves active fibroblastic proliferation in the capsule of the shoulder joint, accompanied by some transformation of fibroblasts to myofibroblasts.^{2,3} Despite this knowledge of the pathology, there is no consensus on the most favorable method of managing the disease. Suggestions for management range from supervised neglect to corticosteroids, physiotherapy, manipulation, hydrodilatation and arthroscopic capsular release.⁴

Recently, Zu Ckerman and Cuomo defined frozen shoulder, or adhesive capsulitis, as a condition of uncertain etiology characterized by substantial restriction of both active and passive shoulder motion that occurs in the absence of a known intrinsic shoulder disorder.⁵

Although it is generally believed to be a self-limiting condition lasting 2–3 years, some studies have reported that up to 40% of patients have persistent symptoms and stiffness beyond 8-years. Therefore, effective treatment that shortens the duration of symptoms and disability has the potential to be of significant value in terms of reduced morbidity and costs.⁶ Many treatments have been advocated for adhesive capsulitis: rest, analgesia, active and passive mobilization, physical therapy, oral and injected corticosteroids, capsular distension, manipulation under anesthetic, and arthroscopic capsular release. Currently, there is no consensus as to which is the most effective treatment.⁷

Shoulder pain is a very common problem. Its prevalence in literature indicates a frequency of 7–20% among the adult general population. Frozen shoulder, also called adhesive capsulitis, is one of the diseases that cause shoulder pain. The incidence of this condition in the general population is between 2% and 5%. It is more common among women aged 40–60 years. The disease is characterized by pain, loss of function, and loss of joint range of motion.⁸

Frozen shoulder has been divided into three stages depending on its symptoms. In stage-1

which is known as freezing phase also called the painful phase. This condition lasts for 2-9 months. In stage-II frozen phase also called the stiffening phase, lasts for 4-12 months. In stage-III thawing phase also called the recovery phase, may lasts for 6-9 months.^{9,10}

The general expectations of patients with frozen shoulder in our society are immediate and long lasting benefit from intervention. Some studies report that if given at an early stage of the disease, intra-articular steroid injections and hydrostatic distension resolve pain within a relatively short period, whilst others report they do not influence disease duration or help shorten it. In a comparative study, it has been reported that 86% patients has got complete resolution of pain with intra articular steroid injection while in hydrostatic distension group, pain resolution was 60%, but on the other hand, the overall improvement of pain in both groups was 97% and 92% respectively. In intra-articular steroid injection group, range of motion of shoulder joint was improved in 84% while in hydrostatic distension group, 63% patients did not shown significant improvement.11 The success rate of intra-articular steroid injections varies from 44% to 80%¹¹ while hydrostatic distension has been reported to be effective in 93.67% patients. 13,14

In literature, patients with frozen shoulder are managed with Physiotherapy, non-steroidal anti-inflammatory drugs, intra-articular steroid injections and hydrostatic distensions and manipulation under anesthesia with different results and outcomes. ¹⁵ No treatment modality has been recommended as standard. Regarding these treatment options no local statistics are available. As intra-articular steroid injections and hydrostatic distensions are widely practiced in locally to treat idiopathic frozen shoulder.

Studies regarding the efficacy of intra-articular steroid injection in idiopathic frozen shoulder are available in literature but no comparative study is available locally regarding management of idiopathic frozen shoulder. This study will compare efficacy of these two modalities i.e. intra-articular steroid injection and hydrostatic

distension, in terms of pain relief and improvement in range of motion. My study will also provide local statistics for efficacy of the intraarticular steroid injection and hydrostatic distension and if any modality found to be significantly high, we will disseminate the results with other local orthopedic surgeons and will suggest its routine use in the treatment of idiopathic frozen shoulder. The study will also form a basis for further research.

Our objective was to compare the efficacy of intra articular steroid injection versus hydrostatic shoulder distention in idiopathic frozen shoulder. Idiopathic frozen shoulder is a condition of unknown etiology characterized by pain of any grade on visual analogue scale for the last 3 to 6 months and decreased range of motion of at least 20° measured on gonometer of shoulder joint in any direction from the normal limits in the absence of known intrinsic and extrinsic disorders i.e. any history of trauma, previous surgery, rotator cuff disease and diabetes mellitus etc detected by clinical history and examination. Intra articular Steroids is done Injection of depomedrol 80mg/2ml with local anesthetic (08ml plain injection xylocaine) into shoulder joint using a specific technique i.e the patient in supine position and the shoulder in neutral position.

Hydrostatic distention is done by Injection of distilled water (10ml) into shoulder joint by same technique as for intra-articular steroid injection i.e. the patient in supine position and the shoulder in neutral position. The procedure of intra articular steroid injection or hydrostatic distention was considered effective if there is decrease in at least one grade of pain on Visual Analogue Scale and improvement in range of motion of more than 20 degrees measured with gonometer in any direction at 6-weeks follow up.

Visual analogue scale: has grade 0_No pain, grade 1_Mild pain 1 to 3, grade 2_Moderate pain 4 to 7, grade 3_Severe pain 8 to 10

Range of motion: The following range of mo-

tion directions was measured with gonometer; forward flexion= $0-165^{\circ}$, backward extension= $0-60^{\circ}$ abduction= $0-17^{\circ}$ internal rotation in abduction= $0-70^{\circ}$ external rotation in abduction= $0-100^{\circ}$,

Hypothesis: Intra-articular steroid was more effective than hydrostatic distention for idiopathic frozen shoulder.

Material and Methods:

This study is carried out Department of Orthopedic Surgery, Khyber Teaching Hospital, Peshawar.

Study design: It is a randomized control trail Duration of study: 6 months 2^{nd} February, 2018 to 2^{nd} August 2018.

Sample Size: Sample size was 142. 71-for injection group and 71 for hydrostatic distention group based on overall success rate for both groups 80%¹¹ and 94%¹³ respectively. The level of confidence taken was 95% and power of test 80%.

Sampling technique: Consecutive (Non probability) sampling. Our inclusion criteria all patients of 18-50 years of age with idiopathic frozen shoulder with mild to severe pain on Visual Analogue Scale and decreased range of motion of at least 20° measured on goniometer of shoulder joint in any direction from the normal limits of either gender.

Our Exclusion criteria is patients having prior history of trauma with or without fracture around shoulder. Previous surgery rotator cuff disease. Patient with diabetes mellitus and hypothyroid patients was excluded. Patients already treated with intra-articular steroid injections or hydrostatic distension. Patients who failed to did regular physiotherapy exercises 4-times daily at home or did not come for follow up at 6-weeks after intra-articular steroid injection or hydrostatic distension.

The above mentioned conditions were act as confounders and if included in the study sample were introduce bias in the study result. Permission was obtained from "Hospital Ethical

Committee". The study was carried out at Department of Trauma & Orthopedics Surgery, Khyber teaching hospital Peshawar. The patients ful-filling the inclusion criteria were included in the study through out patient department.

The purpose and benefits of the study was explained to all patients and it was also be explained to the patients that this study was done purely for research and data publication purpose in order to improve the treatment outcomes and it was according to medical ethics. Written informed consent was taken from all patients.

After inclusion in the study, patients was divided into two groups by lottery method; group-A and group-B and was receive intra articular steroid injection and hydrostatic distention respectively. In lottery method, group-A and group-B were written on a slip of paper. There were 144 slips of papers. 78 were labeled as group-A for injection and 66 were labeled as group-B for hydrostatic distention. Then, they were kept into a box and they are thoroughly shuffled. Then, the slips were selected randomly by the patients of idiopathic frozen shoulder as per operational definition.

A detailed clinical history of patient with idiopathic frozen shoulder was taken, followed by general physical and systemic examination for assessment of pain and range of motion of shoulder. For both type of procedures the patient was placed in supine position and the shoulder was in neutral position. In case of female patients, the procedures were carried out in the presence of a charge nurse.

The patients in both groups were under go intraarticular injection by following procedure. Skin was prepared with povidone iodine solution. 3ml of 1% plain lidocaine was injected into the skin and soft tissues overlying the joint capsule with a 23gauge x 1" needle. 8 ml of 1% plain lignocaine was mixed with 2 ml of Injection Depomedrol 80mg/2ml (methyl prednisolone acetate). Patients in Group A were injected this solution (steroid+Lignocaine) intra-articularly and in group B with 10ml Distilled water, by anterior

approach (with the needle passing through the deltopectoral groove and then below and medial to the tip of the coracoid process, through the coracobrachialis - biceps origin and subscapularis13 with a 21 gauge x 1.5" needle). All patients of both groups then would have active and assisted range of motion exercises under supervision of a physiotherapist for 3 days and once the exercises are learnt by the patient, then the patient was allowed to do these exercises at home. These exercises were consist of pendulum exercises (Internal rotation in abduction and in extension, External rotation in abduction and in extension) and abduction exercises (patient in standing position, arms by the side of the body so that palms facing toward the body, then raise the arms out to the sides until they are parallel to the floor, reaching shoulder height. Hold for five seconds then slowly lower back down to the side of the body) along with oral medicines (NSAIDS). The patients were continue regular home physical therapy exercises performed four times daily assisted by the family members and for compliance of these exercises, patient was asked at 6 weeks follow up. Those who are irregular with these exercises were excluded from the study. Patients were reassessed at six weeks follow up to determine intervention effectiveness in terms of decrease in at least one grade of pain on Visual Analouge Scale and increase in range of motion of shoulder joint more than 20 degrees on gonometer.

All information including name, age, gender, address, regularity of physical therapy exercises, pain and range of motion of shoulder joint at time of intervention and at 6-weeks follow up was recorded in a especially self designed proforma, which is attached as annexure I. Confounders and bias were controlled by strictly following exclusion criteria.

All data collected was entered and analyzed using SPSS version 17. Descriptive statistics was used to calculate mean and standard deviation of age, duration of pain. Frequency and percentages was calculated for gender, affected side and efficacy. Comparison between two groups for efficacy was done using Chi square test. p-value

Table-1: Age Distribution (n=142)

Age	Group-A	Group-B
20-30 years	9(12%)	10(14%)
31-40 years	19(27%)	21(30%)
41-50 years	43(61%)	40(56%)
Total	71100%)	71(100%)
Mean and SD	38 year ±10.53	40 year ± 9.48

Group-A: Intra articular steroid infection, group-B: Hydrostatic Distention, T-Test was applied in which P value was 0.2363

Table-2: Gender distribution (n=142)

Gender	Group A	Group B	
Male	30(42%)	28(40%)	
Female	41(58%)	43(60%)	
Total	71(100%)	71(100%)	

Group-A: Intra articular steroid infection, group-B: Hydrostatic Distention, Chi Square test was applied in which P-value was 0.7327

Table-3: Duration of idiopathic frozen shoulder (n=142) Duration of idiopathic frozen shoulder (n=142)

Duration	Group A	Group B	
≤ 1 month	23(33%)	25(35%)	
>1 month	48(67%)	46(65%)	
Total	71(100%)	71(100%)	
Mean and SD	1 ± 2.77	1 ± 2.68	

Group-A: Intra articular steroid infection, Group-B: Hydrostatic Distention, T-Test was applied in which P value was 1.0000

Table-4: Affected side (n=142)

Affected side	Group-A	Group-B	
Left	39(55%)	37(52%)	
Right	32(45%)	34(48%)	
Total	71(100%)	71(100%)	

Group-A: Intra articular steroid infection, group-B: Hydrostatic Distention, Chi-Square test was applied in which P-value was 0.7364

Table-5: Efficacy (n=142)

Efficacy	Group A	Group B	
Effective	66(93%)	62(87%)	
Not effective	5(7%)	9(13%)	
Total	71(100%)	71(100%)	

Group-A: Intra articular steroid infection, group-B: Hydrostatic Distention, Chi-Square test was applied in which P value was 0.2601

≤ 0.05 was taken as significant. Effect modifier like age, gender, duration of idiopathic frozen shoulder, duration of pain in affected side was addressed through stratification. Chi square test was applied. P-value less than and equal to .05 was taken as significant.

Results:

In this study age distribution among two groups was analyzed as in group-A 9(12%) patients were in age range 20-30 years, 19(27%) patients were in age range 31-40 years, 43(61%) patients

were in age range 41-50 years. Mean age was 38 years with SD \pm 10.53. Where as in group-B 10(14%) patients were in age range 20-30 years, 21(30%) patients were in age range 31-40 years, 40(56%) patients were in age range 41-50 years. Mean age was 40 years with SD \pm 9.48. (as shown in table no 1)

Gender distribution among two groups was analyzed as in group-A 30(42%) patients were male and 41(58%) patients were female. Where as in group-B 28(40%) patients were male and 43(60%) patients were female (as shown in table no 2)

Duration of idiopathic frozen shoulder among two groups was analyzed as in group-A 23(33%) patients had duration of idiopathic frozen shoulder was ≤1 month and 48(67%) patients had duration of idiopathic frozen shoulder >1 month. Mean duration of idiopathic frozen shoulder was 1-month with SD±2.77. Where as in group-B 25(35%) patients had duration of idiopathic frozen shoulder was ≤1 month and 46(65%) patients had duration of idiopathic frozen shoulder >1 month. Mean duration of idiopathic frozen shoulder was 1-month with SD±2.68. (as shown in table no 3). Side affected among two groups was analyzed as in group-A 39(55%) patients had left side affected while 32(45%) patients had right side affected. In group-B 37(52%) patients had left side affected while 34(48%) patients had right side affected. (table no 4). Efficacy among two groups was analyzed as group-A (Intra-articular steroid infection) was effective in 66(93%) patients and was not effective in 5(7%) patients. Whereas group-B (Hydrostatic distention) was effective in 62(87%) patients and was not effective in 9(13%) patients. (table no 4)

Stratification of efficacy with respect to age, gender, duration of idiopathic frozen shoulder. Affected side is given in table 5,6,7,8

Table-6: Stratification of efficacy w.r.t age distribution

Age	Efficacy	Group-A	Group-B	P value
20-30 years	Effective	8	9	0.9371
	Not effective	1	1	
Total		9	10	
31-40 years	Effective	18	18	0.3421
	Not effective	1	3	
Total		19	21	
41-50 years	Effective	40	35	0.3942
	Not effective	3	5	
Total		43	40	
Group-A: Intra art	icular steroid infection, g	roup-B: Hydrostatic	Distention	

Table-7: Stratification of efficacy w.r.t gender distribution

Gender	Efficacy	Group-A	Group-B	P value
Male	Effective	28	24	0.3410
	Not effective	2	4	
Total		30	28	
Female	Effective	38	38	0.5010
	Not effective	3	5	
Total		41	43	

Group-A: Intra articular steroid infection, group-B: Hydrostatic Distention

Table-8: Stratification of efficacy w.r.t duration of idiopathic frozen shoulder

Gender	Efficacy	Group-A	Group-B	P value
≤ 1 months	Effective	21	22	0.7081
	Not effective	2	3	
Total		23	25	
>1 month	Effective	45	40	0.4034
	Not effective	3	6	
Total		48	46	

Group-A: Intra articular steroid infection, group-B: Hydrostatic Distention

Discussion:

The term frozen shoulder was first used in 1934 by Codman, who described the common features of a slow onset of pain felt near the insertion of the deltoid muscle, inability to sleep on the affected side, and restriction in both active and passive elevation and external rotation, yet with a normal radiological appearance.1 The pathology of frozen shoulder involves active fibroblastic proliferation in the capsule of the shoulder joint, accompanied by some transformation of fibroblasts to myofibroblasts.^{2,3} Despite this knowledge of the pathology, there is no consensus on the most favorable method of managing the disease. Suggestions for management range from supervised neglect to corticosteroids, physiotherapy, manipulation, hydrodilatation and arthroscopic capsular release.4 Our study shows that mean age in group-A was 38 years with SD \pm 10.53 while mean age in group-B was 40 years with SD±9.48. In group-A 42% patients were male and 58% patients were female. While in group-B 40% patients were male and 60% patients were female. More over group-A (Intra articular steroid infection) was effective in 93% patients while group-B (Hydrostatic distention) was effective in 87% patients. Similar results were observed in another study conducted by Asghar K et al¹³ in which it has been reported that 86% patients has got complete resolution of pain with intra articular steroid injection while in hydrostatic distension group, pain resolution was 60%, but on the other hand, the overall improvement of pain in both groups was 97% and 92% respectively.

Similar results were observed in another study conducted by Singh GP et al¹¹ in which intra-articular steroid injection group, range of motion of shoulder joint was improved in 84% while in hydrostatic distension group, 63% patients didn't shown significant improvement. Similar results were observed in two other study conducted by Cho NS et al¹² and Quraishi NA et al¹⁴ in which the success rate of intra-articular steroid injections varies from 44% to 80% while hydrostatic distension has been reported to be effective in 93.67% patients.

In another study conducted by Kim MT et al¹⁵ the pooled standardized mean difference (SMD) of functional improvement and pain reduction revealed equal efficacy at 3 follow-up time points. With respect to ER improvement, distension has a superior effect compared with IA steroid injection in the short term [(2-4wk; SMD, -.36; 95% confidence interval [CI], -.68 to -.04) and medium term (6-16wk; SMD, -0.80; 95% CI, -1.32 to -0.29). The network metaanalysis indicated a better efficacy for distension than for IA steroid injection in ER improvement only in the medium term (6-16wk; SMD, -0.70; 95% CI, -1.19 to -0.21).17-20 More over they had concluded that IA steroid injection was as effective as distension in shoulder function improvement, pain reduction, and increasing ER of the shoulder.²¹⁻²⁴ Distension yielded better ER improvement in the medium term but to a minor extent in the long term.²⁵⁻²⁷ For patients with predominant ER limitation, early distension could be considered the primary choice of treatment.²⁸⁻³⁰

Conclusion:

Our study concludes that Intra articular steroid is more effective than hydrostatic distention for idiopathic frozen shoulder

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Role and contribution of authors:

Dr. Aimal Sattar, conceived the idea, collected the data and references and did the initial write up

Dr M Ayaz Khan, criticically review the article and made the final changes

Dr Mahmood ul Hassan, collected the data and helped in intoroduciton writing

Dr. Muhammad Shabbir, collected the referenes and helped in discussion writing

Dr Zeeshan Faisal, collected the references and helped in result writing.

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