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Original Research Article

A PROSPECTIVE STUDY OF CLINICAL AND FUNCTIONAL OUTCOME OF MANAGEMENT OF PRIMARY FROZEN SHOULDER BY HYDRAULIC DISTENSION, INTRA-ARTICULAR STEROID INJECTION AND MANIPULATION UNDER GENERAL ANAESTHESIA

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ABSTRACT

Background: Frozen shoulder is characterized by significant restriction of both active and passive movements with varying treatment options. It affects 2% to 5% of general population with increased incidence seen in diabetics up to 20%. The primary objective of the present study was to assess the clinical and functional outcome of primary frozen shoulder after saline hydraulic distension, intra-articular steroid injection and manipulation under general anaesthesia. The secondary objective was to determine the effect of diabetes on final outcomes.

Materials and Methods: This prospective observational study was conducted on patients diagnosed with Reeves clinical stage II frozen shoulder who presented to Orthopaedic out-patient facility at a tertiary care hospital. The clinical and functional outcomes were assessed using the American Shoulder and Elbow Surgeons (ASES) score and range of motion at pre-manipulation stage and at every follow up at 1 month, 3 months, 6 months and 1 year. Statistical analysis and evaluation was done with MS-Excel 2007 using Student paired 't' test.

Results: A total of 41 patients including 1 bilateral case were included in the present study with a Mean age of 57.44±8.46. The Mean ASES Pain score improved from 10.71±4.36 at pre manipulation stage to 37.02±2.93 at 1 month, 38.81±2.16 at 3 months, 40.51±2.51 at 6 months and 40.83±2.45 at 1 year follow up; while the ASES Functional score improved from 11.24±1.53 at pre manipulation stage to 35.21±1.70 at 1 month, 38.02±1.36 at 3 months, 39.94±1.11 at 6 months and 40.90±1.31 at 1 year which was statistically significant ($p<0.001$). Also, there was significant improvement in clinical and functional outcome in both diabetic and non-diabetic group of patients ($p<0.001$) while the difference in improvement compared between both the groups was not statistically significant ($p>0.05$).

Conclusion: From the present study we conclude that frozen shoulder can be safely and effectively managed with hydraulic distension, intra-articular steroid injection and manipulation under GA with good clinical and functional recovery with or without presence of underlying diabetes.

Keywords: Frozen Shoulder, Hydraulic Distension, Steroid, Manipulation, Diabetes.

INTRODUCTION

Frozen shoulder, also called as adhesive capsulitis, is a condition of uncertain aetiology characterized by significant restriction of both active and passive shoulder motion that occurs in the absence of a known intrinsic shoulder disorder.[1] It affects 2% to 5% of general population but in diabetic patients the incidence can reach up to 20%.[2] It is most commonly seen between 4th and 6th decades of life with preponderance for female population.[3] Apart from diabetes mellitus,[4] thyroid disorders,[5] asthma, cardiovascular diseases,[6] and prolonged immobilization following trauma are high risk factors.[7] The non-dominant side is commonly affected in unilateral affection while 6% to 17% of cases have bilateral involvement.

The patho-aetiology of frozen shoulder is complex and multifactorial with both genetic and environmental factors attributed in its causation.[8] The natural course of frozen shoulder can be clinically divided into 3 stages as proposed by Reeves et al,[9] namely (i) freezing or painful stage, (ii) frozen or stiff stage and (iii) thawing of recovery stage. It is a self-limiting disorder spanning an average of 2.5 years after which full functional recovery may be expected in most patients.

Literature supports various non-operative and operative treatment strategies for frozen shoulder. Most patients will experience resolution of symptoms with supervised non-operative treatment in a short period of time and only small proportion of patients require operative intervention. The goal of treatment is to relieve pain, improve function and achieve permanent recovery. Various non-operative treatments options used either in isolation or in varying combination includes physical therapy,[10] NSAID's, oral corticosteroids, intra-articular corticosteroid injections,[11] hydraulic distension,[12] supra-scapular nerve block,[13] etc. Operative treatment includes open,[14] or arthroscopic release,[15] which is reserved for refractory cases.

The primary objective of the present study was to assess the clinical and functional outcome of primary frozen shoulder after saline hydraulic distension, intra-articular steroid injection and manipulation under general anaesthesia. The secondary objective was to determine the effect of diabetes on final outcomes.

MATERIALS AND METHODS

Study Design and Population: The present study was commenced after Institutional Ethics Committee approval was granted. Written informed consent was obtained from all the patients enrolled in the study. This prospective observational study was conducted on patients diagnosed with Reeves clinical stage II frozen shoulder,[9] who presented to Orthopaedic out-patient facility at a tertiary care hospital in Mumbai, Maharashtra, India. The diagnosis of frozen shoulder was defined based on Shaffer's criteria,[16] which includes the following:

1. At least one month history of pain and stiffness of shoulder.
2. Documented restriction both active and passive gleno-humeral and scapula-thoracic motion of equal or less than 100° abduction and less than 50% external rotation as compared to the contralateral side.
3. Normal findings on true antero-posterior radiograph of gleno-humeral joint.

Inclusion and Exclusion Criteria:

All patients with Reeves clinical stage II frozen shoulder who were treated conservatively with medications and physiotherapy for 3 months but had no relief of symptoms and who consequently underwent hydraulic distension, intra-articular steroid injection and manipulation under general anaesthesia after voluntarily consenting were included in the present study. On the other hand, patients with frozen shoulder with concomitant history of shoulder trauma or fracture; rotator cuff pathology; local pathology including tumours; acromio-clavicular joint arthritis; neuromuscular disorders; previous surgical intervention around the shoulder; follow up <3 months or those not willing to consent were excluded.

Data Collection and Measurements:

Demographic characteristics of patients such as age, gender, laterality and hand dominance were recorded. A detailed history, systemic examination and through clinical evaluation of shoulder joint was performed. Presence of pre-existing comorbidities such as diabetes mellitus, thyroid disorders, hypertension, coronary artery disease etc. was noted. Baseline laboratory investigations and radiographs (shoulder true AP and lateral view) were done in all patients. Specific investigations were done in selected patients to rule out other causes of shoulder pain or diagnose suspected co-morbidities.

The range of shoulder movements were measured using goniometer in standing position including passive forward flexion, combined abduction and rotations with shoulder in neutral position. Internal rotation was evaluated using the Constant Score.[17] Circumferential measurement was done to evaluate muscle atrophy. Values were recorded at pre-manipulation stage and post manipulation at every follow up at 1 month, 3 months, 6 months and 1 year. The assessment of pain and functional outcomes of patients were recorded at pre manipulation stage and at each follow up using the American Shoulder and Elbow Surgeons (ASES) score.[18] The score consists of 2 domains namely the ASES pain score and the ASES functional score with maximum score up to 50 in each domain. The ASES pain score is based on VAS scale ranging from 0 to 10 with maximum score of 50 given for least pain i.e. 0 on the scale and minimum score of 0 for maximum pain i.e. 10 on the scale. Similarly, the ASES functional score is based on set of 10 questions assessing functional abilities of the involved shoulder. Each question has a maximum

score of 5 and minimum of 0. Each question has 4 answers ranging from 'unable to do' (score 0) to 'not difficult' (score 5).

Procedural Technique: Written informed consents were obtained from the patients undergoing the procedure. Drug sensitivity testing was performed for injection lignocaine and injection bupivacaine. If no adverse reaction was seen, the patients were shifted to operation theatre and administered general anaesthesia.

The injecting solution comprised of normal saline (60ml), 2% lignocaine without adrenaline (3-5 mg/kg), 0.5% bupivacaine (2-3 mg/kg) and Inj. Depomedrol 80mg.

Using the posterior approach an 18G, 1.5 inch needle, was introduced through the soft spot between infraspinatus and teres minor into the gleno-humeral joint under aseptic conditions. The soft spot was marked 2 to 3cm inferior and 1cm medial to the postero-lateral tip of the acromion with the needle pointing towards ipsilateral coracoid process anteriorly. [Figure 1] Appropriate position of the needle into the joint was indicated by free flow of injecting solution with minimal resistance.

Figure 1: Technique demonstrating saline hydraulic distension of the left shoulder joint via the posterior approach.

After the hydraulic distension the shoulder was gently manipulated taking care to prevent any fractures. Manipulation involved moving the shoulder in flexion; abduction including cross body abduction; external rotation in neutral and 90 degrees abduction; and internal rotation in 90 degrees abduction.

Post Procedure Protocol and Follow Up:

After manipulation, the upper limb was kept in overhead abduction for six hours. Range of motion exercises were started on the same day and the patient was discharged after 24 hours. All patients were followed at 1 month, 3 months, 6 months and 1 year. [Figure 2 and 3] shows the clinical images of a patient depicting range of motion at pre-manipulation stage and at final follow up respectively.

Figure 2: Clinical image of Case no.1 showing the range of motion of left shoulder as assessed during pre-manipulation stage

Figure 3: Clinical image of Case no. 1 showing range of motion of left shoulder at one year follow up post manipulation.

Statistical Analysis: The statistical analysis was done using IBM SPSS Statistics for windows version 26.0 (Chicago Inc.). The qualitative variables were presented as frequency and percentage and quantitative variables were summarized as mean and standard deviation. The continuous variables were assessed using the independent student 't' test while the Chi square test was used to analyse the categorical data. Level of significance was set at 5% and all p-values less than 0.05 were treated as significant.

RESULTS

In the present study, 41 patients with frozen shoulder met the inclusion criteria and were included. Out of all patients, 19 were followed up to 1 year, 12 patients up to 9 months, 7 patients up to 6 months and 3

patients up to 3 months. As 1 patient had bilateral involvement, a total of 42 shoulders were studied. The Mean age was 57.44 years with standard deviation of ±8.46. Majority of patients (41.46%) belonged to 51-60 years age group whereas about two third (68.23%) of the patients were females. More than half (56.10%) of patients had involvement on the left side. Also majority (56.09%) of patients had non dominant side involvement. More than two third (70.73%) of all patients were diabetic (n=18). The demographic characteristics of patients including the presence of associated comorbidities are as illustrated in [Table 1].

Table 1: Demographic characteristics of patients (n=41) and associated medical comorbidities.

Character	Frequency	Percentage
Age Group		
31-40	1	2.44
41-50	8	19.51
51-60	17	41.46
61-70	12	29.27
71-80	3	7.32
Gender		
Male	13	31.71
Female	28	68.23
Total	41	100
Side of Involvement		
Right	17	41.46
Left	23	56.10
Bilateral	1	02.44
Dominance		
Dominant side involvement	18	43.90
Non-dominant side involvement	23	56.09
Medical Comorbidities		
Diabetes	18	43.90
Hypertension	6	14.63
Low backache	5	12.20
Neck Pain	4	9.76
Coronary Artery Disease	3	7.32
Hypothyroidism	2	4.88
None	12	29.27

The improvement in range of motion as measured in the pre manipulation stage and at every follow up is illustrated in [Table 2] and depicted in [Figure 4]. There was statistically significant improvement in the range of motion.

Table 2: Range of motion at pre manipulation stage and at every follow up.

	Mean	Std. deviation	P value	Significance
Flexion				
Pre-manipulation	96.81	2.83		
1 month	143.86	6.07		
3 month	153.90	5.31		
6month	158.82	3.63		
Final follow up	159	3.48	<0.001	Yes
Abduction				
Pre-manipulation	93.26	4.13		
1 month	146.33	4.89		
3 month	150.95	4.76		
6month	153.59	4.38		
Final follow up	153.76	4.82	<0.001	Yes
External Rotation				
Pre-manipulation	10.10	1.92		
1 month	57.71	4.06		
3 month	58.71	3.66		
6month	60.61	3.90		
Final follow up	61.23	4.12	<0.001	Yes
Internal Rotation				
Pre-manipulation	1.81	0.97		
1 month	4.05	0.70		
3 month	4.24	0.79		
6month	4.56	1.02		
Final follow up	4.57	1.01	<0.001	Yes

Active Internal Rotation	Constant Score
Interscapular region	10
Inferior tip of scapula	8
Twelth rib	6

Lumbosacral region	4
Buttock	2
Lateral thigh	0

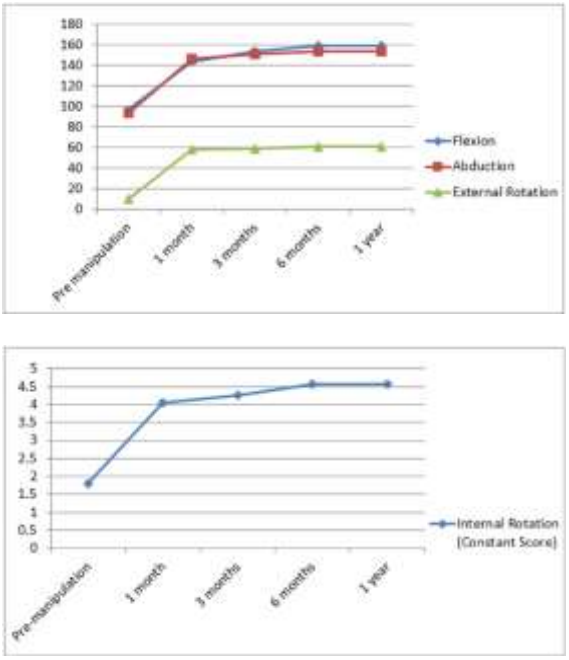

Figure 4: Range of motion at pre-manipulation stage and at every follow up.

The ASES pain scale and score is demonstrated in Table 3 and depicted in Figure 5. The Mean ASES-Pain score at pre manipulation was 10.71±4.36. The score significantly improved at 1 month (37.02±2.93), at 3 months (38.81±2.16), at 6 months (40.51±2.51) and at 1 year (40.83±2.45). Thus the overall improvement was 30.12 points at final follow up which was statistically significant p<0.001).

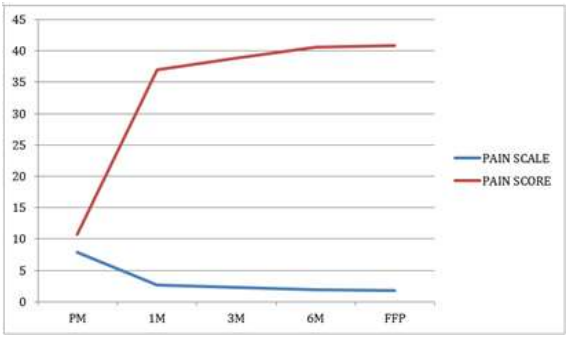

Figure 5: American Shoulder and Elbow Surgeons (ASES) pain scale and score at pre manipulation stage and at final Dfollow up.

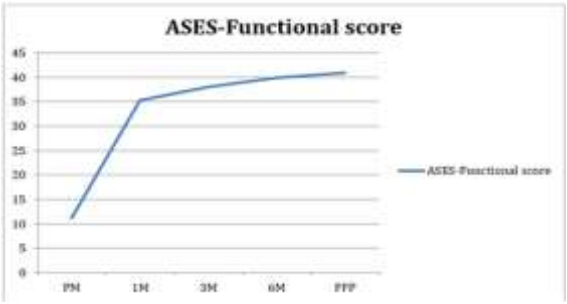

Figure 6: American Shoulder and Elbow Surgeons (ASES) functional score at pre manipulation stage and at final follow up.

Table 3: American Shoulder and Elbow Surgeons (ASES) pain scale and score.

Pain	ASES-Pain Scale	Std. Dev.	ASES- Pain score	Std. Dev.	p value	Significance
Pre-manipulation	7.86	0.87	10.71	4.36		
1 month	2.60	0.59	37.02	2.93		
3 months	2.24	0.43	38.81	2.16		
6 months	1.90	0.50	40.51	2.51		
1 year	1.83	0.49	40.83	2.45	<0.001	Yes

Similarly, the ASES functional score is demonstrated in [Table 4] and depicted in [Figure 6]. The Mean ASES functional score at pre manipulation was 11.24±1.53. The score improved significantly at 1 month (35.21±1.70), at 3 months (38.02±1.36) and at 6 months (39.94±1.11) and at 1 year (40.90±1.31). Thus, the overall improvement was 29.66 points at final follow up which was statistically significant (p<0.001).

Table 4: American Shoulder and Elbow Sugeons (ASES) functional score at pre manipulation stage and at final follow up.

ASES- Function	Mean	Std. Dev.	p value	Significance
Pre-manipulation	11.24	1.53		
1 month	35.21	1.70		
3 months	38.02	1.36		
6 months	39.94	1.11		
1 year	40.90	1.31	<0.001	Yes

On observing the range of motion, ASES pain and functional score values at pre manipulation stage and at final follow up of both diabetic and non-diabetic group of patients, there was statistically significant improvement in both groups respectively (p<0.001) [Table 5].

Table 5: Range of motion, ASES pain and functional score in both diabetic and non-diabetic groups at pre manipulation stage and final follow up.

	Diabetic (n=14)			Non Diabetic (n=18)			Significance
	Pre-manipulation	1 year		Pre-manipulation	1 year		
Flexion	96.42±2.71	159.26±4.07	<0.001	97.13±2.94	158.78±2.99	<0.001	Yes
Abduction	93.79±3.82	154.42±3.98	<0.001	92.87±4.42	153.22±5.45	<0.001	Yes
External Rotation	9.89±1.82	61.79±3.94	<0.001	10.26±2.02	60.78±4.30	<0.001	Yes
Internal Rotation	1.58±0.83	4.31±1.00	<0.001	2.00±1.04	4.78±0.99	<0.001	Yes
Pain scale	7.68±0.95	1.74±0.65	<0.001	8.00±0.80	1.91±0.29	<0.001	Yes
Pain score	11.58±4.73	41.32±3.27	<0.001	10.00±3.99	40.43±1.44	<0.001	Yes
ASES-functional	11.16±1.66	40.66±1.45	<0.001	11.32±1.45	41.10±1.80	<0.001	Yes

Also, on comparing the difference in range of motion, the ASES pain and functional scores, between both the diabetic and non-diabetic groups of patients at pre manipulation stage and at final follow up, there was no statistically significant difference in the improvement between both groups (p>0.05) [Table 6].

Table 6: Comparison of the difference in range of motion, ASES pain and functional score at pre manipulation stage and at final follow up between diabetic and non-diabetic groups.

	Diabetic (n=19)	Non Diabetic (n=23)	p value	Significance
diff Flexion	62.84 ±1.36	61.65±0.06	0.12	No
diff Abduction	60.63±0.15	60.35±1.03	0.13	No
diff ER	51.89±2.11	50.52±2.27	0.14	No
diff IR	2.74±0.17	2.28±0.04	0.47	No
diff Pain scale	5.94±0.30	7.09±0.51	0.37	No
diff Pain score	29.73±1.45	30.43±2.55	0.16	No
diff ASES Functional score	29.50±0.22	29.78±0.27	0.07	No

No complications were observed in the present study.

DISCUSSION

As frozen shoulder was previously thought to be primarily an inflammatory condition, initial treatment usually consists of intra-articular steroid injection followed by physiotherapy. In a randomised trial by Van Windt DAWN der et. al., early resolution of symptoms and improved functional outcomes was reported with isolated treatment with injections over physiotherapy alone.[19] However there is literature supporting superior outcomes of adding physiotherapy after a gleno-humeral joint injection.[20] There is evidence to suggest that hydraulic distension has beneficial role in short term management of patients not improving by analgesics and physiotherapy.[21] Although its precise mechanism of action is debatable, one possible intrinsic factor is reduction of elevated glycosaminoglycan concentration in joint capsule, there by inhibiting myofibroblast activity.[22] In the present study, we combined the benefits of hydraulic distension, intra-articular steroid injection and manipulation under anaesthesia with an aim to achieve enhanced outcomes. The aim of manipulation under anaesthesia (MUA) is to forcibly break the contracted joint capsule. It is frequently combined with intra-articular steroid injection to minimize inciting an inflammatory response and to accelerate rehabilitation.

The functional outcome of patients with adhesive capsulitis as evaluated using the ASES functional score showed statistically significant improvement over the duration at 1 month, 3 months, 6 months and at final follow up. This was evident from the fact that the patients regained the ability to comb their hair, lift weights above the head, throw ball etc. However, many found it difficult to reach up the inter-scapular region. Results consistent with this study were also reported by others.[23,24] Park S.W. et al,[25] in their comparative randomized study in 2014 observed most significant improvement in functional outcome amongst patient group treated with intensive mobilization after one steroid injection with capsular distension (IMSID) as compared with other treatment groups namely intensive mobilization (IM), one steroid injection with capsular distension (SID) and general physical therapy only (GPT).

Pain is the most common presenting complaint in patients with adhesive capsulitis which is further aggravated while performing shoulder movements. The results in the present study showed significant improvement in the pre manipulation Mean ASES pain scale and score. Although some residual pain may persist, patients had no difficulty in performing daily activities as seen by ASES functional score. In a randomised control trail conducted by Khan AA. Et al,[26] comparing 2 treatment groups, superior outcomes using the Visual Analogue Scale (VAS) and range of motion were reported in the group treated with distension arthrography with intra-articular steroid plus physiotherapy compared to the group treated with physiotherapy alone.

Co-morbidities have significant effect on pain and dysfunction of shoulder which influences the

management of frozen shoulder.[27] Although some previous studies,[28] excluded patients with pre-existing co-morbidities, we compared the efficacy of our treatment protocol in patients of frozen shoulder with and without co-morbidities. Diabetes was the most common (43.9%) associated co-morbidity in the present study, followed in decreasing order of frequency, hypertension (14.63%), low backache (12.20%), neck pain (9.76%), coronary artery disease (7.32%) and hypothyroidism (4.88%). Bridgman et. al,[29] and other studies,[27] also reported higher association of diabetes in patients with frozen shoulder. Presence of hyperglycemia in diabetic patients promotes collagen cross-linking with leads to decrease tissue compliance and resultant limited joint motion.[30]

In the present study, both diabetic and non-diabetic group of patients demonstrated significant improvement in functional outcome using the ASES pain and functional score as well as range of motion at final follow up which was statistically significant ($p<0.001$). Moreover, on comparing the difference in improvement of these outcome variables at final follow up, there was no statistically significant improvement of one group over the other ($p>0.05$). Thus we can conclude that the presence or absence of diabetes does not alter the final clinical and functional outcome.

The Mean age of patients in the present study was 57.44±8.46 with more than two third cases belonging to fifth and sixth decade of life. Similar age distribution was also observed in other studies such that largest prevalence was seen between 40 and 60 years.[31] A high preponderance of incidence of frozen shoulder in female population with male: female ratio of 1:2.25 was also reported in other studies.[32] Affection of non-dominant side is more commonly seen in patients with frozen shoulder.[31] In the present study, slightly more than half (54.76%) of the patients had involvement of the non-dominant side.

In the present study all patients tolerated the procedure well. No complications were noticed either during the procedure or at follow ups. None of the patients developed recurrent frozen shoulder post treatment. Few complications have been documented in the current literature. Clement et al,[33] reported one patient of septic arthritis after hydraulic distension. Specific complications of manipulation under anaesthesia (MUA) include fractures of glenoid, proximal humerus or clavicle as well as brachial plexus injury.[34]

The present study is not without limitations. The study involved small sample size of 41 patients with a minimum follow up of 3 months. We recommend larger sample size with longer minimum follow up duration. No control group was utilized in the present study. It is unlikely that a control group will be required for evaluating long term outcomes at 2 years as similar outcomes are expected due to tendency of spontaneous improvement of the disease. The regimen for hydraulic distension in terms of volume and individual components is not standardised amongst different authors,[21] which is an area for further research.

CONCLUSION

From the present study we conclude that frozen shoulder can be safely and effectively managed with hydraulic distension, intra-articular steroid injection and manipulation under GA with good clinical and functional recovery with or without presence of underlying diabetes.

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