

Functional outcome assessment of frozen shoulder treated by distension hydrodilatation and viscosupplementation: A prospective study

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Abstract

Purpose: The purpose of this study is to assess the role of distension hydrodilatation and viscosupplementation of the glenohumeral joint in the management of frozen shoulder.

Materials and Methods: A total of 50 Patients suffering with frozen shoulder presented to Yashoda hospital, malakpet, Hyderabad. All patients were treated by distension hydrodilatation and viscosupplementation under fluoroscopy (C-ARM) guidance as a day care procedure. The study period was from August 2018 to February 2019. All the patients were followed-up for a minimum period of 6months to maximum 1 year. The mean age of the study group was 45.86 years.

Results: All cases were assessed by oxford shoulder score (OSS) and visual analogue score (VAS) pre-procedure and post-procedure. All the patients regained near normal to normal shoulder movements in all directions by the end of 3rd week. Complete pain relief was seen by 2 weeks following the procedure. There was decrease in Oxford Shoulder Score (OSS) by mean of 18.22 (pre-procedure was 31.34 and post-procedure was 13.12), Visual Analogue Scale (VAS) mean was also decreased from 8.42 to 1.14. 43 of 50 patients obtained full free range of movements. Remaining 7 patients had restriction of terminal rotational movements, 3 of 7 patients had restriction of 10⁰ of external rotation, 4 of 7 had restriction of 10⁰ of internal rotation.

Conclusion: Distension hydrodilatation and viscosupplementation is a definitive treatment modality in patients with frozen shoulder. It results in significant and sustained relief of pain and also results in regaining of full range of shoulder movements.

Keywords: Frozen shoulder, Distension hydrodilatation, Viscosupplementation.

Introduction

Frozen shoulder¹ also known as adhesive capsulitis or periarthritis shoulder, is a condition characterized by pain and stiffness of shoulder joint. Frozen shoulder affects approximately 2–5% of the population.¹ Frozen shoulder typically affects the rotator interval and coracohumeral ligament, which causes early restriction of external rotation.² As the disease progresses, glenohumeral capsule is contracted and glenohumeral ligaments thickened.³ Night pain with a reduced range of movement, particularly external rotation is one of the cardinal symptoms³ of frozen shoulder. It may be idiopathic or secondary to preceding trauma. It has female preponderance and has strong association with diabetes mellitus.⁴ Frozen shoulder is usually self-limiting, typically lasting between 12 months and 36 months with spontaneous resolution, although some studies demonstrate up to 41% of patients had persisting symptoms associated with pain and functional loss. Treatment methods for the management⁵ of adhesive capsulitis are broad, they include medical treatment and physiotherapy, manipulation under anaesthesia, arthroscopic 360⁰ capsular release, intra-articular steroid injections and distension hydrodilatation of the shoulder joint (either by fluoroscopy or ultrasound guidance).⁶⁻⁸

Distension of the shoulder joint capsule was attempted by injecting contrast medium or saline solution under pressure was described by ANDREN and LUNDBERG (1965).

In distension hydrodilatation⁸⁻¹⁰ the shoulder joint capsule distended by injecting a substantial amount (80-100ml) of normal saline into the joint. It distends joint capsule with capsular rupture as the desired endpoint.

Pathophysiological increased glycosaminoglycan concentration seen in the joint capsule in frozen shoulder promotes myofibroblast activity and this is reversed by the joint distension.⁷ It is technically easy to perform and it is minimally invasive. Hydrodilatation is more effective than physiotherapy and it is also without complications like iatrogenic proximal humerus, rotator cuff tears, glenohumeral ligament tears, labral tears, osteochondral fractures occurred by manipulation under anaesthesia.¹¹ Arthroscopic 360⁰ capsular release is an effective method but it is more invasive and expensive.¹² Some studies^{9,10,14} have suggested an improvement of pain and movements following hydrodilatation and steroid injections. In our study we managed frozen shoulder by distension hydrodilatation and viscosupplementation (inj. Synviscone).

Materials and Methods

A prospective study was carried out from August 2018 to February 2019, a total number of 50 patients who diagnosed clinically as frozen shoulder and confirmed by high resolution ultrasound (HRUS) (Fig. 1a & 1b) were treated by distension hydrodilatation and viscosupplementation followed by 6-12weeks of physiotherapy (in terms of progressive, active assisted and active ROM shoulders in all directions followed by strengthening of various muscles around shoulder). The inclusion criteria were patients with painful restriction of active and passive shoulder movements, after failed conservative management for a minimum period of 3 months, worsening of symptoms even after physiotherapy and steroid injections, patients with already complete restriction of movements with less pain component. All the patients in this study had idiopathic frozen shoulder.

The exclusion criteria include shoulder stiffness in post-infective cases; rotator cuff tears, post fracture and Post-surgery around the shoulder. Following the procedure all 50 patients were followed-up for a minimum period of 6months and maximum period of 1year, none of the patients lost to follow-up. Among the 50 patients, 20 were male and 30 were female. 28 patients were associated with type2 diabetes mellitus. The mean age of study group (patients) was 45.86 years (range 30 to 60years). The average procedure duration was 15 minutes.

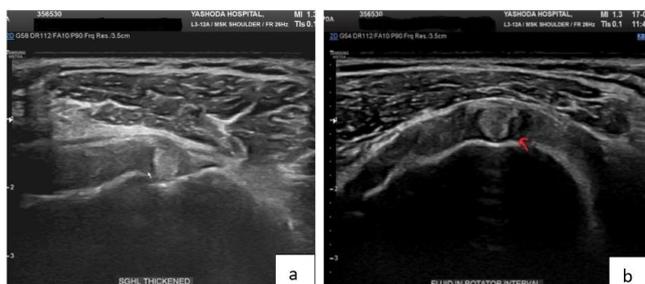


Fig 1a & 1b: Ultrasound images showing thickened SGHL and hypo echoic thickening of rotator interval (red arrow) suggestive of peri arthritis shoulder or frozen shoulder.

Procedure technique

Patient in supine position, under short general anaesthesia, with a folded towel under the scapular body, a 22 gauge spinal needle was passed into the gleno-humeral joint. The needle position was confirmed under fluoroscopy¹³ guidance, an injection of 2.5 ml of non-ionic contrast material (OMNIPAQUE 350) was passed to confirm that the needle is completely intra-articular (Fig. 2b). Then 80-100 ml normal saline was injected into gleno-humeral joint. In most of cases while pushing the normal saline we observed distension of joint fluoroscopically (Fig. 2c) and clinically palpable click sounds due to stretching of joint capsule.¹⁴ Then shoulder was moved through smooth arc of movements in all directions while the assistant stabilizing the scapula blade, in a sequential manner without any manipulation throughout the procedure (Fig. 2d-2h). This was followed by injecting inj. HYLAN-GF 20 (injection Synviscane 8mg/ml)^{15,16} into the gleno humeral joint. Post-procedure initial 24 hours the shoulder was immobilized. From the 2nd day the shoulder was mobilized and progressive physiotherapy was carried out.

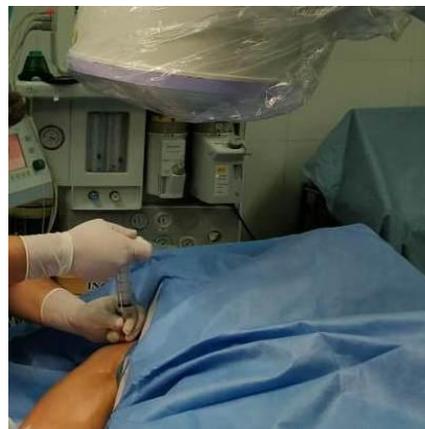


Fig. 2a: Placement of needle



Fig. 2b: C-ARM image – Arthrography



Fig 2c: Image showing distension of shoulder



Fig. 2d: Abduction range of movement



Fig. 2e: External rotation in 90° abduction



Fig. 2f: internal rotation in 90°



Fig. 2g: Complete adduction



Fig. 2h: Complete abduction

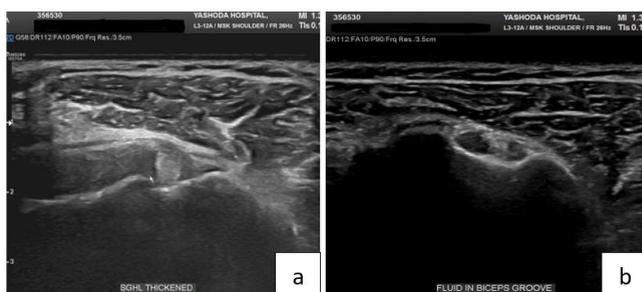


Fig. 3a & 3b: Pre-procedure USG images showing thickened superior glenohumeral ligament and fluid in biceps groove.

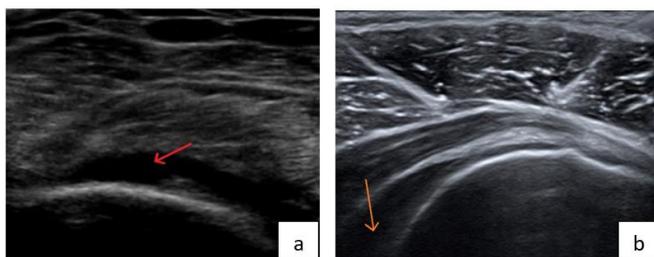


Fig. 4a & 4b: Immediately after distension hydrodilatation USG images shows distended gleno-humeral joint and distended posterior recess (red and orange arrows).

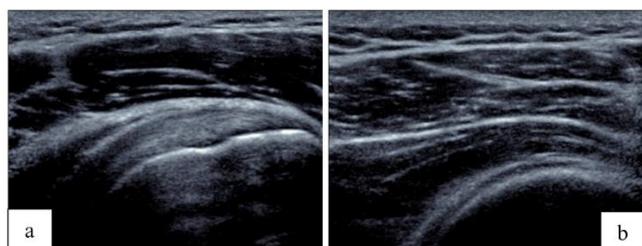


Fig 5a & 5b: Follow-up USG images showing normal supraspinatus and infraspinatus with well-maintained gleno-humeral joint line.

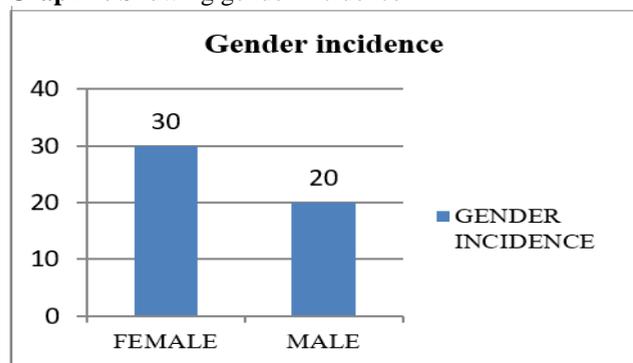
Results

A total of 50 patients with frozen shoulder underwent distension hydrodilatation and viscosupplementation, with post-procedure physiotherapy. The mean age of study group was 45.86 years (range 30 years to 60 years), 30 were female and 20 were male, and 28 patients were associated with type 2 diabetes mellitus. We observed decrease in the intensity of

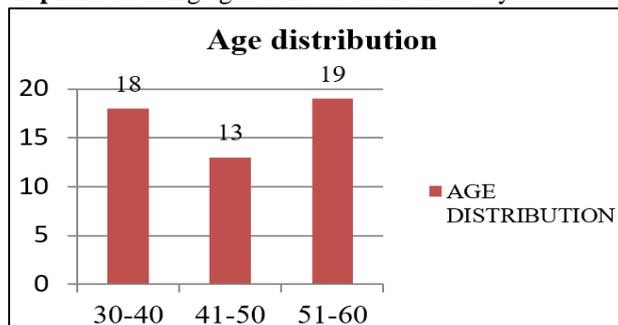
pain as early as 2nd day following the procedure and complete relief of pain by the end of 2nd week. Shoulder range of movement initiated from 2nd of post procedure in sequential manner i.e. assisted active range of movements followed by active range of movements and strengthening of peri-shoulder musculature over a period of 2-3 weeks. 43 patients regained full range of movements. Remaining 7 patients had terminal restriction of movements, out of them 3 patients had restriction of 10° of external rotation, 4 had restriction of 10° of internal rotation. These 7 patients were associated with type2 diabetes. All the patients were able to do their normal routine activities.

Pre-procedure OSS (mean 31.34) and VAS scores (mean 8.42) were functionally worse at the time of presentation. A significant improvement in functional scores was demonstrated at the end of 3rd week of post-procedure, with the mean oxford shoulder score (OSS) post-procedure was 13.12 (decreased by 18.22) and the mean VAS score was also reduced from 8.42 to 1.14. No recurrence of shoulder stiffness and any other complications during or post-procedure were noted.

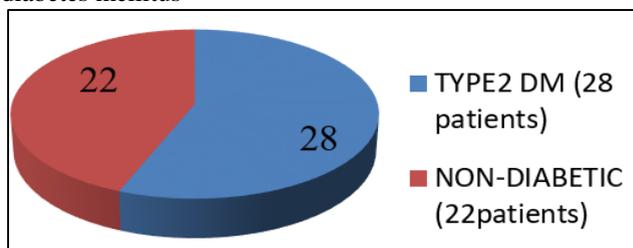
Graph 1: Showing gender incidence



Graph 2: Showing age distribution in this study



Graph 3: Pie chart showing patients associated with type2 diabetes mellitus



Graph 4: Showing functional outcome of procedure assessed by OSS (OXFORD SHOULDER SCORE, 12-60) and VAS (VISUAL ANALOGUE SCALE, 0-10).

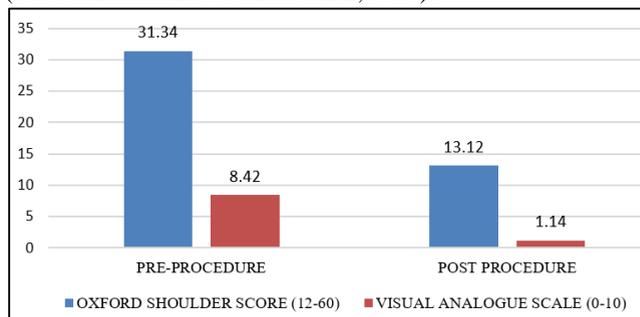


Table 1: Showing pre-procedure shoulder movements.

Pre- procedure abduction			Pre-procedure external rotation		
ROM	Number of patients	Percentage (%)	ROM	Number of patients	Percentage (%)
0-50°	6	12	0-15°	9	18
0-70°	31	62	0-20°	18	36
0-100°	13	26	0-30°	23	46

Table 2: Showing post-procedure limitation of shoulder movements in patients

Movements	Post-Procedure ROM	Number of patients (50)
Abduction	No limitation	All
Internal rotation	10° limitation	04 out of 50
External rotation	10° limitation	03 out of 50
Forward flexion	No limitation	All
Extension	No limitation	All
Adduction	No limitation	All

Table 3: Showing statistical analysis, OSS- oxford shoulder score

Paired Samples Statistics

		Mean	N	Std. Deviation	T Test	P Value
Paired Sample T Test	PRE-OSS	31.32	50	8.948	16.91	0.001
	POST-OSS	13.02	50	1.974		

Table 4: Showing correlations for pre-OSS and post- OSS, OSS- oxford shoulder score

Correlations			
		PRE-OSS	POST-OSS
PRE-OSS	Pearson Correlation	1	0.721**
	P Value		0.001
POST-OSS	Pearson Correlation	0.721**	1
	P Value	0.001	

**Correlation is significant at the 0.01 level (2-tailed).

Correlation and significance is calculated for pre and post OSS which showed a positive correlation $r = 0.721$ ($r =$ Pearson correlation Coefficient) - Indicates a correlation and the p - value is <0.05 which is significant.

Correlation and regression analysis between DM and post procedural ROM shows an absence of correlation $r=0$ indicating absence of correlation and P - value is 1 which indicates that there is no significance.

Table 5: Showing comparison of different studies

Study	Patients	Used material	Number of injections	Outcome
Rajendranath et al ⁸ (2017)	118	Normal Saline, corticosteroid	Single	Good
Clement et al ¹⁸ (2013)	57	40ml saline, steroid, local anaesthetic	Single	62.71%
Tveita et al ¹⁹ (2008)	62	10ml saline, steroid, local anaesthetic	3 injections at 2 weeks interval	64.51%
Quraishi et al ¹¹ (2007)	19	Various amounts of saline, 30mg steroid, local anaesthetic	single	81%
Vad VB et al ²¹ (2003)	22	60 ml saline	Single	86.36%
Gavant et al ²⁰ (1994)	16	30ml saline, steroid, local anaesthetic	Single	87.50%
Jacob's et al ¹⁷ (1991)	47	20ml saline, steroid, local anaesthetic, air	3 injections at 6 weeks interval	82%
Our study	50	80-100 ml saline, viscosupplementation (HYLAN GF20)	Single	86%

Discussion

Frozen shoulder^{1,2} is characterised by pain and stiffness of the shoulder with restriction of active and passive shoulder movements and results in functional disability and thus affecting the activities of daily living. The aetiology of frozen shoulder is unknown, some studies reported pathophysiological similarity to Dupuytren's contracture.³ Some studies reported resolution of the frozen shoulder often takes up to 2 to 3 years and even more.³ We managed all frozen shoulder patients by distension hydrodilatation and viscosupplementation^{15,16} under fluoroscopy guidance as a day care procedure. It is minimally invasive radiological intervention. Distension hydrodilatation⁶⁻⁸ works by the injected fluid into the shoulder joint under pressure will distends the joint volume by disrupting the adhesions and scar tissue and thereby improves range of movements of shoulder. Some studies⁸⁻¹⁰ reported that they infused normal saline and corticosteroid; some studies have used air¹⁷ instead of saline.

We distended shoulder joint capsule by injecting 80-100 ml normal saline combined with injection HYLAN GF 20 (inj. Synviscone 8mg/ml)^{10,12} under fluoroscopy guidance. HYLAN GF 20 (inj. Synviscone) is an elastoviscous fluid contains hylan A and hylan B polymers produced from chicken combs. Hyaluronan is a chemically cross linked high molecular weight long-chain polymer containing repeating disaccharide units of sodium-glucuronate-N-acetyl glucosamine. HYLAN GF20 elasticity and molecular weight is similar to the molecular weight and elasticity of the natural lubricants in the joints of young people. Inj.Synviscone reduces pain and improves shoulder function.¹³ Adverse effects rarely seen after inj.Synviscone ($<2\%$ incidence), it includes pain, swelling, heat, and redness, fluid accumulation in or around the joint.

Average time taken for procedure was 15 minutes. Post-procedure Shoulder range of movement initiated from 2nd day of post procedure in sequential manner i.e. assisted active range of movements followed by active range of movements and strengthening of peri-shoulder musculature over a period

of 2-3 weeks. We observed decrease in the intensity of pain as early as 2nd day following the procedure and complete relief of pain by the end of 2nd week. Clinical outcomes of the present study showed an 86% (43 of 50 patients) success rate regarding attained full range of shoulder movements with no recurrence of stiffness. In remaining 14% (7 of 50 patients), 3 patients had restriction of 10⁰ of external rotation, 4 had restriction of 10⁰ of internal rotation. Clinical results were favourable, even when the average follow-up was short (6 months to 1 year). Clinical outcomes in diabetic patients also showed improvement. All patients were able to do their regular activities like combing hair and to reach objects above head level. No complications occurred during or post-procedure in our study.

Rajendranath et al⁸ study (2017) reported distension hydrodilatation in 118 cases with frozen shoulder had significant functional improvement after procedure. Quraishi et al study¹¹ (2007) reported post-hydrodilatation outcomes in 19 patients with 81% patients get near shoulder function. For distension he used 20 ml saline, 30 mg steroid and local anaesthetic.

Clement et al study¹⁸ (2013) reported post-hydrodilatation outcomes in 51 patients with a mean follow-up of 14 months. For distension of shoulder he used saline 40ml and mixture of triamcinolone and lignocaine. 62.74% of patients (32 of 51) get normal or near-normal shoulder function as assessed by the Oxford Shoulder Score. One patient developed septic arthritis after hydrodilatation. This study shows similar outcome in diabetic patients.

Tveita et al study¹⁹ (2008) reported good outcome in 40 of 62 (64.51%) patients, for distension he used 10ml saline, local anaesthetic and steroid. He gave 3 injections at 2 week intervals.

Gavant et al²⁰ (1994) reported that 87.50% (14 of 16) patients experienced immediate pain relief and increased range of motion after infiltration of 30 mL of mixture of saline, lidocaine and corticosteroids.

Jacob's et al study¹⁷ (1991) reported post-hydrodilatation outcomes in 47 patients with 82% patients get near shoulder function. For distension he used 20 ml saline, steroid and local anaesthetic. In this study he gave 3 injections at 6 week intervals.

In a prospective²¹ study (2003) by Vad VB, Sakalkale D, Warren RF, 22 patients underwent capsular distension followed by a physiotherapy program followed for a period of one year. 19 patients showed an improved range of motion (86.36%). The three patients without significant improvement had more severe disease at the time of intervention.

In our study we infused 60-80ml normal saline and injection Synviscone 8mg/ml for distension of shoulder joint in 50 patients, 86% (43 of 50) patients experienced pain relief and get normal shoulder movements, out of remaining 7, 3 patients had restriction of 10⁰ of external rotation, 4 patients had restriction of 10⁰ of internal rotation, all these 7 patients were associated with type 2 diabetes. A significant improvement in functional scores was present with oxford shoulder score (OSS) pre-procedure mean was 31.34 post-

procedure mean was 13.12 (decreased by 18.22) and the VAS score mean was also reduced from 8.42 to 1.14. None of the patients had any complications during or post-procedure.

Conclusion

Distension hydrodilatation and viscosupplementation injection HYLAN GF20 (inj. Synviscone) is a definitive treatment modality in patients with frozen shoulder. It results in significant and sustained relief of pain and also results in regaining full range of shoulder movements in patients with frozen shoulder and even in diabetic cases without any complications during or post-procedure.

Conflict of interest

None

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