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Dr. Harish Babu J

M.S (Ortho), Department of Orthopaedics, Saveetha Medical College and Hospital, Thandalam, Chennai, Tamil Nadu, India

Dr. Gadhamsetty Sai Ganesh

M.S (Ortho), Department of Orthopaedics, Saveetha Medical College and Hospital, Thandalam, Chennai, Tamil Nadu, India

Dr. Shri Vishnu M

M.S (Ortho), Department of Orthopaedics, Saveetha Medical College and Hospital, Thandalam, Chennai, Tamil Nadu, India

Dr. C Nissanth

M.S (Ortho), Department of Orthopaedics, Saveetha Medical College and Hospital, Thandalam, Chennai, Tamil Nadu, India

Dr. Yeshwanth Subash

D.N.B (ORTHO), M.N.A.M.S Professor of Orthopaedics, Saveetha Medical College and Hospital, Thandalam, Chennai, Tamil Nadu, India

Corresponding Author:

Dr. Yeshwanth Subash

D.N.B (ORTHO), M.N.A.M.S Professor of Orthopaedics, Saveetha Medical College and Hospital, Thandalam, Chennai, Tamil Nadu, India

Comparison of functional outcome between corticosteroid injection alone vs combination with physiotherapy for frozen shoulder

Dr. Harish Babu J, Dr. Gadhamsetty Sai Ganesh, Dr. Shri Vishnu M, Dr. C Nissanth and Dr. Yeshwanth Subash

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Abstract

Introduction: Most common cause for shoulder pain and disability is frozen shoulder affecting approximately 2-4% of the general population. With the increase in age there is increase in the incidence of frozen shoulder with peak incidence of fifth and sixth decade and slightly female predominance. The aim of this study is to investigate the additional effect of physiotherapy after corticosteroid injections in first 2 stages of frozen shoulder.

Methods: This is randomised controlled trial. Painful frozen shoulder is the eligible criteria for this study. Patients were randomised into two group after obtaining patients consent. Ultrasound guided corticosteroid injection intra-articularly was given to both the groups. The physiotherapy group underwent physiotherapy whereas the other group did not. The shoulder pain and disability index were the primary outcome index. Range of motion and pain were the secondary outcome index. The patients were followed up after 6, 12, 26 weeks.

Result: A number of 30 patients were considered in this study in order to compare the relationship between CSI with and without physiotherapy out of which 16 patients were in the non-PT and 14 were in PT group. At baseline range of movements such as external rotation, abduction, anterior flexion was equally restricted in both the groups with mean range of 5.8 degree, 52.4 degree and 83.6 degree respectively. At the end of 26 weeks shoulder range of movements measurements were available for 90% of patients. No complications or adverse events were reported in both groups.

Conclusion: Physiotherapy along with corticosteroid injection improves ROM and functional movement restrictions in the early stage of frozen shoulder in the first 12 weeks when compared with corticosteroid alone.

Keywords: Corticosteroid's injection, SPADI scoring, frozen shoulder, adhesive capsulitis

Introduction

Most common cause for shoulder pain and disability is frozen shoulder affecting approximately 2-4% of the general population [1, 2]. With the increase in age there is increase in the incidence of frozen shoulder with peak incidence of fifth and sixth decade and slightly female predominance.

The usually accepted theory comprises of anterosuperior capsule, the rotator interval and the coracohumeral ligaments contracture due to inflammatory cascade. The loss of passive external rotation in frozen shoulder is due to this reason [2]. Frozen shoulder is considered to be self-limiting with three stages; the freezing, frozen, and thawing stages with unclear distinction between the stages [3, 4]. Mostly functional outcome recovers in the initial 1-3 years but remaining pain and range of motion of the shoulder joint can be for a longer time. There is no widely agreed treatment options for frozen shoulder.

There is a wide gap in the optimal management of frozen shoulder [5, 6, 7] With the advancement of treatment modalities the treatment options used are invasive manipulation and arthroscopic capsular release and less invasive management options are intra-articular CSI and physiotherapy. These are the mainstay treatments in the management of FS [8, 9] Corticosteroid injection shows positive effect on FS at least in short-term.

The role of physiotherapy in the management of FS is more unclear^[10, 11]. Supportive therapy and exercises within pain limits, has been opted as an appropriate treatment for FS. There were studies on combination of physiotherapy and CSI but with lack of support^[12]. This study is therefore to know the efficacy of additional physiotherapy after an intra-articular CSI in the management of early-stage idiopathic FS.

Materials and Methods

The approval for this study trial was obtained by the ethical committee. After obtaining the clearance the trial was registered. The study was then undertaken in the participated hospital from January 2020 to January, 2021. Patients with clinical signs of frozen shoulder were only eligible which includes pain and stiffness of the involved shoulders with no history of trauma and symptoms persisting for more than 3 months. In the numeric pain scale the required level for pain is 6 out of 10.

A minimum of 30 degree of restriction of external rotation and second direction range of movement that is abduction/forward flexion when compared with unaffected side was required as it is considered as inclusion criteria. Rotator cuff injuries and osteoarthritis are ruled out using conventional radiographic x-ray and ultrasound of the involved shoulder. CSI in the shoulder joint in the previous 6 weeks, neurological disorder, use of anticoagulants as therapeutic use are the exclusion criteria for the study.

These selection criteria help in selecting the patients as a well defined population with early-stage idiopathic frozen shoulder. Informed and written consent were obtained from all the patients included in the study.

Randomization and Interventions: Patients were included into two groups randomly. The group undergoing PT is PT-group and the one without PT is non-PT group. With the use of an online website the patients were randomly allocated into these two groups. Orthopaedic surgeons who assessed patient to be included in the study had no access to the randomization software as to secure allocation concealment. USG guided glenohumeral joint injection of 1 mL Kenacort of 40 mg in 4 mL lidocaine 1%, administered to both the groups within 2 weeks after inclusion. The participants in both the groups were clearly explained about the possible self-limiting nature of frozen shoulder.

They also received optional NSAIDs if needed. The non-PT group did not receive any form of physiotherapy. Patients were advised to use their affected arm in day-to-day activity within their pain limit. Physiotherapy was given to those patients in PT group. All participating physiotherapy professionals treated the recommended research participants twice a week for a maximum of three months, according to a predefined methodology. In accordance with the experienced physiotherapist, this physiotherapy protocol was framed.

The PT was aimed to decrease pain, increase range of motion and restoring shoulder for daily activity. Scapulothoracic movements were addressed in order to improve scapulohumeral kinematics. In the physiotherapy program active and self-assisted stretching is alone included. The intensity of physiotherapy was decided by considering the tissue irritability.

The intensity of the physiotherapy program is planned according to the tolerance of the patient. Hot packs, icing, and massage techniques were the only techniques allowed to reduce pain.

Outcome Parameters and Follow-Up: Shoulder pain and disability index (SPADI) is the main outcome parameter of this study at 26 weeks follow up, consisting 13 questions in 2

domains namely pain and disability. The responses were rated on a scale of 11 points (0-10) leading to a score between 0 (best) and 100 (worst).

Ten-point Numeric pain-rating scale (NPRS) were used to scale average pain on last week and pain at nights. With the use of goniometer and in standing position, passive range of movements are measured. With the elbow adducted to the body external rotation is measured in the horizontal plane whereas abduction and anteflexion are measured in frontal and sagittal plane respectively. On a five-point Likert scale ("worse", "unchanged", "unsatisfactory improved", "satisfactory improved" and "good to very good improved") patient satisfaction on their change in pain and function were assessed.

If the level of pain has not dropped to at least 50% repeat corticosteroid injection were allowed after 6 weeks. The patients were followed up after 6, 12 and 26 weeks.

Statistical Analysis

SPSS statistical package software was used to perform the statistical analysis. Clinical epidemiologist was the one who performed statistical review. Analysis was performed non-parametrically due to small sample size.

The demographic and baseline details were described and then compared. Mann-Whitney U tests were used to assess the treatment. P-value of <0.05 were considered statistically significant.

Results

Patient Population: A number of 30 patients were included in this study in order to compare the relationship between CSI with and without physiotherapy out of which 16 patients were in the non-PT and 14 were in PT group [Fig 1]. The mean age of the patients included in this study is approximately 50 years.

Patients having symptoms of frozen shoulder for more than 6 months (P value 0.08) are 12 and 18 had symptoms persisting less than 6 months [Fig 2]. The shoulder x-rays of all the patients were with no abnormalities. At baseline range of movements such as external rotation, abduction, anterior flexion was equally restricted in both the groups with mean range of 5.8 degree, 52.4 degree and 83.6 degree respectively [fig. 3]

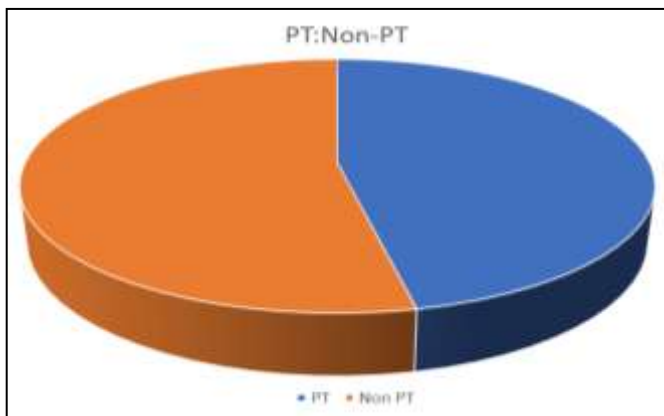
At the end of 26 weeks shoulder range of movements measurements were available for 90% of patients. No complications or adverse events were seen in both groups.

Clinical and Functional Outcome

At baseline the median total SPADI scores were 81, which indicates the severe pain and disability associated with the early stage of frozen shoulder. Both groups demonstrated significant progress at the end of the 26-week period. In the SPADI scores but there is a drastic difference between the two groups at 6 weeks follow up.

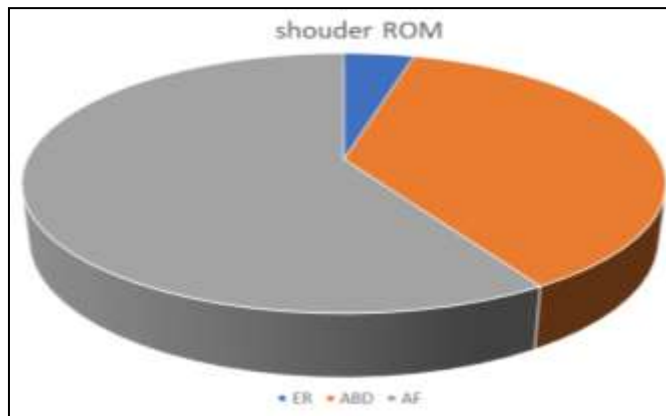
Average SPADI score of PT group at 6 weeks is 16 whereas in non-PT group it is 60 [Fig 4]. The minimal clinical importance difference of SPADI is significant (p=0.01). There is a significant increase in the passive ROM at the 6 weeks when compared with the baseline. This difference is significant in all three range of movements considered in this study but at the final follow up that is at 26 weeks this difference is still in favour of PT group but were not significant.

Only night pain at 6 weeks was in favour of the PT group with no significant differences overall. There is a slightly higher satisfaction score by the physiotherapy group at 6-week follow-up.



PT- physiotherapy

Fig 1: PT and Non- PT groups



ROM- range of motion, ER- external rotation, ABD- abduction, AF- anterior flexion

Fig 3: Shoulder ROM at baseline

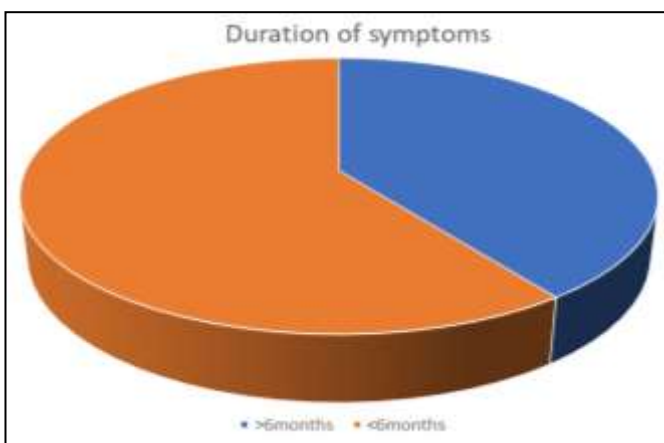


Fig 2: Duration of symptoms



PT- physiotherapy, SPADI- shoulder pain and disability index.

Fig 4: SPADI score

Table 1: Patients Demographics and data

S. No	Age/ Sex/ S	Duration of Pain	Comorbidity	With PT	Baseline				6 weeks				12 weeks				26 weeks			
					SPADI	ER	ABD	ANT.FLX	SPADI	ER	ABD	ANT.FLX	SPADI	ER	ABD	ANT.FLX	SPADI	ER	ABD	ANT.FLX
1	48/m/L	>6m	T2DM	-	85	0	50	70	40	15	45	80	45	20	65	90	15	30	85	110
2	50/f/L	<6m	T2DM	-	80	4	55	75	35	10	50	85	48	15	70	95	12	25	90	110
3	48/m/R	>6m	NIL	+	78	10	45	90	20	40	85	110	15	45	95	120	14	55	110	130
4	55/f/R	>6m	T2DM	-	60	5	60	70	60	20	55	80	35	20	70	90	16	35	90	115
5	52/m/L	>6m	NIL	+	65	8	48	95	10	35	90	115	30	40	100	130	20	50	120	155
6	50/m/L	>6m	NIL	-	68	5	55	78	65	15	50	90	50	20	75	100	15	30	95	120
7	47/f/R	<6m	T2DM	-	79	8	50	70	60	8	55	100	45	15	80	120	18	25	100	120
8	56/f/R	>6m	NIL	+	75	15	50	100	25	40	80	100	24	45	90	120	13	55	120	145
9	55/f/L	<6m	NIL	-	72	5	55	75	70	10	60	75	50	15	85	95	16	30	95	110
10	54/m/L	>6m	T2DM	+	69	9	55	90	20	30	100	120	23	40	110	140	17	50	130	160
11	52/m/L	<6m	NIL	-	60	2	50	80	55	15	75	90	55	15	90	100	19	39	100	110
12	49/m/R	<6m	NIL	-	77	0	55	80	55	20	90	95	45	25	100	110	18	36	120	125
13	50/f/L	<6m	SHTN	-	75	0	55	85	68	20	80	85	35	20	95	100	20	35	130	120
14	51/m/L	>6m	SHTN	+	78	6	60	90	15	38	100	135	30	45	120	145	22	55	130	165
15	56/f/L	<6m	NIL	-	80	0	50	75	70	15	55	75	50	18	80	90	25	30	120	130
16	57/f/R	<6m	NIL	-	80	5	40	70	40	15	50	80	45	20	85	90	23	40	90	120
17	53/m/R	<6m	SHTN	-	75	4	55	75	45	20	45	85	50	25	75	95	21	45	100	125
18	54/f/L	>6m	NIL	+	79	5	60	100	18	40	90	140	30	40	110	150	22	60	130	160
19	58/f/R	<6m	NIL	-	80	5	55	75	45	15	45	90	40	15	75	110	21	35	90	130
20	55/f/R	<6m	NIL	+	82	10	42	95	20	40	95	135	20	50	110	140	20	60	120	165
21	48/m/L	>6m	NIL	+	85	8	50	90	20	40	95	130	21	50	110	140	18	60	130	160
22	48/m/R	<6m	SHTN	-	87	8	50	80	70	15	55	95	50	20	80	100	14	35	95	120
23	60/f/R	<6m	NIL	-	87	5	55	80	75	10	60	90	55	15	90	100	18	30	100	120
24	52/m/R	<6m	SHTN	+	90	6	55	85	24	35	100	140	24	40	110	120	19	55	135	155
25	49/m/L	>6m	SHTN	+	82	5	55	80	21	30	105	149	25	40	115	120	18	55	135	150
26	47/m/R	<6m	NIL	+	70	6	60	90	20	35	100	120	28	45	120	120	19	55	140	150
27	50/m/R	<6m	NIL	+	83	6	60	90	18	40	90	120	27	50	110	130	20	60	130	155
28	52/f/R	>6m	SHTN	-	89	4	55	80	70	8	60	85	50	15	90	95	19	40	95	125
29	52/m/L	<6m	Nil	+	88	10	45	100	17	40	85	140	24	40	110	140	18	45	130	165
30	51/m/R	<6m	Nil	+	79	10	42	95	15	40	90	145	29	45	110	150	20	45	130	160

m- male, f- female, L-left, R- right, T2DM- type 2 diabetes mellitus, SPADI- Shoulder pain and disability index, ABD- abduction, ER- external rotation, Ant.Flex- Anterior flexion.

Discussion

The aim of this study is to evaluate whether physiotherapy in Frozen shoulder at early stages after intra articular steroid injection is of additional value. There is no significant clinical or functional differences between the two groups at the final follow up. But at the first follow up that is the 6 weeks, there is favorable outcome in ROM measurement, SPADI scores and NPRS for pain at night in the PT group. Passive ROM were in favor and most considered differences between the 2 groups at the 12-week follow-up. With the addition of physiotherapy there is better shoulder function with limitation in the recovery process in frozen shoulder patient after CSI. For both the groups there is good improvement in the CSI. In a study conducted by Carette *et al.* [10] the benefit of additional Physiotherapy after CSI was reported. This trial gives us information on the faster recovery of shoulder function in physiotherapy group when compared with non PT group or placebo injection along with Physiotherapy. Ryans *et al.* [11] studied a randomised control trail for the treatment strategies of frozen shoulder and concluded that the use of corticosteroids along with physiotherapy is more effective by former helping shoulder disability and pain relief and later in restoring ROM. considering both the studies and comparing it with our study the finding were quit similar that the difference were more distinct in the early follow up(6 and 12 weeks).

On the other side, some studies are against the use of PT in addressing frozen shoulder. blanchard *et al.* [12] reported a systematic review which showed physiotherapy to have inferior results when compared with CSI. Some studies even reported that physiotherapy is unadvisable in the early stages of frozen shoulder. Tissue irritability being the possible factor responsible for physiotherapy being inferior in the treatment of FS. Irritability is nothing but the tissues' ability to withstand the stress. At early stages of frozen shoulder intensive physiotherapy is unadvisable since it may worsen the symptoms of frozen shoulder. In Diercks *et al.* [13] study he reported that physiotherapy of any form has a negative effect in comparison with supportive therapy. Intra articular CSI by itself is an independent factor reducing tissue irritability [14] hence it is advised to start PT after intra-articular CSI.

This is a prospective study where the study population is clearly defined according to inclusion criteria. Rehabilitation physiotherapy was performed by specialised physiotherapist according to a uniform physiotherapy protocol. Experienced surgeons were not blinded for allotted intervention, for the assessment of ROM.

The limitation of this study is the patients included are less in number. This study is based on the primary outcome parameter SPADI. Two factors attributing to the lesser sample size are the expenses for physiotherapy and there was unexpected amount of patient not willing to participate in the eligible group. Even with this small sample size we were able to observe the positive effect of physiotherapy up to 3 months of follow up. It is to be noted that significant differences could have been made out if the study number is larger.

CSI is made mandatory in both the groups included in this study because we assumed that it may be difficult to convince to the patients to participate. No patients had crossover that is starting physiotherapy on their own once assigned to non-PT group. At 6 weeks, SPADI scores and ROM measurements were lower. In the non-Physiotherapy group could be the confounding role of diabetes in two patients in this group. There is no clear understanding on the mechanism responsible for the course of FS. Expert advice and education of the

patient are important aspect of treatment. With this study we suggest that addition of physiotherapy along with CSI for FS has upper hand in the early mobilisation and increase in the SPADI score in the first two follow ups. with time that is at the time of 26 weeks the positive effect of the physiotherapy fades out and there are no significant differences between the two group. PT can improve shoulder function and minimise the period of functional restrictions in early frozen patients during the recovery phase, which lasts up to three months.

Conclusions

Treatment of FS with intra-articular corticosteroid infiltration is successful. Up to three months of additional physical therapy can enhance shoulder function and reduce the duration of functional impairments in early-stage FS patients. The intensity of physiotherapy should be determined by tissue irritation. Future study should concentrate on populations other than those with idiopathic FSs, such as those with post-operative or post-traumatic FSs. Furthermore, conservative treatments such as injections and physiotherapy are ineffective for a small group of patients. It would be fascinating to see if these patients with a protracted and resistant course of disease might be recognised sooner rather than later.

Conflict of Interest

Not available

Financial Support

Not available

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