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Original Article

Orthopaedics Section

A Prospective Study Comparing Arthroscopic Release, Intra-articular Steroid and Physical Therapy for Frozen Shoulder

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ABSTRACT

Introduction: Frozen shoulder or Adhesive Capsulitis (AC) is a painful condition with fibrotic and contracted shoulder joint capsule. There is a lack of development of an effective treatment protocol for idiopathic AC.

Aim: To evaluate the relative efficacy of Arthroscopic Capsular Release (ACR) and intra-articular steroid injections compared to standard physical therapy in isolation for frozen shoulder.

Materials and Methods: This prospective interventional study was conducted at Maulana Azad Medical College, New Delhi, India between October 2012 to October 2015. Patients older than 40 years of age, with symptoms of AC for atleast six months, without any related trauma or surgery or uncontrolled diabetes mellitus, and who did not respond to the conservative treatment, were selected. Ten patients were recruited each in the ACR, intra-articular steroids injection, and physical therapy groups. Shoulder Range of Motions (ROM), and the pre and post-treatment Shoulder Rating Questionnaire (SRQ) scores were calculated. Data analysis was performed using a Statistical Package for the Social Sciences (SPSS version 17.0).

Results: Total 30 patients were included, of which 12 male (40%) and 18 female (60%) patients with an average age of 52.2 years were studied. There was no difference between the groups as far as the demographic characteristics were concerned. The SRQ scores and ROM in all the groups registered significant improvement compared to their pretreatment levels with a p-value <0.0001 for all three groups. However, the relative efficacy of different modes of treatment i.e. ACR, intra-articular steroid injection, and physical therapy, were found to be similar (p-value 0.165).

Conclusion: The ACR does not provide any significant advantage over less invasive treatment alternatives. Therefore the authors recommend ACR only as a last option where other less invasive treatment modalities have failed.

Keywords: Immobilisation, Management, Restricted shoulder movement, Shoulder joint capsule

INTRODUCTION

Frozen shoulder or Adhesive Capsulitis (AC) is a common disorder affecting 2-5% of the general population, wherein the shoulder joint capsule is fibrotic and contracted [1]. It generally affects elderly patients and is more commonly observed in those with diabetes and obesity [1]. It is a debilitating condition associated with night pain and restricted active and passive shoulder movements. It affects sleep, activities of daily living, leisure, and work [2]. Pathology of frozen shoulder involves active fibroblastic proliferation in the capsule of the shoulder joint, which is accompanied by the transformation of some fibroblasts to myofibroblasts [3]. Though in many cases antecedent trauma or surgery, or a period of immobilisation, may initiate the condition, in most patients, the cause remains uncertain, where it is referred to as idiopathic frozen shoulder [4].

Benign neglect with analgesia is a recommended treatment of idiopathic AC, based on the fact that the natural history of this condition has been supposed to be self-resolving [5]. Behind this lack of development of an effective treatment protocol for idiopathic AC is the quasi-scientific belief of subsequent generations of clinicians after Codman that idiopathic frozen shoulder recovers fully [6]. Shaffer B et al., have demonstrated that patients may not fully recover from the symptoms and disability of AC, even with long-term follow-up [7]. Numerous investigators over the last few decades have reported residual pain and restriction of movement in 23-60% of patients [7-11].

Treatment options for adhesive AC can be either conservative or operative. Traditionally, idiopathic AC at most institutions is treated non operatively by local heat, anti-inflammatory medications and supervised physiotherapy, followed by a home exercise program [12]. Other non surgical options for AC are oral corticosteroid and intra-articular corticosteroid injection [8]. Patients who do not respond to non operative treatment require surgical intervention like closed manipulation under anaesthesia, open surgical release, and ACR [12]. Its treatment remains controversial as there is an insufficiency of a high level of evidence in favour of any one treatment modality. A systematic review comparing conservative and surgical treatment favoured intra-articular steroid injections in terms of pain relief in the short and mid-term [13]. Only limited evidence was found regarding the effectiveness of other commonly applied treatment options such as manipulation under anaesthesia, laser therapy, and oral corticosteroids [13].

While some authors have suggested against the use of arthroscopy in either the diagnosis or the treatment of stiff shoulder [14], others have recommended its use to help delineate abnormalities, document the results of closed manipulation, and assist in distention of the contracted joint capsule [15]. Moreover, some investigators have proposed arthroscopically guided sectioning of the contracted capsule as a treatment for idiopathic AC with good short-term outcomes [16,17]. Although, there are favourable short-term and long-term reports in favour of ACR in the literature, there seems to be a paucity of similar data for an Indian sub-population. In this background, the present study was designed to prospectively test the efficacy of ACR and intra-articular steroid injections compared to a control group of patients put on standard physical therapy alone.

MATERIALS AND METHODS

This prospective interventional study was conducted in Maulana Azad Medical College, New Delhi, India from October 2012 to October 2015. Clearance from the Institutional Ethical Committee was obtained prior to the conduction of study (IRB 1234). Sample size for

the study was based on the patient load and the frequency of surgical treatment performed for frozen shoulder in the study period. Written informed consent was obtained from all patients who participated in the study.

Patients with shoulder pain around the deltoid insertion for atleast one month with inability to lie on the affected side, sleep disturbances due to night pain, restriction of both active and passive movements in all directions, a reduction in external rotation of atleast 50%, and essentially normal reported radiographs of the shoulder in Anterio-posterior (AP) view, were diagnosed as idiopathic AC of the shoulder.

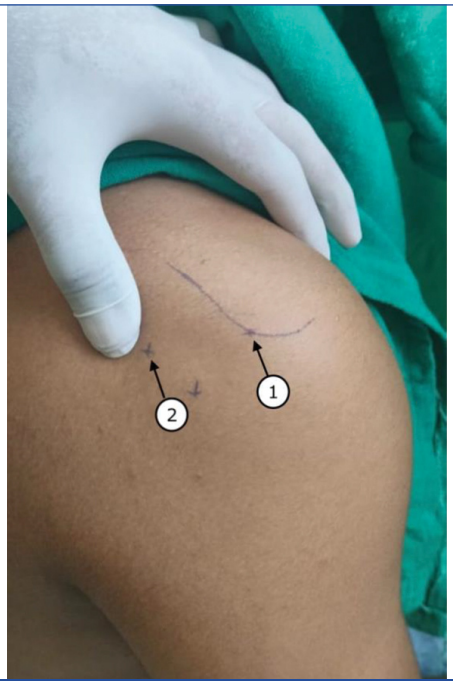
Inclusion and Exclusion criteria: Patients of more than 40 years age group of both gender in whom symptoms of AC had persisted for atleast six months were recruited for the study. Patients with a significant injury to the ipsilateral shoulder or arm and patients with the surgical procedure performed on the ipsilateral shoulder, cervical spine, thorax, and breast within the past two years, and patients with uncontrolled diabetes mellitus i.e. glycosylated Haemoglobin (HbA1c) level of more than 7%, were excluded from the study.

Study Procedure

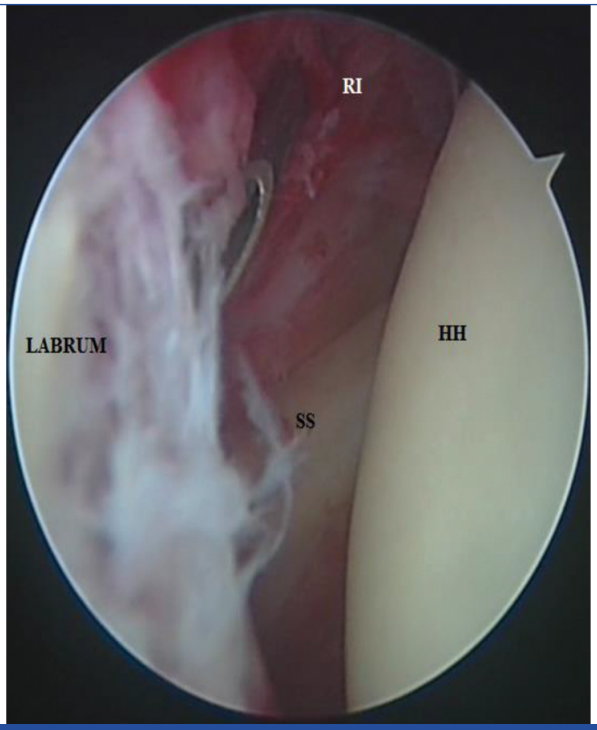
Patients qualifying the inclusion criteria and willing to undergo ACR were included in the surgical group. Ten such patients underwent ACR by a technique described below followed by supervised physiotherapy and home exercises program. Ten patients were recruited in the injection group and received intra-articular steroid injections and supervised physiotherapy followed by a home exercise program. In these patients, triamcinolone acetate 40 mg (1 mL)+lignocaine 2% (9 mL) was injected using a 21 gauge needle into the capsule of the shoulder joint through a posterior approach [Table/Fig-1], as described by Cyriax JH and Russell G [18]. Finally, 10 patients who did not receive any treatment other than the standard treatment of analgesics (diclofenac sodium 50 mg BD for 2 weeks), hot water fomentation, shortwave diathermy and supervised physiotherapy, followed by a home exercise program, were included in the control group.

Thorough history and detailed physical examination was carried out for all the patients. The ROM of the affected shoulder consisting of passive glenohumeral abduction, passive external rotation, passive internal rotation, and active overhead abduction was recorded using a goniometer. Shoulder Rating Questionnaire (SRQ) scores were also calculated. The SRQ is a validated self-administered questionnaire consisting of 21 questions analysing pain, daily activities, work, recreational or athletic activities, overall satisfaction, and areas of improvement. The total score varies from 17 to 100 points, the latter being the best functional status [19]. The questionnaire was distributed by the principal investigator to all the study participants at the start of the study. The study participants were then instructed to fill it and submit the same before the start of the study. The same questionnaire was then given to the study participants at the end of 6 months after completion of their treatment. The pre study SRQ scores were calculated for each patient at the start of the study and were compared with post study SRQ scores for assessment of functional outcomes of the three treatment modalities. Final assessment for the purposes of this study was done six months after the interventions, in which re-examination of shoulder ROMs and recording of the post-treatment scores on SRQ was performed. The improvement in the ROM and SRQ was compared for statistical significance.

Surgical technique for ACR: The procedure was performed under general anaesthesia with the patient in the beach chair position. A standard posterior portal was established, and a diagnostic arthroscopy was performed to visualise the contracted capsule and the rotator interval. An anterolateral portal was created under vision, entering the joint just anterior to the biceps tendon. Visualising from the posterior portal and introducing the radiofrequency ablator from the anterior portal, anterior capsulotomy was performed near the anterior labrum [Table/Fig-2]. The rotator interval release and freeing of the coracohumeral ligament was performed to complete the anterior structure release. The adequacy of anterior release was confirmed by performing external rotation movement, which is gained entirely with a satisfactory release. The arthroscope was then switched to the anterolateral portal, and the radiofrequency device was introduced inside the joint from the posterior portal to release the posterior capsule. A 360° capsular release was considered



[Table/Fig-1]: Clinical picture showing the technique to apply the intra-articular steroid injection via the posterior approach, the postero-lateral corner of the acromion is marked (arrow 1) and a second mark is made medial and inferior to this point which is the site of the injection (arrow 2). The latter is directed towards the tip of the coracoid palpated with index finger



[Table/Fig-2]: Arthroscopic picture taken through posterior portal sowing the position of anterio-lateral portal (needle) through which the radiofrequency wand is used in ACR.

essential in only three out of 10 patients in whom an inferior capsule release was also performed to gain adequate forward flexion and abduction movement. A gentle manipulation was performed after capsular release. The portals were approximated using single sutures.

STATISTICAL ANALYSIS

Data analysis was performed using Statistical Package for the Social Sciences (SPSS) version 17.0. The improvement in the ROM of all three groups was compared to know the relative efficacy of above mentioned three treatment modalities. The comparison was performed by computing the mean improvements in three groups and comparing it using the Independent t-test for statistical significance. Similarly, post-treatment scores on the SRQ were compared for a significant difference in improvement. Statistical significance was set at a p-value of less than 0.05 in the present study. Analysis of Variance (ANOVA) test among means of pretreatment scores was performed.

RESULTS

A total of 30 patients meeting the inclusion criteria were included in the study. The average age of patients in the ACR group was 54.4±7.4 years, in the injection group was 54.9±12.8 years, and that of patients in the control group was 46.8±5.6 years. There were two men in the ACR group. The difference in proportion of women of the three groups was statistically non significant (p-value=0.28). No significant difference in the pretreatment SRQ scores was observed between the three groups [Table/Fig-3].

Treatment modality	Mean±SD	Median	Skewness	N	p-value ANOVA
ACR group	34.9±5.3	36.150	-0.826	10	0.28
Steroid group	39.4±6.2	40.500	-0.857	10	
Conservative group	39.3±9.1	39.500	-0.823	10	
Total	37.9±7.1	37.500	-0.459	30	

[Table/Fig-3]: Means of pretreatment SRQ scores of different groups.
ACR: Arthroscopic capsular release; ANOVA: Analysis of variance; SD: Standard deviation; SRQ: Shoulder rating questionnaire

Diabetes was found to be associated with AC in a very high percentage of patients (63.3%) in the present study [Table/Fig-4]. Mean SRQ scores postintervention was 80.53 in the conservative group, 84.3 in the steroid group, and 87.9 in the ACR group [Table/Fig-5].

Age group (years)	ACR group		Steroid group		Conservative group	
	Male N (n)	Female N (n)	Male N (n)	Female N (n)	Male N (n)	Female N (n)
40-50	0	3 (1)	3 (0)	2 (1)	5 (2)	4 (3)
51-60	2 (1)	3 (3)	1 (1)	1 (1)	0	1 (1)
61-70	0	2 (2)	1 (1)	1 (1)	0	0
71-80	0	0	0	1 (1)	0	0
Total	2 (1)	8 (6)	5 (2)	5 (4)	5 (2)	5 (4)

[Table/Fig-4]: Age and gender based distribution of subjects and proportion of diabetics among each group.
ACR: Arthroscopic capsular release, N: Number of patients in the age and sex category, n: Number of diabetic patients among 'N'

Improvement gained in external rotation ROM was statistically significant (p-value<0.05) in ACR group as compared to conservative/control group at 6 months of follow-up [Table/Fig-6].

No significant difference between mean improvements of ROM of intra-articular steroid group and conservative management group was found [Table/Fig-7]. SRQ scores were also consistent with same findings and showed no statistically significant difference.

Similarly, comparison between ACR and intra-articular steroid injection revealed, no significant difference in mean improvements of ROM of the two groups [Table/Fig-8] and post-treatment SRQ score improvement was also not significantly different between the two groups.

Variables		ACR group	Steroid group	Conservative/ control group
Abduction	Pretreatment	41±13.4°	41.5±13.8°	38.5±15.6°
	Post-treatment	80.2±15.1°	80±8.2°	78±11.4°
	p-value	<0.0001	<0.0001	<0.0001
External rotation	Pretreatment	3±5.4°	15±9.7°	15±15.1°
	Post-treatment	31±9.6°	34±9.7°	29.5±11.2°
	p-value	<0.0001	0.0002	0.01
Internal rotation	Pretreatment	20.5±12.4°	29.5±9.9°	24±15.1°
	Post-treatment	37.5±12.8°	36±7.4°	34.5±6.0°
	p-value	0.007	0.05	0.03
Overhead elevation	Pretreatment	101±30.4°	85±22.7°	76±19.6°
	Post-treatment	158.5±20.3°	136±27.6°	129±27.3°
	p-value	<0.0001	<0.0001	<0.0001
SRQ score	Pretreatment	34.9±5.3	39.44±6.2	39.31±9.1
	Post-treatment	87.9±11.2	84.3±7	80.53±3.6
	p-value	<0.0001	<0.0001	<0.0001

[Table/Fig-5]: Pre and post-treatment outcomes of all parameters of the three groups.
The p-value shown is calculated using student t-test comparing the pre and post-treatment measures; p-value<0.05 considered significant

Parameter	Mean±Standard deviation		p-value*	Mean difference (95% CI)
	ACR group	Conservative group		
Improvement in external rotation in degrees	27.5±11.6	14.5±15	0.044	13 (0.404-25.596)
Improvement in internal rotation in degrees	17±15.5	10.5±12.1	0.310	6.5 (-6.568-19.568)
Improvement in abduction in degrees	39.70±12.8	39.50±10.1	0.969	0.2 (-10.628-11.028)
Improvement in elevation in degrees	57.50±20.4	53±23.1	0.650	4.5 (-16.004-25.004)
Post-treatment SRQ score	87.90±11.2	80.53±3.6	0.165	-

[Table/Fig-6]: Analysis of mean improvements in ROM and Post-treatment SRQ scores at 6 months follow-up comparing ACR group and Conservative group.
*Independent t-test; ACR: Arthroscopic capsular release; CI: Confidence interval; ROM: Range of motion; SRQ: Shoulder rating questionnaire; p-value<0.05 considered significant

Parameter	Mean improvement (in degrees)		p-value*	Mean difference (95% CI)
	Steroid group	Conservative group		
External rotation	18.5±10	14.5±15	0.492	4 (-7.977-15.977)
Internal rotation	6.5±9.1	10.5±12.1	0.416	4 (-14.087-6.087)
Abduction	38.5±10.6	39.5±10.1	0.831	1 (-10.716-8.716)
Elevation	51.0±18.5	53.0±23.1	0.833	2 (-21.683-17.683)
Post-treatment SRQ score	84.3±7	80.5±11.2	0.388	-

[Table/Fig-7]: Analysis of mean improvements of ROM and Post-treatment SRQ scores at 6 months follow-up comparing Steroid and Conservative Groups.
*Independent t-test; CI: Confidence interval; SRQ: Shoulder rating questionnaire

Parameter	Mean improvement (in degrees)±Standard deviation		p-value*	Mean difference (95% CI)
	ACR	Steroid		
External rotation	27.5±11.6	18.5±10.0	0.080	9 (-1.185-19.185)
Internal rotation	17.0±15.5	6.5±9.1	0.081	10.5 (-1.451-22.451)
Abduction	39.7±12.8	38.5±10.6	0.821	1.2 (-12.208-9.808)
Elevation	57.5±20.4	51.0±18.5	0.466	6.5 (-11.832-24.832)
Post-treatment SRQ	87.9±11.2	84.3±7.0	0.401	-

[Table/Fig-8]: Analysis of mean improvements of ROM and post-treatment SRQ scores at 6 months follow-up in ACR group and Intra-articular Steroid group
*Independent t-test; ACR: Arthroscopic capsular release; CI: Confidence interval; ROM: Range of motion; SRQ: Shoulder rating questionnaire

DISCUSSION

There is not much evidence in literature over relative efficacy of different treatment programs for AC with only a few studies drawing comparison between operative and conservative management of AC [13,20]. Recently, Forsythe B et al., have performed a network meta-analysis of randomised controlled trials comparing different managements of AC and have found no treatment to be superior to other with regard to clinical outcomes, ROM or pain reduction [21]. Analysis of our results, did not find any significant difference in the outcome at six months of follow-up in these three groups of patients, namely ACR, intra-articular steroid injection, and conservative treatment group.

First, it is noteworthy that a highly stringent inclusion criteria was followed in the present study. Only those patients were recruited who had had the symptoms for a minimum of six months and who had received conservative treatment for a minimum of six weeks. As a result, patients who started responding to conservative treatment were automatically eliminated from the study, thus removing a major confounding factor from the result analysis.

Although all the three groups of patients showed improvement in the rotational movements of glenohumeral ROM, only external rotation improvement in the ACR group was found to be statistically significant (p-value<0.05) when compared to the control group. A similar study has been conducted previously by Musil D et al., [22], wherein 27 patients with severe frozen shoulder syndrome who had failed to respond to conservative therapy were treated by ACR. Their study showed marked improvement in the ROM with a minimum of postoperative complications. However in our study, only external rotation, in ACR group was significantly better in terms of absolute values as compared to the patients in the control group. However, in actual terms it did not translate significantly into the patient satisfaction levels in the two groups as revealed by the comparison of post-treatment SRQ scores between ACR and control groups. A possible explanation for this, authors conjectured, was due to the fact that external rotation required for routine activities of daily living (ADL) had, anyway been gained by the patients in all the three groups.

Though it appears a trifle premature to draw any conclusions, but the small data i.e. 12 patients out of 20 in whom diabetes mellitus was found to be associated with idiopathic AC, did make us suspect as to whether AC can be taken as presenting symptom of diabetes mellitus in elderly population. These 12 patients were not aware of their diabetes status and had come to us with symptoms of AC. Similar observation has also been recorded by Tighe C and Oakley WS, in their study [23].

A passive restriction of external rotation has been found to be most consistent and reliable clinical sign for the diagnosis of idiopathic AC in the present study. However, it did not distinguish idiopathic from secondary AC, which is generally found to be associated with degenerative rotator cuff tendinopathies in this age group. A meticulous clinical examination and Magnetic Resonance Imaging (MRI) evaluation helped the authors in resolving this dilemma in most patients. A clinical sense has emerged from the present study that most patients, if first put on conservative line of treatment (i.e. local heat application and assisted ROM exercise followed by home exercises program with anti-inflammatory drugs titrated to the need) will respond favourably. Conservative management is usually the first line of management offered for AC at many institutions. Observations of our study make us believe that it is still an effective treatment modality with consistent results and devoid of any iatrogenic complications. We were not able to draw any superiority of ACR and Intra-articular steroid injection over this time tested management, except for a finding of significantly improved external rotation movement after six months of follow-up in ACR group. Those section of patient population who fail to respond to the conservative line of management may respond to a single shot of intra-articular steroid injection and distension therapy. However, there remains a miniscule of patient population of recalcitrant idiopathic AC who will benefit by ACR.

Limitations(s)

This study had small sample size of 30 patients and follow-up period of 6 months only. Randomised control trial would perhaps have been preferred study design in a different setting, having larger number of patients followed over a longer duration of time.

CONCLUSION(S)

Supervised physiotherapy programme should be the first line of management for patients with AC of shoulder and ACR should be reserved for only recalcitrant cases not responding to the conservative line of treatment.

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