International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 13, No. 10, October 2024 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_13.10.2024.136

ORIGINAL RESEARCH

A prospective study to evaluate the functional outcome of hydrodilatation in primary frozen shoulder [adhesive capsulitis]

[1]Dr. Ramesh Krishna. K, [2]Dr. Jagadeesh, [3]Dr. Basil. S. Mathew, [4]Dr. Preetham. N

[1]Professor, [2,3]Senior Resident, [4]Assistant Professor, Department of Orthopaedics, Bangalore Medical College and Research Institute, Bengaluru, Karnataka, India

Corresponding Author
Dr. Preetham. N
Assistant Professor, Department of Orthopaedics, Bangalore Medical College and Research Institute, Bengaluru, Karnataka, India

Received Date: 21 August, 2024 Accepted Date: 25 September, 2024

ABSTRACT

Aim: The study aimed to evaluate the effectiveness of hydrodilatation in treating primary frozen shoulder by assessing improvements in functional range of motion (ROM), pain intensity using the Visual Analogue Scale (VAS), and disability through the Shoulder Pain and Disability Index (SPADI) score. **Materials and Methods:** Twenty-five patients aged 30-70 years with first-time diagnoses of primary frozen shoulder, experiencing shoulder pain and reduced shoulder motion (flexion, abduction, and external rotation) for at least one month, were included. Exclusion criteria encompassed patients with hematologic disorders, autoimmune diseases, previous shoulder surgeries, infections, fractures, neuromuscular diseases, or those on anticoagulant therapy.Patients underwent hydrodilatation with a mixture of 5 mL 1% lignocaine, 1 mL triamcinolone (40 mg), and 40 mL normal saline. Evaluations were conducted immediately after injection, and again at 1 week, 1 month, and 6 months post-treatment, measuring ROM, VAS, and SPADI scores. **Results:** Statistical analysis showed significant improvements in shoulder ROM, along with decreased VAS and SPADI scores, at all follow-up intervals ($p < 0.001$), indicating reduced pain and improved shoulder function. **Conclusion:** Hydrodilatation proved to be a safe, effective, and cost-efficient treatment for primary adhesive capsulitis, demonstrating marked improvements in patient outcomes. However, further multi-centric studies are recommended to explore the long-term efficacy of hydrodilatation compared to alternative treatments.

Keywords: Adhesive capsulitis, Hydrodilatation

INTRODUCTION

Adhesive capsulitis, commonly referred to as "frozen shoulder," presents as a condition marked by progressive pain and the loss of both active and passive movement in the glenohumeral joint due to increasing fibrosis and contracture of the joint capsule **[1]**. It is estimated to affect 2-5% of the population, predominantly females **[2]**, and typically appears between the ages of 40 and 60 **[3]**. Most often, frozen shoulder impacts the non-dominant arm, though around 20-30% of individuals may eventually experience it in both shoulders **[4]**.The term “frozen shoulder” was initially introduced by Codman, who described it as any condition leading to rotator cuff spasms or joint adhesions **[5]**. While the exact pathogenesis of adhesive capsulitis remains unclear, factors like female sex, age, diabetes, thyroid disease, trauma, and autoimmune conditions are frequently associated. It is hypothesized that synovitis initiates a fibrotic cascade involving growth factors, particularly TGF-beta, which contributes to tissue fibrosis **[6]**.The condition generally progresses through three stages: the "freezing" stage with increasing pain and stiffness lasting up to nine months, the "frozen" stage of steady symptoms lasting between four and twenty months, and the "thawing" stage, marked by gradual improvement over five to twenty-six months **[7]**.Adhesive capsulitis is categorized as primary or secondary. Primary adhesive capsulitis is idiopathic, typically with no radiographic signs of other shoulder conditions. Secondary adhesive capsulitis may be due to conditions like chondral or labral injuries, rotator cuff tears, or immobilization following trauma or surgery **[8-10]**. Diagnosis is generally clinical, with

DOI: 10.69605/ijlbpr_13.10.2024.136

typical signs including pain, restricted motion, especially in abduction and rotations, and functional limitations like difficulty reaching behind the back **[11-12]**.Treatment options are varied, encompassing both conservative and surgical approaches, such as oral steroids, intra-articular injections, physiotherapy, hydrodilatation, and even surgical release in some cases **[13]**. Hydrodilatation, specifically, combines the anti-inflammatory effect of steroids with the mechanical expansion of the joint, which may reduce intra-articular pressure and increase shoulder volume. This study was conducted to further evaluate the effectiveness of hydrodilatation in managing primary frozen shoulder, with a focus on improving pain, mobility, and function in affected patients.

MATERIAL AND METHODS

In this prospective interventional study, conducted at Victoria & Bowring & Lady Curzon Hospital from February 2021 to August 2022, 25 patients aged 30-70 years with symptoms indicative of Adhesive Capsulitis were enrolled after obtaining ethical clearance. Eligible participants included patients who had shoulder pain for a minimum of one month, had lost more than one-third of passive shoulder movement (flexion, external rotation, and abduction), had no prior treatment for the condition, and presented normal shoulder radiographs. Exclusion criteria encompassed glenohumeral arthritis, previous shoulder surgeries, neuromuscular disease, secondary frozen shoulder, shoulder infections, recent trauma, skin issues at the injection site, hematological disorders, anticoagulant or antiplatelet therapy, and allergies to study medications.

Upon enrollment, patients' demographic and clinical data were documented, and baseline shoulder range of motion (ROM), pain scores (VAS), and functional status (SPADI) were recorded. Diagnostic ultrasonography of the affected shoulder confirmed active-phase Adhesive Capsulitis, characterized by restricted supraspinatus movement, a thickened coracohumeral ligament, echogenic material around the biceps, and increased vascularity.

Intervention

Under aseptic conditions, a combination of 1% lignocaine (5 mL), Triamcinolone 40 mg (1 mL), and normal saline (40 mL) was injected into the glenohumeral joint. The injection was administered 2 cm below and medial to the acromion, with the needle angled towards the coracoid process to rupture the joint capsule, indicated by a reduction in resistance.

Post-Procedure Protocol

Post-injection, patients received a 5-day regimen of Paracetamol and Tramadol for pain relief. They were also advised to perform home-based ROM exercises, including pendulum movements, wall climbing, and stretching exercises.

Follow-Up and Assessments

Follow-up assessments were conducted at 1 week, 1 month, and 6 months post-intervention, evaluating pain (VAS), functional outcomes (SPADI), and shoulder ROM. Adverse events or complications, if any, were documented.

Statistical Analysis

Data was analyzed using SPSS version 22. Frequencies and proportions were used for categorical data, while means and standard deviations described continuous data. The normality of continuous variables was tested using Kolmogorov–Smirnov and Shapiro–Wilk tests. Repeated Measures ANOVA (RMANOVA) was employed to identify significant changes over time, with the post hoc Bonferroni test for intergroup comparisons. Graphs were generated using MS Excel and Word, with a p-value <0.05 considered statistically significant.

RESULTS

Demographic and Baseline Characteristics (Table 1): The majority of participants were aged 51 to 60 years (64%), with a mean age of 55.08 ± 5.08 years. Slightly more participants were male (56%) than female (44%), and most (60%) had a right-sided shoulder condition. The duration of the shoulder condition ranged from 3 to 7 months, with a mean duration of 5.16 ± 1.21 months.

External Rotation (ER) ROM Improvement (Table 2): There was a significant increase in ER ROM from a baseline mean of 43.40 ± 3.14 to 79.20 ± 3.44 at the 6-month follow-up ($p < 0.001$). Each follow-up interval showed a progressive and significant improvement, suggesting that the intervention was effective in restoring ER motion over time.

Abduction ROM Improvement (Table 3): Similarly, abduction ROM improved significantly from a baseline mean of 69.60 ± 9.23 to 152.80 ± 5.42 at 6 months ($p < 0.001$). This significant improvement across all follow-up periods indicates the intervention's effectiveness in enhancing shoulder abduction.

Flexion ROM Improvement (Table 4): Flexion ROM showed substantial improvement, with baseline values of 35.60 ± 11.49 increasing to 146.40 ± 5.11 by the 6-month mark ($p < 0.001$). This significant increase highlights the intervention's effectiveness in improving flexion range over time.

ER Restriction Reduction (Table 5): Restriction in ER decreased significantly from a baseline mean of 46.60 ± 3.14 to 11.00 ± 3.54 at 6 months ($p < 0.001$). This reduction in restriction indicates the intervention's success in alleviating stiffness associated with ER.

Abduction Restriction Reduction (Table 6): Abduction restriction also decreased markedly, from 109.60 ± 9.23 at baseline to 27.40 ± 5.23 at 6 months ($p < 0.001$). The steady decrease in abduction

DOI: 10.69605/ijlbpr_13.10.2024.136

restriction further supports the intervention's benefit in restoring shoulder mobility.

Flexion Restriction Reduction (Table 7): Flexion restriction showed significant improvement, with baseline values of 144.40 ± 11.49 reduced to 33.60 ± 5.11 at 6 months ($p < 0.001$). This marked decrease in restriction highlights the intervention's effectiveness in reducing flexion-related limitations.

VAS Score for Pain (Table 8): Pain levels, as measured by the Visual Analogue Scale (VAS), significantly decreased from a baseline mean of 7.00 ± 0.58 to 0.88 ± 0.60 at 6 months ($p < 0.001$). The continuous decrease across each follow-up interval reflects the intervention's success in pain reduction.

SPADI Score for Disability (Table 9): The Shoulder Pain and Disability Index (SPADI) score, which assesses functional disability, decreased significantly from 75.28 ± 7.18 at baseline to 26.04 ± 4.50 at 6 months ($p < 0.001$). This reduction signifies substantial improvement in functional abilities and reduced disability due to the intervention.

Table 1: Demographic and Baseline Characteristics of Participants

Characteristic	Category	Count	Percentage (%)
Age Group	<50 years	5	20.0%
	51 to 60 years	16	64.0%
	>60 years	4	16.0%
	Total	25	100.0%
	Mean Age		55.08 ± 5.08
Sex	Female	11	44.0%
	Male	14	56.0%
	Total	25	100.0%
Side of Affected Shoulder	Left	10	40.0%
	Right	15	60.0%
	Total	25	100.0%
Duration of Shoulder Condition	3 months	3	12.0%
	4 months	4	16.0%
	5 months	7	28.0%
	6 months	8	32.0%
	7 months	3	12.0%
	Total	25	100.0%
	Mean Duration		5.16 ± 1.21

Table 2: External Rotation (ER) Range of Motion (ROM) Distribution Across Follow-Up Periods

Time Point	N	Mean ROM (ER)	SD	95% CI Lower	95% CI Upper	F Value	P Value
Baseline	25	43.40	3.14	42.11	44.69	**17203.72**	<0.001
1 Week	25	54.20	3.12	52.91	55.49		
1 Month	25	69.40	3.33	68.03	70.77		
6 Months	25	79.20	3.44	77.78	80.62		

Table 3: Abduction ROM Distribution at Different Periods of Follow-Up

Time Point	N	Mean ROM (Abduction)	SD	95% CI Lower	95% CI Upper	F Value	P Value
Baseline	25	69.60	9.23	65.79	73.41	**11415.74**	<0.001
1 Week	25	89.80	6.69	87.04	92.56		
1 Month	25	116.60	4.01	114.95	118.26		
6 Months	25	152.80	5.42	150.56	155.04		

Table 4: Flexion ROM Distribution at Different Periods of Follow-Up

Time Point	N	Mean ROM (Flexion)	SD	95% CI Lower	95% CI Upper	F Value	P Value
Baseline	25	35.60	11.485	30.859	40.341	**3857.79**	<0.001
1 Week	25	60.00	11.815	55.123	64.877		
1 Month	25	93.40	6.727	90.623	96.177		
6 Months	25	146.40	5.107	144.292	148.508		

DOI: 10.69605/ijlbpr_13.10.2024.136

Table 5: ER Restriction Distribution at Different Periods of Follow-Up

Time Point	N	Mean Restriction (ER)	SD	95% CI Lower	95% CI Upper	F Value	P Value
Baseline	25	46.60	3.136	45.306	47.894	**3713.143**	<0.001
1 Week	25	34.60	3.136	34.511	37.089		
1 Month	25	20.60	3.329	19.226	21.974		
6 Months	25	11.00	3.536	9.541	12.459		

Table 6: Abduction Restriction Distribution at Different Periods of Follow-Up

Time Point	N	Mean Restriction (Abduction)	SD	95% CI Lower	95% CI Upper	F Value	P Value
Baseline	25	109.60	9.233	105.789	113.411	**5269.24**	<0.001
1 Week	25	90.20	6.690	87.439	92.961		
1 Month	25	63.40	4.010	61.745	65.055		
6 Months	25	27.40	5.228	25.242	29.558		

Table 7: Flexion Restriction Distribution at Different Periods of Follow-Up

Time Point	N	Mean Restriction (Flexion)	SD	95% CI Lower	95% CI Upper	F Value	P Value
Baseline	25	144.40	11.485	139.659	149.141	**4779.757**	<0.001
1 Week	25	121.20	13.251	115.730	126.670		
1 Month	25	86.60	6.727	83.823	89.377		
6 Months	25	33.60	5.107	31.492	35.708		

Table 8: VAS Score Distribution at Different Periods of Follow-Up

Time Point	N	Mean VAS Score	SD	95% CI Lower	95% CI Upper	F Value	P Value
Baseline	25	7.00	0.577	6.762	7.238	**1774.842**	<0.001
1 Week	25	3.52	0.823	3.180	3.860		
1 Month	25	2.16	0.800	1.830	2.490		
6 Months	25	0.88	0.600	0.632	1.128		

Table 9: SPADI Score Distribution at Different Periods of Follow-Up

Time Point	N	Mean SPADI Score	SD	95% CI Lower	95% CI Upper	F Value	P Value
Baseline	25	75.28	7.179	72.317	78.243	**3345.371**	<0.001
1 Week	25	67.08	6.964	64.206	69.954		
1 Month	25	47.64	4.517	45.775	49.505		
6 Months	25	26.04	4.495	24.184	27.896		

DISCUSSION

Primary adhesive capsulitis, or “frozen shoulder,” is a common condition in orthopedic clinics, characterized by spontaneous onset of shoulder pain and significant limitation of both active and passive shoulder motion. It is one of the most prevalent causes of shoulder pain in the outpatient setting, affecting about 2% to 5% of the population, with a majority of cases seen in females [2]. Typically, the condition affects individuals aged 40-60, with the non-dominant hand being more frequently involved [3]. Additionally, about 20% to 30% of those affected will develop the condition in the opposite shoulder [4].In our study, most subjects fell in the age group of 51 to 60 years (64%), with a mean age of 55.08 ± 5.08 years, showing a slight male predominance. Interestingly, the dominant shoulder was more frequently affected, contrasting with existing literature that suggests a higher prevalence in the non-dominant shoulder. This disparity calls for long-term follow-up studies and meta-analyses encompassing larger populations.Adhesive capsulitis is often self-limiting, but up to 40% of patients may experience persistent symptoms beyond three years [14]. The chronic nature of this condition and its impact on quality of life highlight the need for effective treatment options. However, randomized controlled trials to date provide limited data on the effectiveness of treatment options, including NSAIDs, corticosteroid injections, and physiotherapy. Hence, more robust clinical trials are required to establish the efficacy of these treatments for periarthritis.Treatment for frozen shoulder ranges from conservative methods such as oral medications, physical therapy, and steroid injections to more intensive interventions like hydrodilatation and surgical procedures, including manipulation under anesthesia and arthroscopic capsular release. Among these, hydrodilatation is recognized for its day-care convenience and effectiveness, offering comparable or superior outcomes to corticosteroid injections

DOI: 10.69605/ijlbpr_13.10.2024.136

without the need for general anesthesia, making it suitable for patients with multiple comorbidities [15].Hydrodilatation works by adjusting glycosaminoglycan concentrations in the joint capsule and mechanically alleviating shoulder stiffness. In this study, we sought to evaluate hydrodilatation's efficacy in our clinical setup, focusing on patients with primary frozen shoulder within the most commonly affected age range. Our results demonstrated a significant increase in shoulder range of motion (ROM) and pain relief, particularly in external rotation (ER), abduction, and flexion. Specifically:ER ROM improved from 43.40° ± 3.14 at baseline to 79.20° ± 3.44 at six months, showing a significant increase between each follow-up point ($p < 0.001$).Abduction ROM increased from 69.60° ± 9.23 at baseline to 152.80° ± 5.42 at six months ($p < 0.001$).Flexion ROM improved from 35.60° ± 11.49 at baseline to 146.40° ± 5.11 after six months ($p < 0.001$).Pain levels also significantly decreased, with VAS scores dropping from 7.00 ± 0.58 at baseline to 0.88 ± 0.60 at six months. SPADI scores, reflecting functional ability, decreased from 75.28 ± 7.18 at baseline to 26.04 ± 4.50, demonstrating a marked improvement in quality of life.Comparative studies, such as that by Mun SW et al. [16], have shown similar age distributions in frozen shoulder cases, with an average affected age of 59.89 ± 9.33 years. Furthermore, our findings align with Calis et al.'s 2019 study, which recorded a mean duration of symptoms around five months [17].Our hydrodilatation approach used 40ml of saline, consistent with other studies such as Buchbinder et al. [18], who reported a mean volume of 43ml. Variations in GH joint volume likely depend on the degree of shoulder joint contraction and patient-specific factors. Rymurk et al. suggested in a meta-analysis that saline volumes should be injected until resistance is felt, with variations based on patient characteristics [15].Ultimately, our findings underscore hydrodilatation's potential to restore near-normal shoulder ROM and alleviate pain in frozen shoulder, supporting it as a practical, outpatient treatment option.

CONCLUSION

In our study, there was a significant improvement in terms of clinical and functionaloutcome in patients who underwent hydrostatic saline dilatation with intraarticularcorticosteroidinjection andphysiotherapy of the shoulder. However, multicentricrandomizedcontrolledtrialsarerequiredtoes tablishtheefficacy of Hydrodilatation over long term follow up period and to further strengthenevidence-basedpracticein treatment of Adhesive Capsulitis.

REFERENCES

1. Neviaser J. Adhesive capsulitis of the shoulder: a study of the pathological findings in periarthritis of the shoulder. *J Bone Joint Surg*. 1945;27:211-22.
2. Binder AI, Bulgen DY, Hazleman BL, Roberts S. Frozen shoulder: a long-term prospective study. *Ann Rheum Dis.* 1984;43(3):361-364.
3. Lloyd-Roberts GC, French PR. Periarthritis of the shoulder: a study of the disease and its treatment. *Br Med J*. 1959;1(5137):1569-1571.
4. Levine WN, Kashyap CP, Bak SF, Ahmad CS, Blaine TA, Bigliani LU. Nonoperative management of idiopathic adhesive capsulitis. *J Shoulder Elbow Surg.* 2007;16(5):569-573.
5. Codman EA. *The Shoulder: Rupture of the Supraspinatus Tendon and Other Lesions in or about the Subacromial Bursa*. Codman EA, editor. Boston Mass.: T. Todd Company printers; 1934. 78–215 p.
6. Rodeo SA, Hannafin JA, Tom J, Warren RF, Wickiewicz TL. Immunolocalization of cytokines and their receptors in adhesive capsulitis of the shoulder. *J Orthop Res.* 1997;15(3):427-436.
7. Griesser MJ, Harris JD, Campbell JE, Jones GL. Adhesive capsulitis of the shoulder: a systematic review of the effectiveness of intra-articular corticosteroid injections. *J Bone Joint Surg Am.* 2011;93(18):1727–33.
8. Xiao RC, Walley KC, Deangelis JP, Ramappa AJ. Corticosteroid injections for adhesive capsulitis: A review. *Clin J Sport Med.* 2017;27(3):308–20.
9. Yip M, Francis A-M, Roberts T, Rokito A, Zuckerman JD, Virk MS. Treatment of Adhesive Capsulitis of the Shoulder. *JBJS Rev.* 2018 Jun;6(6)
10. Neviaser AS, Hannafin JA. Adhesive capsulitis: A review of current treatment. *Am J Sports Med.* 2010;38(11):2346–56.
11. Grey RG. The natural history of "idiopathic" frozen shoulder. *J Bone Joint Surg Am.* 1978 Jun;60(4):564. PMID: 670287.
12. Chauhan S, Kothari SY, Laisram N. Comparison of ultrasonic therapy, sodium hyaluronate injection and steroid injection in the treatment of periarthritis shoulder. *IJPMR.* 2012;23(3):105-10.
13. Dias R, Cutts S, Massoud S. Frozen shoulder. *BMJ.* 2005;331(7530):1453–56.
14. Buchbinder R, Hoving JL, Green S, et al. Short course prednisolone for adhesive capsulitis (frozen shoulder or stiff painful shoulder): A randomized, double-blind, placebo-controlled trial. *Ann Rheum Dis.* 2004;63(11):1460-1469.
15. Rymaruk S, Peach C. Indications for hydrodilatation for frozen shoulder. *EFORT Open Rev.* 2017;2(11):462-468.
16. Mun SW, Baek CH. Clinical efficacy of hydrodistention with joint manipulation under interscalene block compared with intra-articular corticosteroid injection for frozen shoulder: a prospective randomized controlled study. *J Shoulder Elbow Surg.* 2016;25(12):1937-1943.
17. Talay Çalış H, Karabaş Ç, Güler E. Effects of Platelet-rich Plasma Injection on Adhesive Capsulitis: An Interventional Case Series. *Erciyes Med J.* 2019;41(1):102-104.
18. Buchbinder R, Zadro JR, O'Keeffe M, et al. Diagnostic Labels for Rotator Cuff Disease Can Increase People's Perceived Need for Shoulder Surgery: An Online Randomized Controlled Experiment. *J Orthop Sports Phys Ther*. 2021;31(0):1-45.