Scholars Journal of Applied Medical Sciences
Abbreviated Key Title: Sch J App Med Sci
ISSN 2347-954X (Print) | ISSN 2320-6691 (Online)
Journal homepage: https://saspublishers.com

OPEN ACCESS

Orthopaedic Surgery

Comparison between Intra-Articular Corticosteroid Injection with Physiotherapy and Corticosteroid Injection Alone in Management of Early Stage Frozen Shoulders: A Randomized Clinical Trial

Md. Nasiruddin[1*], Mushfique Manjur[2], Md. Sazzadul Haque[3], Md. Jafrul Islam[4], Md. Kamrul Islam[5], Md. Alamgir Hossain[6]

[1]Md. Nasiruddin, Professor, Department of Orthopaedic Surgery, Monno Medical College Hospital, Manikganj, Dhaka, Bangladesh
[2]Mushfique Manjur, Assistant Professor, Department of Orthopaedic Surgery, Monno Medical College Hospital, Manikganj, Dhaka, Bangladesh
[3]Md. Sazzadul Haque, Assistant Professor, Department of ENT, Monno Medical College Hospital, Manikganj, Dhaka, Bangladesh
[4]Md. Jafrul Islam, Assistant Professor, Department of Surgery, Monno Medical College Hospital, Manikganj, Dhaka, Bangladesh
[5]Md. Kamrul Islam, Assistant Professor, Department of Paediatrics, Monno Medical College Hospital, Manikganj, Dhaka, Bangladesh
[6]Md. Alamgir Hossain, Assistant Professor, Department of Paediatric Surgery, Basundhara Ad-din Medical College Hospital, Keraniganj, Dhaka, Bangladesh

DOI: 10.36347/sjams.2023.v11i10.009 | **Received:** 28.08.2023 | **Accepted:** 01.10.2023 | **Published:** 18.10.2023

***Corresponding author:** Md. Nasiruddin
Professor, Department of Orthopaedic Surgery, Monno Medical College Hospital, Manikganj, Dhaka, Bangladesh

Abstract **Original Research Article**

***Introduction*:** Frozen shoulder (FS) is the most prevalent cause of shoulder pain and impairment, affecting 2-4% of all adults. As an appropriate strategy of treatment for FS, supportive physiotherapy treatment (PT) and exercises within the limits of pain has been recommended. ***Objective*:** To compare between intra-articular corticosteroid injection with physiotherapy and corticosteroid injection alone in the management of early-stage frozen shoulder. ***Methods*:** This prospective randomized clinical trial study was done among 23 patients with symptoms of early-stage (stage I or II) FS in the Department of Orthopedics, Monno Medical College Hospital from July to December 2022. Two groups were formed out of all the patients. While the other group (non-PT) did not receive any additional physiotherapy treatment, one group did. A follow-up was planned for weeks 6, 12, and 26. ***Results*:** Patients who had symptoms for ≥6 months was significantly higher in PT group (81.8%) in comparison to non-PT group ($p<0.05$). Patients who took physiotherapy treatment was significantly higher in PT group (72.7%) in comparison to non-PT group ($p<0.05$). The median total SPADI scores in the PT group at baseline, which were 82 (IQR: 35-86) and in the non-PT group, which were 80 (IQR: 65-87), showed the significant pain and limitations of frozen shoulder (FS) in its early stages. Both therapy groups significantly improved at the primary endpoint of 6 weeks for SPADI scores ($p<0.05$). At 6 weeks compared to baseline, passive ROM increased significantly ($p<0.05$). Each of the three ROM orientations showed significant changes in favor of the PT group after 12 weeks ($p<0.05$). At 6 weeks after baseline, both pain scores and Rand-36 physical component scale scores significantly increased ($p<0.05$). ***Conclusion*:** In the first 12 weeks of the early stage of frozen shoulder, physiotherapy in addition to corticosteroid injection improves range of motion (ROM) and functional mobility limitations compared to corticosteroid alone.

Keywords: Frozen Shoulder, Corticosteroids Injection, Physiotherapy Treatment, Tertiary Level Hospital.

INTRODUCTION

Clinically, frozen shoulder is characterized by shoulder pain that progresses to include passive and active mobility restrictions, along with normal radiography images of the gleno humeral joint [1]. A painful limitation of both active and passive movements characterizes this clinical condition [2]. It is usually a self-limiting condition that solves up within one to three years [3]. Globally, the incidence was 4% in the general population and up to 36% in diabetic individuals [4, 5]. Data on its pathophysiology include inflammation of the synovial membrane and joint capsule, which leads in adhesion between the head of the humerus and the joint capsule. FS is the most prevalent cause of shoulder pain and impairment, affecting about 2-4% of the general population [6, 7]. The frequency of frozen shoulder rises with age, with a peak incidence in the fifth and sixth decades and slightly female predominance. The commonly recognized explanation includes antero-superior capsule, rotator interval, and coraco-humeral ligament constriction as a result of an inflammatory cascade. This is the cause of FS's loss of passive external rotation [8].

FS is speculated to be self-limiting, having three stages: freezing, frozen, and thawing, with no clear distinction between them [9]. The majority of functional outcomes improve within the first 1-3 years, but residual pain and range in motion (ROM) of the shoulder joint can last for much longer. It has no well accepted therapeutic approach [10]. However, without defined cut-off criteria, distinguishing between individual stages is difficult, and a continuous spectrum is more acceptable. Functional recovery usually takes one to three years [11, 12]. Pain and restriction in shoulder joint ROM may persist for a long time [13]. There is no widely accepted consensus on the most effective treatment plan for FS [14, 15]. These are the most prevalent FS treatment techniques in both primary and secondary care settings [16].

Corticosteroid injections improved shoulder pain and range of motion, at least in the short term [17]. With the improvement of therapeutic procedures, invasive manipulation and arthroscopic capsular release are used, whereas intra- articular CSI and physiotherapy are less invasive management options. These are the major therapy for FS management [18].

METHODS

Study Design and Settings

This prospective randomized clinical trial study was commenced to compare between intra-articular corticosteroid injection with physiotherapy and corticosteroid injection alone in the management of early-stage frozen shoulder in the Department of Orthopaedics, Monno Medical College Hospital, Manikganj, Dhaka, Bangladesh.

Sample Selection Criteria

A total of 23 patients were selected conveniently. Patients were eligible for this study if they had clinical symptoms of early-stage (stage I or II) FS, such as pain and stiffness in the affected shoulder, without prior trauma that lasted at least 3 months. The exclusion criteria were that patients had a history of taking corticosteroid injections in the shoulder joint region during the past 6 weeks, previous shoulder surgery, systemic inflammatory disease, neurological problems with upper limb impairment and usage of anticoagulation therapy at a therapeutic dosage.

Patients were randomly divided into two groups. All the patients received intra-articular corticosteroid injections. One group (11 patients) took additional physiotherapy treatment (PT) and the other group (12 patients) did not take physiotherapy treatment (non-PT).

Data Collection Procedures

The studied participants were interviewed using a pretested, semi-structured questionnaire through a face-to- face interview from July to December 2022. The primary outcome was measured by the 'Shoulder Pain and Disability Index' (SPADI). Secondary outcomes were measured by pain (by the numeric pain rating scale), range of motion (ROM), quality of life (by the RAND-36 score) and patient satisfaction.

Outcome Parameters and Follow-Up

Shoulder pain and disability index (SPADI) is the main outcome parameter of this study at 26 weeks of follow- up, consisting of 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). A ten-point numeric pain-rating scale (NPRS) was used to scale average pain last week and pain at night. With the use of a goniometer and in a standing position, the passive range of movements is measured. With the elbow adducted to the body, external rotation is measured in the horizontal plane, whereas abduction and ante-flexion are measured in the frontal and sagittal planes, respectively. A five-point 'Likert scale' (worse, unchanged, unsatisfactory improved, satisfactory improved and good to very good improved) was used to assess the patient's pain changes and functions. If the level of pain has not dropped to at least 50%, repeat corticosteroid injections are allowed after 6 weeks. The patients were followed up after 6, 12 and 26 weeks.

Statistical Analysis

Data were coded, entered, edited, and cleaned cautiously and then exported into SPSS v25. Descriptive statistics such as mean, standard deviation, and percent were computed for the continuous variables of the participants. Chi-square ($\chi 2$), independent sample 't' test and Mann Whitney U tests were used to assess the treatment. A p-value of <0.05 at a 95% confidence interval was taken as significant. The results were presented in tables and charts.

Ethical Approval

The study was conducted in accordance with the 'Declaration of Helsinki' (1964). Informed written assent and consent were obtained from concerned authorities and each participant. Confidentiality of data was ensured, and unauthorized access to data was not allowed.

RESULTS

Figure 1 illustrates that a total of 23 patients were included in this study, with 12 patients in the non-PT and 11 in the PT group. All patients had normal radiographs of their shoulders. External rotation was limited in both patient groups at baseline, with a median external rotation of five degrees (IQR: 0-20) for all patients. Figure 2 shows stages of frozen shoulder among the both groups.

Table 1 depicts the demographic and patient characteristics. The mean age of the non-PT group was 50.4±6.1 years and PT group was 53.3±3.8 years. Duration of symptoms prior to intervention of the participants was significantly higher in PT group (81.8%) in comparison to non-PT group (p=0.002). 3 patients from each group were unable to work due to their FS symptoms. Three patients in each group had previously received a corticosteroid injection more than three months before enrollment. The median NPRS last week was 8 on average (IQR: 7-8.5). For 81.8% of the patients, ROM measures were available after 26 weeks. After 12 weeks, 2 patients from each group received another intra-articular corticosteroid injection. Patients who had symptoms for ≥6 months was significantly higher in PT group (81.8%) in comparison to non-PT group (p=0.002). Patients who took physiotherapy treatment was significantly higher in PT group (72.7%) in comparison to non-PT group (p=0.024).

Table 2 demonstrates that the significant pain and limitations of frozen shoulder (FS) in its early phases were corroborated by the median total SPADI scores in PT group at baseline, which was 82 (IQR: 35-86) and non-PT group 80 (IQR: 65-87). At the primary end-point of 6 weeks for SPADI scores, both treatment groups had significant improvements (p<0.05). The median SPADI total scores had decreased to 61 (IQR: 44-75) in the non-PT group and 18 (IQR: 8-36) in the PT group at the 6-week follow-up. In the non-PT group, the median SPADI score was 25 (IQR: 12-38), while in the PT group, it was 14 (IQR: 2-26). This difference was not significant (p>0.05) and higher than the SPADI's minimal clinically significant difference (range 2-38).

In both groups, passive ROM increased significantly at 6 week from baseline (p<0.05 for all comparisons). After 12 weeks, there were significant differences in favor of the PT group in each of the three ROM orientations (p<0.05 for all comparisons). All ROM assessments at the 26 week follow-up were still in favor of the PT group but were not statistically significant (p>0.05 for all comparisons).

In both groups, pain scores and RAND-36 physical component scale scores increased significantly at 6 week from baseline (p<0.05 for all comparisons), but at the 26 week follow-up were still in favor of the PT group but were not statistically significant (p>0.05 for all comparisons).

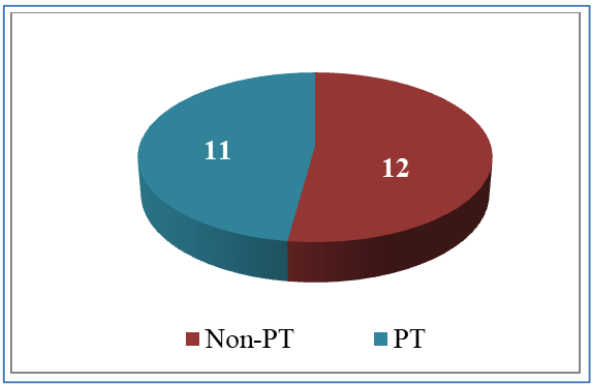

Figure 1: Distribution of the patient's groups (n=23)

Table 1: Patient's characteristics of the study (N=23)

Characteristic		**Study groups (N=23)**		**Test of significance**	**p value**
		Non-PT (n=12)	**PT (n=11)**		
		n(%)	n(%)		
Age (year)	Mean±SD	49.4±5.6	52.2±4.7	t=2.610	0.124
Gender	Male	4(33.3)	6(54.5)	$\chi2$= 11.572	0.096
	Female	8(66.7)	5(45.5)		
Duration of symptoms prior to intervention	<6 months	4(33.3)	9(81.8)	$\chi2$= 0.963	*0.002
	≥6 months	8(66.7)	2(18.2)		
Previously took corticosteroid injection	Yes	7(58.3)	7(63.6)	$\chi2$= 5.231	0.106
	No	5(41.7)	4(36.4)		
Previously took physiotherapy treatment	Yes	3(25.0)	8(72.7)	$\chi2$= 1.021	*0.024
	No	9(75.0)	3(27.3)		
Disabled to work related to shoulder	Present	3(25.0)	3(27.3)	$\chi2$= 4.124	0.924
	Absent	10(83.3)	9(81.8)		
Repeatedly took corticosteroid injection	Yes	2(16.7)	2(18.2)	$\chi2$= 1.231	0.852
	No	10(83.3)	9(81.8)		

*Statistically significant value

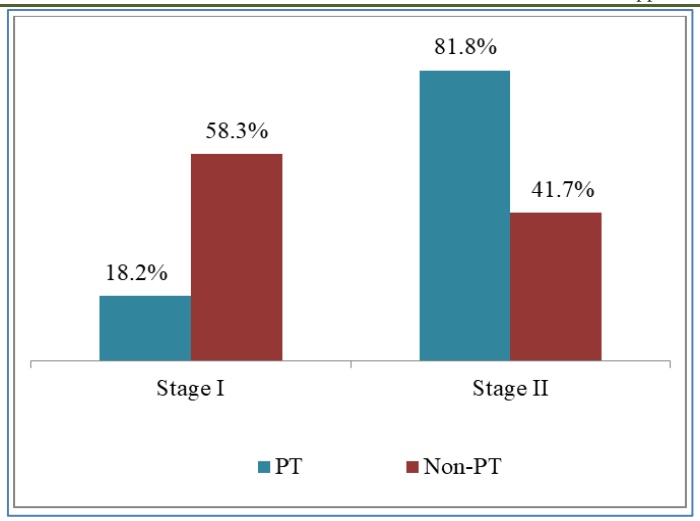

Figure 2: Stages of frozen shoulder (N=23)

Table 2: SPADI scores for pain, ROM and pain scores measurements (medians with interquartile range) (N=23)

Characteristic		Study groups (N=23)		p-value
		Non-PT (n=12)	PT (n=11)	
SPADI scores for pain, disability and total SPADI scores				
SPADI pain	At baseline	82(70-90)	86(46-92)	0.162
	At 6 weeks	71(24-79)	18(9-43)	*0.006
	At 12 weeks	48(22-68)	20(9-57)	0.215
	At 26 weeks	14(8-30)	13(4-32)	0.154
SPADI limitations	At baseline	81(58-88)	74(28-84)	0.122
	At 6 weeks	69(47-76)	11(4-36)	*0.013
	At 12 weeks	38(25-72)	14(5-58)	0.151
	At 26 weeks	10(9-50)	8(1-25)	0.351
SPADI total	At baseline	80(65-87)	82(35-86)	0.524
	At 6 weeks	61(44-75)	18(8-36)	*0.021
	At 12 weeks	42(25-72)	16(7-58)	0.127
	At 26 weeks	25(12-38)	14(2-26)	0.404
Range of motion measurements scores				
Abduction	At baseline	50(40-60)	50(41-102)	0.329
	At 6 weeks	70(43-90)	100(80-140)	*0.011
	At 12 weeks	80(65-98)	100(90-165)	*0.013
	At 26 weeks	85(80-149)	130(85-170)	0.313
Ante-flexion	At baseline	70(70-80)	95(48-120)	0.215
	At 6 weeks	90(75-111)	140(105-165)	*0.002
	At 12 weeks	90(80-146)	130(115-155)	*0.006
	At 26 weeks	100(90-160)	155(110-170)	0.155
External rotation	At baseline	0(0-5)	8(0-24)	0.214
	At 6 weeks	13(5-26)	40(30-43)	*0.011
	At 12 weeks	18(8-29)	40(25-65)	*0.014
	At 26 weeks	30(13-44)	50(35-60)	0.077
Pain scores, RAND-36 scores and patient satisfaction scores				
NPRS average last week	At baseline	8(7-9)	8(5-8)	0.337
	At 6 weeks	4(2-8)	2(1-4)	*0.019
	At 12 weeks	4(2-7)	1(0.5-5)	0.317
	At 26 weeks	3(1-4)	2(0-3)	0.241
NPRS night	At baseline	8(8-9)	9(7-9)	0.194
	At 6 weeks	4(3-7)	2(0-3)	*0.002
	At 12 weeks	5(2-7)	1(0-6)	0.311
	At 26 weeks	2(1-3)	2(0-3)	0.548

Characteristic		Study groups (N=23)		p-value
		Non-PT (n=12)	PT (n=11)	
RAND-36 PCS	At baseline	33(31-40)	39(34-46)	0.161
	At 6 weeks	43(35-46)	47 (44-52)	*0.010
	At 12 weeks	45(43-50)	47(43-55)	0.683
	At 26 weeks	43(35-56)	40(46-56)	0.576
RAND-36 MCS	At baseline	47(36-54)	44(35-54)	0.954
	At 6 weeks	49(35-52)	50(42-56)	0.353
	At 12 weeks	43(29-51)	52(40-55)	0.230
	At 26 weeks	52(50-57)	52(35-57)	0.516
Satisfaction (week)	At baseline	0(0-1)	0(0-1)	-
	At 6 weeks	3(2-3)	4(3-4)	*0.012
	At 12 weeks	2(0-4)	3(2-4)	0.212
	At 26 weeks	3(3-4)	3(3-4)	0.745

DISCUSSION

In this study, the mean age of the non-PT group was 50.4±6.1 years and PT group was 53.3±3.8 years. Duration of symptoms prior to intervention of the participants was significantly higher in PT group (81.8%) in comparison to non-PT group (p=0.002). 3 patients from each group were unable to work due to their FS symptoms. Three patients in each group had previously received a corticosteroid injection more than three months before enrollment. The median NPRS last week was 8 on average (IQR: 7-8.5). For 81.8% of the patients, ROM measures were available after 26 weeks. After 12 weeks, 2 patients from each group received another intra-articular corticosteroid injection. Patients who had symptoms for ≥6 months was significantly higher in PT group (81.8%) in comparison to non-PT group (p=0.002). Patients who took physiotherapy treatment was significantly higher in PT group (72.7%) in comparison to non-PT group (p=0.024). These findings were almost similar to the studies [4- 19].

This study revealed that the significant pain and limitations of frozen shoulder (FS) in its early phases were corroborated by the median total SPADI scores in PT group at baseline, which was 82 (IQR: 35-86) and non-PT group 80 (IQR: 65- 87). At the primary endpoint of 6 weeks for SPADI scores, both treatment groups had significant improvements (p<0.05). The median SPADI total scores had decreased to 61 (IQR: 44-75) in the non-PT group and 18 (IQR: 8-36) in the PT group at the 6-week follow-up. In the non-PT group, the median SPADI score was 25 (IQR: 12-38), while in the PT group, it was 14 (IQR: 2-26). This difference was not significant (p>0.05) and higher than the SPADI's minimal clinically significant difference (range 2-38). Carette et al., reported that SPADI score at 6th week was significantly improved in patients treated with physiotherapy and corticosteroid from baseline scores [20].

The present study showed that in both groups, passive ROM increased significantly at 6 week from baseline (p<0.05 for all comparisons). After 12 weeks, there were significant differences in favor of the PT group in each of the three ROM orientations (p<0.05 for all comparisons). All ROM assessments at the 26 week follow-up were still in favor of the PT group but were not statistically significant (p>0.05 for all comparisons). In a randomized controlled trial, patients with adhesive capsulitis were compared with intra-articular triamcilone and physiotherapy against physiotherapy alone. In one international study, patients who got intra-articular corticosteroids, he saw a significant change in their clinical condition by the sixth week (p=0.004). Additionally, he found that physical treatment enhanced external rotation by the sixth week (p=0.002) [21]. In another study, it was found that the participants with adhesive capsulitis treated with intra-articular corticosteroids and physical therapy reported similar positive outcomes by the 12th week [22].

In both groups, pain scores, rand-36 physical component scale scores increased significantly at 6 week from baseline (p<0.05 for all comparisons), but at the 26 week follow-up were still in favor of the PT group but were not statistically significant (p>0.05 for all comparisons).

However, at 6th weeks, the physiotherapy group had significantly higher overall SPADI scores, ROM measurements and NPRS scores for discomfort. Up until the 12th week of follow-up, the ROM showed the greatest differences between the groups, favoring the PT group. Up to the first three months following a corticosteroid injection in the shoulder joint, PT helps patients with FS recover from shoulder dysfunction with less restriction. Studies utilizing corticosteroid injection for FS typically show an initial satisfactory response [4- 23].

CONCLUSION

The shoulder pain and impairment could be treated more successfully with a combination of corticosteroid injection and physical therapy than with a

corticosteroid injection alone. When compared to physiotherapy, it can be used as a more effective treatment technique for the early reduction of frozen shoulder and for reducing patient discomfort.

Acknowledgments: The authors are thankful to all the participants and hospital authorities for their heartfelt cooperation.

Competing Interests: All the authors declared no competing interest.

Funding: This study did not receive any grants.

REFERENCES

1. Harris, G., Bou-Haidar, P., & Harris, C. (2013). Adhesive capsulitis: review of imaging and treatment. Journal of medical imaging and radiation oncology, 57(6), 633-643.
2. Siraj, M., Anwar, W., Iqbal, M. J., Rahman, N., & Kashif, S. (2012). Effectiveness of intra-articular corticosteroid injection in the treatment of idiopathic frozen shoulder. J Surg. Pak (International), 17, 2.
3. Sharma, S., & Jacobs, L. (2011). Management of frozen shoulder–conservative vs surgical?. The Annals of The Royal College of Surgeons of England, 93(5), 343-343.
4. Mobini, M., Kashi, Z., Bahar, A., & Yaghubi, M. (2012). Comparison of corticosteroid injections, physiotherapy, and combination therapy in treatment of frozen shoulder.
5. Nagy, M. T., MacFarlane, R. J., Khan, Y., & Waseem, M. (2013). Suppl 3: The Frozen Shoulder: Myths and Realities. The open orthopaedics journal, 7, 352.
6. Tasto, J. P., & Elias, D. W. (2007). Adhesive capsulitis. Sports medicine and arthroscopy review, 15(4), 216-221.
7. Hand, G. C. R., Athanasou, N. A., Matthews, T., & Carr, A. J. (2007). The pathology of frozen shoulder. The Journal of Bone & Joint Surgery British Volume, 89(7), 928-932.
8. Reeves, B. (1975). The natural history of the frozen shoulder syndrome. Scandinavian journal of rheumatology, 4(4), 193-196.
9. Rangan, A., Hanchard, N., & McDaid, C. (2016). What is the most effective treatment for frozen shoulder?. Bmj, 354.
10. Jayson, M. I. (1981). Frozen shoulder: adhesive capsulitis. British medical journal (Clinical research ed.), 283(6298), 1005.
11. Griggs, S. M., Ahn, A., & Green, A. (2000). Idiopathic adhesive capsulitis: a prospective functional outcome study of nonoperative treatment. JBJS, 82(10), 1398.
12. Guyver, P. M., Bruce, D. J., & Rees, J. L. (2014). Frozen shoulder–A stiff problem that requires a flexible approach. Maturitas, 78(1), 11-16.
13. Hand, C., Clipsham, K., Rees, J. L., & Carr, A. J. (2008). Long-term outcome of frozen shoulder. Journal of shoulder and elbow surgery, 17(2), 231-236.
14. Maund, E., Craig, D., Suekarran, S., Neilson, A., Wright, K., Brealey, S., ... & McDaid, C. (2012). Management of frozen shoulder: a systematic review and cost-effectiveness analysis. Health Technol Assess, 16(11), 1-264.
15. Lewis, J. (2015). Frozen shoulder contracture syndrome–Aetiology, diagnosis and management. Manual therapy, 20(1), 2-9.
16. der van Windt, D. A. W. M., Koes, B. W., Deville, W. L. J. M., Boeke, A. J. P., De Jong, B. A., & Bouter, L. M. (1998). Effectiveness of corticosteroid injections versus physiotherapy for treatment of painful stiff shoulder in primary care: randomised trial. Bmj, 317(7168), 1292-1296.
17. Shah, N., & Lewis, M. (2007). Shoulder adhesive capsulitis: systematic review of randomised trials using multiple corticosteroid injections. British Journal of General Practice, 57(541), 662-667.
18. Song, A., Higgins, L. D., Newman, J., & Jain, N. B. (2014). Glenohumeral corticosteroid injections in adhesive capsulitis: a systematic search and review. PM&R, 6(12), 1143-1156.
19. Afzal, T., Chaudhry, A. A., Gillani, S. F. U. H. S., Rafiq, A., Dar, U. Z., & Sultan, N. (2019). Intra-articular Corticosteroid with Physiotherapy Versus Physiotherapy alone for the Treatment of Frozen Shoulder: A Randomized Controlled Trial. Journal of Pakistan Orthopaedic Association, 31(03), 85-89.
20. Carette, S., Moffet, H., Tardif, J., Bessette, L., Morin, F., Frémont, P., & Blanchette, C. (2003). Intraarticular corticosteroids, supervised physiotherapy, or a combination of the two in the treatment of adhesive capsulitis of the shoulder: A placebo-controlled trial. Arthritis & rheumatism, 48(3), 829-838.
21. Ryans, I., Montgomery, A., Galway, R., Kernohan, W. G., & McKane, R. (2005). A randomized controlled trial of intra-articular triamcinolone and/or physiotherapy in shoulder capsulitis. Rheumatology, 44(4), 529-535.
22. Arslan, S., & Çeliker, R. (2001). Comparison of the efficacy of local corticosteroid injection and physical therapy for the treatment of adhesive capsulitis. Rheumatology international, 21, 20-23.
23. Vermeulen, H. M., Rozing, P. M., Obermann, W. R., Le Cessie, S., & Vliet Vlieland, T. P. (2006). Comparison of high-grade and low-grade mobilization techniques in the management of adhesive capsulitis of the shoulder: randomized controlled trial. Physical therapy, 86(3), 355-368.