

ORIGINAL RESEARCH

Efficacy of tapered short course Deflazacort and Acetaminophen versus Acetaminophen in early stage periarthritits of shoulder in adults- A Randomised controlled Trial

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ABSTRACT

Objectives: To evaluate whether a tapered short term course of Deflazacort given with Acetaminophen has any additional benefit in treatment of frozen shoulder for improving pain, function and range of motion compared to Acetaminophen alone.

Design: Randomised control trial.

Participants: 59 participants [27 Group A, 32 Group B].

Interventions: Group A – Tapered short course Deflazacort + Acetaminophen
Group B - Acetaminophen

Main outcome measures: Activity related pain, DASH, range of active motion measured at presentation, 1st, 3rd, 6th and 12th weeks.

Results: Overall VAS score outcome at 12th week was better in group-B than group-A [2(1-3) vs. 0(0-2), p value <.05]. No significant difference was seen in DASH score at presentation (42.31±15.86 vs 36.24±18.28, p value=0.183) to 12th week (34.27±14.87 vs 25.97±20.69, p value=0.079) between the two groups. In the short term, better outcome in range of movement was seen in group A in flexion upto 3 weeks [160(150-170) vs 140(130-160), p value=0.006] and extension upto 6 weeks [40(30-43.75) vs 30(30-40), p value=0.015] which was not maintained at further follow-up at 12th week. No significant difference in abduction, adduction, external rotation, internal rotation was seen between the two groups.

Conclusion: Providing a short tapered course of oral Deflazacort as an adjuvant in treatment of frozen shoulder showed short term improvement in single plane of movement which was not maintained by 12th week and with poorer outcomes in the long term on pain and no additional benefits in daily functional ability and other movements.

Keywords: Frozen shoulder, Periarthritis, Deflazacort, DASH Score.

INTRODUCTION

Frozen shoulder is described as "a condition characterised by functional restriction of both active and passive shoulder motion for which radiographs of the glenohumeral joint are essentially unremarkable except for the possible presence of osteopenia or calcific tendonitis" in Zukerman et al's updated definition ⁽¹⁾Duplay was the first to describe this condition as a

"scapulohumeralperi arthritis" in 1872. The term "frozen shoulder" was first used in 1934 by Codman.⁽²⁾

In the global population, incidence of peri arthritis is around 3% to 5%⁽³⁾, but in diabetic patients it is as high as 10-36%.⁽⁴⁾ Though frozen shoulder is a self-limiting condition and shows spontaneous recovery in 2 -3 years, about 40% of patients still continue to have symptoms, and more debilitating permanent functional loss will be present in 7%–15% of patients.⁽⁵⁾ Symptoms of frozen shoulder are caused by the development of a thickened, fibrosed joint capsule, with joint contraction, and decreased intra-articular volume.⁽⁶⁾ The clinical presentation includes a painful phase that lasts between two to nine months, Phase of stiffening or freezing lasting four to twelve months and Phase of "thawing," lasting five to twelve months.⁽¹⁾ Histologically, frozen shoulder tissue exhibits mast cells, T-cells, B-cells, and macrophages as well as fibroblasts, myofibroblasts, and chronic inflammatory cells.⁽⁷⁾

Treatment of frozen shoulder includes – non-operative management such as non-steroidal anti-inflammatory medication, physiotherapy, oral steroids, intra-articular steroid injections, hydro-dilatation, operative management such as manipulation under general anaesthesia, and arthroscopic capsular release(ACR).⁽⁸⁾ Of the above treatment methods, oral steroid therapy in combination with physiotherapy has been shown to be an effective treatment in the initial stages of peri arthritis.⁽⁹⁾ They act by inhibiting both the proliferation of mononuclear cells that are derived from human peripheral blood, and the release of inflammatory cytokines by these cells.⁽¹⁰⁾

Studies comparing the effect of oral steroids like prednisolone have been few and varied in approach.^(11,12) The available studies on various oral steroids have been described in table 1. Deflazacort has been chosen as the oral steroid for this study as it has a smaller impact on calcium metabolism⁽¹³⁾ and carbohydrate metabolism and its osteoporotic potential is much lower than other steroids.⁽¹⁰⁾

The aim of this study is to evaluate if a short course of Deflazacort can be a useful adjuvant in treatment of early stage of peri arthritis in the adult population for improving pain, function, and range of motion and to determine if its benefits could be maintained for over 12 weeks.

Table 1: Comparison of studies that used oral steroids for treatment of frozen shoulder

Study	Drug & Dose	Prednisolone equivalent	Taper-off	Total duration	Total Dose (Prednisolone equivalent)	No. of Patients (Total)
Present study	Deflazacort 18 mg	15mg	Dose decrease by 6mg per week	21 days	210mg	30(63)
Atici et al. ⁽¹⁷⁾	Prednisolone 1mg/kg/day	1mg/kg/day	Dose decreased by 10mg every 3 days	24 days	1080mg	18
Takase et al. ⁽¹⁸⁾	Prednisolone 7.5mg	7.5mg	Dose tapered by 2.5mg each week	21 days	105mg	76
Canbulat et al. ⁽⁹⁾	Methylprednisolone 0.5mg/kg/day	0.6mg/kg/day	Dose halved each week	28 days	395mg	33

Widiastuti-Samekto and Sianturi ⁽²⁰⁾	Triamcinolone 12mg/day	15mg/day	Dose decreased by 4 mg each week	21 days	210mg	14(26)
Lorbach et al. ⁽¹⁹⁾	Prednisolone 40mg/day	40mg/day	Dose decreased by 10 mg each 5 days and 5 mg for last 5 days	25 days	525mg	20(40)
Blockey et al. ⁽²¹⁾	Cortisone acetate 200mg/day	40mg/day	Dose reduced to 10 mg after 3 days and in decrements of 12.5 mg every 2 days after the second week	28 days	500mg	16(32)
Buchbinder et al. ⁽¹¹⁾	Prednisolone 30mg/day	30mg/day	None	21 days	630mg	24(50)

METHODOLOGY

STUDY DESIGN AND TREATMENT

The study was carried out in the Department of Orthopaedics, Christian Medical College Ludhiana, Punjab between 16th December 2020 to 15th June 2022. A total of 59 patients were included in this study, with 63 affected shoulder joints (4 patients having bilateral shoulder joint involvement) (Group A n=27, Group B n=32). After the ethical clearance and patients consent, the patients were randomised into two groups – either receiving Deflazacort and Acetaminophen or only Acetaminophen for 3 weeks.

RANDOMISATION

The patients were randomly allocated to both the groups using block randomisation of ratio 1:1. With six blocks and patients equally divided between two intervention groups. The randomisation list was obtained using online software Sealed Envelope Ltd. 2020. Available from: <https://www.sealedenvelope.com/simple-randomiser/v1/lists>

STUDY PARTICIPANTS

The patients were recruited from the Out-patient Department of CMC Hospital. The inclusion criteria were as follows -

1. Clinical Early stage (1 & 2) of peri-arthritis.
2. Shoulder pain and stiffness in one shoulder for 3 weeks or more.
3. Restriction of passive motion by 30^o or more in two or more planes.
4. Mild to moderate pain (VAS Score 1-6)
5. Age of 18 years or above

Exclusion Criteria were -Systemic inflammatory joint disease, Oral steroids in the previous three months, Uncontrolled Diabetes mellitus, Contraindications to oral steroids including peptic ulceration, serious infection, or uncontrolled diabetes and hypertension, Calcification about the shoulder joint, Reason to suspect a complete rotator cuff tear (weakness of arm

elevation, a positive 'drop arm sign', a high riding humerus visible on x ray of the shoulder or demonstration of a complete rotator cuff tear on ultrasound), Septic arthritis shoulder and lack of willingness to participate in the study.

INTERVENTION

Group A was given a tapered short course of Deflazacort which was tapered from 18mg daily in 1st week by 6mg each week and stopped by end of 3rd week along with Acetaminophen 650mg given thrice daily. Group B was given Acetaminophen 650mg thrice daily. Both groups were taught simple pendular exercises during their treatment. Blinding was not done in this study.

For the duration of the experiment, no further procedures, such as intraarticular steroid injections, arthrographic joint distension, massage, chiropractic, or manipulation under anaesthesia, were permitted. Patients who did not follow-up were removed from the study and the final analysis was done only on the patients who completed the 12 week follow-up.

OUTCOME ASSESSMENT

A single outcome assessor evaluated all participants at presentation and at 1st, 3rd, 6th, and 12th weeks. Data collected at presentation included personal details and clinical characteristics including duration of symptoms, severity of the condition and comorbidities. Outcomes were measured by VAS score, DASH score and range of movement of shoulder.

Pain perception

VAS Score is a pain rating scale that is a validated subjective measure of acute or chronic pain. Scores are based on self-reported assessments of symptoms that are recorded at one position along a 10-cm line.⁽¹⁴⁾

DISABILITY ASSESSMENT

DASH Score is a 30-item, self-reported questionnaire designed to assess the patient's health status during the previous week. Each item has five response options. The DASH questionnaire is used as an indicator of the impact of impairment on the level and type of disability. It assesses the whole person's ability to function, even if the person is compensating with the other limb.⁽¹⁵⁾ The score is expressed as a percentage score (0–100).

RANGE OF MOTION

Assessment of range of movements was done in standing position with a goniometer. Active range of motion of the affected and normal shoulder joints were taken at time of presentation and follow-ups to note for any changes. The movements included – Flexion, Extension, Abduction, Adduction, External rotation and Internal rotation.

The values measured in the affected shoulder joint were analysed for changes in both groups for pain, disability and range of motion.

SAMPLE SIZE

Sample size is calculated by Statulator: An online statistical calculator. Sample Size Calculator for Comparing Two Independent Means, available from <http://statulator.com/SampleSize/ss2M.html>⁽¹⁶⁾

STATISTICAL ANALYSIS

The presentation of the Categorical variables was done in the form of number and percentage (%). The quantitative data were presented as the means \pm SD and as median with 25th and 75th percentiles (interquartile range). The data normality was checked by using Kolmogorov-

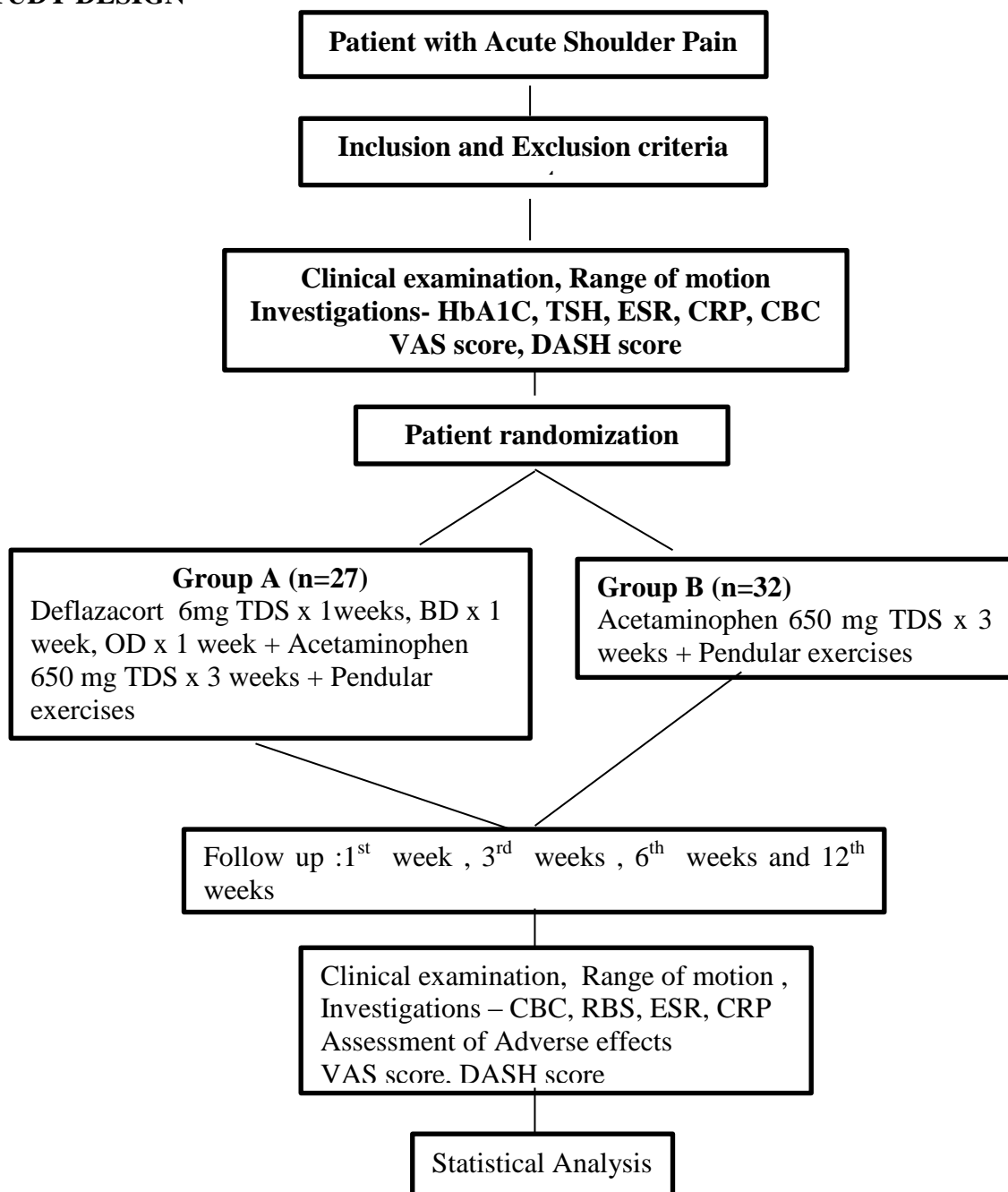
Smirnov test. The cases in which the data was not normal, we used non parametric tests. The following statistical tests were applied for the results:

1. The comparison of the quantitative variables which were not normally distributed were analysed using Mann-Whitney Test (for two groups) and Friedman test (for comparison across follow up) and quantitative variables which were normally distributed were analysed using Independent t test. Post Hoc analysis by Dunn's multiple pairwise comparison test was carried out after the Friedman test.
2. The comparison of the qualitative variables were analysed using the Chi-Square test. If any cell had an expected value of less than 5 then Fisher's exact test was used.
3. The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done using Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver 25.0.

For statistical significance, p value of less than 0.05 was considered statistically significant.

Figure 1: Study Design

STUDY DESIGN



RESULTS

59 patients were recruited for this study. Patients who were lost to follow-up were not included in the final tally. They were moved through the trial as shown in figure 1. Table 2 shows the demographic and outcome variables of the two groups at presentation. There was no significant difference in the demographics of both groups at time of presentation.

Mean changes from presentation for disability and Median (25th – 75th percentile) for pain and range of motion for both groups are presented in table 3.

There was no significant difference in VAS score from presentation (p value=0.26) till 6th week (p value=0.071) between Group A and B. This changed in the 12th week where the Median (25th-75th percentile) of VAS score in group A was 2(1-3) which was significantly higher as compared to group B (0(0-2) (p value=0.012)). This indicated a better tolerance in pain in Group B.

There was improvement in the DASH score in both groups with no statistically significant difference in DASH score from presentation (p value=0.183), till 12th week (p value=0.079) between Group A and B.

There was a significant difference in flexion between Group A and B in the early stages at 1st week [160(132.5-170) vs 130(110-150), p value=0.02] and at 3rd week [160(150-170) vs 140(130-160), p value=0.006] and in extension from presentation [30(22.5-40) vs 30(20-30), p value=0.046], till the 6th week [40(30-43.75) vs 30(30-40), p value=0.015] which was not maintained in further follow-ups. There was no significant difference in abduction, adduction, external and internal rotation between the two groups at any point during the follow-up. It was noted that the clinical status of patients in Group A began to deteriorate following cessation of the oral steroid.

Table 2: Demographics and characteristics of Group A and Group B at presentation

Variable	Group A	Group B	p Value
Age	54.93 ± 7.67	56.69 ± 8.65	0.415
Female	66.67%	65.63%	0.933
BMI	25.98 ± 4.1	26.06 ± 3.15	0.929
Comorbidities			
- Diabetes mellitus	6 (22.22%)	11 (34.38%)	0.304
- Hypothyroidism	3 (11.11%)	2 (6.25%)	0.652
- Hypertension	6 (22.22%)	9 (28.13%)	0.604
- Asthma	1 (3.70%)	0 (0%)	0.458
- Other	3 (11.11%)	4 (12.50%)	1
Shoulder affected			
- Right	14 (51.85%)	15 (46.88%)	0.389
- Left	10 (37.04%)	16 (50%)	
- Both	3 (11.11%)	1 (3.13%)	
Duration of symptoms	5.46 ± 5.75	4.95 ± 2.51	0.618
VAS Score	5(5-6)	5(4-6)	0.26
DASH Score	42.31 ± 15.86	36.24 ± 18.28	0.183
Range of motion			
Flexion	140(120-160)	130(110-150)	0.134
Extension	30(22.5-40)	30(20-30)	0.046
Abduction	110(92.5-160)	120(100-140)	0.638
Adduction	30(30-40)	30(30-40)	0.74
External rotation	70(60-80)	70(60-80)	0.592
Internal rotation	60(50-77.5)	80(60-80)	0.078

Table 3: Comparison of main outcome measures on follow-up between Group A and Group B

	Presentation	1st week	3rd week	6th week	12th week
VAS Score Median (25 th -75 th percentile)					
- Group A	5(5-6)	3(2-4)	2(1-2.5)	2(0-3.5)	2(1-3)
- Group B	5(4-6)	3(2-4)	1(0-3)	0(0-2)	0(0-2)
- p Value	0.26	0.865	0.409	0.071	0.012
DASH Score Mean \pm SD					
- Group A	42.31 \pm 15.86	35.88 \pm 14.98	33.4 \pm 14.9	34.07 \pm 16	34.27 \pm
- Group B	36.24 \pm 18.28	31.57 \pm 19.41	28.94 \pm 20.93	26.4 \pm 19.98	14.87
- p Value	0.183	0.351	0.346	0.114	25.97 \pm 20.69 0.079
ROM Median(25th-75th percentile)					
Flexion					
- Group A	140(120-160)	160(132.5-	160(150-170)	160(150-	160(150-
- Group A	130(110-150)	170)	140(130-160)	170)	170)
- p Value	0.134	130(110-150) 0.02	0.006	160(140- 160)	160(140- 160)
				0.121	0.067
Extension					
- Group A	30(22.5-40)	40(30-40)	40(30-40)	40(30-43.75)	37.5(30-40)
- Group B	30(20-30)	30(20-30)	30(30-40)	30(30-40)	30(30-40)
- p Value	0.046	0.002	0.004	0.015	0.206
Abduction					
- Group A	110(92.5-160)	140(100-	150(112.5-	150(120-	150(120-
- Group B	120(100-140)	167.5)	167.5)	167.5)	170)
- p Value	0.638	130(110-150) 0.187	140(120-160) 0.35	150(120- 160)	150(130- 160)
				0.622	0.708
Adduction					
- Group A	30(30-40)	30(30-43.75)	30(30-45)	30(30-45)	30(30-45)
- Group B	30(30-40)	30(30-40)	30(30-40)	30(30-40)	35(30-40)
- p Value	0.74	0.858	0.783	0.84	0.909
External Rotation					
- Group A	70(60-80)	70(70-80)	80(70-80)	80(70-80)	80(70-80)
- Group B	70(60-80)	70(60-80)	70(70-80)	80(70-80)	80(70-80)
- p Value	0.592	0.146	0.233	0.537	0.744
Internal Rotation					
- Group A	60(50-77.5)	70(60-80)	80(60-80)	75(62.5-80)	70(62.5-80)
- Group B	80(60-80)	80(70-80)	80(70-80)	80(70-80)	80(70-80)
- p Value	0.078	0.353	0.265	0.097	0.085

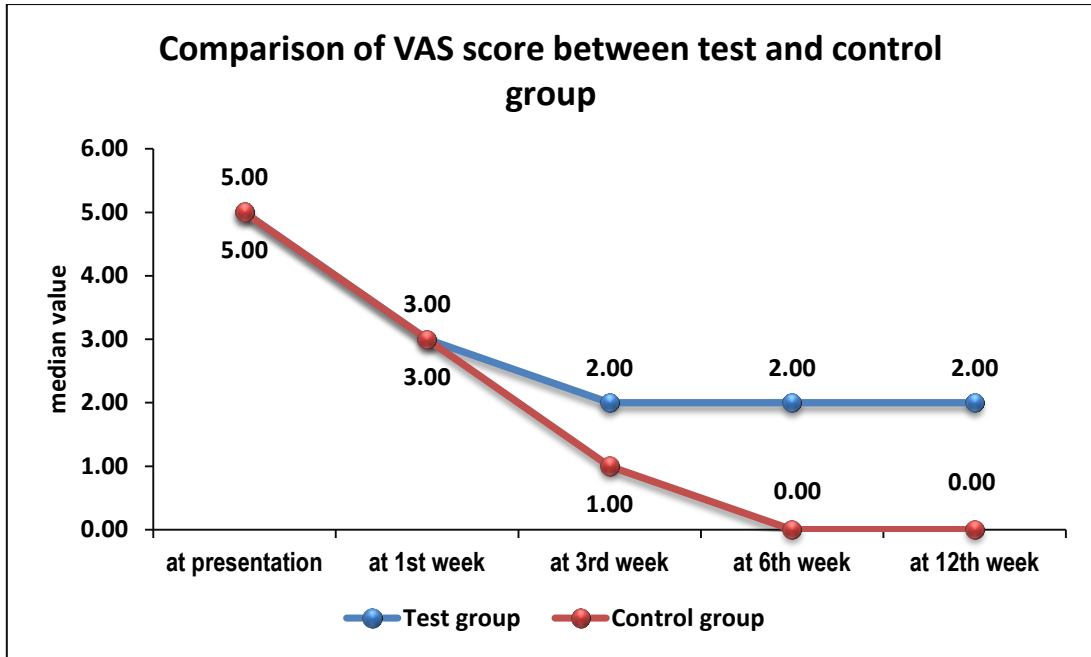


Figure 19:-Comparison of trend of VAS score at different time intervals between test and control group.

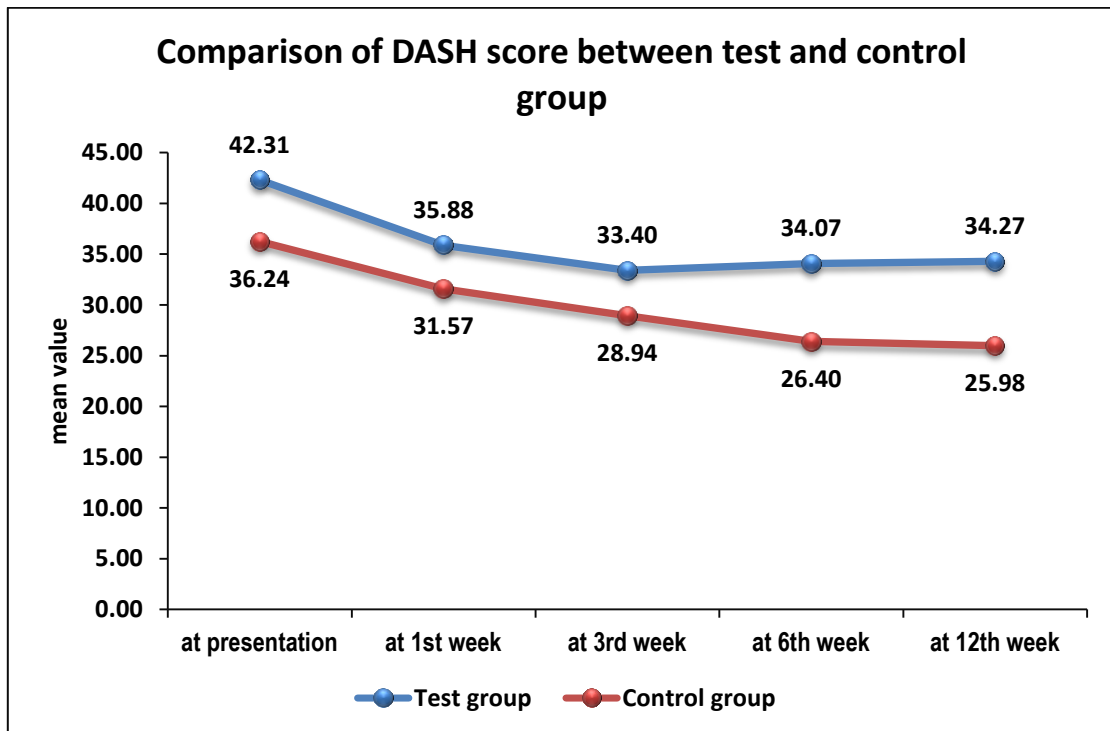
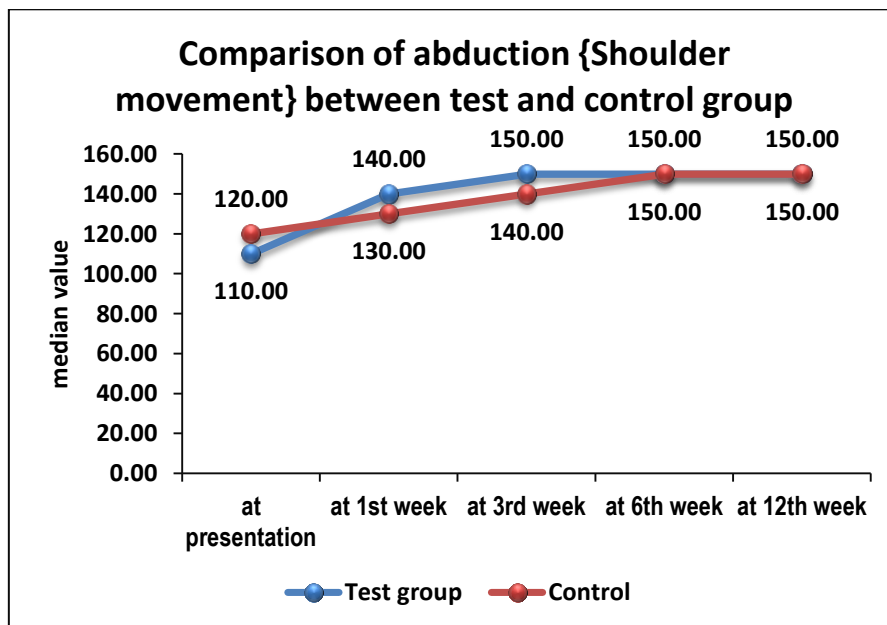
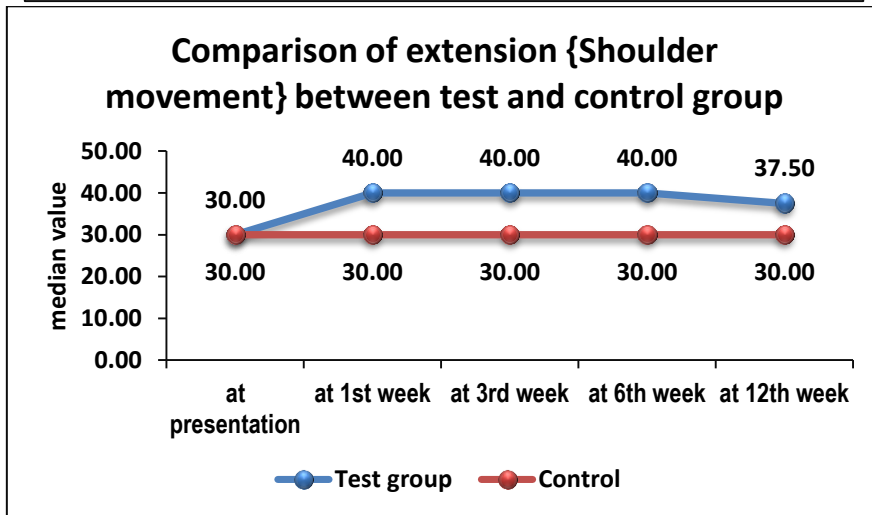
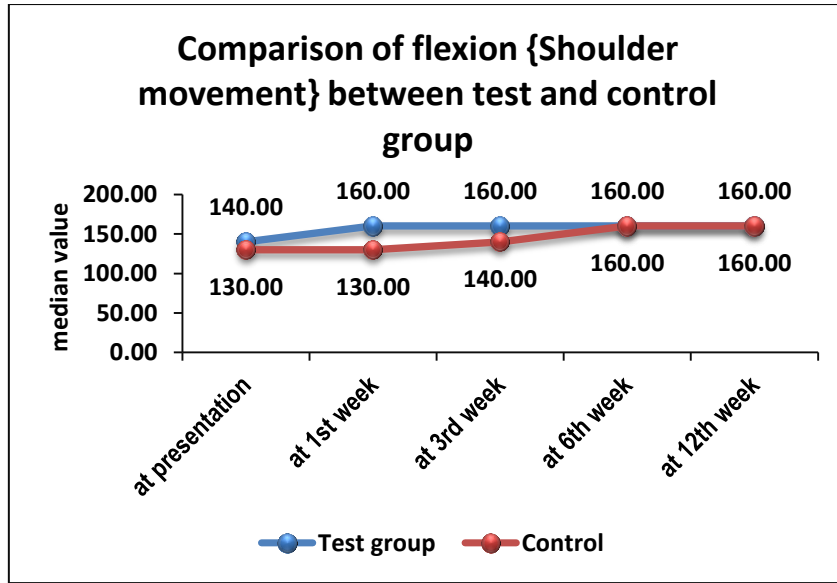


Figure 21:-Comparison of trend of DASH score at different time intervals between test and control group.



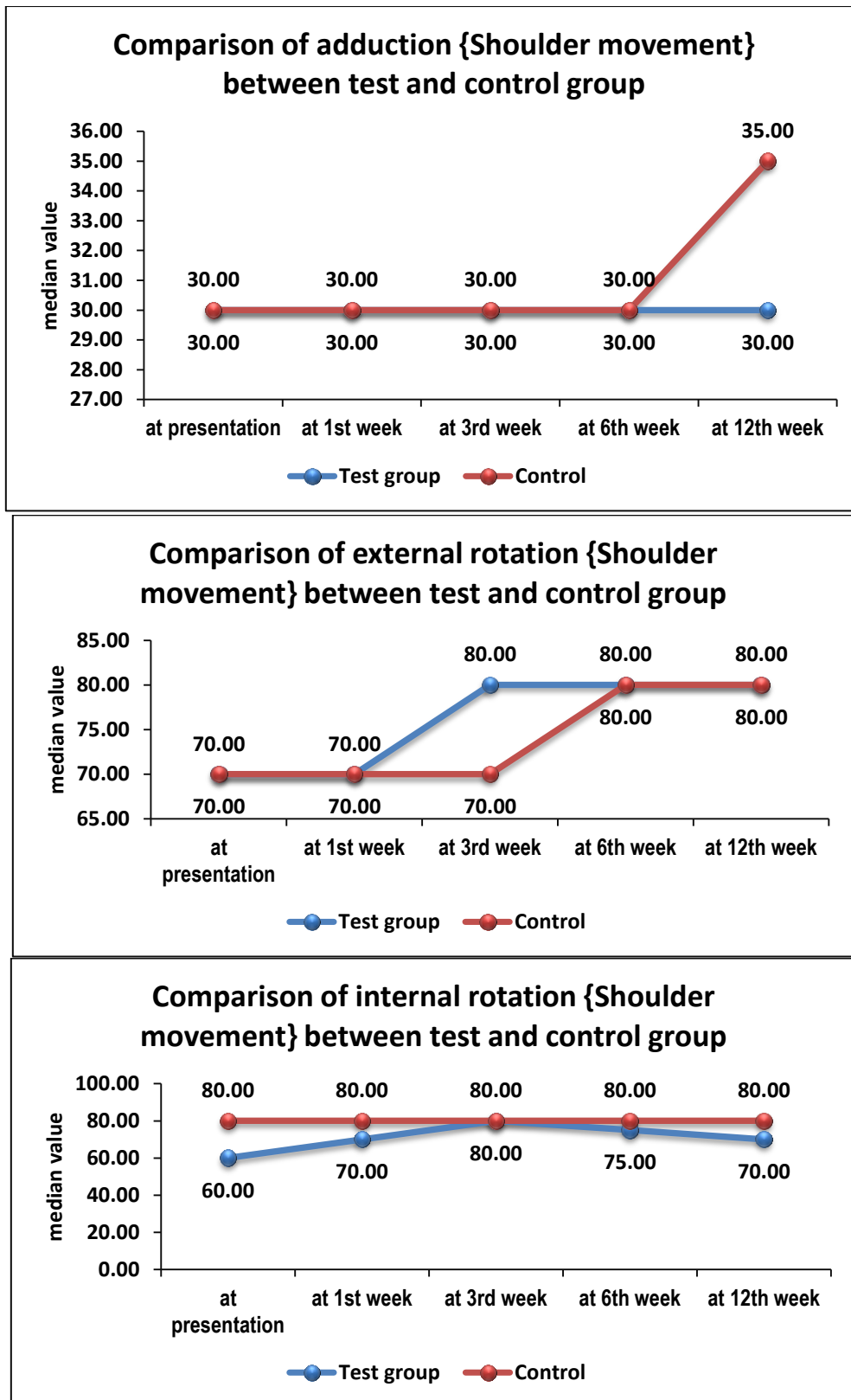


Figure:-Comparison of Shoulder movement at different time intervals between test and control group.

DISCUSSION

There was a significant difference in VAS score at 12th week between Group A and Group B [2(1-3) vs 0(0-2), p value=0.012]. In the study by Atici et al.⁽¹⁷⁾ it was reported that there was

a significant reduction in the VAS scores (p value < 0.018) compared to values at presentation. Buchbinder et al.⁽¹¹⁾ reported a baseline VAS score between test and control group of 7.3 ± 1.4 vs 6.8 ± 1.8 which improved at 3rd week in test group but in the long term showed better results in the control group. These findings were comparable to the present study.

There was a reduction in the DASH score in both groups by the 3rd week, with no difference between the two groups up to the 12th week (Table 3). The DASH score was comparable at presentation between the two Groups (p value = 0.183) with a total average Mean as 39.02 ± 17.34 and at 12th week it showed similar improvement (p value = 0.079) with total average being 29.77 ± 18.58 . Atici et al.⁽¹⁷⁾ and Canbulat et al.⁽⁹⁾ found improvement in the DASH score in their study which was noted by the 4th week and 6th week respectively which continued in long term follow-ups. The mean values in the study by Atici et al.⁽¹⁷⁾ at presentation was $54.5(22.7-70.5)$ and at 4th week $35(10-40)$. The average DASH score in the study by Canbulat et al.⁽⁹⁾ at initial presentation was 50.97 ± 18.34 and 16.02 ± 12.45 at the 6th week follow-up. Buchbinder et al.⁽¹¹⁾ reported comparable findings of initial improvement in test group which was caught up by the control group in the long term.

In the present study, there was an improvement seen in all the movements of shoulder in Group A, however, when compared to Group B these changes had no significant difference though the improvement started earlier in Group A. There was a significant difference in flexion between Group A and B in the early stages at 1st week (p value = 0.02) and at 3rd week (p value = 0.006). This change was not maintained in further follow-up at 6th and 12th week (p value = 0.067). Similarly, a significant difference was seen in extension at presentation (p value = 0.046) till 6th week (p value = 0.015) between Group A and B which was also not maintained by the 12th week (p value = 0.206) of follow-up. There was no significant difference between the two groups in the other movements that were measured. Atici et al.⁽¹⁷⁾ reported significant improvement in functional outcomes and ROM as early as 3 weeks which was maintained at the 6th month of follow-up. The findings were in contrast to the findings in our study which showed some deterioration in ROM after stopping the oral steroids. This may be due to the increased dosage of steroid which was given in their treatment which on average was 1080 mg for an 80kg male. The study by Takase⁽¹⁸⁾ showed better results as compared to the present study. Prior to treatment, the average ROM was 102.8 degrees of forward flexion, 11.3 degrees of external and internal rotation was attained up to the buttocks. By the end of the first treatment course of 3 weeks, the average ROM forward flexion was 136 degrees, external rotation was 33.7 degrees, and internal rotation was only limited in the buttocks in six patients. Canbulat et al.⁽⁹⁾ reported that all patients achieved full range of motion at the end of the 1 year (p value < 0.05). This improvement was rapid at the beginning and slowed down with time in all directions. Active external rotation improvement was statistically significant until the 2nd week (p value = 0.004). Active flexion, abduction, and internal rotation improvements were statistically significant until the 4th week (p value = 0.019, p value = 0.046, p value = 0.016, respectively). Lorbach et al.⁽¹⁹⁾ reported improved ROM at 4 weeks. Flexion increased from 75 ± 16 before treatment to 120 ± 20 at 12th week. The abduction improved from 66 ± 15 before treatment to 104 ± 21 at 12th week. External rotation was 3.9 ± 16.1 at the beginning of the treatment and improved to 31 ± 24 after 12 weeks. The internal rotation increased from 43 ± 14 before treatment to 60 ± 8 at 12 weeks. Buchbinder et al.⁽¹¹⁾ reported an initial improvement in test group that either stayed the same or slightly deteriorated in the long term.

CONCLUSION

To conclude, giving a short term tapered course of Deflazacort as an adjuvant along with acetaminophen showed a temporary improvement in a single plane of shoulder movement

and no other benefits in movement or functional ability and lead to a poorer pain tolerance in the long term. Giving Acetaminophen alone gave an overall better outcome in the long term.

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