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Functional Outcome Of Supra Scapular Nerve Block With 0.5% Bupivacaine Versus Intra Articular Steroid Injection Of Methyl Prednisolone Acetate For Idiopathic Adhesive Capsulitis Shoulder Stage I & II – A Randomized Control Trial.

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ABSTRACT

Idiopathic Adhesive capsulitis, one of the commonest conditions presenting to physiatric OPD, is characterized by pain and restriction of shoulder ROM in patients with normal radiograph. Though self-limiting, it is yet difficult to treat due to varying presentation in terms of severity and duration in different individuals. To compare the pain relief, ROM and functional outcome of supra scapular nerve block using bupivacaine with intra articular injection of Methyl prednisolone acetate in idiopathic adhesive capsulitis shoulder stage I & II. After informed consent 60 subjects (age: 30 – 60 years, both sex) diagnosed to have idiopathic adhesive capsulitis stage I and II were included in the study as per inclusion and exclusion criteria specified and randomized into two treatment groups, each with 30 shoulders. Group A was treated with SSNB with 5 ml of 0.5% Bupivacaine and Group B was treated with 40 mg of methyl prednisolone acetate. Both the groups underwent the same scheduled physiotherapy. All the shoulders in both the groups were assessed periodically with VAS, Penn Shoulder Score, Constant shoulder score, SPAD index and DASH scale. Statistical analysis was done with standard soft wares and both the groups were compared. Both the groups showed statistically significant ($p < 0.05$) improvement in all the parameters mentioned when compared with pre-treatment status. And SSNB group showed better outcome than IAS. Supra scapular nerve block is a safer treatment approach to treat adhesive capsulitis shoulder Stage I and II, and when followed by regular exercise therapy it gives better functional outcome than intra articular steroids with exercise.

Keywords: Range of Movements (ROM), Supra scapular nerve block (SSNB), Visual analogue scale (VAS), Penn Shoulder Score (PSS), Constant shoulder score (CSS), Shoulder pain and disability index (SPADI) and Disabilities of arm, shoulder and hand (DASH) score.

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INTRODUCTION

Chronic shoulder pain is one of the commonest musculoskeletal system related complaints encountered in PMR-OPD and with varying etiology. Adhesive capsulitis (AC) also known as Periarthritis (PA) shoulder and commonly referred to as Frozen shoulder is one among them and it is an idiopathic condition affecting shoulder joint, usually presenting with pain and stiffness of the joint. As the shoulder joint is a unique anatomical structure with an extraordinary Range of motion (ROM) that allows us to interact with our environment to accomplish various activities of daily living, any pain or compromised mobility of this joint will cause significant morbidity [1]. Though the natural history of the disease may be self-limiting [2-4] the duration of the disease progress varies widely due to vicious cycle of self-propagating symptomatology, its secondary consequences and the individual's response towards them. So that adhesive capsulitis has disabling capability if left untreated or if approached in unscientific manner. The treatment approaches are ranging from pharmacological management, physical therapy & therapeutic exercises, nonsurgical interventions like nerve blocks, intra articular injections or manipulation under anaesthesia and surgical approaches like arthroscopic release, or to combinations of them which are briefed about in "Review Literature" in subsequent sections.

MATERIALS AND METHODS

Prospective Assessor and Therapist Blinded Stratified, Block Randomized controlled clinical trial with allocation concealment. Subjects were selected according to inclusion and exclusion criteria from individuals attending PMR-OPD. Selected subjects were randomized (1:1) to one of the treatment groups (A or B) using standard software/internet based computer aided distant third party employed block randomization. Block Randomization was employed with varying block size ensuring allocation concealment.

Blinding: Assessors and physiotherapist were blinded to know the treatment group of the patient.

Stratification: Stratification of three possible common confounding factors (age group, sex, diabetes) which may affect treatment response/functional outcome, was done. Group A: Supra Scapular Nerve Block and exercise therapy. Group B: Intra articular steroid injection and exercise therapy. The same schedule of exercise therapy will be followed for all three groups. After obtaining informed consent & 1:1 stratified block randomization, subjects of Group A and B were administered a test dose of 2% Lignocaine. Ensuring that there is no adverse reactions, subjects were taken to operation theatre and parts (according to intervention) will be cleaned with surgical spirit followed by Betadine and draped with sterile towel. Under strict aseptic precautions the injection site (as per the need) was anaesthetized with 2% Lignocaine. For Group A: Supra scapular Nerve of the affected side was blocked with 5 ml of 0.5% Bupivacaine by indirect technic of anatomical landmarks guided clinical method, followed by Codman's three plane rotation of shoulder joint with in initial 15 minutes. For Group B: 40 mg of Methyl prednisolone acetate was injected into intra articular space of the affected shoulder joint through posterior approach. After the intervention, the subjects were observed for 15 minutes for any adverse reactions. Subjects were asked to report immediately in case of adverse reactions like post injection flare (increased pain, swelling) / hypersensitivity reactions,...etc. Both Groups (A & B) underwent the Scheduled Exercise Therapy. The assessor and the physiotherapist attending the patients were blinded to know the treatment group to which the subjects belong to and were prevented from asking any question regarding the same throughout the study.

Inclusion Criteria

Clinically proven cases of Idiopathic Adhesive Capsulitis Shoulder Stage I & II

- Age 30 – 60 years
- Both Sex (Male/Female)
- Either side (Right/Left)
- Painful Shoulder movements
- +/- Night pains
- +/- Rest pains
- Restricted Shoulder ROM
- Normal radiology

Exclusion Criteria

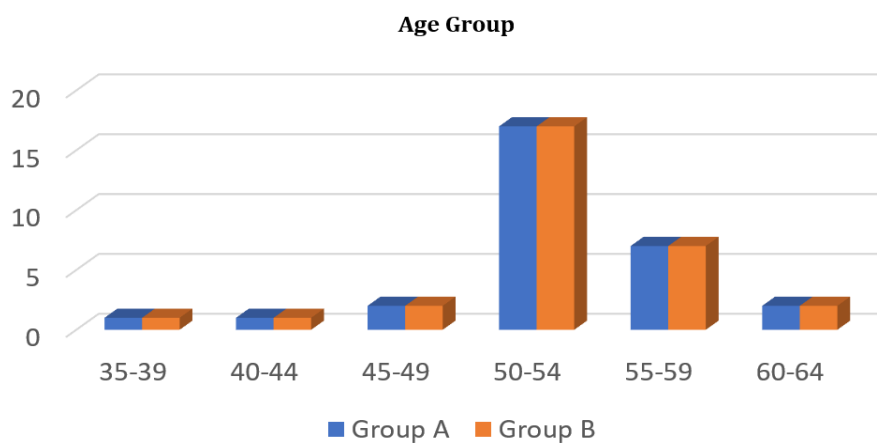
- Stage III & IV adhesive capsulitis
- Age <30 & >60 years
- Local Infections
- Fracture / Dislocation
- Rotator Cuff Tear
- Previous Surgery in Shoulder
- Allergic to Agents used
- Severe Osteoporosis
- Uncontrolled Diabetes
- Patients with Angina

Subjects were assessed before the treatment, after the treatment and during regular follow up visits using Visual Analogue Scale, SPAD Index, Penn Shoulder Score, Constant Shoulder Score & DASH Scale according to protocol as submitted.

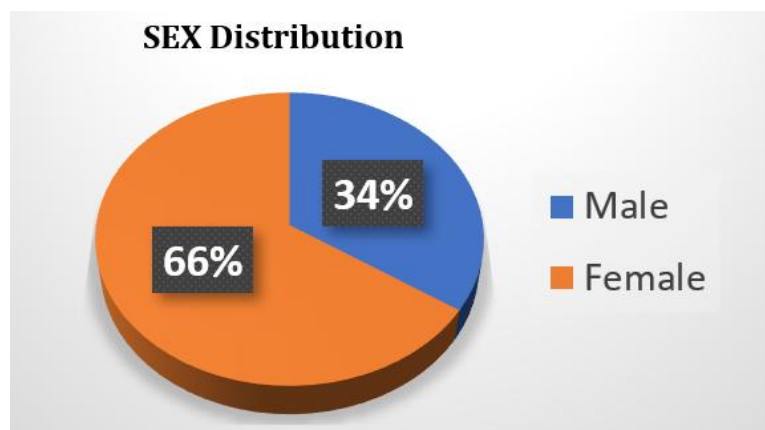
OBSERVATION AND RESULTS

Totally 60 subjects were included in the study with equal numbers in each study groups. (Group A: SSNB, Group B: IAS). And most of them belong to low socio-economic status (56.7%) as per modified Kuppusamy’s classification. Since, age, sex and diabetic status are the three major confounding factors which may affect disease behavior and treatment outcome in AC, those factors were stratified during randomization. So that the subjects of different age group, sex and H/O Diabetes +/- were equally distributed among both the study groups.

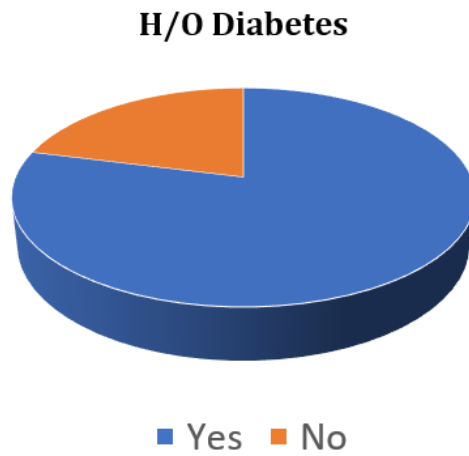
Graph 1: Age group.



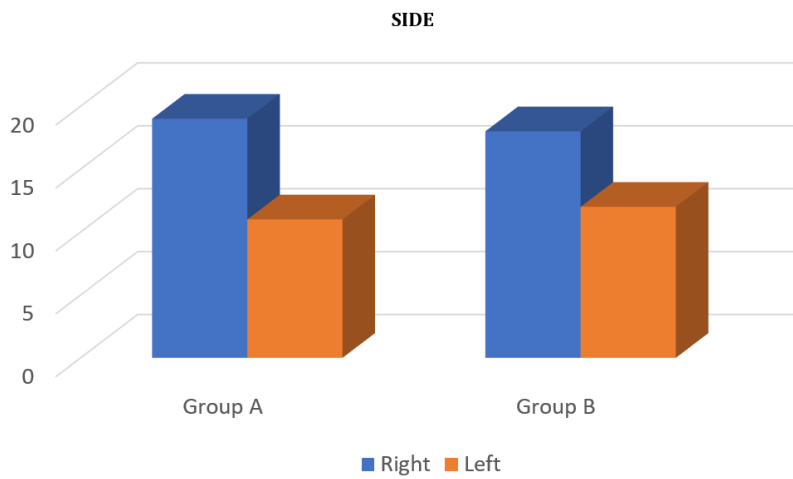
Graph 2: Sex wise Distribution.



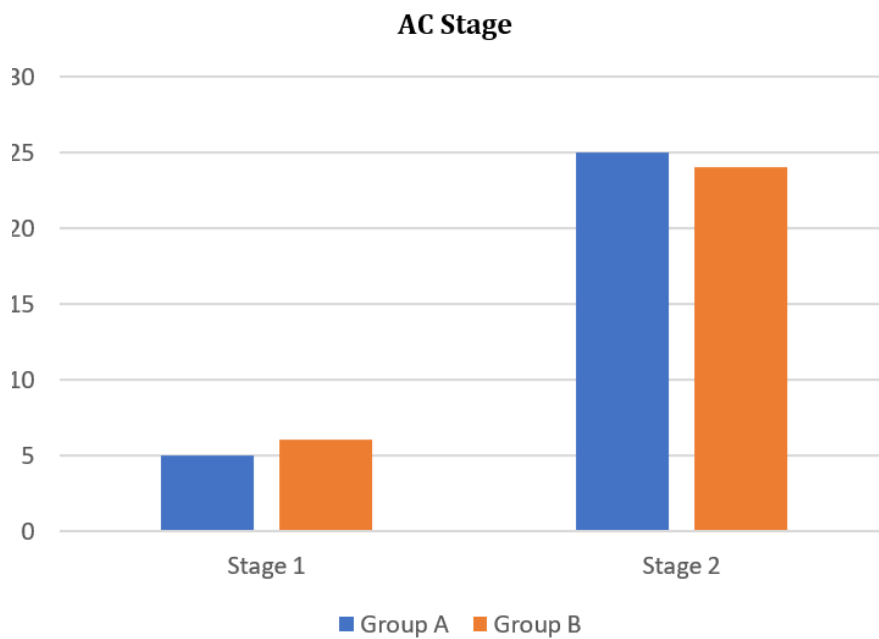
Graph 3: H/O Diabetes/



Graph 4: Laterality



Graph 5: Stage of the Disease.



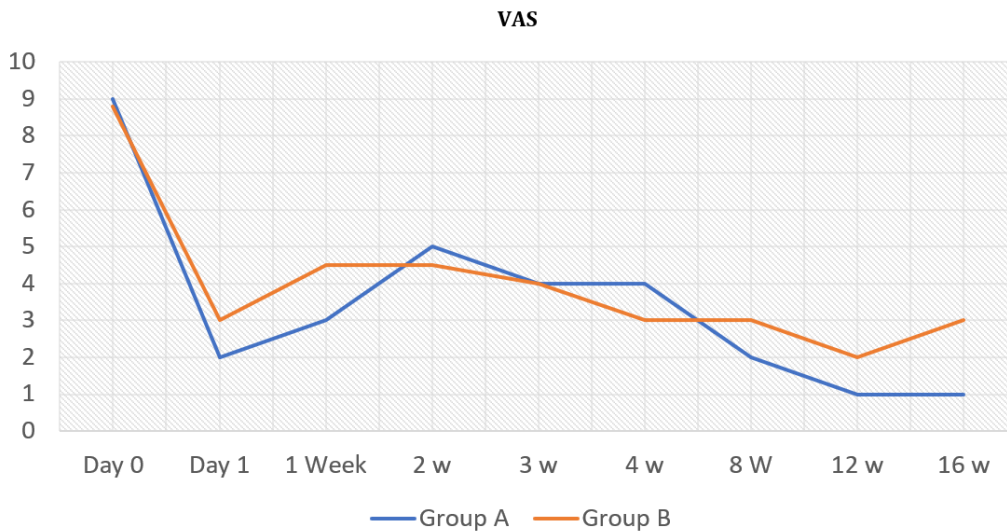
Subjects with stage 2 AC out-weighted those with stage 1 in both the groups. The ratio of stage 1 and 2 was 1:5 (5,25) in Group A and Group C, whereas 1:4 (6,24) in Group B.

Table 1: Pre intervention VAS & ROM.

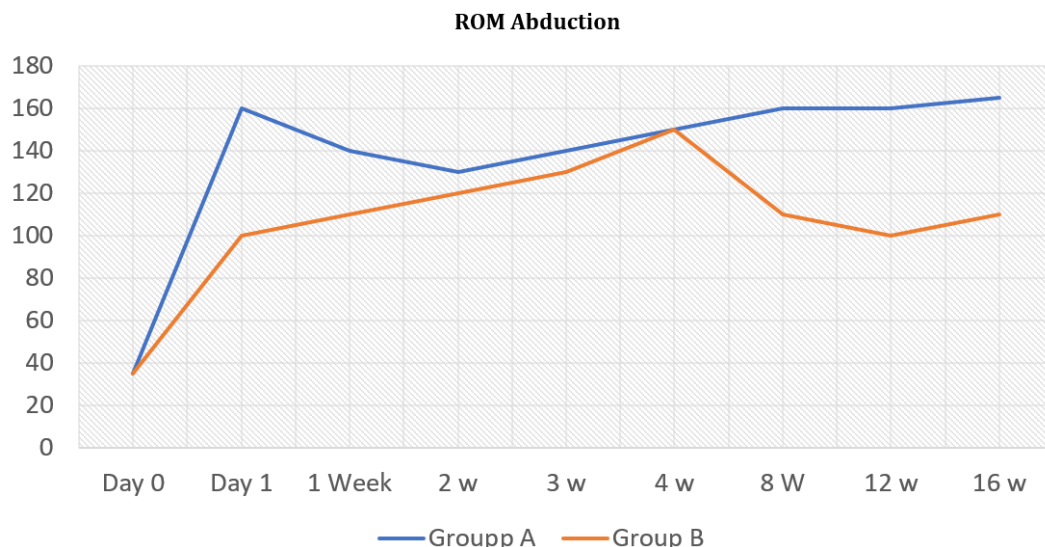
Features	Treatment Group				ANOVA (0.05)		
	A		B		F	p	F crit
	Mean	Var	Mean	Var			
VAS	8.7	1.11	8.73	1.16	0.199	0.819	3.101
Abduction	48.83	58.07	48.33	47.1	0.144	0.866	3.101
Flexion	67.16	49.45	66.5	115.	0.068	0.934	3.101
Extension	19	35.17	23.33	55.7	2.921	0.059	3.101
IR	42	76.89	41.83	102	2.834	0.064	3.101
ER	15.66	20.23	14.16	19.1	2.634	0.078	3.101

The study groups are comparable in terms of pre intervention parameters.

Graph 6.

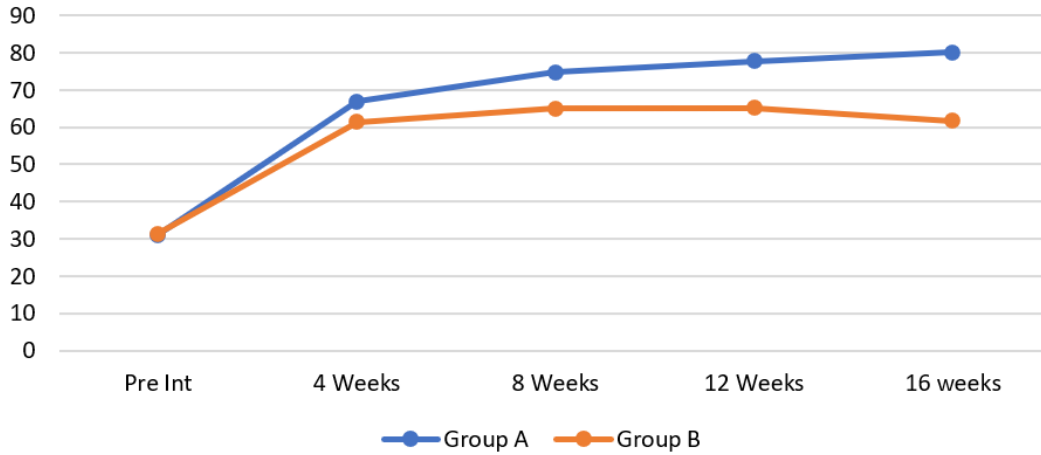


Graph 7: Abduction ROM.

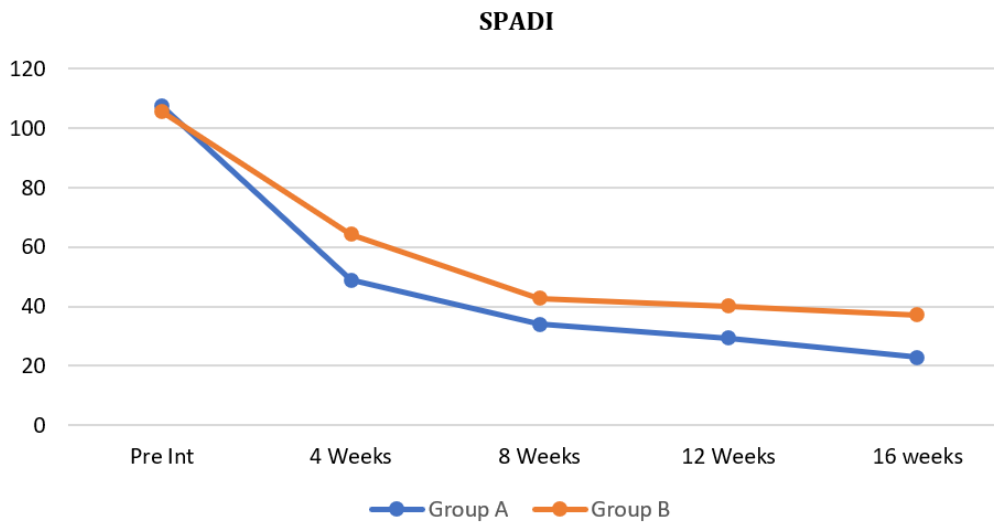


The outcome scales used in this study were Visual Analogue Scale (VAS), Penn Shoulder Scale (PSS), Constant Shoulder Score (CSS), Shoulder Pain and Disability Index (SPADI) and Disability Arm Shoulder Hand (DASH) Score.

Graph 8: Penn Shoulder Scale.
PSS



Graph 9: SPADI.



POST

Table 2: Intervention Data Analysis.

SCALE	Group A		Group B	
	Pre Int	Post Int	Pre Int	Post Int
VAS M	8.7	2.23	8.7	2.2
SD	1.05	1.13	1.01	1.8
PSS M	31.1	68.1	31.3	60.7
SD	2.7	9.6	2.3	5.7
CSS M	31.5	68.2	31.3	60.8
SD	3.1	9.6	2.3	5.7
SPADI M	107.3	47.2	105.5	60.4
SD	15.4	18.6	14.5	20.1
DASH M	94.73	61.8	76.2	62.1
SD	9.5	12.3	4.8	9.3

Table 3. Intra - Group Comparison Pre Int Vs. Post Int.

Study group	Paired t test p value			
	4 wk	8 wk	12 wk	16 wk
A	< 0.0001	<0.0001	<0.0001	<0.001
B	<0.0001	<0.0001	<0.001	<0.001

Table 4: Inter Group Comparison.

Group setting	Unpaired t test p value			
	4 wk	8 wk	12 wk	16 wk
A vs B	<0.0001	<0.0001	<0.0001	<0.0001

DISCUSSION

In this study, the peak occurrence of Adhesive capsulitis was in the age group of 50-60 years. And females out-weighed males. Age group, Sex and Diabetic status are the three major confounding factors which may influence the severity of disease presentation, out-come and functional recovery after treatment [6]. They were stratified during randomization and hence the three groups (Group A: SSNB, Group B: IAS) were comparable [7]. In addition, other base line characteristics among the study groups did not vary significantly (p value:0.14 to 4.82) and were proved by statistical analysis that they were comparable and null hypothesis, in terms of baseline characters, was not rejected. (p value > 0.05) ANOVA showed pre-treatment clinical parameters like pain scores and ROM were also almost evenly distributed among the two study groups and null hypothesis was not rejected. p value:0.059-0.934, i.e., p value > 0.05 and F (0.59 – 0.93) was less than F crit (3.101) [8]. Parameters and scores with in each group were analyzed with two factor ANOVA within the group. And paired t test was used to analyze pre intervention data with post intervention data at each step and showed significant difference from initial follow ups onwards till 16 weeks in group A and group B (p value <0.00001)

Unpaired t test p values (<0.0001) between Group A & B rejected the null hypothesis and it was inferred that there were statistically significant differences in the treatment outcome among the groups, Group A had better pain relief and functional outcome [9, 10].

CONCLUSION

Supra scapular nerve block is a safer treatment approach to treat adhesive capsulitis shoulder Stage I and II, and when followed by regular exercise therapy it gives better pain relief and functional outcome than intra articular steroids with exercise therapy. In view of prevalence of diabetes and since adhesive capsulitis is strongly associated with elderly diabetics, this subset of patients can be readily and effectively treated with SSNB and supported with regular exercise therapy.

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