# Suprascapular Nerve Block (SSNB) improves the outcome in exercise based management of Primary Adhesive Capsulitis (PAC): A prospective randomized comparative study

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#### Abstract

**Background and Aims:** Increased pain and associated stiffness hinders the advantages of exercise and process of recovery in primary adhesive capsulitis. We hypothesized that suprascapular nerve block may positively affect the outcome due to its role in pain relief of acute or chronic shoulder pain. We compared the effect of suprascapular nerve block and exercise with only exercise on the recovery of primary adhesive capsulitis.

**Material and Methods:** A total of 96 patients of both sexes presenting with primary adhesive capsulitis were divided by computer randomization in two equal groups (n = 48). Group A received exercise only and Group B received suprascapular nerve block followed by exercise. Oral paracetamol was given for analgesia as desired. Patients were followed up at 4, 8, 16, and 24 weeks. Pain was assessed by visual analog scale; functional outcome by Shoulder Pain and Disability Index and range of movement by goniometer.

**Results:** The pain scores and Shoulder Pain and Disability Index scores were significantly lower at all observation points of 4, 8,16, and 24 weeks in Group B than Group A (P < 0.05). The range of movement in all the ranges of forward flexion, extension, internal and external rotation, and abduction at all observation points was significantly higher in Group-B (P < 0.05) compared to Group A. The consumption of analgesics was significantly more in Group A than Group B at 4 and 8 weeks (P = 0.020 and P = 0.044) but comparable at 12 and 24 weeks (P = 0.145 and P = 0.237 respectively).

**Conclusion:** Combining SSNB with exercise is more effective in treatment of primary adhesive capsulitis than exercise alone and reduces the use of analgesics. SSNB it is effective and safe to use in primary adhesive capsulitis.

**Keywords:** Adhesive capsulitis, exercise, frozen shoulder, shoulder, treatment, suprascapular nerve block, ultrasound-guided nerve blocks

# Introduction

Primary adhesive capsulitis (PAC) or "FROZEN" shoulder is one of the leading causes of shoulder pain with unclear etiology.<sup>[1,2]</sup> It is a self-limiting disease; however, timely and aggressive management is required to prevent long-term deficits

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in the range of motion (ROM) that may last up to 10 years.<sup>[2,3]</sup> In the management of PAC, therapeutic exercises play the most vital role but it is often difficult to mobilize the joint due to existing pain and fear of further aggravation.<sup>[1,4]</sup> SSNB has been used successfully to manage both acute or chronic shoulder pain.<sup>[5]</sup> We proposed a hypothesis that SSNB in addition to the

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therapeutic exercises may facilitate the recovery of PAC. SSNB may decrease the muscle spasm and thereby will decrease the pain felt by the patient on movement. This in turn would facilitate active patient participation in the exercise regimen leading to faster and better outcome. Not enough studies have been done to compare the outcome with exercise alone or exercise with SSNB in the management of PAC. The aim of the study was to compare the effectiveness of exercises with and without suprascapular nerve block on the outcome of PAC.

# **Material and Methods**

This prospective randomized comparative study was conducted at a teaching industrial hospital during July 2018 and November 2020 (including 6 months of the follow-up period) after hospital ethical committee approval and registration with CTRI (CTRI/2018/07/014723). A total of 100 patients who visited the orthopedic outpatient department (OPD) with complaints of pain at shoulder and difficulty in shoulder movements were scrutinized. Patient's age >18 years with clinical diagnosis of PAC having shoulder pain for >1 month and <12 months, restriction of both active and passive shoulder movements, pain at night with difficulty to lie on that side and two negative tests out of following three tests (Neer's impingement test, Hawkins Kennedy test, Jobe's isolation test), were included in the study after written informed consent.

Exclusion criteria were patients with history of any surgery, injections, or therapy of shoulder, evidence of underlying fracture or arthritic changes on X-ray. Patients with painful arc between 40 degrees and 120 degrees of abduction, who had pregnancy, malignancy, severe cardiac disorder, psychiatric illness, or contraindication to SSNB. Patients were thoroughly examined and investigated to exclude causes of shoulder pain other than PAC. An information sheet was provided and written informed consent was taken from all the patients. Patients who satisfied the inclusion and exclusion criteria were included in the study.

The sample size was based on our pilot study of 30 patients, conducted during July 2017–June 2018. In the exercise group, at 6 months, the Shoulder Pain and Disability Index (SPADI) scores, mean ( $\pm$  SD) were 35.50 ( $\pm$  5.89). To detect 10% difference in the mean score between the comparative groups, the required total sample size was 86 (n = 43 subjects per group) at 80% power and 95% confidence interval and significance (P < 0.05). Considering 10% attrition a total of 96 patients were included and randomly divided in two equal groups (n = 48) in exercise group (Gr-A), and (n = 48) in exercise with SSNB group (Gr-B) by computer randomization [Figure 1].

All the patients were educated about the use of "Visual Analogue scale" (VAS) of (0 = no pain, 10 = intolerable pain). All the patients were evaluated before starting the treatment using VAS score for pain, SPADI for functional limitation (activity of daily living) and Goniometry for ROM assessment. The pretreatment range of motion were measured by a calibrated goniometer.

The patients in exercise only group (Gr-A) were taught exercises to promote flexion, abduction, internal and external rotation of the shoulder under supervision by a professional physiotherapist for a week, and then were guided to practice at home, 10 times per session, twice a day during morning and evening. They were asked to keep a diary at home to keep a record of the exercises practiced by them, in order to ensure compliance. Weekly telephone calls were also made in order to make the patients Model of ultrasound compliant. They were instructed to come for follow-up at 4, 8, 16 and 24 weeks.

In the exercise and SSNB group (Gr-B), patients were given a single suprascapular nerve block on the affected side under ultrasound (US) guidance (SonoSite M-turbo<sup>®</sup>, Fuji India Ltd.) with due aseptic precautions and standard posterior approach using high-frequency US probe (6-13 MHz) and in-plane approach.<sup>[6]</sup> Injection bupivacaine 10 mL, 0.25% plus 40 mg depot steroid (methylprednisolone acetate) was injected using 100-mm 21-gauge blunt tip nerve stimulating needle (Stimuplex®, B-Braun). All the blocks were administered by a single experienced anesthesiologist. Patients were observed for any untoward effect of local anesthetic or block in the recovery room for 30 minutes before discharge. They were then assessed the very next day for any changes in their shoulder pain perception. Special attention was given to look for any signs of hematoma formation and suprascapular nerve injury. Then a 7-day supervised exercise regime similar to the first group was started, followed by the pre-described exercise and follow-up schedule.

Both the treatment groups were put on analgesics and 20 tablets paracetamol were given at each follow-up. Patients were advised to take tab paracetamol (500 mg) whenever pain became intolerable (up to 4 tablets/24 hours). If any patient demands any alternative treatment, he/she was excluded from the study and offered other modes of treatment.

All the data was entered in the excel sheet. The results were analyzed using the statistical software (MedCalc version 20., MedCalc Software Ltd., Ostend Belgium). Continuous data was assessed for normality using the Kolmogorov-Smirnov test of normality. Normally distributed data (represented as Mean  $\pm$  SD) was assessed using the student's t-test (two-tailed, equal variances) and non-normally



Figure 1: CONSORT flow diagram for enrollment, group allocation, follow-up and analysis

distributed data [represented as median (range)] was assessed using the Mann-Whitney U-test. Ordinal data were represented as median and interquartile range (IQR) and assessed using the Mann–Whitney U test. Chi-square statistic was used for categorical data. A value of P < 0.05was considered significant. The effect size was calculated either with Choen's D or Glass's delta depending upon the values of standard deviation (SD) variability.

The primary objectives were to compare the improvement in the range of motion of the shoulder, decrease in shoulder pain, and improvement in activity of daily living (functional limitation). The secondary objectives were to compare the cumulative amount of analgesic required to control the pain in each group and to observe the suprascapular nerve block-related complications like nerve injury, hemothorax, hematoma formation and increase of shoulder pain.

#### Results

The demographic variables like age, weight, BMI, side of affected shoulder and male/Female ratio were comparable between Gr-A and Gr-B (P < 0.05) [Table 1]. The pre-procedure pain scores (VAS) and scores on SPADI were comparable [Table 2]. The pain scores in both the groups were significantly lower at 24 weeks compared to pre-intervention levels (P < 0.0001). The SPADI scores in both the groups

were significantly lower (P < 0.0001) at 24 weeks compared to pre-intervention [Table 2]. The Glass's delta at 24 weeks was 0.57 and 0.54 for pain and SPADI respectively. The pain scores and SPADI scores were significantly lower at all observation points of 4, 8, 16, and 24 weeks in Gr-B than Gr-A (P < 0.05) [Table 2]. Pre-intervention ROM were comparable between Gr-A & Gr-B (p > 0.05) [Table 3]. The ROM in all the ranges of forward flexion, extension, internal and external rotation, and abduction at all observation points of 4, 8, 12 and 24 weeks were significantly higher (P < 0.05) in Gr-B compared to Gr-A [Table 3]. The consumption of analgesics was significantly more in Gr-A than Gr-B at 4 and 8 weeks (P = 0.020 and P = 0.044 respectively). The analgesics consumption was comparable at 12 and 24 weeks (P = 0.145 and P = 0.237 respectively) [Figure 2]. In Gr-B no patient developed any local anesthetic or SSNB related complication except one patient who reported increased pain next day of the block and was managed with Tab. Paracetamol and local ice application.

#### Discussion

Shoulder pain with decreased ROM due to PAC is one of the common pain presentations in our orthopedic OPD. This study was conducted to analyses the effect of SSNB on the recovery of patients suffering with PAC and managed with guided exercise regimen. The reduction in the pain and SPADI was significantly more in Gr-B (exercise & SSNB group). Other than the calculations of statistical 'p' values we also calculated effect size (Glass's delta). Effect size quantifies the size of the difference between two groups, and may therefore be said to be a true measure of the significance of the difference. If value is 0.2 it is considered a 'small' effect size, 0.5 represents a 'medium' effect size and 0.8 a 'large' effect size. It was 0.57 for pain 0.54 for SPADI [Table 2], signifies medium effect size values.

Conservative management is effective in about 90% of patients of PAC and exercise is the main stay.<sup>[1,7]</sup> The extent of exercise, the nature and the prescribed schedule for exercise are debatable.<sup>[8]</sup> One study has suggested that a hospital-based exercise class can produce a rapid recovery from a frozen shoulder with a minimum number of visits to the hospital and is more effective than individual physiotherapy or a home exercise program.<sup>[9]</sup> Another study did not find any significant difference in clinical outcomes between supervised physiotherapy in addition to a home exercise program and a self-directed home exercise program in isolation.<sup>[10]</sup> Home self-exercise has been shown to be equally

 Table 1: Demographic variables including age, weight,

 BMI and side of involved shoulder

Variables	Gr-A (n=48)	Gr-B ( <i>n</i> =48)	Р
Age: Mean (SD)	58.09±10.53	60.18±10.67	0.352*
Sex: M/F	16/29	19/26	$0.517^{\dagger}$
Side: Left/Right	24/21	23/22	0.833†
Height	$155.4 \pm 8.39$	$154.92 \pm 10.14$	0.811*
Weight	$70.98 \pm 8.23$	$71.78 \pm 6.24$	0.605*
BMI	$29.5 \pm 3.67$	$30.15 \pm 3.76$	0.409*

P>0.05 Nonsignificant, SD-standard deviation, Gr-A (Only exercise), Gr-B (Suprascapular nerve block and exercise), \* Student t test, <sup>†</sup>Chi-square test

effective or superior to supervised stretching-exercise.<sup>[11,12]</sup> We used a composite approach where for the initial 7 days exercise and passive stretching was done with the help of a professional physiotherapist in the hospital (on OPD basis) and then home-based schedule was advised with telephonic follow-up. Both the groups showed significant improvement in the pain SPADI and ROM (P < 0.05). Our findings are similar to earlier reported exercise-based outcomes.<sup>[10,13]</sup> Tanaka et al.,<sup>[12]</sup> have concluded that early intervention and self-exercise in the home setting are more important factors than session frequency of joint mobilization in the hospital setting for the successful management of rehabilitation for limited glenohumeral joint mobility (LGHM). In our study, we did not categorize our patients according to the stages of PAC. However, most of our patients presented with significant pain and decreased ROM which are the signs of early PAC. This could have been the reason of better outcome in our patients.



Figure 2: Comparison of Analgesics consumed between the study groups at different follow up periods

Follow up time periods	Group-A (n=45) (Mean±SD)	Group-B (n=45) (Mean±SD)	<b>P</b> *
	Pain	score	_
Pre-intervention	70.66±11.82	75.02±10.74	0.071
4 <sup>th</sup> week	$52.49 \pm 14.66$	46.53±13.07	0.045
8 <sup>th</sup> week	35.87±12.77	$30.36 \pm 11.92$	0.037
16 <sup>th</sup> week	22.31±9.92	18.84±7.96	0.041
24 <sup>th</sup> week	13.64±6	$10.53 \pm 4.83$	0.008
Calculated effect size at 24 <sup>th</sup> week between groups	Glas	ss's delta=0.57	
<i>P</i> value for Pre-intervention Vs 24 <sup>th</sup> Week	<0.0001 <0.0001		
	SPADI score		
Pre-intervention	69.86±7.63	72.86±8.13	0.075
4 <sup>th</sup> week	$55.59 \pm 8.43$	52.11±8	0.048
8 <sup>th</sup> week	42.73±8.18	38.69±7.93	0.020
16 <sup>th</sup> week	$32.13 \pm 6.63$	$28.58 \pm 5.96$	0.009
24 <sup>th</sup> week	$22.46 \pm 5.44$	$19.63 \pm 4.88$	0.011
Calculated effect size at 24 <sup>th</sup> week between groups	Glass's delta=0.54		
<i>P</i> value for Pre-intervention Vs 24 <sup>th</sup> Week	<0.0001	< 0.0001	

P<0.05 Significant, P>0.05 Non-significant, SD-standard deviation, Gr-A (Only exercise), Gr-B (Suprascapular nerve block and exercise), \* Student t test

Table 3: Comparison of Forward flexion, Extension,
Internal rotation, External rotation and Abduction
between the study groups at different follow up time periods

Follow up	Group-A ( <i>n</i> =45)	Group-B ( <i>n</i> =45)	$P^{\dagger}$		
time periods	Forward flexion, Degrees Median (IQR)				
Pre-intervention	90 (77.5, 100)	90 (80, 100)	0.889		
4 weeks	110 (100, 125)	125 (110, 130)	0.002		
8 weeks	125 (110, 135)	135 (125, 140)	< 0.001		
16 weeks	135 (127.5, 140)	145 (135, 147.5)	< 0.001		
24 weeks	145 (140, 150)	150 (145, 155)	0.005		
Ex	tension, Degrees	Median (IQR)			
Pre-intervention	20 (15, 30)	20 (15, 25)	0.268		
4 weeks	25 (20, 30)	35 (27.5, 35)	< 0.001		
8 weeks	30 (30, 35)	40 (35, 40)	< 0.001		
16 weeks	35 (35, 45)	45 (40, 45)	< 0.001		
24 weeks	45 (40, 50)	50 (45, 55)	< 0.001		
Intern	nal Rotation, Degre	ees Median (IQR)			
Pre-intervention	30 (30, 35)	30 (27.5, 40)	0.842		
4 weeks	40 (35, 45)	45 (40, 47.5)	0.006		
8 weeks	45 (40, 45)	50 (45, 55)	< 0.001		
16 weeks	50 (45, 52.5)	55 (50, 60)	0.003		
24 weeks	55 (55, 60)	60 (55, 65)	0.019		
External Rotation, Degrees Median (IQR)					
Pre-intervention	40 (35, 45)	40 (32.5, 42.5)	0.160		
4 weeks	45 (42.5, 50)	50 (45, 57.5)	0.034		
8 weeks	55 (50, 60)	60 (55, 65)	< 0.001		
16 weeks	60 (57.5, 65)	65 (62.5, 70)	< 0.001		
24 weeks	70 (65, 75)	75 (70, 78.75)	< 0.001		
Abduction, Degrees Mean (SD) P*					
Pre-intervention	$113.18 \pm 10.88$	108.67±10.19	0.045		
4 <sup>th</sup> week	$131.44 \pm 8.57$	127.67±8.96	0.044		
8 <sup>th</sup> week	$139.22 \pm 7.68$	$142.44 \pm 7.51$	0.047		
$16^{th}$ week	151.11±6.82	154±6.09	0.037		
24 <sup>th</sup> week	$160.89 \pm 7.25$	$165.67 \pm 5.5$	< 0.001		

P<0.05 Significant, P>0.05 Non-significant, SD-standard deviation, Gr-A (Only exercise), Gr-B (Suprascapular nerve block and exercise), \* Student t test, † Mann-Whitney U Test)

We used SSNB to reduce the initial pain of exercise and better compliance which resulted in better outcome in terms of pain relief, SPADI and ROM. A study by Van de Laar *et al.*,<sup>[4]</sup> has suggested that pain and over stretching should be avoided as it will cause discomfort to the patient without improved range of motion. Other authors have also reported that single or multiple injections to block suprascapular nerve in the treatment of frozen shoulder resulted in improved pain score and ROM<sup>[14,15]</sup> and found it to be safe.<sup>[16]</sup> We conducted this study because there was a lack of high-quality evidence in favor of suprascapular nerve block along with exercise. We also did not observe any block-related complications like increased pain, nerve injury, hematoma or pneumothorax or anesthetic toxicity.

We observed that the average no of tablets consumed by the patients (analgesic consumption) were significantly less in Gr-B at 4 and 8 weeks (P < 0.05) however, at 12 and 24 weeks it was comparable (P > 0.05). This short-lived advantage in reduced consumption of analgesics could be because of steroid or SSNB.<sup>[17]</sup>

There are many other invasive and non-invasive treatments for PAC depending upon the stage and severity of disease. Manipulation under anesthesia and arthroscopic capsular release are costly and invasive treatments and their effectiveness remains uncertain. When these two surgical interventions were compared with early structured physiotherapy plus steroid injection, none of them was superior to the other.<sup>[18]</sup> Until a few years back, PAC remained an unresolved clinical problem. There was no universally accepted and effective treatment protocol and there was a strong need for further research and development of more effective treatment strategies.<sup>[17]</sup> New clinical guidelines to treat PAC have been suggested but the quest for the most effective treatment was still on.<sup>[19]</sup> However, one recently published study has given level-1 evidence that SSNB in combination with noninvasive rehabilitation is an effective and safe mode of treatment for idiopathic frozen shoulder.<sup>[20]</sup> A narrative review of various techniques and approaches has mentioned about few complications of SSNB;<sup>[21]</sup> however, US-guided posterior technique is a safe procedure as suggested by other studies.<sup>[20,22]</sup> We used US-guided posterior approach in our patients and did not have any block-related complications.

The present study has incorporated many positive points. Firstly, it has used a practical and economical model by combining the hospital-based and home-based exercise schedule. Secondly, the study period was 6 months which was a good enough time periods to review the success or failure and to decide the further course (may be invasive treatment, if required) without delay. Last but not the least, the SPADI was used to measure the functional quality of improvement.<sup>[23]</sup> Although there are many scales to assess the functional outcome of shoulder in PAC, [24,25] SPADI has indicated adequate measurement properties and superior responsiveness when compared to other scales in patients with PAC.<sup>[26]</sup> Our study also has a few limitations. Diabetes plays an important role in the pathophysiology as well as in the prognosis of PAC.<sup>[27,28]</sup> However, we did not do the sub-group analysis between diabetic and normoglycemic populations. This would have given some insight in the outcome variables and future management including PAC in normoglycemic population.<sup>[29]</sup> Also, this was a single-center study in a captive population and therefore the results cannot be generalized without a supportive result by other RCTs with a larger sample size. Lastly, biases could not be ruled out as it was an open-label study.

# Conclusion

On the basis of our results, we conclude that exercise is effective to treat the pain and decreased range of motion in early stages of primary adhesive capsulitis (PAC). Combining ultrasound-guided suprascapular nerve block with exercise is more effective in treatment of PAC then exercise alone. The suprascapular nerve block (SSNB) reduces the use of analgesics when used with exercise and it is effective and safe to use in PAC.

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#### **Conflicts of interest**

There are no conflicts of interest.

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