Brief Communication

# Effectiveness of ultrasound-guided pulsed radiofrequency ablation of suprascapular nerve versus local anaesthetics with steroids in patients with chronic shoulder pain: A randomised controlled trial

## INTRODUCTION

Chronic shoulder pain significantly impacts psychosocial well-being and quality of life.[1-3] When conservative methods prove insufficient, minimally invasive interventions like intra-articular or soft tissue injections and suprascapular nerve (SSN) blocks may be employed for patients who do not respond to conservative treatment.[4,5]

This study compares the effectiveness of ultrasound (USG) guided pulsed radiofrequency (PRF) lesioning and local anaesthetics with steroid injection for chronic shoulder pain. We hypothesised that employing USG PRF would result in substantial pain relief and functional improvement in individuals suffering from chronic shoulder pain compared to local anaesthetic and steroid injection to the SSN.

## METHODS

The study was a randomised, triple-blinded, active-controlled trial conducted at a tertiary care hospital, approved by the Institutional Ethics Committee (vide approval number NK/3830/MD/359, dated 23/10/2017) and registered with the Clinical Trials Registry-India (vide registration number CTRI/2018/07/014772, www.ctri.nic.in/). Enrolment for the study occurred from July 2018 to August 2019, with patients providing written informed consent for participation in the study and use of the patient data for research and educational purposes. Adherence to the Helsinki Declaration of 2013 was ensured.

Patients aged 18–80 years experiencing shoulder pain and restricted motion for over three months due to shoulder conditions like adhesive capsulitis, chronic tendinitis, impingement syndrome, and chronic rotator cuff injuries, with an average numerical rating score (NRS) of five or higher, were included, while those with rheumatoid arthritis, shoulder malignancy, a previous diagnosis of the herniated cervical disc confirmed by cervical spine magnetic resonance imaging (MRI), any recent interventional pain management such as intra-articular injection, local anaesthetic with steroid injection, transcutaneous electrical nerve stimulation (TENS) or PRF in the past three months, fibromyalgia, coagulation disorders, uncontrolled diabetes, allergies to local anaesthetics, malignancy, psychiatric illness that hindered effective communication, and pregnancy were excluded.

Patients were randomly assigned to groups using a computer-generated table. Group assignments were sealed in sequentially numbered opaque envelopes and opened just before the procedure. The Group PRF received PRF treatment for the SSN, while the Group BS got an SSN block with bupivacaine and methylprednisolone, both under ultrasound guidance using a 6–13 MHz linear probe (SonoSite, Inc. M Turbo, Bothell, WA98021, USA). All procedures were carried out by a single physician. The patient and the follow-up physician were unaware of group assignments. A screen separated the patient from the procedure shelf, and light music masked the radiofrequency (RF) machine's sound in both groups. Both groups used RF cannula for SSN localisation, local anaesthetic infiltration, and sensory/motor stimulation. In the Group PRF, an RF probe connected to an RF generator was used for PRF at the SSN, followed by saline injection. The RF machine was not activated after stimulation in the Group BS. After a 480 s delay, drug injection followed. Unaware of the intervention, investigators at the pain clinic conducted patient follow-ups. The statistician analysing the data was also blinded to the groups.

In the Group PRF, patients underwent pulsed radiofrequency (Cosman Medical, INC, Cambridge St., Burlington, USA) treatment administered to the SSN within the suprascapular notch. This treatment comprised three cycles, with durations of 180 s, 180 s, and 120 s, totaling 480 s. In the Group BS, an SSN block with 0.25% bupivacaine (4 ml) and 40 mg methylprednisolone was administered.

The primary outcome was NRS at three months in both groups. The secondary outcomes included assessing the number of patients who achieved effective pain relief (defined as a ≥50% reduction in mean NRS) at three months as well as measuring a passive range of motion (PROM) with a goniometer, shoulder pain

and disability index (SPADI), and NRS at 2, 4, 8, and 12 weeks. Additionally, any reported side effects were documented.

To detect a minimal clinically important difference (MCID) of 2.17 for chronic shoulder pain at three months with a pooled standard deviation (SD) of 2.0 with an equivalence margin of 0.2 (10%), to achieve a power of 80% and at a level of significance of 5%, 18 patients per group were required.[6] We recruited 20 patients per group to account for an attrition rate of 10%. Statistical analysis was performed using Statistical Package for Social Sciences version 22 (IBM SPSS Statistics for Windows, Armonk, NY) with a significance level set at $P < 0.05$. Demographics like age, gender, weight, height, baseline NRS, SPADI, passive range of motion (PROM), and duration of pain were compared using t-tests, and percentage variables like diagnosis of patients were compared using Chi-square tests. Repeated measures analysis of variance (RMANOVA) was conducted to analyse NRS, SPADI, and PROM at different time intervals. The incidence of effective pain relief was analysed using the Chi-square test.

## RESULTS

Among the 54 patients assessed for eligibility, 40 were enroled in the study [Figure 1]. Baseline demography, clinical assessment, etiological diagnosis, and pain assessment were comparable [Table 1].

The mean NRS scores between the PRF and BS groups were similar at the 3rd month ($P = 0.211$). RMANOVA indicated a statistically significant relationship between time and pain scores ($P = 0.001$) but no significant interaction between pain scores and groups ($P = 0.233$). Both groups showed a significant decrease in NRS scores compared to the baseline. When comparing the groups, except for a 2-week interval where Group BS exhibited significantly lower NRS scores than Group PRF ($P = 0.014$), the two groups were similar at all other time points [Table 2]. The number of patients achieving EPR at three months was 11 in the Group PRF and 13 in the Group BS, with no statistically significant difference ($P = 0.122$). SPADI assessment included parameters like total pain score (TPS), total disability score (TDS), and overall SPADI. RMANOVA results indicated a

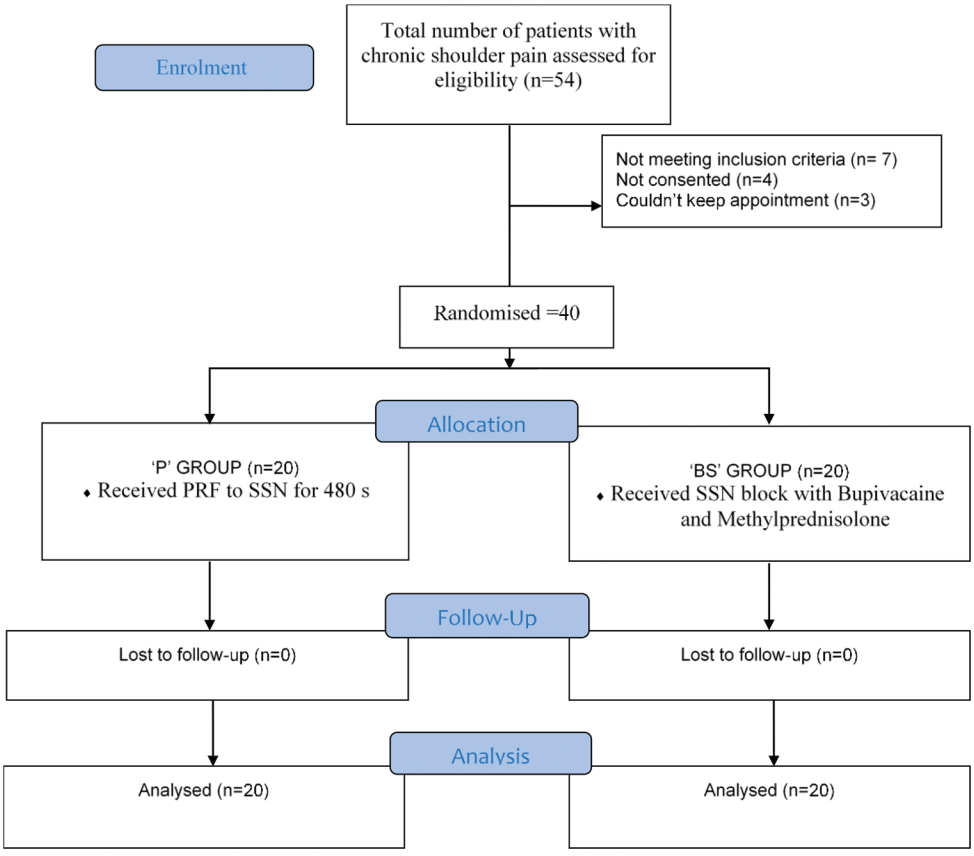


**Figure 1:** Consolidated Standards of Reporting Trials (CONSORT) diagram showing flow of patients. PRF = Pulsed radiofrequency, SSN = Suprascapular nerve

significant time and TPS interaction ($P = 0.001$) but no TPS and group interaction ($P = 0.442$). TPS decreased significantly in both groups at all follow-up times compared to baseline, with no intergroup differences ($P > 0.05$) [Figure 2a]. For TDS, RMANOVA revealed significant TDS and time interaction ($P < 0.001$) and also significant TDS and group interaction ($P = 0.001$), with TDS decreasing significantly in both groups at all follow-up times [Figure 2b]. Regarding overall SPADI, RMANOVA showed significant time and SPADI ($P < 0.001$) but no SPADI and group interaction ($P > 0.05$). SPADI decreased significantly in both groups at all follow-up times, with no intergroup differences [Figure 2c].

For PROM, the results of RMANOVA revealed significant time and PROM interaction ($P < 0.001$) and no PROM and group ($P > 0.05$) interaction. PROM improved significantly in both groups at all follow-up times compared to the baseline. Both groups were comparable at all time intervals [Figure 2d]. Injection site pain lasting for 48 h was observed in three patients.

**Table 1: Demographic data and baseline details**

| | Group PRF (n=20) | Group BS (n=20) |
|---|---|---|
| Age (years), mean (SD) | 52.6 (11.12) | 49.7 (10.83) |
| Gender: male/female, n | 4/16 | 5/15 |
| Weight (kg), mean (SD) | 63.82 (9.54) | 65.7 (10.72) |
| Height (cm), mean (SD) | 158.62 (7.52) | 163.2 (7.94) |
| Baseline NRS, mean (SD) | 8.42 (0.24) | 8.14 (0.28) |
| Baseline TPS, mean (SD) | 37.92 (1.18) | 36.60 (1.12) |
| Baseline TDS, mean (SD) | 66.75 (1.83) | 67.65 (1.92) |
| Baseline SPADI, mean (SD) | 103.65 (2.75) | 104.25 (2.73) |
| Baseline PROM (abduction angle), mean (SD) | 63 (7.07) | 66 (4.67) |
| Duration of pain (months), mean (SD) | 19.63 (12.51) | 21.51 (14.82) |
| Diagnosis, *n* | | |
| Adhesive capsulitis | 16 | 17 |
| Rotator cuff injury | 4 | 3 |

Data expressed as mean (standard deviation) or numbers. NRS=Numeric rating scale, TPS=Total pain score, TDS=Total disability score, SPADI=Shoulder pain and disability index, PROM=Passive range of motion, SD=Standard deviations, *n*=Number of patients

**Table 2: Pain score (NRS) assessment at various time intervals**

| | Group PRF Mean (SD) (95% CI) (*n*=20) | Group BS Mean (SD) (95% CI) (*n*=20) | *P* |
|---|---|---|---|
| Baseline | 8.42 (0.24) (8.34, 8.49) | 8.14 (0.28) (8.05, 8.22) | 0.472 |
| 2 weeks | 6.95 (0.98) (6.64, 7.25) | 5.70 (1.20) (5.32, 6.07) | 0.014 |
| 4 weeks | 5.85 (1.24) (5.46, 6.23) | 5.80 (1.19) (5.42, 6.17) | 0.315 |
| 8 weeks | 5.40 (1.45) (4.94, 5.85) | 4.60 (1.38) (4.17, 5.03) | 0.072 |
| 12 weeks | 4.60 (1.60) (4.10, 5.10) | 3.75 (2.14) (3.08, 4.41) | 0.211 |

Pain scores are presented as mean (standard deviation) (95% confidence interval). NRS=Numerical rating scale for pain, SD=Standard deviation, CI=Confidence interval, *n*=Number of patients

## DISCUSSION

We observed that both interventions yielded similar pain relief and improved SPADI score and PROM. However, it is worth noting that the block group exhibited significantly lower pain at a single time point, specifically during the 2-week follow-up period.

The notable reduction in pain experienced can be attributed to the anti-inflammatory properties of the steroid. This outcome aligns with a study by Lee *et al*.[6], where epidural steroid injection led to the greatest pain reduction at the 2-week mark, followed by consistently lower VAS scores thereafter. Although in the case of PRF, the onset of analgesic effect has been reported between 7 and 10 days, the maximum reduction is seen between 4 and 12 weeks. Therefore, we can state that the significant reduction in pain at two weeks in the Group BS occurred

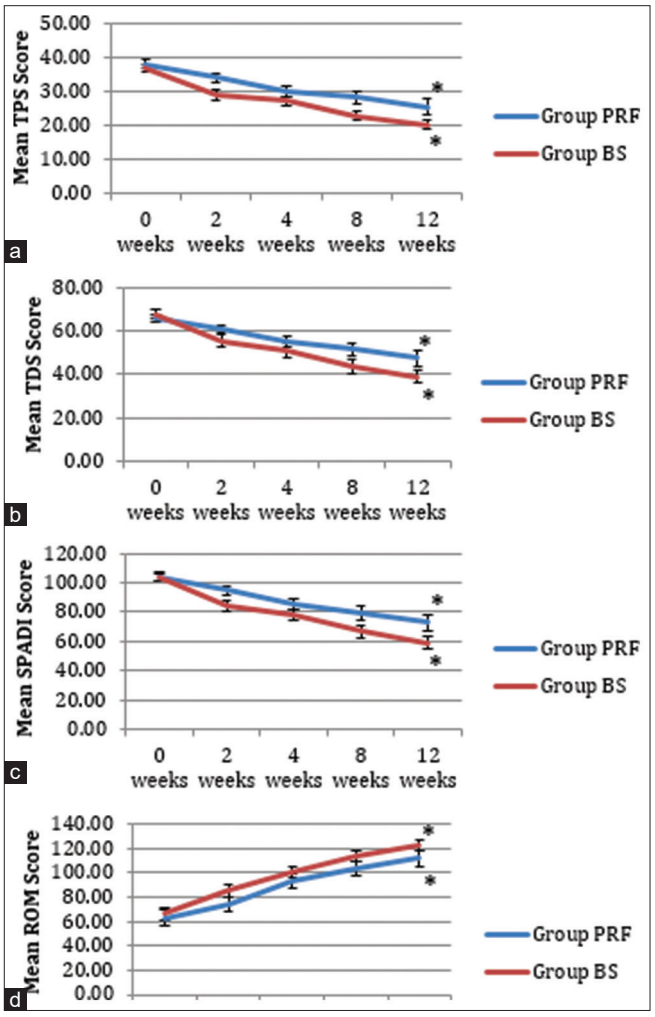


**Figure 2:** (a) Mean TPS, (b) Mean TDS, (c) Overall SPADI and (d) PROM at various time intervals in both groups. TPS= Total pain score, TDS=Total disability score, SPADI=Shoulder pain and disability index, PROM= Passive range of motion. None of the values were statistically significant between the groups

due to the administration of steroids. In contrast, the analgesic effects of PRF due to its neuromodulatory effects were achieved later, around four weeks. The SSN gives 70% of the shoulder joint's sensory proprioception and nociception output.[7,8] Shanahan *et al*.[9] the SSN block demonstrated significant improvements in pain relief, PROM, and reduced disability compared to the placebo group over a 12-week follow-up.

## CONCLUSION

Both ultrasound-guided PRF treatment of the SSN and bupivacaine-steroid block demonstrated substantial and comparable pain reduction and improvements in the SPADI score and PROM in patients with chronic shoulder pain lasting up to a 12-week follow-up period.

### Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' Institution policy.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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