Original Article

Efficacy of pulsed radiofrequency on the suprascapular and axillary-circumflex nerve for shoulder pain: A randomised controlled trial

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ABSTRACT

Background and Aims: Painful shoulder is one of the most frequent consultation causes. Multiple treatments have been described to relieve pain, restore range of motion and improve functionality. **Methods:** This randomised clinical trial was conducted in 60 patients. The treatment group received combined pulsed radiofrequency (PRF) on suprascapular nerve (SN) and axillary-circumflex nerve (ACN). The control group received PRF on SN only. The primary outcome was pain intensity measured by the Numerical Rating Scale (NRS). The secondary outcomes were the Shoulder Pain and Disability Index (SPADI), the Constant–Murley range of motion scale and Disability of the Arm, Shoulder and Hand (DASH) scale. The patients were monitored at the baseline visit and at 1, 3, 6 and 9 months. A mixed ordinal regression model was estimated to evaluate the association between the study group and pain measured with NRS. **Results:** A global decrease in pain at the end of the study was noted. The global baseline NRS was 8.4, and the global final NRS at 9 months of follow-up was 6.2. Combined PRF on SN and ACN was not associated with lower NRS pain scores compared to single SN PRF [odds ratio (OR) =1.04, 95% confidence interval (CI) 0.91–1.20, $P = 0.507$]. Secondary outcomes showed no significant differences: SPADI (OR = 1.04, 95% CI 0.92–1.18), Constant–Murley (OR = 1.01, 95% CI 0.90–1.14), DASH (OR = 1.04, 95% CI 0.92–1.17). **Conclusion:** Combined PRF applied to SN and ACN was not superior to PRF applied to SN alone.

Keywords: Axillary-circumflex nerve, pulsed radiofrequency, shoulder pain, Shoulder Pain and Disability Index, suprascapular nerve

INTRODUCTION

Painful shoulder is one of the most frequent consultations in primary care. According to a recent systematic review, restoring function and improving quality of life through physical rehabilitation is questionable.[1] Multiple studies[2-6] assessed the efficacy of various interventional techniques to treat painful shoulder. Intra-articular injections with local anaesthetic (LA) and corticosteroids, suprascapular nerve (SN) block with LA with or without corticosteroids, and combined SN and axillary-circumflex nerve (ACN) block are some of the interventional techniques classically used to treat

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patients with painful shoulder. In addition, various studies have shown that pulsed radiofrequency (PRF) on SN can effectively treat painful shoulders of different aetiology. However, the sensory branch of the shoulder joint, the muscles involved in its movement and the adjacent skin are innervated primarily by SN and ACN.

We hypothesised that a PRF performed simultaneously on SN and ACN gives greater shoulder pain relief than a PRF on SN alone. Therefore, our primary objective is to evaluate the decrease in the intensity of pain and disability, measured using the Numerical Rating Scale (NRS) and the Shoulder Pain and Disability Index (SPADI), respectively. As secondary objectives, we intend to evaluate the improvement in the Constant–Murley range of motion scale and analyse the recovery in shoulder functionality and performance of basic activities of daily living using the Disability of the Arm, Shoulder and Hand (DASH) scale.

METHODS

This single-centre, double-blind, randomised clinical trial was carried out after the approval from the Clinical Research Ethics Committee of La Fe University and Polytechnic Hospital was obtained (vide approval number ESP-RF-2016-01, dated 27 June 2016), and the trial was registered at Clinicaltrials.gov (vide registration number NCT number: 03498976). Written informed consent was obtained from each subject before inclusion, and all patients were informed that their data could be used for educational and research purposes. The study was carried out in accordance with the principles of the Declaration of Helsinki, 2013, and good clinical practice.

Patients were screened in our pain unit outpatient clinic. Therapeutic alternatives were presented if they had chronic painful shoulder syndrome, and the possibility of being included in the study was explained. Patients had to meet at least one inclusion criterion from the list of criteria given in Table 1. Exclusion criteria included refusal to undergo interventional techniques, those who had undergone anticoagulant treatment or coagulopathy (all patients underwent a control analysis to rule out coagulopathy), patients with infection at the puncture site or psychopathologies (depression, anxiety) or with psychiatric diseases (schizophrenia, bipolar disorder) and patients facing an ongoing medico-legal dispute.

Patients were randomly allocated into two groups in a 1:1 allocation ratio by a sequence generated from a pseudorandom number seed (seed: 243657). Patients were assigned to each group following this randomisation. The randomisation sequence was kept in a closed envelope before the start of the study and was thus concealed. At the time of treatment for each patient, the nurse assigned the patient to the corresponding group following the order established by this sequence. This way, double-blinding was maintained since neither the doctor nor the patient knew which group they were assigned to. The treatment group (Group A) received combined PRF on SN and ACN nerves. The control group (Group B) received PRF on SN only.

The technique was performed using ultrasound (US) (SonoSite S-nerve ultrasound machine; FUJIFILM SonoSite, Bothell, WA, USA) and nerve stimulation guidance with Cosman RFG-4G radiofrequency generator (Cosman Medical Inc, Burlington, VT, USA). We followed our previously published PRF technique on SN.[7] The patient was placed in lateral decubitus with the affected shoulder facing up. SN localisation was performed with a high-frequency linear transducer (6–13 MHz) in sagittal orientation (parallel to the spine) to identify the supraspinatus muscle, the pleura and the suprascapular fossa. Then, the needle (CU, Cosman Medical Inc; 10 cm long with a 5-mm active tip, 22G, with temperature control) was inserted in a medial to lateral plane and its position was confirmed by electrical stimulation (sensory stimulation less than 0.6 V with paraesthesia in the skin above the shoulder and motor response through fasciculations of the supraspinatus muscle less than 1.2 V) performed using the Cosman RFG-4G radiofrequency generator (Cosman Medical Inc).

For ACN localisation, with the patient in the same position, the posterior aspect of the humerus was scanned along its longitudinal axis using the same high-frequency linear transducer. The posterior humeral circumflex artery and ACN were identified using a short-axis in-plane approach. Then, the needle (6 cm long with a 5-mm active tip, 22G, with temperature control) was inserted in-plane along the longitudinal axis of the US beam. The needle tip position was finally confirmed by electrical stimulation (sensory stimulation less than 0.6 V with paraesthesia in the skin above the deltoid and motor response of the deltoid muscle less than 1.2 V)

performed using the Cosman RFG-4G radiofrequency generator.

After confirming the correct needle position on both nerves, PRF was performed using a Cosman RFG-4G with the following parameters: one cycle of 6 min at 42°C and 45 V. At the end of the PRF technique, both groups received 5 mg of levobupivacaine and 4 mg of dexamethasone through each PRF needle in the combined technique and into the single needle over SN in the simple technique.

The principal investigator (PI) performed all treatments and recruited all patients. After locating both nerves and before starting PRF, all the acoustic signals from the radiofrequency generator were turned off, and the PI left the technical room. Next, the nurse applied the single or combined technique to the randomisation sequence. If the method was performed on SN only, the nurse momentarily disconnected the electrode corresponding to ACN from the radiofrequency generator while maintaining both needles in place. All patients had to stay in the room for 10 min to reinforce double-blinding. At the end of the procedure, the PI removed the needles. After observation and surveillance, the patient was discharged if no side effects or complications appeared.

To avoid delaying the treatment, we performed the technique during the first 30 days after the first visit to the pain unit. The clinical follow-up visits were carried out in pain unit consultation as part of the study, followed by follow-up visits at 1, 3, 6 and 9 months after the intervention. None of the patients followed specific physiotherapy or rehabilitation treatment. However, those who required it continued with pharmacological therapy.

To assess pain intensity, we use the NRS scale in which 0 corresponds to no pain and 10 to the worst pain imaginable. To assess the secondary objectives, we also had to use other specific tests for the clinical–functional evaluation of the shoulder. To assess shoulder pain and physical function, we used the SPADI test, which has reasonably good properties to ensure that the scores accurately reflect the patient's condition. A higher score indicates a more significant disability. Moreover, the Constant–Murley rating scale was recorded, which comprises individual parameters that define pain intensity and can also specify the ability to perform basic activities of the patient's daily life. The higher the score the patient gets, the better the functionality. The DASH test assessed shoulder functionality and quality of life related to upper limb problems. It also allowed comparison and measurement of the treatments administered in different territories of the said limb. The higher the score, the greater the disability. All tests were performed on the patients on the day of the intervention and subsequently at 1, 3, 6 and 9 months. The PI was in charge of collecting and analysing the test results. The following variables were recorded: reason for consultation, personal history, previous treatments performed, history of pain, physical examination, weight, height, age and sex. We also recorded the following variables during the study: body mass index, nonsteroidal anti-inflammatory drugs (NSAIDs), adjuvant drug usage and opioid requirements defined as morphine equivalents in mg every 24 h.

To calculate the sample size, we considered a 25% decrease in pain measured by NRS, and after performing SN PRF, the mean pain was 4 out of 10 points with a standard deviation of 1.3, based on data from a previous study.[4] We calculated that with an alpha error of 5%, 52 patients (26 per group) were needed to achieve a significant result with a power (beta error) of 80%. We decided to increase the sample size to 60 patients (30 per group) to cover potential losses to follow-up. We used the mean and standard deviation to report all continuous variables when the distribution was normal or median and interquartile range if otherwise. The normality of the distributions was evaluated by inspection of the quantile–quantile graphs and by the Shapiro–Wilk test. The difference in the follow-up time for analgesic requirements was carried out using an analysis of variance for repeated measures. The difference in the occurrence of complications was analysed using the Chi-square test and Fisher's exact test. To avoid misspecification bias, we performed the intention-to-treat analysis. Categorical variables were expressed in percentages and proportions. We estimated the influence of the study group on pain measured with NRS, with a mixed-effect ordinal regression model, adjusting for opioid requirements, NSAIDs and adjuvants and introducing patients as random factors to control interindividual variability and the longitudinal nature of the data. The association between the study group and the DASH, SPADI and Constant–Murley scales was evaluated by estimating a mixed-effect ordinal regression model with the same covariate structure used in the model to assess pain. The difference in the appearance of complications was analysed using the Chi-square

test. To avoid misspecification bias, we performed an intention-to-treat analysis. Multiple imputation of missing values was preplanned if more than 10% of missing values were observed in any of the variables included in the models. No correction for multiple comparisons was prespecified. Thus, secondary outcome results should be seen as exploratory. The analysis used the R program version 3.5.2 (The R Foundation for Statistical Computing, http://www.R-project.org/).

RESULTS

We screened 74 patients, and 14 were excluded [Figure 1]. Of the 300 assessed time points evaluated, there were 12 losses, representing 4% of missing values; therefore, we did not perform missing imputation.

The demographic characteristics were comparable [Table 1]. The pain score (NRS) was comparable among the groups [odds ratio (OR) =1.04, 95% confidence interval (CI) 0.91, 1.20, P = 0.507]. Both groups maintained an improvement in NRS throughout the follow-up period [Table 2].

There was a global improvement in the evolution of the SPADI test throughout the study [Table 2] (OR = 1.04,

Table 1: Demographic characteristics, baseline characteristics and inclusion criteria

	Group A (*n*=30)	Group B (*n*=30)
Age (years)	61.3 (12.39)	60.47 (13.14)
Gender:Male/female	8/22	8/22
Height (cm)	161 (10)	162 (9)
Weight (kg)	77.52 (14.75)	74.77 (15.40)
Body mass index (kg/m^2)	30.93 (8.30)	29.47 (8.55)
Numeric Rating Scale	8.6 (1.3)	8.1 (1.8)
SPADI	78.8 (16.1)	77.02 (19.5)
Constant–Murley test	33.3 (11.4)	34.1 (17.8)
DASH	65.7 (18.3)	66.7 (20.8)
Inclusion criteria		
Frozen shoulder syndrome	6	12
Massive rotator cuff tear	6	1
Partial rupture of some tendon of the rotator cuff	10	9
Osteoarthritis	3	4
Periarthritis	1	3
Calcific tendinitis	3	3
Bursitis	11	11
Nervous compression	1	2
Subacromial syndrome	2	4

Data expressed as mean (standard deviation) or numbers. DASH=Disabilities of the Arm, Shoulder and Hand, SD=Standard deviation, SPADI=Shoulder Pain and Disability Index, n=number of patients

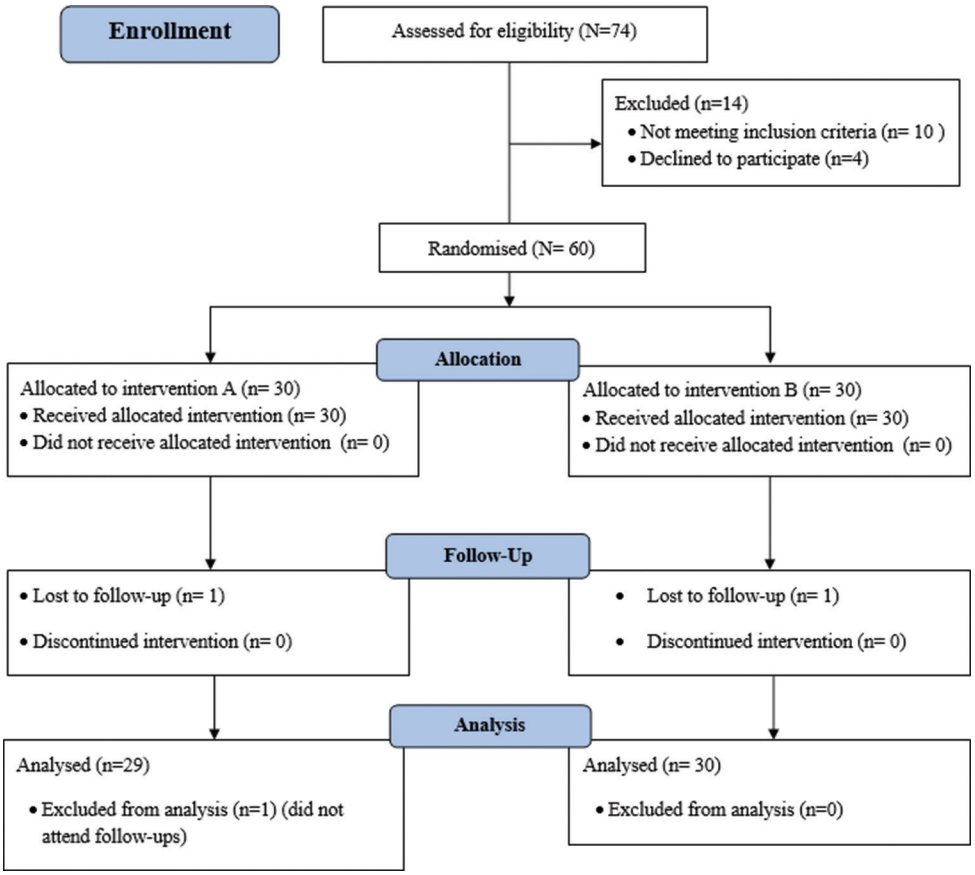

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram

Table 2: Study parameters

	Group A	Group B	Mean difference (95% CI)	*P*	SPADI	Group A	Group B	Mean difference (95% CI)	*P*
NRS									
Baseline (*n*=60)	*n*=30 8.6 (1.3)	*n*=30 8.17 (1.8)	0.43 (-0.34–1.21)	0.26	Baseline (*n*=60)	*n*=30 78.82 (16.16)	*n*=30 77.02 (19.50)	1.79 (−7.47–11.05)	0.70
T1m (*n*=59)	*n*=29 6.72 (2.37)	*n*=30 6.30 (2.10)	0.42 (-0.74–1.59)	0.47	T1m (*n*=59)	*n*=29 67.47 (23.02)	*n*=30 69.61 (20.15)	-2.13 (-13.44–9.16)	0.70
T3m (*n*=59)	*n*=29 6.67 (2.90)	*n*=30 5.80 (2.31)	0.86 (-0.49–2.22)	0.20	T3m (*n*=59)	*n*=29 66.66 (28.56)	*n*=30 63.61 (21.38)	3.07 (-10.13–16.29)	0.64
T6m (*n*=56)	*n*=28 6.45 (2.72)	*n*=28 5.50 (2.01)	0.94 (-0.32–2.21)	0.14	T6m (*n*=56)	*n*=28 67.66 (27.69)	*n*=28 63.53 (24.16)	4.13 (−9.79–18.05)	0.55
T9m (*n*=54)	*n*=27 6.70 (2.78)	*n*=27 5.70 (2.30)	1 (-0.39–2.39)	0.15	T9m (*n*=54)	*n*=27 67.66 (28.10)	*n*=27 64.61 (22.72)	3.04 (-10.92–17.01)	0.66
Constant–Murley									
Baseline (*n*=60)	*n*=30 33.39 (11.49)	*n*=30 34.18 (17.82)	-0.79 (−8.57–6.98)	0.83	Baseline (*n*=60)	*n*=30 65.74 (18.32)	*n*=30 66.73 (20.85)	-0.98 (-11.21–9.23)	0.84
T1m (*n*=59)	*n*=29 49,48 (20.06)	*n*=30 52.67 (20.36)	-3.18 (-13.72–7.35)	0.54	T1m (*n*=59)	*n*=29 63.77 (23.22)	*n*=30 65.21 (21.30)	-1.44 (−13.19–10.31)	0.80
T3m (*n*=59)	*n*=29 55.36 (23.92)	*n*=30 56.47 (22.28)	-1.10 (-13.31–11.10)	0.85	T3m (*n*=59)	*n*=29 27.93 (16.10)	*n*=30 28.73 (16.05)	-0.8 (−9.10–7.50)	0.84
T6m (*n*=56)	*n*=28 55.46 (23.70)	*n*=28 58.68 (21.96)	-3.21 (-15.46–9.03)	0.60	T6m (*n*=56)	*n*=28 61.18 (24.87)	*n*=28 59.04 (21.60)	2.14 (-10.44–14.73)	0.73
T9m (*n*=54)	*n*=27 56.41 (21.92)	*n*=27 54.78 (21.30)	1.6 (-10.17–13.43)	0.78	T9m (*n*=54)	*n*=27 62.39 (25.79)	*n*=27 61.93 (21.93)	0.46 (-12.61–13.54)	0.94

Data expressed as mean (standard deviation). Baseline=Measurements of all the tests on the day of intervention, T1m=Measurements of all the tests after 1 month, T3m=Measurements of all the tests after 3 months, T6m=Measurements of all the tests after 6 months, T9m=Measurements of all the tests after 9 months. CI=Confidence interval, DASH=Disabilities of the Arm, Shoulder and Hand, NRS=Numerical Rating Scale, SPADI=Shoulder Pain and Disability Index

95% CI 0.92, 1.18). The Constant–Murley rating scale significantly improved in both treatment groups, which was maintained throughout the study (OR = 1.01, 95% CI 0.90, 1.14).

The DASH test showed a significant improvement in both treatment groups at three months of follow-up. Subsequently, a tendency to recover values similar to the basal values was observed with no statistically significant differences [Table 2] (OR = 1.04, 95% CI 0.92, 1.17). We did not observe any complications in the groups.

DISCUSSION

We observed that the combined PRF technique on SN and ACN is safe and effective in treating painful shoulder syndrome. It produces reasonable pain relief without causing adverse effects or significant complications. It also showed decreased pain in NRS, improved quality of life in SPADI, improved functionality in DASH, and improved range of motion and activities of daily living in the Constant–Murley test. Despite the promising results, we have yet to achieve statistical significance. The results also suggest that pain relief, improvement in range of motion and quality of life were independent of performing simple or combined techniques.

Given the results obtained in similar studies, we could only compare our work with those published by Gofeld *et al.*[3] since it is the only double-blind, randomised clinical trial. The results regarding pain relief measured using the Visual Analogue Scale and improvement on the SPADI and Constant scales are the same as our study results and are not statistically significant.

We positioned the patient in lateral decubitus with the target shoulder upwards. The new approach performed with the patient in lateral decubitus minimises complications. The most feared is the realisation of a pneumothorax when constantly visualising the tip of the needle and having the spine of the scapula as a natural protection barrier. In addition, the possibility of puncturing the axillary artery is also reduced, so we can affirm that it is a very safe technique with little chance of complications.

Previous studies focused on treating SN using nerve block with LA plus corticosteroids. Still, none of the studies analysed the influence of PRF

on SN and ACN in treating painful shoulder.[2-6] Liu *et al.*[5] conducted a systematic review in which five of 114 studies involving PRF treatment on SN met the inclusion criteria. These studies compared the clinical outcomes of PRF with those of other treatments, such as intra-articular corticosteroid injection and conventional Transcutaneous Electrical Nerve Stimulation (TENS). All reported improvements in passive range of motion, VAS as a measure of shoulder pain and SPADI index on PRF treatment that persisted for at least 12 weeks. Furthermore, no complications were reported in all trials. However, they concluded that PRF on SN provides good results for at least 12 weeks, but it needs to clarify whether PRF is superior to the other treatments studied. Lewis[2] carried out an observational study, and 16 participants were included. They underwent a combined block of SN and the articular branches of ACN, along with phenolisation of both nerves. A decrease in the average value of pain intensity of 69% was observed, with an improvement in the ranges of motion during a 13-week follow-up period. The author finally stated that the neural blockade on these nerves reduces pain in the osteoarthritis joint, improves the movement of the glenohumeral joint and improves quality of life. The clinical case described by Kim *et al.*[8] was a patient with a painful shoulder for more than three years with calcifying tendinitis in the rotator cuff complex. They performed a blockade of SN and ACN with LA and corticosteroids, which gave complete pain relief for two weeks. Thus, they finally decided to perform PRF on both nerves, maintaining analgesic effectiveness for over three months.

We acknowledge some limitations of this study. We can highlight as a limitation the absence of a group without intervention as a comparator since we could incur an ethical problem with this. Using a placebo when there is an effective treatment may mean the patient is denied the opportunity to receive the best treatment. There is no gold standard treatment for painful shoulders due to the multitude of pathologies included in this syndrome, and treatment must be individualised for each patient. When a new treatment is studied and compared with the standard treatment without including any placebo arm of the study, the opportunity to fully assess the latest treatment's negative effects is also lost. Another limitation is that there are no different groups with different exposure times to therapy or with varying numbers of exposure cycles. Inclusion criteria can be very broad, covering a wide range of pathologies included in painful shoulder syndrome. This reason makes extrapolation of the results difficult. The cohort of patients treated in our study did not have significant pathology in the joint's anteroinferior and posterior inferior compartments. If we had treated a group with these characteristics, it would have been necessary to add PRF on ACN, which is an essential limitation of the work.

CONCLUSION

PRF over SN or over SN and ACN produces sustained pain relief in patients with painful shoulders, as measured by NRS. This relief is similar in both techniques, so the combined technique does not provide statistically significant benefits over the single puncture technique over SN.

Study data availability

De-identified data may be requested with reasonable justification from the authors (miespmi@gmail.com) and shall be shared upon request.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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