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## ORIGINAL ARTICLE

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# Pulsed Radiofrequency of Suprascapular Nerve for Chronic Shoulder Pain: A Randomized Double-Blind Active Placebo-Controlled Study

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### ■ Abstract

**Background:** The suprascapular nerve block is frequently implemented to treat chronic shoulder pain. Although effective the nerve blockade provides only a short-term relief, and more compelling approaches have been investigated. Pulsed radiofrequency (pRF) has been anecdotally reported as safe and reliable method. However, formal efficacy study has not been published. Ostensibly evidence-based validation of a new method is necessary for both scholastic and practical purposes.

#### **Methods:**

This study was designed as a randomized active placebo-control double-blind trial. Because of encountered difficulties in recruitment and high rate of dropout, the study was redesigned as to allow a smaller sample size and statistical

analyses were performed utilizing the last observation carry forward method. Lidocaine injections alone or with combination of the pRF were performed. Participants were followed up during 6 months, and multiple subjective and objective outcome variables were recorded.

**Results:** Thirteen of 22 participants completed 6 months follow-up. Dropout rate was higher in the lidocaine group. A significant linear trend ( $P < 0.05$ ) for improvement on the numeric rating scale, Shoulder Pain and Disability Index and Constant-Murley score was observed in the pRF group, but not in the lidocaine group. Patients in the pRF group were on average more satisfied than the lidocaine group at 1 month ( $P = 0.041$ ) and at 3 months ( $P = 0.035$ ).

**Discussion:** Considering limitations of the study design and statistics, it seems plausible to attribute better results in the pRF group to unique properties of this physical modality. ■

**Key Words:** pulsed radiofrequency, shoulder pain, suprascapular nerve, randomized controlled trial

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### INTRODUCTION

Suprascapular Nerve Block (SSNB) remains a useful tool for pain control for different shoulder chronic

pain syndromes as well as for acute pain relief following trauma and surgery.<sup>1</sup> Usually, SSNB is administered as a supplement to physiotherapy once or twice weekly until clinical recovery is achieved or the therapy considered unsuccessful and discontinued.<sup>2</sup>

There are several disadvantages in this approach. First, repeated injections increase the risk of complications, for example, pneumothorax, intravascular injection, infection, nerve injury, and steroid-related side effects.<sup>3</sup> Second, patient compliance tends to decrease over the time. Third, there are substantial medical expenditures related to return hospital visits.

In the 1990s, a new treatment modality has emerged. Pulsed radiofrequency (pRF) treatment has been reported as an effective and simple tool for management of chronic shoulder pain. Single session treatment was claimed to provide long-term pain relief and to facilitate functional rehabilitation.<sup>4,5</sup> Notwithstanding the anecdotally reported effectiveness of the method, it has never been contested in a rigorous experimental setting. The placebo response might have enhanced patient expectations, resulting in dramatic subjective improvement.

This study was attempted to demonstrate superiority of the pRF of the suprascapular nerve (SSN) vs. conventional local anesthetic injection.

## METHODS

The study was approved by the Research Ethical Board of the Sunnybrook Health Sciences Centre, Toronto, Canada. Using the initial estimate of a treatment difference and a conservative assessment of the common standard deviation of 0.1 points, and alpha two-tailed set of 0.05 to provide 0.80 power for a *t*-test to detect pain score treatment differences, a sample size of 29 cases per group was calculated. Because of a slow accrual rate, the sample size was recalculated based on the assumption of a typical pain reduction observed in interventional pain studies. Numerous positive clinical studies report approximately 70% success rate with  $\geq 50\%$  pain reduction. The placebo response is usually estimated as high as 30%. Using calculation of difference between proportions, the sample size was estimated as 24 patients total. Randomization 1:1 was performed. Secondary outcomes, such as the satisfaction Likert scale index (LSI), Shoulder Pain and Disability Index (SPADI), and Constant–Murley Score (CMS) were also measured. During 3 years, 28 patients were recruited and 22 underwent the study procedure

(Figure 1). Patients with shoulder pain > 3 months duration, clinical and imaging confirmation of adhesive capsulitis, tendinosis, arthritis, rotator cuff or capsular tears were eligible for participation. Medical review was performed and stability of the condition was confirmed. In addition, failure of conservative medical therapy (3 months of medications  $\pm$  physiotherapy and  $\pm$  corticosteroid injections) was documented. Exclusion criteria comprised refusal to participate, extrinsic source of shoulder pain (eg, cervical radiculopathy), pain related to bony fracture, postsurgical pain, anticoagulation therapy, major psychopathology, or psychiatric illness. Subjects with ongoing litigation and secondary gain, including those on the workers compensation benefits, were also excluded. Most common reasons for noninclusion were previous shoulder surgery and patient refusal to participate. Unwillingness to be enrolled was related to the voluntary election to have either the study procedure or an open-labeled pRF of the nerve. Unsurprisingly, majority of potential candidates choose the open-labeled procedure, which does not impose any obligations and has no significant additional risks.

Treatment options and potential hazards were discussed with patients. Informed consent was obtained. Patients were informed about goals and objectives of the study. Those patients, who reported no pain relief and were dissatisfied, had an option to withdraw themselves and undergo pRF procedure any time after the first follow-up visit. Patients were able to dropout from the study any time.

The randomization was carried out by a staff nurse and delivered in sealed envelopes marked “R” (Radiofrequency) or “L” (Lidocaine). Both patient and physician were blinded. All procedures were performed by a single operator (M.G.) to minimize individual technical differences.

The patients were positioned prone with the ipsilateral arm held alongside the body and head turned to the opposite side. The suprascapular notch was fluoroscopically localized. Standard monitoring (ECG, NIBP, SaO<sub>2</sub>) was applied. O<sub>2</sub> supplement and sedation was provided on as needed basis. A 100-mm SMK cannula (Baylis Medical, Montreal, QC, Canada) with 10-mm active tip was inserted down to suprascapular notch under fluoroscopy (Figure 2). The correct position was verified by an injection of 2 mL of iopamidol and by sensory and motor responses. After removal of the stylet from the cannula, RF probe was inserted and connected to the radiofrequency generator (RFG-2b; Baylis Medical, Montreal, QC, Canada) and the stimulation was

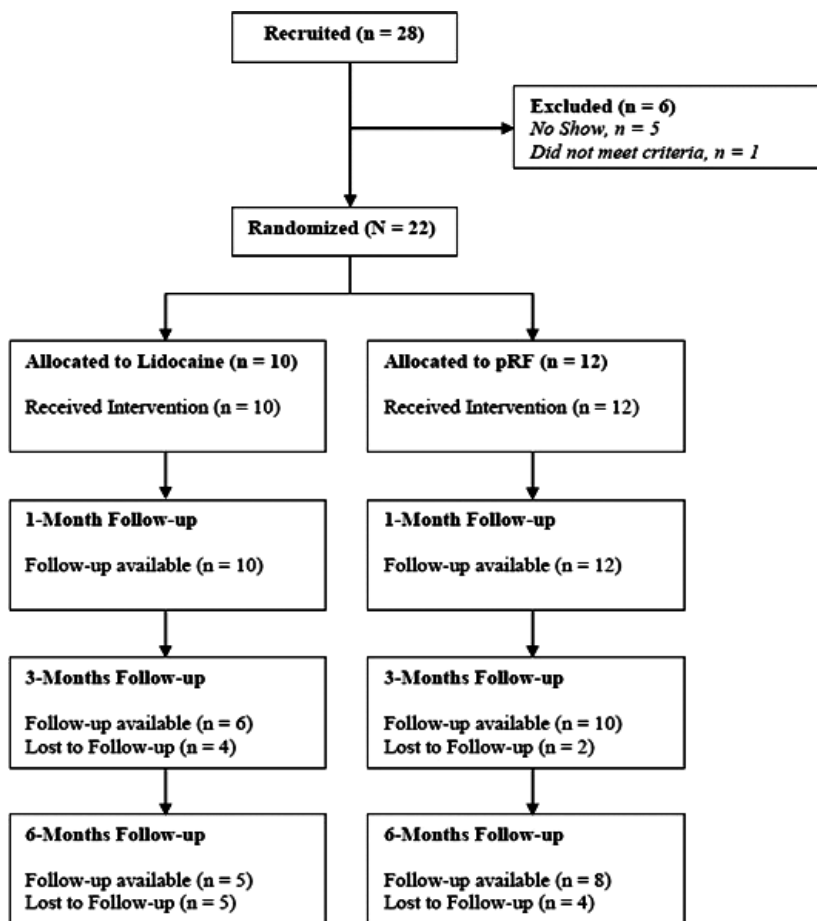


Figure 1. CONSORT diagram.

performed. All patients reported paresthesia in the shoulder region with 50 Hz stimulation at 0.3 to 0.5 mA. A motor response of the supraspinatus and/or infraspinatus muscle was seen with 2 Hz stimulation. Then, 2 mL 1% lidocaine was injected. At this point, the operator had to leave the room and the nurse carried out the treatment assignment. In the group “R” 120 second, 42 °C pRF was performed. In the group “L”, a demo-box was connected to the RFG and the timer was switched on for 120 second. The patients had the same experience as the “R” group hearing typical sounds produced by working RFG and remaining same period of time on the table. Because head was rotated away from RFG, subjects were unaware of the cable disconnection and the use of the demo-box. After 2 minutes, the RFG or the demo-box was switched off, and in the “L” group, the probe cable was reconnected to the machine and demo-box was removed. Upon completion of either active pRF or sham procedure, the operator was called into the room. The cannula was removed and a sterile adhesive was applied at the puncture site.

Patients were instructed to continue routine care as prescribed by referring orthopedic surgeon or primary care physician. Follow-up visits (1, 3, and 6 months)



Figure 2. Radiofrequency cannula is inserted into the supraspinular notch. Radiopaque dye is injected (arrowhead).

were scheduled. During the visits, outcome measurements were performed. Primary outcome of pain reduction was gauged on 11-points numeric rating scale (NRS). Secondary outcome, that is, a satisfaction (7-points Likert Scale) index, CMS for Shoulder Pain<sup>6</sup> and SPADI<sup>7,8</sup> were used to assess the outcome.

We selected SPADI as our outcome measure of disability. The SPADI is a self-administered index consisting of 13 items divided into two subscales, the pain and the disability. It has functioned well on testing older populations, particularly in older men. It shows good internal consistency, test-retest reliability, and criterion and construct validity. It can detect change over time and accurately discriminates between patients who have improved or worsened.<sup>8</sup>

The European Society for Shoulder and Elbow Surgery (ESSES) adopted the scoring system of Constant and Murley.<sup>6</sup> This scoring system consists of four variables that are used to assess the function of the shoulder. The right and left shoulders are assessed separately. The objective variables are range of motion and strength, which give a total of 65 points. The most important thing is that range of motion is performed and measured in a standardized way.

### Data Analysis

Demographic variables were compared using a *t*-test or chi-squared test for continuous and categorical variables, respectively. Repeated measures ANOVA was utilized for the primary outcome of Pain NRS and the secondary outcomes of the SPADI and CMS. Planned contrasts examining the linear trend effect of each group's scores over time (pRF vs. Lidocaine) were also included in the analysis. For the Likert-based satisfaction scale, paired-sample *t*-tests were conducted to compare pRF vs. Lidocaine groups, at each time epoch.

Because of the high number of dropouts in the study (Figure 1), a last observation carried forward (LOCF) method was used to impute missing data for all analysis. Per protocol analysis was also conducted to determine whether results were consistent with the LOCF method.

### RESULTS

Patients in both groups were comparable to demographic and baseline characteristics, with no significant differences between the groups (Table 1). Using the

**Table 1. Demographic and Baseline Characteristics of the Cohort (N = 22)**

Variable	Lidocaine	pRF	P-value
	(N = 10)	(N = 12)	
Age (SD)	70.4 (11.2)	68.1 (11.4)	0.638
Gender [% female (n)]	90% (9)	67% (8)	0.193
Pain duration [months (SD)]	42 (20)	28 (19)	0.125
Baseline pain numeric rating scale	6.4 (3.7)	6.3 (1.8)	0.957
Previous treatments includes opioids	20% (2)	17% (2)	0.84

pRF, Pulsed Radiofrequency.

LOCF method, repeated measures ANOVA on NRS, SPADI, and CMS did not indicate statistically significant differences between the pRF and Lidocaine groups over time. However, a significant linear trend ( $P < 0.05$ ) for improvement in outcomes was observed for the NRS within the pRF group, but not for the Lidocaine group (Figure 3). A similar trend was observed on the SPADI (Figure 4) and the CMS (Figure 5) (all  $P$ 's  $< 0.05$ ). When these analyses were performed per original protocol; however, none of these findings were replicated and no significant  $P$ -values were observed. This is likely due to the tests being underpowered, where dropout rates as high as 50% are observed in both the groups as previously indicated in Figure 1.

In terms of the Likert-based patient satisfaction scale, patients in the pRF group were on average more satisfied than the Lidocaine group at 1 month (5.7 vs. 3.7,  $P = 0.041$ ) and at 3 months (6.0 vs. 3.9,  $P = 0.035$ ) (Figure 6). At 6-month post-treatment, there was no statistically significant difference between the groups in terms of satisfaction score (5.6 vs. 4.2, ns), although the high dropout rate may be a confounding factor.

### DISCUSSION

This study is the first randomized active placebo-controlled trial of a peripheral nerve pRF. The results suggest additional therapeutic benefit obtained when pRF was performed in addition to lidocaine injection. Statistically significant improvement in pain score and function was demonstrated using LOCF method. Likewise, patient satisfaction was higher in pRF group and dropout rate was lower. Evidently, a small sample size and significant dropout made not possible to provide strong conclusive results. As was outlined in the Methods section, the fact that in the Ontario, pRF is routinely available and reimbursed made it dif-

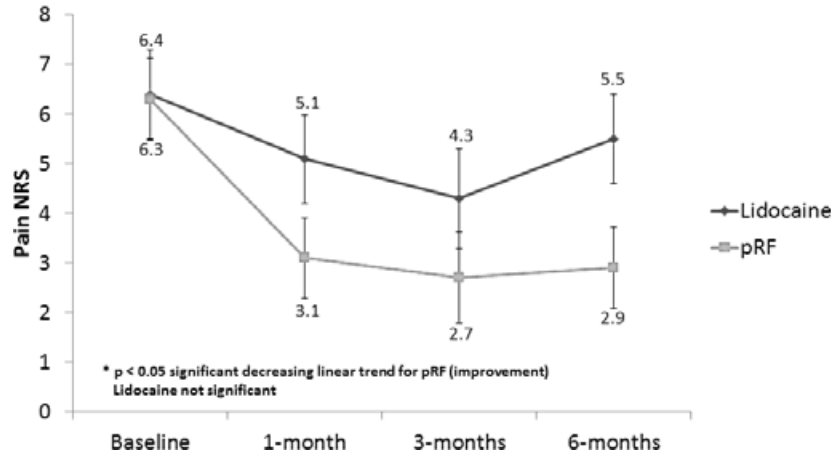


Figure 3. Pain numeric rating scale post-treatment follow-up (last observation carried forward).

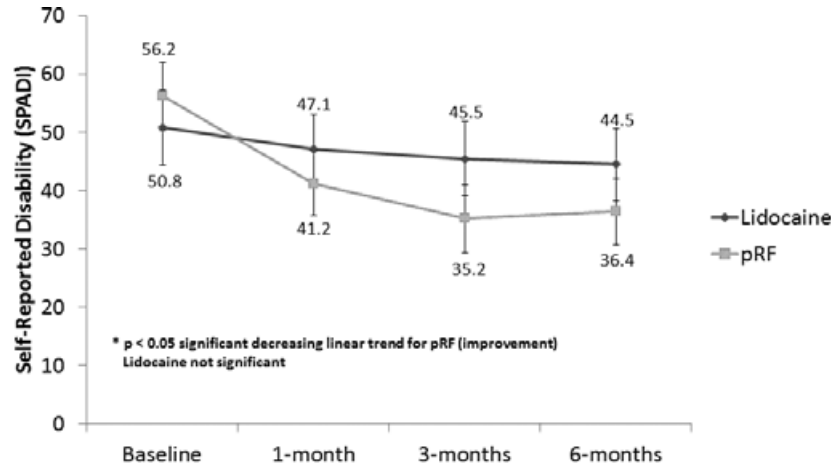


Figure 4. Shoulder Pain and Disability Index post-treatment follow-up (last observation carried forward).

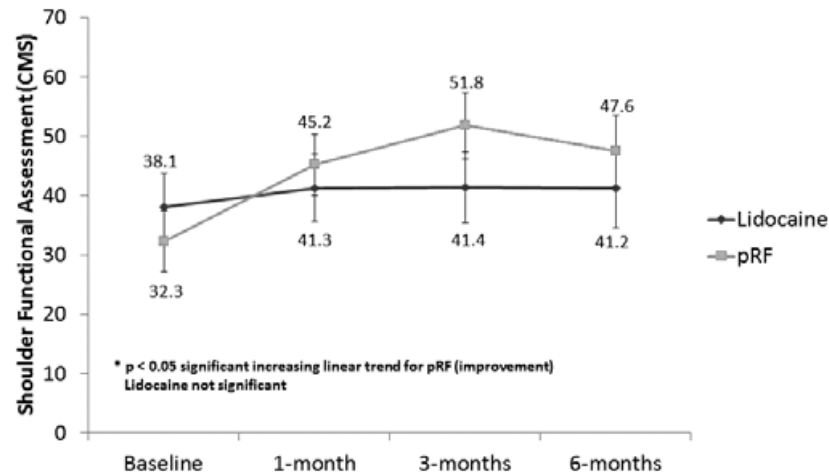
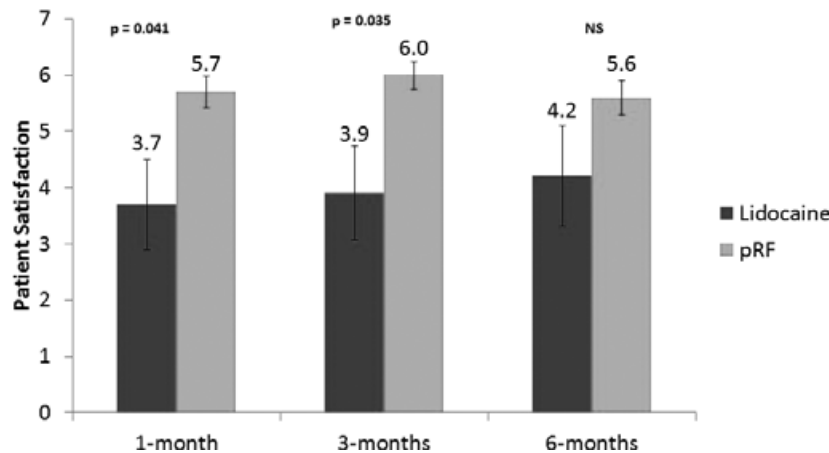


Figure 5. Constant-Murley Score post-treatment follow-up.



**Figure 6.** Patient satisfaction at 1-month, 3-month and 6-month post-treatment.

difficult to recruit participants and the accrual rate was extremely slow. Therefore, statistical plan was changed and LOCF method was used. The method assumes no changes in pain and disability happened after voluntary withdrawal when patients were lost for the follow-up. One may conclude that positive results occurred by chance and even those who had lidocaine injection improved over the time. However, it does not explain statistically significant difference in dropout. Moreover, the natural history of anatomically defined (eg, severe tendinopathy, rotator cuff tear, glenohumeral arthritis) moderately to severe chronic shoulder pain is not favorable. Shoulder pain in the population is a long-term disabling symptom and it likely to continue beyond the 6 months allocated for the study follow-up period.<sup>9</sup> Long duration of complaints and high disability score at baseline predict a poorer outcome in primary care.<sup>10</sup> Our study population was completely congruent with this unfavorable prognosis; therefore, we assumed that no significant positive changes happened in participants who were lost for the follow-up.

Suprascapular nerve carries sensory output from the shoulder joint capsule (both anterior and posterior), acromioclavicular joint, and subdeltoid bursa.<sup>11</sup> In addition, SSN provides motor innervation to the infraspinatus and supraspinatus muscles.<sup>11</sup> Overall, the nerve carries approximately 70% of sensory proprioception and nociception output of the shoulder joint. The nerve has no cutaneous branches. Therefore, studying potential long-term analgesia of pRF-induced cessation of the nociception makes SSN almost ideal target for clinical studies, eliminating majority of anatomical confounding related to complex innervation of

other joints. Besides the scientific prospective, it may be relatively straightforward and inexpensive routine method in palliation of chronic shoulder pain.

Suprascapular nerve analgesic blockade has been implemented for managing chronic shoulder pain secondary to adhesive capsulitis, glenohumeral and rheumatoid arthritis, and chronic rotator cuff tears.<sup>2,12-14</sup> Usually, serial blockade is required because the analgesia is not sustainable. These well-designed prospective studies with the longest follow-up of 12 weeks demonstrated no long-term benefit. Addition of a corticosteroid, which is usually added to the local anesthetic,<sup>15</sup> is a questionable practice and a prospective randomized study revealed no benefit for adding methylprednisolone to bupivacaine.<sup>16</sup>

Ostensibly, chemical or surgical severing of the SSN may provide long-lasting pain relief. Only one small published study supported the idea. Injection of 4 mL of 1% prilocaine and 4 mL of 6% aqueous phenol was performed on 16 patients suffering from rheumatoid or osteoarthritis of the shoulder joint. All patients complained of pain and limitation of active movement of the shoulder joint. Mean pain severity decreased by 69% and, surprisingly, range of motions increased by 36% to 67%.<sup>17</sup> Two obvious weaknesses of the study should be mentioned: relatively short mean time follow-up of 13 weeks and the final 3% of phenol concentration, which doubtfully can produce significant chemical neurolysis. Most probably, irreversible loss of function and development of new nerve injury pain are the factors that making chemical neuroablation unattractive for interventional pain physicians.

Pulsed radiofrequency is considered to be a non-neurolytic neuromodulation method, which showed



some effectiveness in alleviation of experimental and clinical neuropathic pain.<sup>18–22</sup> Countless case reports and small series studies were published, demonstrating anecdotal effectiveness of pRF applied onto peripheral nerves and reporting no adverse outcome. Several papers addressed effects of pRF specifically delivered onto SSN treating variety of chronic shoulder painful conditions. Rohof was the first to report beneficial effect of pRF on 49 patients<sup>23</sup> and later provided detailed technical description of the fluoroscopy-guided pRF of the SSN.<sup>4</sup> Several case series<sup>24,25</sup> including the one where ultrasound guidance<sup>26</sup> was used and three clinical studies were published.<sup>27–29</sup> One randomized study compared pRF with the transcutaneous electrical stimulation and did not find statistical differences in multiple outcome measurements.<sup>27</sup> Another prospective open-label study on 57 patients showed clinical and statistical improvement in pain and modified McNab scores up to 6 months following pRF procedure.<sup>28</sup> Gabrhelik et al.<sup>29</sup> retrospectively reviewed results of 28 cases where pRF performed under lidocaine analgesia either with or without additional injection of corticosteroids. More than 50% of patients in both groups had significant pain relief after 3 months.

The results of this study provide some preliminary evidence on the efficacy of the pRF procedure which was evaluated using the highest evidence-based standard randomized double-blind placebo-controlled trial. Significant trends toward reduction in pain and improvement in function are observed among the pRF group, but not in the lidocaine group. Furthermore, patient satisfaction with the pRF procedure was sustained for at least 3-month postprocedure, and these patients reported greater satisfaction than the patients in the lidocaine group. Despite these findings, caution is advised in the generalizability of these results, because of the high dropout rates and the small sample size.

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