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The effects of preadministration of local anesthetic on pulsed radiofrequency

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Background/aim: Pulsed radiofrequency (PRF) has been reported to be a safe and reliable method for the management of a variety of chronic pain syndromes. It is not known whether the preadministration of local anesthetic increases the size of the electrical field. We revealed the effects of administering local anesthetic on PRF and investigated whether they were related to local anesthetic or fluid effects.

Materials and methods: Group 1 (n = 18) received PRF to the suprascapular nerve with 1 mL of bupivacaine, group 2 (n = 20) received PRF with 1 mL of physiological saline solution, and group 3 (n = 18) received PRF only.

Results: There were significant improvements in visual analog scale (VAS) scores at 30 min, 1 month, and 3 months after treatment in group 1 ($P < 0.05$) and at 1 month and 3 months in groups 2 and 3 ($P < 0.05$). There was a significant improvement in VAS scores in group 1 compared with groups 2 and 3 at 30 min after treatment.

Conclusion: PRF applied to the nerve along with local anesthetic may increase pain relief, especially in the early posttreatment period. The favorable effects may depend on the pharmacodynamic features of the local anesthetic.

Key words: Pulsed radiofrequency, local anesthetic, suprascapular nerve blockage

1. Introduction

Pulsed radiofrequency (PRF) has been reported to be a safe and reliable method for the management of a variety of chronic pain syndromes (1–3). The advantages of PRF over neurodestructive procedures are that it is safe and causes minimal destruction of nerve tissues (3–5). It has been applied successfully to peripheral nerves such as the suprascapular nerve (3,6).

Chronic shoulder pain is a common musculoskeletal problem that can cause important functional disabilities. However, the treatment of chronic shoulder pain is difficult and it takes a long time. There are various treatments for this problem, including physiotherapy, nonsteroidal antiinflammatory drugs (NSAIDs), intraarticular injections, and suprascapular nerve pulsed radiofrequency (PRF) (7,8). PRF treatment of the suprascapular nerve is reported to be an effective tool and provides long-term pain relief for the management of chronic shoulder pain (5,7,9). The suprascapular nerve is responsible for 70% of the sensory innervation to the shoulder joint. It also innervates two of the rotator cuff muscles, the supraspinatus and infraspinatus muscles (10). PRF applied to the suprascapular nerve does not create a risk of paralysis of these muscles.

The effect of PRF on nerve tissue is not completely understood and is currently being investigated. Various parameters such as time of application and output voltage have been examined to identify the factors that have an impact on PRF (11–13). Since none of the studies have examined the effects of local anesthetics on PRF, we decided to conduct this research with the aim of revealing the effects of applying a local anesthetic on PRF and investigate whether the effects are related to either local anesthetic or fluid effects in PRF treatment of the suprascapular nerve for painful shoulders.

2. Materials and methods

2.1. Patients

The study was approved by the Institution of Medicine and Medical Equipment, Ministry of Health. It was planned as a double-blinded, randomized, comparative clinical trial. The study population consisted of 60 patients aged 18–80 years. Patients with shoulder pain for at least 3 months, clinical and imaging confirmation of supraspinatus tendinopathy, partial tear of the supraspinatus tendon, acromioclavicular joint osteoarthritis, and adhesive capsulitis were included in the study. Exclusion criteria

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comprised refusal to participate, extrinsic source of shoulder pain, pain related to bone fractures, postsurgical pain, previous shoulder surgery, anticoagulation therapy, major psychopathology, inflammatory arthritis, a history of shoulder surgery, unstable chronic or terminal systemic disease, intraarticular injection within the last 3 months, and neurological impairment.

Treatment options and potential risks were discussed with patients. All the volunteers gave their written consent to participate in the study. Patients were informed about the objectives of the study and they were told that they could withdraw from the study at any time. Patients did not receive any additional treatment for the duration of the study. They could use only paracetamol for pain relief and the amount taken by the patients was recorded at subsequent visits.

The 60 patients were divided into three equal groups by a random number table; however, two patients in group 1 and two in group 3 did not continue with the study. PRF was applied to the suprascapular nerve with 1 mL of bupivacaine (n = 18) in group 1 or with 1 mL of physiological saline solution in group 2 (n = 20), and PRF only was applied in group 3 (n = 18). Randomization was carried out by a staff nurse. Both patients and the physician were blinded to the treatments assigned. All procedures were performed by a single operator to minimize individual technical differences.

2.2. Intervention procedure

The PRF procedure was performed in the operating room under fluoroscopy. Patients were positioned prone with their heads turned to the opposite side. The skin area was aseptically draped with sterile towels. Standard monitoring (ECG, NIBP, oxygen saturation) was applied. The suprascapular notch was identified by fluoroscopy. The C-arm was 10°–20° obliquely and about 15°–30° rotated in the cephalocaudal direction. The entry point was marked and local anesthesia was applied to the skin. A disposable 5-cm radiofrequency cannula with 5-mm active tip was introduced to the suprascapular notch under fluoroscopy through the skin. The correct needle tip was confirmed, relative to the suprascapular notch, by fluoroscopic images. The stylet was withdrawn from the cannula, the RF electrode was inserted and connected to the radiofrequency generator, and stimulation was performed. All patients reported paresthesia in the shoulder region with stimulation at 50 Hz and amplitude 0.3–0.5 mA. Motor response of the supraspinatus and/or infraspinatus muscles was seen at 2 Hz stimulation. After determining that the needle was in the right place, the attending physician left the room and treatment was performed by the nurse. Group 1 received injections of 1 mL of 0.5% bupivacaine (Marcaine 0.5%), group 2 received injections of 1 mL of physiological saline, and group 3 received no injections. Thereafter, each patient received PRF at 45 V, 2 Hz frequency, 20 ms pulse width, at 42 °C (Neurotherm JK25T; RDG Medical, Croydon, UK) for 4 min. Following treatment, the cannula was removed and a sterile adhesive plaster was placed over the puncture site.

2.3. Pain and functional outcome evaluation

Assessments of all patients were performed before and after procedures by the same physician who was blinded to the treatment protocols. The patients were evaluated for pain and range of motion before and after treatment (at 30 min, 1 month, and 3 months). Shoulder Pain and Disability Index (SPADI) scores were evaluated before and after treatment (months 1 and 3). The patient satisfaction was evaluated as 0 = unsatisfied, 1 = less satisfied, 2 = moderately satisfied, 3 = satisfied, and 4 = very satisfied at 3 months.

Pain was assessed in motion and at rest using the 10-cm standard visual analog scale (VAS), where 0 cm represented no pain and 10 cm represented the worst pain imaginable.

Range of motion (ROM) at flexion, abduction, external rotation (ER), and internal rotation (IR) were assessed as active and passive with the use of a universal goniometer.

The SPADI is a self-administered index consisting of 13 items; participants rate how their shoulder functions in terms of two subscales: pain (5 items) and disability (8 items). Scores can range from 0 to 50 on the pain scale, from 0 to 80 on the disability scale, and from 0 to 130 on the total scale. An increasing score indicates increasing pain or disability (14,15).

2.4. Statistical analysis

Sociodemographic characteristics were evaluated using descriptive statistical methods. Variance between more than one continuous dependent variable not normally distributed was assessed using the Friedman test. Wilcoxon signed rank testing was used as the post hoc method for relationships between two continuous dependent variables not normally distributed. Continuous variables belonging to more than two groups not normally distributed were compared using the Kruskal–Wallis test. The Mann–Whitney U test was used as the post hoc method to compare two continuous independent variables not normally distributed. Categorical variables were evaluated with chi-square or Fisher exact tests. The results were analysed using MedCalc Statistical Software, version 12.7.7 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org). The significance threshold was set at $P < 0.05$.

3. Results

There were no significant differences between the groups in terms of demographic characteristics (Table 1) ($P > 0.05$). In group 1, there were significant improvements in VAS

Table 1. Demographic characteristics of the patients.

	Group 1 (n = 18)	Group 2 (n = 20)	Group 3 (n = 18)
Age, years (±SD)	60.9 ± 11.2	55.1 ± 9.7	54.6 ± 12.1
Female/male ratio	11/7	12/8	10/8
Pain duration, months (±SD)	35.6 ± 25.7	33.5 ± 26.8	36.6 ± 27.4
Diagnosis, n			
Supraspinatus tendinopathy	7	6	5
Partial tear of the supraspinatus tendon	5	7	7
Acromioclavicular joint osteoarthritis	5	5	4
Adhesive capsulitis	1	0	0

P > 0.05.

scores (at rest and movement) at 30 min, 1 month, and 3 months after treatment compared with the pretreatment period (P < 0.05). In group 2, there were significant improvements in VAS (at rest and movement) at 1 and 3 months after treatment compared with the pretreatment period (P < 0.05). There were no significant differences in VAS (at rest and movement) between pretreatment and 30 min after treatment. In group 3, there were significant improvements in VAS (at rest and movement) at 1 and 3 months after treatment compared with the pretreatment period (P < 0.05). There was no significant difference in VAS (at rest and movement) between pretreatment and 30 min after treatment (Figures 1 and 2).

When the groups were compared, a significant improvement was found in VAS scores (at rest and movement) in group 1 compared with groups 2 and 3 at 30 min after treatment. There was a significant improvement in group 1 compared with groups 2 and 3 in VAS scores at rest at 1 month. VAS movement scores at 1 month were significantly different between groups 1 and 3. There was a significant difference in VAS at rest between group 1 and groups 2 and 3 at 3 months in favor of group 1. VAS movement scores at 3 months were significantly different in group 1 compared with group 3. There was no significant difference in VAS scores between groups 2 and 3.

In group 1, there were significant improvements at 30 min, 1 month, and 3 months after treatment in ROM (active and passive) compared with the pretreatment period (P < 0.05). In groups 2 and 3, there were significant improvements in ROM (active and passive) at 1 and 3 months compared with the pretreatment period (P < 0.05) but no improvements at 30 min after treatment (Table 2).

A comparison of ROMs between the groups revealed significant differences in favor of group 1 at 30 min after treatment in active abduction, passive abduction, and active flexion compared with groups 2 and 3. The other parameters of ROM were not significantly different between the groups.

There were significant differences in SPADI pain, disability, and total subscores in all groups at 1 and 3 months compared with the pretreatment period (P < 0.05) (Table 3). However, when the groups were compared,

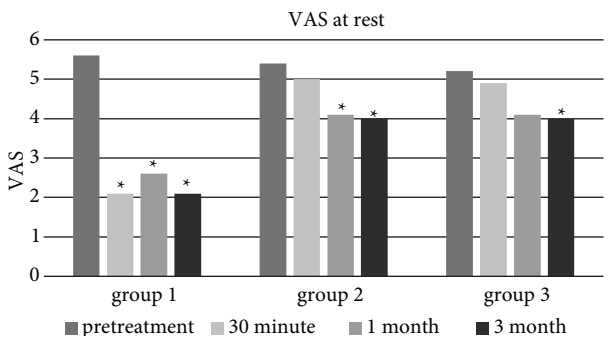

Figure 1. Visual analog scale (at rest) scores before and 30 min, 1 month, and 3 months after procedure. *P < 0.05. P represents the difference between the pretreatment parameters and posttreatment at 30 min, 1 month, 3 months.

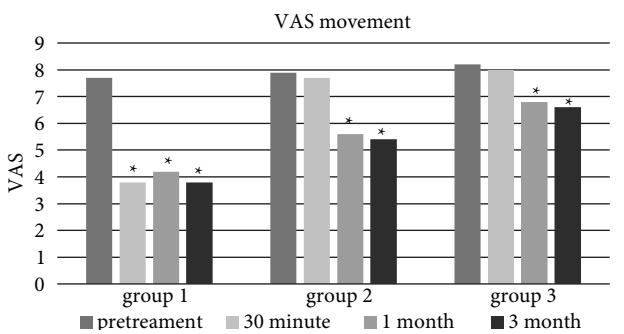

Figure 2. Visual analog scale (movement) scores before and 30 min, 1 month, and 3 months after procedure. *P < 0.05. P represents the difference between the pretreatment parameters and posttreatment at 30 min, 1 month, and 3 months.

Table 2. Range of motion (ROM) scores before and 30 min, 1 month, and 3 months after procedure.

Parameter	Group	Pretreatment	Posttreatment (30 min)	1 month	3 months
A-AB	Group 1	110.4 ± 22.1	130.4 ± 23.8*	125.4 ± 23.2*	127.8 ± 24.8*
	Group 2	103 ± 28.1	109.4 ± 28.8*	113.6 ± 31.5*	113.6 ± 31.7*
	Group 3	110.6 ± 23.8	113.5 ± 25.5	124.7 ± 21.4*	125.6 ± 23.1*
P-AB	Group 1	115.1 ± 20.2	135.2 ± 22.7*	134.2 ± 21.4*	135.1 ± 22.6*
	Group 2	105.3 ± 27.6	105.3 ± 28.5	115.1 ± 31.2*	115.7 ± 31.2*
	Group 3	114.9 ± 23.6	117.7 ± 24.3	116.6 ± 18.9	127.1 ± 20.0*
A-F	Group 1	123.1 ± 14.8	137.7 ± 18.1*	136.7 ± 18.3*	137.8 ± 18.7*
	Group 2	120 ± 28.0	121.6 ± 29.2	125.9 ± 29.5*	125.5 ± 29.4*
	Group 3	125.9 ± 14.5	139 ± 18.6	137.8 ± 18.3	138.9 ± 18.4
P-F	Group 1	125.9 ± 14.5	139 ± 18.6*	137.8 ± 18.3*	138.9 ± 18.4*
	Group 2	122.4 ± 27.9	127.7 ± 29.5*	128.2 ± 29.3*	128.4 ± 29.6*
	Group 3	124.6 ± 23.4	127.9 ± 23.6	139.9 ± 14.9*	138.4 ± 20.6*
A-IR	Group 1	37.1 ± 14.3	39.1 ± 18.1	44.9 ± 14.7*	46.2 ± 15.9*
	Group 2	34.7 ± 17.7	38.8 ± 16.7	38.1 ± 16.2*	38.4 ± 16.2*
	Group 3	37.8 ± 20.1	39.8 ± 19.0	43.3 ± 18.9	42.4 ± 18.8
P-IR	Group 1	38.9 ± 14.2	44.1 ± 17.8*	46.3 ± 14.9*	47.3 ± 15.7*
	Group 2	36.2 ± 17.4	40.1 ± 16.4	39.3 ± 16.2*	39.5 ± 15.9*
	Group 3	39.2 ± 20.2	41.6 ± 19.1	45.2 ± 18.3*	44.6 ± 18.4*
A-ER	Group 1	36.1 ± 18.4	40.7 ± 18.4*	37.1 ± 16.5	45.1 ± 16.4*
	Group 2	35.5 ± 17.8	37.5 ± 16.7	38.1 ± 17.3*	37.7 ± 17.5*
	Group 3	28.5 ± 21.0	30.7 ± 21.1	37.7 ± 21.7*	32.9 ± 21.9
P-ER	Group 1	38.2 ± 18.5	42.3 ± 17.8*	46.6 ± 16.1*	46.3 ± 15.9*
	Group 2	37.1 ± 17.1	38.9 ± 16.6	40.1 ± 17.2*	39 ± 17.2*
	Group 3	30.6 ± 21.2	32.7 ± 20.9*	34.9 ± 21.3*	35.4 ± 21.5*

*P < 0.05. P represents the difference between the pretreatment parameters and posttreatment at 30 min, 1 month, and 3 months.
A-AB: Active abduction, P-AB: passive abduction, A-F: active flexion, P-F: passive flexion, A-IR: active internal rotation, P-IR: passive internal rotation, A-ER: active external rotation, P-ER: passive external rotation.

Table 3. Shoulder Pain and Disability Index (SPADI) scores before and 1 month and 3 months after procedure.

Parameter	Group	Pretreatment	1 month	3 months
SPADI-Pain subscale	Group 1	83.9 ± 11.8	60.8 ± 21.2*	70.6 ± 18.4*
	Group 2	77.1 ± 16.6	65.5 ± 18.8*	64.2 ± 19.4*
	Group 3	82.4 ± 10.8	72.8 ± 15.9*	70.3 ± 16.6*
SPADI-Disability subscale	Group 1	77.5 ± 18.4	59.8 ± 24.9*	50.3 ± 23.9*
	Group 2	74.1 ± 17.6	63.8 ± 19.2*	63.9 ± 18.2*
	Group 3	78.7 ± 10.1	69.4 ± 14.2*	68.1 ± 15.3*
SPADI-Total scale	Group 1	79.9 ± 15.4	63.4 ± 22.6*	54.8 ± 22.9*
	Group 2	75.5 ± 16.9	64.5 ± 18.8*	75.2 ± 15.3*
	Group 3	79.8 ± 9.8	71.1 ± 14.7*	69.5 ± 15.9*

*P < 0.05. P represents the difference between the pretreatment parameters and 1 month and 3 months.

Table 4. Patient satisfaction.

	Group 1 (n = 18)	Group 2 (n = 20)	Group 3 (n = 18)
Unsatisfied (0)	0 (0.0)	1 (33.3)	2 (66.7)
Less satisfied (1)	2 (16.7)	4 (33.3)	6 (50.0)
Moderately satisfied (2)	5 (20.8)	11 (45.8)	8 (33.3)
Satisfied (3)	8 (61.5)	4 (30.8)	1 (7.7)
Very satisfied (4)	3 (75.0)	0 (0.0)	1 (25.0)

there was no statistical difference among SPADI scores. The consumption of paracetamol did not differ between the groups. Patient satisfaction rates were higher in group 1 (Table 4). None of the patients experienced serious side effects or complications.

4. Discussion

The exact mechanism of PRF is unknown and it is still being investigated (16). Higuchi et al. (2) suggest a neuromodulatory effect via changes of gene expression in pain-processing neurons. Among the effects of PRF, studies suggest that the main factor is associated with electrical fields. Electrical fields induce transmembrane potentials, which have significant effects on cells. Induced transmembrane potentials can disrupt the tissues. These effects occur at subcellular and biomolecular levels and can cause ion channel disruption and resting and threshold potential alterations (17). Recent studies of ultrastructural axonal changes have shown microscopic damage after exposure to PRF, including abnormal membranes and morphology of mitochondria, and disruption and disorganization of microfilaments and microtubules (18). The biochemical effects of PRF include c-Fos immunoreactivity, upregulation of ATF-3 (activating transcription factor-3), and enhanced descending noradrenergic and serotonergic inhibitory pathways (2,19,20). These findings are believed to be caused by high transmembrane potentials (17), which result in decreased conduction in C- and A-delta fibers (16); transmembrane potentials are proportional to the strength of the electrical field (17). Moreover, immune modulation via proinflammatory cytokines is decreased by electrical fields (21,22). The electrical field is adversely proportional to the electrical conductivity of tissue (17). In general, the electrical properties of tissue are mainly determined by water, NaCl, and protein content. The infusion or injection of ion-containing fluids leads to an improvement in the conductivity of electrical tissue, thereby lowering tissue impedance (23). NaCl solutions increase electrical conductivity and current delivery from the electrode to the tissue (23,24). In previous conventional RF studies, the preadministration of local anesthetics was shown to increase the size of the lesion, but it is not known whether it increases the size of the electrical field (16). Taking this into consideration, we investigated whether injecting local fluid anesthetic into tissue would have any effect on the function of PRF.

It has been determined that fluid injection before radiofrequency ablation enhances the effects, and different fluids increase the size of lesions to different degrees according to previous ex vivo studies (25–27). Provenzano et al. (25) performed an ex vivo study comparing a combination of monopolar RF ablation with preinjection of fluid (sterile water, 0.9% sodium chloride, 1% lidocaine, and hydroxyethyl starch) before radiofrequency ablation and RF ablation alone. Their results showed that injecting fluid before lesioning led to larger lesion size parameters relative to controls. In their other study, Provenzano et al. (27) demonstrated that increasing the concentration of NaCl significantly increases the size of the lesion.

Several studies have investigated the factors that have an impact on PRF. Luo et al. (11) showed that increasing intraoperative RF output voltage and electrical field intensity improves the outcome of PRF treatment. Other studies have shown that increasing the duration of PRF application to 6 min produces better results (12,13). Rohof administered caudal epidural PRF treatment at a frequency of 5 Hz, 5 ms pulse width, and 55 V for 10 min to three patients with postherpetic neuralgia and observed long-lasting pain relief in two of the three patients (3). Although the mechanism of PRF remains completely unknown, studies like these may help to clarify its effects.

Conversely, some studies have investigated the coadministration of local anesthetics and steroids with or without PRF on various peripheral nerves. Makharita et al. (28) demonstrated significantly longer pain relief in a bupivacaine + dexamethasone + PRF group compared with a bupivacaine + dexamethasone group. Cohen et al. (16) studied PRF effects on occipital neuralgia or migraine with occipital nerve tenderness. They demonstrated that the group that received local anesthetic + saline + PRF experienced a greater reduction in pain than the local anesthetic + methylprednisolone group. However, the pain relief observed did not translate to improved secondary outcome measures. Likewise, SPADI scores were not significantly different between the groups in our study. PRF treatment for peripheral nerve blockage seems useful because of its long-lasting effects; however, its whole effects can flare up within about 1–4 weeks (3). On the other hand, the effect of local anesthetic starts immediately

and lasts a short time. For this reason, the use of local anesthetics along with PRF may provide both early and late responses. Gofeld et al. (9) observed more significant trends towards the reduction of pain and improvements in function by using a combination of lidocaine and PRF compared with lidocaine alone in patients with painful shoulders. However, it is unknown whether local anesthetics affect the PRF or not. In our study, pain relief was achieved 30 min after treatment in the group given local anesthetic compared with the other two groups. Furthermore, the group that received local anesthetic showed lower VAS scores at rest at months 1 and 3. VAS movement scores were not significantly different between groups 1 and 2 in months 1 and 3. Our findings showed that the administration of a local anesthetic with PRF had some favorable effects. Similar effects were not completely found in the physiological saline solution group. This may indicate that the favorable effects may depend on the pharmacodynamic features of the local anesthetic and are not fluid effects. Therefore, we believe that the use of a local anesthetic with PRF is beneficial. There are two limitations to our study. First, we did not have a control group, and second, diagnostic blocks were not administered.

In conclusion, PRF applied to the nerve along with a local anesthetic may increase pain relief. Moreover, a local anesthetic administered with PRF treatment showed no unfavorable effects in the long-term. We believe that further studies are needed to confirm our results.

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