

Randomized Trial

Effectiveness of Suprascapular Nerve Pulsed Radiofrequency Treatment for Hemiplegic Shoulder Pain: A Randomized-Controlled Trial

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Background: Hemiplegic shoulder pain is one of the most common complications after stroke. Although there are many treatment strategies for this complication, sometimes very resistant cases are also seen.

Objectives: To evaluate the effect of suprascapular nerve pulsed radiofrequency (PRF) treatment for hemiplegic shoulder pain (HSP).

Study Design: A prospective randomized-controlled trial.

Setting: University hospital.

Methods: This study included 30 patients with HSP following stroke. The patients were randomly assigned to receive PRF to the suprascapular nerve (PRF group, n = 15) or suprascapular nerve block (NB) with lidocaine (NB group, n = 15). The patients were randomized into 2 groups (n = 15 both). In addition, the patients received physical therapy to the shoulder, including hot pack, transcutaneous electrical nerve stimulation, and stretching and strengthening exercise (5 days per week for 3 weeks in a total of 15 sessions). Visual Analog Scale (VAS) for pain, the Goal Attainment Scale (GAS) during upper-body dressing, and shoulder range of motion (ROM) were assessed at baseline, 1 month, and 3 months after the procedure.

Results: Between the groups, comparison revealed that decrease in the VAS score was statistically significantly higher at the first (3.5 1.9 vs. 1.2 1.0) and third month (4.2 1.7 vs. 1.2 0.9) in the PRF group compared with the NB group ($P < 0.01$). The PRF group had significantly higher increases in shoulder ROM compared with the NB group ($P < 0.05$). The positive changes in GAS score at month 3 in the PRF group was significantly higher than that in the NB group ($P < 0.05$).

Limitation: There is a need for further studies with a longer follow-up period.

Conclusions: In light of these findings, the combination of PRF applied to the suprascapular nerve and physical therapy was superior to the combination of suprascapular NB and physical therapy.

Key words: Hemiplegic shoulder, stroke, pain, radiofrequency, suprascapular nerve.

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Stroke is a common neurologic disorder causing hemiplegia, and is the most frequent cause of adult disability (1). In the majority of patients, there are various complications secondary to stroke.

As a consequence of upper extremity complications, 16% to 84% of the patients suffer from hemiplegic shoulder pain (HSP) (2,3). Despite its high incidence, the etiology and treatment of shoulder pain following

stroke has not been well-defined. Rotator cuff injury, subluxation of the glenohumeral joint, complex regional pain syndrome, and brachial plexopathy are mainly responsible for shoulder pain in patients with hemiplegia. Shoulder pain and limited movement of the shoulder joint have a negative effect on patient mobility, and prolong the rehabilitation period by delaying functional healing. Various treatments including physical therapy, exercises, and corticosteroid injection are used in the management of HSP.

The suprascapular nerve is thought to constitute approximately 70% of the sensorial fibers of the shoulder joint, so blockade of this nerve is used in the treatment of shoulder pain (4). Destructive procedures, such as neurolysis, may cause permanent paralysis in the supraspinatus and infraspinatus muscles, and are therefore not preferred. However, pulsed radiofrequency (PRF), which is a nondestructive neuromodulator method, may be used (5). Although previous studies have investigated the efficacy of PRF in shoulder pain, to the best of our knowledge, PRF applied to the suprascapular nerve for the treatment of HSP has not been previously investigated.

The aim of this study was to compare the efficacy of PRF application and suprascapular nerve block (NB). The primary hypothesis was that PRF applied to the suprascapular nerve would improve HSP compared with suprascapular NB.

METHODS

Study Design

This prospective, randomized, controlled study included patients who were admitted to the brain injury unit and/or the outpatient clinic at Gazilar Physical Therapy and Rehabilitation Training and Research Hospital, Ankara, Turkey between June 2016 and January 2017. Informed consent was received from all the patients included in the study. The study protocol was approved by Gulhane Military Medical Academy ethics committee.

The patients included in the study were aged 18 years or older, with at least a 3-month history of hemorrhagic or ischemic stroke, and shoulder pain recorded as 5 cm or more on a 10-cm Visual Analog Scale (VAS). Patients were excluded from the study if they had severe difficulty in communication, had received a corticosteroid injection within 3 months prior to enrollment, had bleeding diathesis, a history of shoulder surgery, a preexisting painful shoulder disorder, or had a cardiac

pacemaker.

Using parameters of a 95% confidence interval with an appropriate width and standard deviation, a sample size of 15 patients per group was estimated to be necessary for comparisons of continuous variables.

Procedures

Patients meeting the inclusion criteria were randomly separated into 2 groups using the sealed envelope method. Group 1 (PRF group, $n = 15$) was applied with PRF to the suprascapular nerve, and group 2 (NB group, $n = 15$) was applied with suprascapular NB using lidocaine. All the patients in both groups received physical therapy to the shoulder, including hot pack, transcutaneous electrical nerve stimulation (TENS), and stretching and strengthening exercises of the shoulder girdle and scapulothoracic muscles (a total of 15 sessions at 5 days per week for 3 weeks). The exercises were performed under the supervision of a physiotherapist. The 15 therapy sessions (5 days per week for 3 weeks) consisted of 20 minutes hot pack, 30 minutes TENS, then a 30-minute exercises program. No changes to the analgesic medication were permitted during follow-up. The analgesic drugs were those commonly used in the treatment of HSP as a standard of care.

A computerized radiofrequency (RF) pain management lesion generator and electrode system (Baylis PMG-115-TD, Baylis Medical Company, Inc., Quebec, Canada) were used to apply PRF to the suprascapular nerve. The same physician, who had more than 5 years of experience in PRF application, performed all the procedures under ultrasound guidance. A portable ultrasonography system (GE Logic BT12, GE Healthcare, Marlborough, MA) was used with a 12-MHz linear probe. A sterile sheath containing an ultrasound-conductive gel was used to cover the ultrasonic probe for sterile manipulation. While the patient was in a sitting position, the probe was placed in the coronal plane parallel to the spine of the scapula on the shoulder. Moving slowly in a lateral motion, the trapezius muscle, supraspinatus muscle, and suprascapular notch were scanned. Suprascapular nerves were visualized as a hyperechoic structure in the bone cavity (Fig. 1). The suprascapular artery could be identified on color Doppler imaging in some patients. Prior to injection, a local anesthetic (1 mL of 2% lidocaine hydrochloride diluted with 1 mL of 0.9% NaCl isotonic saline solution) was applied subcutaneously. An RF needle (21-gauge, 5-mm active tip, 100-mm length) was inserted into the suprascapular notch using the "in-plane" technique under ultrasonography

guidance. Sensory and motor stimulation tests were performed when the needle approached the suprascapular nerve. Sensory stimulus was delivered to the suprascapular nerve with the RF generator at a frequency of 50 Hz, pulse width of 0.2 ms, and voltage of 0.1 to 0.2 V. A feeling of paresthesia was anticipated in the innervation area when the voltage was increased to 0.3 V. After the sensory area was located, motor stimulation was tested at 2 Hz, 0.2 ms, and 0.4 to 0.5 V. The procedure continued after observing contractions in the infraspinatus and supraspinatus muscles. PRF was applied to the lesion once for 120 seconds at a maximum temperature of 42°C at 2 Hz, 20 ms, and 45 V (6).

The patients in the NB group were positioned the same as for those in the PRF group. Following the localization of the suprascapular notch under ultrasound guidance, a premixed 10-mL solution (5 mL 2% lidocaine hydrochloride and 5 mL 0.9% NaCl isotonic saline solution) was injected slowly with a 21-gauge x 3.5-inch spinal needle. During the procedure, the PRF device was kept on next to the patient, and the procedure continued for 120 seconds. After the procedure, the needle was removed and the feeling of numbness on the shoulder was determined in patients as in the PRF group.

Outcome Measures

The VAS scores of the patients and the maximum and painful angle of the shoulder were used as the primary outcome measures of the study. Secondary outcome measures were range of motion (ROM; flexion, abduction, internal and external rotation), and the Goal Attainment Scale (GAS) during upper-body dressing.

Demographic data, including age, gender, duration of symptoms, body mass index, and stroke type (hemorrhagic or ischemic), were recorded. Patients underwent systemic and neurologic examinations and were evaluated 3 times by the same physician at baseline, 1 month, and 3 months after the procedure. Although the patients

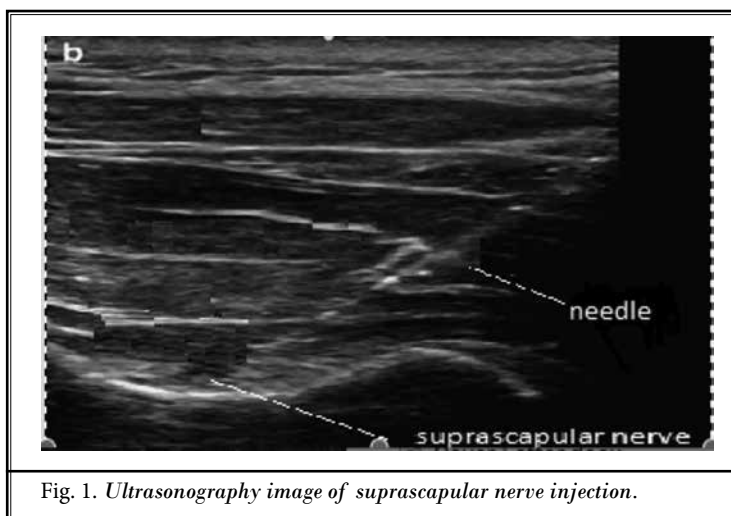


Fig. 1. Ultrasonography image of suprascapular nerve injection.

and physician who performed the procedure were nonblinded, the physician assessing the outcome measures was blinded to the treatment groups. In the baseline examination, the patients were assessed with the Brunstrom Stages of Stroke Recovery for upper extremity staging in the motor level assessment, the Modified Ashworth Scale for muscle tone grading, the Modified Rankin Scale for disability assessment, and the Mini-Mental State Examination for cognitive status. Shoulder ultrasonography and shoulder x-ray were also performed for radiologic evaluation. At all the assessments, the 10-cm VAS pain score, maximum passive shoulder ROM, and shoulder ROM were measured. In the functional evaluation, the GAS during upper-body dressing was used to assess the effect of shoulder pain on functional capacity. GAS is a mathematical technique for quantifying the achievement (or otherwise) of goals set, and it can be used in rehabilitation (7). According to this scale, pain during upper extremity dressing was evaluated (–2: severe pain, –1: moderate pain, 0: mild pain, +1: pain at the end of movement, and +2: painless motion).

Statistical Analyses

Statistical data analyses were performed with SPSS for Windows Version 20.0 software (IBM Corporation, Armonk, NY). Descriptive statistics were expressed as mean \pm standard deviation for continuous variables, and as number and percentage for discrete variables. Normal distribution of the data were assessed with the Kolmogorov–Smirnov test. The intragroup variations in continuous variables during the pretreatment (baseline) and posttreatment (month 1 and month 3) periods were analyzed with the related samples Wilcoxon signed-rank test, and intergroup comparisons were performed with the independent samples Mann–Whitney U test. The discrete variables were compared with the chi-square test. An alpha level of 0.05 ($P < 0.05$) was used for statistical significance in all statistical tests. Bonferroni correction was used in all possible

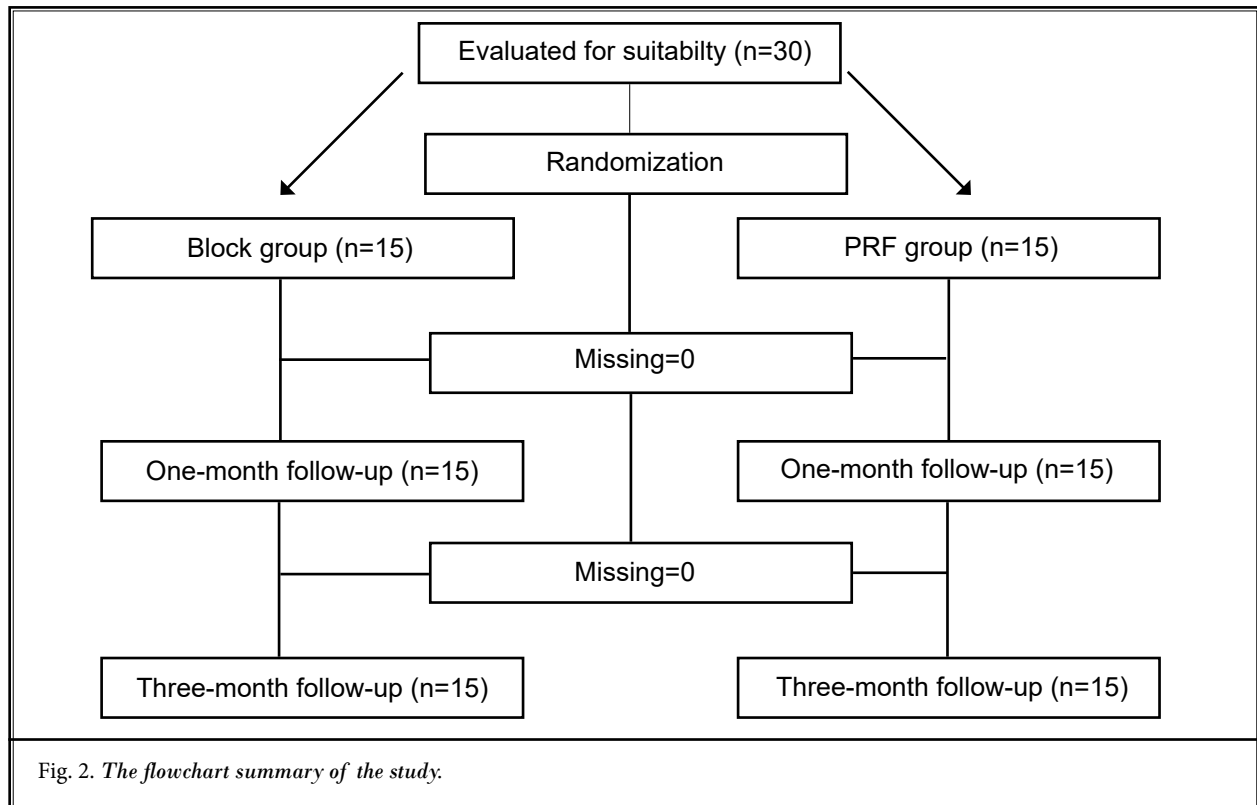


Fig. 2. The flowchart summary of the study.

multiple comparisons to control type-1 error. After Bonferroni correction, the results were considered statistically significant at a level of $P < 0.006$ in intragroup comparisons, and $P < 0.012$ in intergroup comparisons for all repeated measurements.

RESULTS

All the patients attended all the follow-up appointments. No side effects or complications were observed during or after the treatment. The flowchart summary of the study is shown in Fig. 2. The baseline demographic data of the patients are given in Table 1. No significant difference was found between the groups in terms of any demographic variable ($P > 0.05$). Baseline ultrasonography (biceps effusion, supraspinatus tendinosis, subscapularis tendinosis, infraspinatus tendinosis, subacromial-subdeltoid bursitis, acromioclavicular joint degeneration) and direct x-ray findings (glenohumeral subluxation, acromioclavicular joint subluxation, subacromial spur, calcific tendonitis) were not significantly different between the groups ($P > 0.05$) (Table 2).

The intragroup comparisons of VAS scores and hemiplegic shoulder ROM are shown in Table 3. There was no significant difference in baseline VAS scores

between the groups ($P > 0.05$). A significant decrease in the VAS scores was observed in the within-group comparisons in both groups at the third month compared with baseline ($P = 0.001$, for both groups). There were no significant changes in maximum or painful shoulder ROM in the NB group at any time point ($P > 0.05$). In comparison with baseline, the PRF group showed a significant increase in the maximum abduction angle (at 1 month, $P = 0.002$; at 3 months, $P = 0.001$), painful flexion angle (at 1 month, $P = 0.001$; at 3 months, $P = 0.001$), painful abduction angle (at 1 month, $P = 0.002$; at 3 months, $P = 0.001$), and painful external rotation angle (at 3 months, $P = 0.003$).

The intergroup comparisons revealed that the decrease in the VAS score was statistically significantly higher at the end of the first and third months in the PRF group compared with the NB group ($P < 0.01$). Increases in some shoulder ROMs were significantly higher in the PRF group compared with the NB group. There was a significant difference in the change in shoulder ROM measurements of maximum flexion angle (1 month, $P = 0.003$; 3 months, $P = 0.002$), maximum abduction angle (1 month, $P = 0.008$; 3 months, $P < 0.001$), painful flexion angle (1 month, $P = 0.001$; 3 months, $P =$

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Table 1. Patients' demographic characteristics, medical history, and baseline examination findings.

	All		NB		PRF		P
	Mean	SD	Mean	SD	Mean	SD	
Age (year)	64.6	11.2	64	12.4	65.2	10.2	> 0.05
	n	%	n	%	n	%	
Gender							> 0.05
Male	18	60	9	60	9	60	
Female	12	40	6	40	6	40	
Stroke type							> 0.05
Ischemic	22	73.3	11	73.3	11	73.3	
Hemorrhagic	8	26.7	4	26.7	4	26.7	
Hemiplegia							> 0.05
Right	12	40	8	53.3	4	26.7	
Left	18	60	7	46.7	11	73.3	
BSUE score							> 0.05
1	8	26.7	3	20	5	33.3	
2	9	30	4	26.7	5	33.3	
3	9	30	6	40	3	20	
4	4	13.3	2	13.3	2	13.3	
MRS score							> 0.05
2	3	10	1	6.7	2	13.3	
3	17	56.7	10	66.7	7	46.7	
4	10	33.3	4	26.7	6	40	

BSUE, Brunnstrom stage for upper extremity; MRS, Modified Rankin Scale; SD, standard deviation.

Table 2. Baseline ultrasonography* and direct x-ray radiography** findings.

	All		NB		PRF		P
	n	%	n	%	n	%	
Biceps effusion*							> 0.05
Yes	9	30	5	33.3	4	26.7	
No	21	70	10	66.7	11	73.3	
Supraspinatus tendinosis*							> 0.05
Yes	20	66.7	9	60	11	73.3	
No	10	33.3	6	40	4	26.7	
Subscapularis tendinosis*							> 0.05
Yes	19	63.3	10	66.7	9	60	
No	11	36.7	5	33.3	6	40	
Infraspinatus tendinosis*							> 0.05
Yes	9	30	4	26.7	5	33.3	
No	21	70	11	73.3	10	66.7	
Subacromial bursitis*							> 0.05
Yes	11	36.7	6	40	5	33.3	
No	19	63.3	9	60	10	66.7	
Acromioclavicular joint degeneration*							> 0.05
Yes	25	83.3	13	86.7	12	80	
No	5	16.7	2	13.3	3	20	

Table 2 (cont.). Baseline ultrasonography* and direct x-ray radiography** findings.

Glenohumeral subluxation**							
Yes	4	13.3	0	0	4	36.3	> 0.05
No	26	86.6	15	100	11	73.3	
Acromioclavicular joint subluxation**							
Yes	0	0	0	0	0	0	> 0.05
No	30	100	15	100	15	100	
Subacromial spur**							
Yes	1	3.3	0	0	1	93.3	> 0.05
No	29	96.7	15	100	14	6.7	
Calcific tendonitis**							
Yes	6	20	2	13.3	4	26.7	> 0.05
No	24	80	13	86.7	11	73.3	

Table 3. Intragroup comparisons of VAS scores and hemiplegic shoulder ROM.

	NB				PRF			
	Baseline	Month 1	Month 3	P	Baseline	Month 1	Month 3	P
VAS score*	7.4 1.4	6.2 1.4	6.2 1.2	P1 = 0.020 P2 = 0.001 P3 > 0.05	7.13 1.3	3.6 2	2.8 2	P1 = 0.010 P2 = 0.001 P3 = 0.041
Flexion (maximum angle)	140 37.9	142 38.6	143.3 37.3	P1 > 0.05 P2 > 0.05 P3 > 0.05	128.6 31.8	152.6 20.5	154.3 23.3	P1 = 0.030 P2 = 0.010 P3 = 0.340
Abduction (maximum angle)	132.6 31.7	136.6 32.6	133.3 35.5	P1 > 0.05 P2 > 0.05 P3 > 0.05	123.6 27.1	142.6 25.4	152 24.5	P1 = 0.002 P2 = 0.001 P3 = 0.020
Internal rotation (maximum angle)	78 15.5	82.3 12.7	84 12.1	P1 > 0.05 P2 > 0.05 P3 > 0.05	76 18.9	85 10.5	89.3 19.5	P1 = 0.030 P2 = 0.020 P3 > 0.050
External rotation (maximum angle)	73.6 18.8	77 17.5	79.3 18.3	P1 > 0.05 P2 > 0.05 P3 > 0.05	67.6 25.2	81.3 16.8	83 16.8	P1 = 0.010 P2 = 0.010 P3 = 0.102
Painful flexion angle	110.3 28.1	113.3 31.9	118.6 30	P1 > 0.05 P2 > 0.05 P3 = 0.01	101.3 30.6	124.6 32.9	134.6 34.4	P1 = 0.001 P2 = 0.001 P3 = 0.005
Painful abduction angle	102.6 31.7	110 28.5	110.6 35.5	P1 > 0.05 P2 = 0.01 P3 > 0.05	97 29.1	113.3 31.7	127.3 35.1	P1 = 0.002 P2 = 0.001 P3 = 0.007
Painful internal rotation angle	62.3 18.2	62 18	64 16	P1 > 0.05 P2 > 0.05 P3 > 0.05	57.6 21.9	66.3 21.9	72 21.3	P1 = 0.061 P2 = 0.007 P3 > 0.05
Painful external rotation angle	57.7 15.2	57 16.4	59 17	P1 > 0.05 P2 > 0.05 P3 > 0.05	49.6 22.7	67.3 25	69 22.5	P1 = 0.007 P2 = 0.003 P3 = 0.498

P1: P value for change from baseline to month 1. P2: P value for change from baseline to month 3. P3: P value for change from month 1 to month 3. *There was no significant difference in baseline VAS scores between the groups (P > 0.05).

0.001), painful abduction angle (3 months, P = 0.001), and painful external rotation angle (1 month, P = 0.004; 3 months, P = 0.002) (Table 4).

In the analysis of the effect of pain on upper-body dressing activity using the GAS score, the number of cases with a positive change (from -2 to +2) are shown

Table 4. Comparison of the changes (from baseline to month 1 and from baseline to month 3) in VAS scores and hemiplegic shoulder ROM.

	Baseline Month 1 (degrees)			Baseline Month 3 (degrees)		
	Block	PRF	P	Block	PRF	P
VAS score	1.2 1.0	3.5 1.9	0.001	1.2 0.9	4.2 1.7	<0.001
Flexion (maximum angle)	2.0 12.0	24.0 21.3	0.003	3.3 11.1	25.6 27.3	0.002
Abduction (maximum angle)	4.0 19.1	19.0 17.1	0.008	0.6 13.3	28.3 20.3	<0.001
Internal rotation (maximum angle)	4.3 11.6	9.0 14.4	>0.012	6.0 12.9	13.3 19.5	>0.012
External rotation (maximum angle)	3.3 12.6	13.6 15.0	>0.012	5.6 13.2	15.3 16.7	>0.012
Painful flexion angle	3.0 7.9	23.3 21.2	0.001	8.3 8.7	33.3 25.2	0.001
Painful abduction angle	7.3 15.7	16.3 14.9	>0.012	8.0 10.8	30.3 19.4	0.001
Painful internal rotation angle	-0.3 15.2	8.6 15.9	>0.012	1.6 14.9	14.3 14.2	>0.012
Painful external rotation angle	-0.6 .5.6	17.6 17.9	0.004	1.3 7.4	19.3 16.3	0.002

in Fig. 3. In the PRF group, the number of patients with no change (+0) was 2 (13%), with +1 change was 3 (20%), with +2 change was 7 (47%), and with +3 change was 3 (20%). In the NB group, these numbers were 10 (66%), 3 (20%), 1 (7%), and 1 (7%), respectively. The positive changes at month 3 in the PRF group were determined to be significantly higher than in the NB group ($P < 0.05$).

DISCUSSION

HSP is a common complication after stroke and negatively affects the rehabilitation process. Incidence as high as 84% has been reported in various studies, and it has also been stated that HSP may be seen at a rate of 32% in the long-term follow-up several years after stroke (8). Shoulder pain after stroke leads to negative results associated with the daily life activities, quality of life, and hospital stay (2). Novel therapies are still being sought for a better outcome after stroke. To the best of our knowledge, this is the first study to have investigated the effect of PRF applied to the suprascapular nerve in the treatment of HSP. The present results showed that the PRF

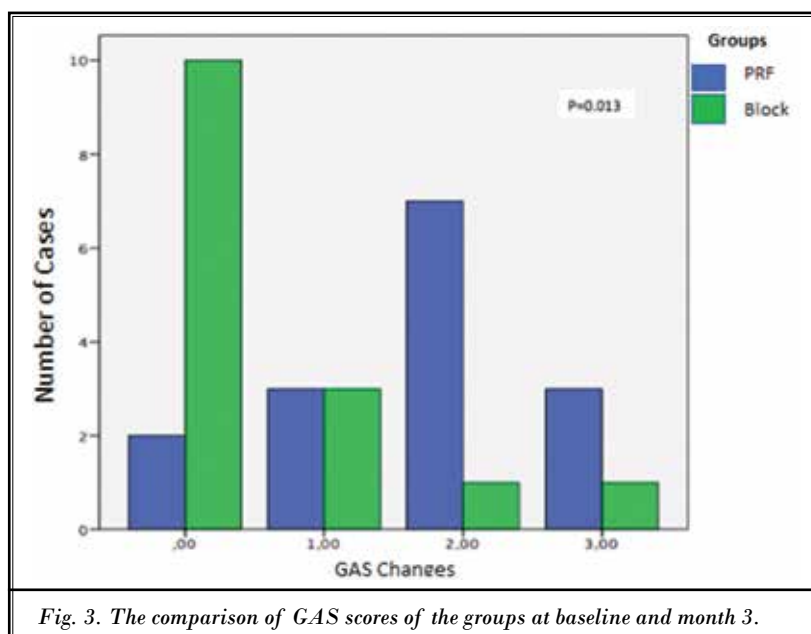


Fig. 3. The comparison of GAS scores of the groups at baseline and month 3.

was more effective in reducing pain than suprascapular NB. Pain relief also seems to have a positive impact on shoulder ROM and the upper-body dressing ability.

The involvement of several interrelated factors that may coexist in the development of HSP affects the treatment strategies. Suprascapular NBs may be used as an effective method for reducing pain in the early period (9). Steroid injections were once commonly used but have been discontinued due to rotator cuff-related complications that might develop in the long term. Yasar et al (10) showed that there is no significant difference between suprascapular NB and intraarticular steroid injection in terms of efficacy. The main drawback of suprascapular NBs is the duration of its efficacy. The findings of the present study support the use of PRF for better long-term results.

Previous studies have studied PRF applied to the suprascapular nerve in chronic shoulder pain not related to stroke. In a randomized, placebo-controlled, double blind study, which investigated the effect of PRF applied to the suprascapular nerve on chronic shoulder pain, significant improvements in pain, disability, and functional assessment lasting as long as 6 months were observed in patients treated with PRF, but not in those who received NB with lidocaine only (6). Gofeld et al (11) showed significant pain relief with both suprascapular nerve PRF and NB in patients with chronic shoulder pain in the third month of follow-up. Suprascapular NB is known to be effective in reducing acute and chronic shoulder pain and increasing joint ROM. PRF application has been reported to be a safe and repeatable method to reduce pain with each application having 4 to 5 months of sustained efficacy (11). In addition, the repeated use of PRF in subacromial compression syndrome has been reported to be effective and fairly safe (12). In the light of the present findings, PRF also seems to be an ideal treatment option for HSP. Further studies comparing PRF not only with NB but also with other conservative therapies will help to confirm the role of PRF in the management of HSP.

Studies investigating the effectiveness of conventional RF application in chronic shoulder pain are very limited (13). Conventional RF applications are destructive methods that carry the risk of neuritis or neuroma. In addition, there is less information about conventional RF application to the suprascapular nerve, which

contains motor fibers, than about PRF applications, and the former may cause additional complications in HSP. Given the possible damage to motor fibers, which may exacerbate muscle weakness in hemiplegia, PRF was preferred over conventional RF in the present study.

There were some limitations of this study. There is a need for further studies with a longer follow-up period to support the results of this study, which demonstrated that the efficacy of the PRF application in patients with HSP lasted for up to 3 months. As one of the key factors in the value of a treatment is the duration of effectiveness, further studies with at least 1-year follow-up may show greater benefit from PRF. The second limitation was the lack of grouping with respect to the cause of HSP. The effect of PRF may be greater or lesser in some certain conditions causing HSP, and this could be a topic for further research.

CONCLUSIONS

It is known that HSP is a common complication after stroke, which has a negative effect on the rehabilitation process, functional improvement, daily life activities, quality of life, and duration of hospital stay. Therefore it is important to reduce the pain effectively and safely. PRF application under ultrasonography guidance is a safe and easily applicable method in the treatment of HSP. PRF applied to the suprascapular nerve may reduce shoulder pain, increase the ROM of the upper extremity joints, and facilitate functional activities, such as upper-body dressing, that have been limited by pain.

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