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Ultrasound-guided caudal epidural pulsed radiofrequency for the treatment of failed back surgery syndrome: Results of a prospective clinical study

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ABSTRACT

Background: The first aim of this study was to investigate the analgesic efficacy of US-guided caudal epidural pulsed radiofrequency (PRF) stimulation in patients with failed back surgery syndrome (FBSS); the second was to evaluate the effects on opioid use, disability, quality of life and patient satisfaction.
Methods: Thirty patients with > 6-month history of chronic leg pain of >4 on a numerical rating scale (NRS) due to FBSS were included. These patients had unsatisfactory responses to conventional treatments and at least two epidural steroid injections. PRF stimulation with ultrasound guidance was administered to the caudal epidural space. NRS was evaluated before treatment, at 2, 4, and 8 weeks after intervention. Short Form-36 (SF-36) for health-related quality of life, Oswestry Disability Index (ODI), changes in opioid use and patient satisfaction were evaluated at baseline and 8 weeks after treatment.
Results: Mean NRS scores were significantly lower at weeks 2, 4 and 8 compared to baseline ($P < 0.001$). There were significant improvements in SF-36 and ODI scores compared with pretreatment ($P < 0.05$). It was found that 31% and 13% of opioid users, respectively, discontinued and tapered off their opioid medication. 40% of patients were overall satisfied with the treatment.
Conclusion: In a cohort of patients with FBSS, caudal epidural PRF stimulation provided pain relief in 36% of treated subjects. Patients also experienced significant improvement in functionality, quality of life and opioid use. This technique can be considered as an alternative before considering neuromodulation, opiate therapy, or reoperation in patients with FBSS.

1. Introduction

Despite advances in spinal surgery, patients with an estimated incidence of about 10–40% have persistent low back or leg pain, or both, as a result of which physicians and researchers refer to these patients as failed back surgery syndrome (FBSS) [1]. Persistent pain with an affective-arousal component often seriously affects the patients' quality of life, daily living activities, psychological status, and overall well being [2]. A variety of surgical and non-surgical etiologies including internal disc disruption, epidural fibrosis, nerve root compression due to recurrent disc herniation, foraminal or central stenosis gather under the umbrella of FBSS [3].

The treatment of FBSS consists of a stepwise approach, which should be tailored to the presenting patient, and is performed in a multi-modal manner. Clinical guidelines recommend starting with conservative treatments such as physical therapy and/or medications. When conservative approaches to symptom control are not effective, interventional pain techniques should be considered [4]. Epidural, transforaminal or caudal steroid injections and epidural adhesiolysis have a demonstrable safety and feasibility record in FBSS [5]. Also, spinal cord stimulation (SCS) has shown important potential in the management of FBSS and is an alternative to further surgical revisions associated with poor outcomes in patients with FBSS [6,7]. However, there are still clear indications for surgical revision such as patients with progressive neurological deficit and motor weakness or problems with surgical hardware [4].

Pulsed radiofrequency (PRF) is a modified radiofrequency technique widely used to provide pain relief in various chronic pain syndromes. PRF uses radiofrequency stimulation in short, high-voltage bursts, followed by a resting phase that allows time for heat elimination, so that the neuro destructive temperature level of 42° is not exceeded and the thermal

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effect is considered to be of minor importance [8,9]. Electric fields produced by PRF that alter the transmission of pain signals are thought to be responsible for the clinical effect [10]. As PRF has noticeable advantages in controlling pain without tissue destruction and provides a margin of safety, it has been rapidly adopted in pain practice and the indications for PRF stimulation have expanded by applying it to manage chronic pain conditions such as trigeminal neuralgia, joint pain and myofascial pain [11–13]. There are several studies suggesting a role for PRF treatment of the lumbar dorsal root ganglion to provide pain relief in FBSS, with both optimism and concern [14,15]. Furthermore, several studies have reported PRF stimulation applied by placing needle electrodes into the caudal epidural space to manage chronic pain [16–19]. The effect of caudal epidural PRF has been explained by decreased nociceptive neuron activity in the spinal dorsal horn at multiple spinal segments from S1 to L3 [20].

Recently, the use of ultrasound (US) technology has increased to guide interventional procedures in regional anesthesia and pain medicine. US-guided procedures have several advantages, such as avoidance of radiation exposure and real-time visualization of the needle. Prior studies have defined the sonoanatomy of the caudal epidural space and the feasibility of US-guided procedures [21,22].

In this current study, we aimed to investigate the effect of US-guided caudal epidural PRF stimulation in patients with FBSS who did not respond to conventional treatment protocols and epidural steroid injections. Our primary goal was to investigate the analgesic efficacy of US-guided caudal epidural PRF stimulation in patients with FBSS; secondary outcomes were the effects on opioid use, disability, quality of life and patient satisfaction.

2. Methods

Local ethics committee approval (with decision number 98/08–2020 Turkey) was obtained for this prospective, observational study. Our study was designed and conducted in accordance with the ethical principles specified in the Helsinki Declaration. All participants were informed about the study and written informed consent was obtained from all patients. This study was registered at ClinicalTrials.gov PRS under Registration No. NCT05062993. The STROBE checklist was used to help design and conduct the study.

2.1. Patients

After applying the inclusion and exclusion criteria in Table 1, 30tbl30 patients who presented to our pain clinic with at least 6 months of chronic persistent leg pain due to FBSS were included in this study. Patients were advised to keep their antiepileptic and antidepressant drug doses stable throughout the study and not to change their prescribed regimens. Changes in opioid drugs were allowed during the follow-up period.

Table 1
Inclusion and exclusion criteria.

Inclusion criteria
The patients who met all of the following criteria were included
● > 6-month history of persistent pain in one or both legs with back pain after laminectomy or discectomy for spinal stenosis or herniated nucleus pulposus
● 18 years of age or older
● Capable of giving informed consent
● > 4 pain score in NRS
● Unsatisfactory response to conventional treatments including physical therapy or medications.
● Unsatisfactory response to at least two translaminar, transforaminal, or caudal epidural steroid injections
● No interval change in pain score on NRS for 4 weeks after last epidural steroid injection
Exclusion criteria
Patients who met any of the following criteria were excluded from the study
● Diagnosis of sacroiliac joint or facet joint pain based on clinical or radiological evaluation
● Myelopathy
● Rheumatoid disorders
● Psychiatric disorders
● Infection at the needle entry site
● Bleeding or coagulation disorders

2.2. Intervention

The patient lied in prone position and aseptic techniques were adopted. Under ultrasound guidance, a sterile linear probe was initially placed in the transverse view for anatomic evaluation and the cornua of the sacrum, sacrococcygeal ligament and sacral hiatus were identified. Then, the transducer is rotated 90° to a sagittal plane at the midline to show the hiatus, sacrococcygeal ligament and epidural space. After cutaneous and subcutaneous anesthesia with 3 ml of 2% lidocaine, a 22-gauge 150-mm RF cannula with 20 mm (SMK pole needle, 150 mm with a 20 mm active tip; Cotop International BV, Amsterdam, Netherlands) active tip was advanced through the sacrococcygeal ligament into the caudal epidural space under real-time sonographic imaging (Fig. 1). The active tip of the needle was advanced to the S2-3 intervertebral level, just beyond the apex of the sacral hiatus. The needle tip was confirmed by negative aspiration for blood or cerebrospinal fluid, then a few milliliters of saline (Sodium Chloride 0.9%) was injected to observe the expansion of the epidural space. After correct needle placement was confirmed, an electrode was connected to the cannula, and stimulation was conducted with impedance measured between 250 and 350 Ohms (Cosman G4 radiofrequency generator, Cosman Medical, Burlington, MA). A different sensation or feeling such as fullness, impression, tingling, pulling or plethora at the rectal and/or coccygeal region was observed by the patients when 50 Hz was applied with 0,4 to 0,7 V sensory stimulation. No leg muscle contraction was observed with 2 Hz motor stimulation at 2 V. PRF was performed for 600 s at 5 Hz using a 5-ms pulse width at 55 V, avoiding electrode tip temperatures above 42 °C. Interventional procedures were performed by a physician with 20 years experience in ultrasound-guided spinal interventions, who was not involved in the outcome assessment. None of the patients received a second injection during the study period.

2.3. Outcome measures

Descriptive data collected at baseline included age, gender, body mass index, and surgical history. The primary outcome was pain intensity for leg pain. The numerical rating scale (NRS) is a commonly used scale to assess the severity of pain felt by a patient. The patient rates pain on a scale of 0–10, with 0 representing 'no pain' and 10 'worst pain imaginable'. NRS has been shown to have high sensitivity and reliability as well as a strong correlation with descriptive scales [23]. Pain intensity assessment was calculated as the average NRS available during each visit. Successful pain relief was described as 50% or more reduction in NRS score at 8 weeks compared to baseline.

Secondary outcome measures were changes in opioid use, quality of life (QoL), low back function, and patient satisfaction degree after treatment. Patients' quality of life was assessed using the physical (PCS) and mental (MCS) component summary scores of the Short Form (SF-36). The SF-36 is an overall measure of health-related QoL through eight different dimensions, such as the ability to function and complete everyday tasks, perform usual physical and social activities, as well as capturing aspects relating to an individual's mental well-being such as energy and fatigue. The PCS and MCS typically range from 0 to 100 (with 0 = worst possible state).These two summary scales composed from the eight subscales of the SF-36 are recommended when an overall impact in physical or mental health is expected [24]. The Oswestry Disability Index (ODI) is a self-administered questionnaire covering 10 sections of functional ability, each with six possible levels of severity ranging from 0 to 5. The percentage of disability, total ODI score, is obtained by using the

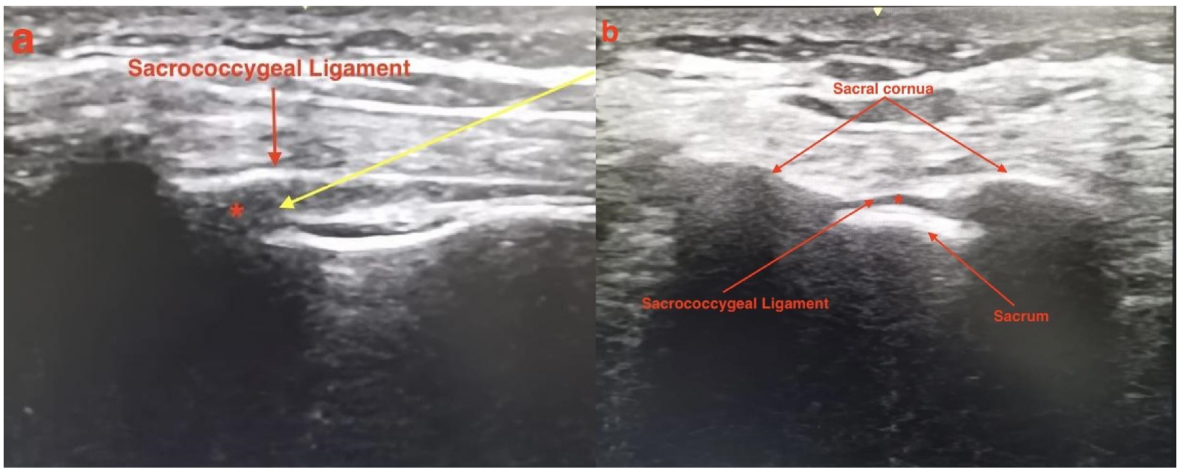

Fig. 1. Sonographic images of the sacral hiatus (a) sagittal and (b) transverse view and epidural space (*).

equation: Total score/50 × 100. A score of 0%–20% indicates minimal disability, 21%–40% moderate disability, 41%–60% severe disability, 61%–80% indicates level of pain that impinges on all aspects of the patient's life, and scores between 81% and 100% shows patients who are bed bound. A change in ODI of 6% is considered clinically meaningful [25]. SF-36 and ODI scores were evaluated at baseline and at the end of the 2nd month.

We determined whether the treatment was effective in patients who were using opioids prior to the procedure by evaluating whether opioid use was reduced, discontinued or not changed. Changes in overall satisfaction were assessed using a 5 point Likert scale [26]. (1, very dissatisfied; 2, dissatisfied; 3, neutral; 4, satisfied; 5, very satisfied).

2.4. Sample size

Sample size calculations were performed using G*Power software version 3.1.9.7 (Heinrich-Heine-Universität, Düsseldorf, Germany) and based on the results of a previous study [19]. In this study, the mean NRS score 8 weeks post-PRF stimulation was 3.8 ± 1.4. Using the results of this previous study and considering NRS as the primary outcome, it was determined that a sample size of 27 patients was requiered to detect a % 20 difference, an α level of 0.05, and a power of 80%. Assuming that 10% of potential patients could be lost during the follow-up period, the final sample size was 30 patients.

2.5. Statistical analysis

Statistical analyses were performed using SPSS 22.0 statistical analysis program (IBM). Shapiro-Wilk test was used to evaluate whether the data conformed to a normal distribution. Descriptive statistics were expressed as mean, standard deviation, median, minimum, and maximum for continuous variables and number of cases and percentage (%) for categorical variables. Categorical data were compared using chi-square test or Fischer exact test as appropriate. Mean changes from baseline for each outcome at each time were compared within groups using the paired *t*-test and the Wilcoxon signed rank test for parametric and non-parametric data, respectively. Pearson's chi-square test was used to investigate whether there was a significant difference in the use of opioids and NSAIDs at 8 weeks compared with baseline. A p value of <0.05 was accepted as statistically significant.

3. Results

All 30 patients completed the study. None of the patients reported immediate or late adverse events during the procedure or during the follow-up period. The demographic characteristics and surgical histories of the patients at the time of enrollment were summarized in Table 2.

At 8 weeks, the median NRS score reported was 4.5 (3.25–5) compared to 7 (6–7) at baseline, with a median reduction of 35% (Table 3). Compared with baseline NRS, those at 2, 4 and 8 weeks after PRF stimulation were significantly lower ($p < 0.001$) (Fig. 2). Two months after caudal epidural PRF stimulation, 11 (36%) patients reported successful pain relief (>50% pain reduction). We found no association between the proportion of successful responders and the presence of herniated nucleus pulposus, fibrosis or stenosis.

The use of opioid was widespread among patients at baseline (22/30). The percentage of post-PRF stimulation opioid use of patients who used opioids before treatment was listed in Fig. 3. At 8 weeks after treatment, the opioid use was reduced and discontinued in 31% (7/22) and 13% (3/22) of these patients, respectively, with statistically significant changes compared to the baseline. Patients who were not using opioid did not start opioid treatment after PRF.

Significant improvement in quality of life was observed at 8 weeks after treatment. The average SF-36 PCS advanced from 29.4 ± 5.9 to

Table 2
Demographic and baseline characteristics.

Mean age (years)	46.36 ± 10.67
Sex ratio (male/female)	
	10/20
Body mass index (kg/m2)	28.41 ± 4.22
Smoking status (former/current/never)	
	6/14/10
Duration from surgery to procedure (mo)	
	29.56 ± 14.14
Duration of symptoms (mo)	24.66 ± 16.97
Back pain	30
Site of leg pain (right/left/both)	
	4/5/21
Residual/recurrent disc herniation	17
Stenosis	12
Epidural fibrosis or scar	4
Surgical techniques (fusion/decompression)	
	6/24
Surgical level (L3-4/L4-5/L5-S1)	
	5/24/9
Baseline NRS at pretreatment	6.53 ± 0.77
Baseline opioid use	
Present 22 (73.3%)	
Absent 8 (27.7%)	

Values are presented as mean ± standard deviation, median (minimum-maximum) and numbers of patients. SD: standard deviation.
NRS: Numeric rating scale; SF-36: Medical Outcomes Study 36-item Short Form Health Survey: NDI: Neck disability index.

Table 3
Summary of pain Numeric Rating Scale scores (0-10).

	NRS	p
Pre-treatment	7 (6–7)	
2 weeks	4 (3.25–5)	***<0,001***
4 weeks	4 (3–5)	***<0,001***
8 weeks	4.5 (3.25–5)	***<0,001***

Data are expressed as median (percentiles 25–75).
Intra group comparison between 2, 4, 8 weeks and pretreatment.
p values were italicized and p values that are written in bold represent statistical significance.
NRS, numeric rating scale.

38.5 ± 6.4 8 weeks after PRF stimulation. As for the SF-36 MCS, the average score increased from 38.7 ± 11.2 to 44.7 ± 9.7 (Table 4).

The mean ODI score at 8 weeks was significantly lower than the mean baseline ODI score (48.9 ± 10.1 vs. 31.6 ± 5.2; $p < 0.001$) (Table 4).

On the 5-point Likert scale, 40% of the patients were very satisfied or satisfied with the treatment. However, 17 (56%) patients were neutral with the results (Table 5).

4. Discussion

This prospective study demonstrated that US-guided caudal epidural PRF stimulation significantly reduced pain scores and opioid use in patients with FBSS. In addition, it resulted in improvement in patient functionality, quality of life and satisfaction.

Several overlapping sub-etiologies leading to many clinical presentations of the persistent pain with an affective-arousal component, and surgically induced changes in the anatomy of the spine render hard to treat FBSS. This difficulty may be aggravated by the psychosocial factors that have an important influence on the perception and chronicity of pain [4,27,28]. FBSS patients experience higher levels of pain scores and lower quality of life and functional capacity compared to those with rheumatoid arthritis, complex regional pain syndrome, and fibromyalgia [29]. Treatment options range from pharmacological drugs and physical therapy to interventional procedures. Epidural steroid injections are widely used in pain practice for epidural fibrosis, disc disruption or herniation, and spinal stenosis which may address several of the etiologies associated with the development of FBSS [30]. Spinal cord stimulation has gained popularity due to its substantial superiority over conventional therapies and reoperations [6,7]. However, patients with FBSS may not achieve sufficient treatment success with revision surgery or interventional treatments and are often refractory to oral medications [29]. In this study, we only included patients who did not respond adequately to conventional therapies and repeated epidural steroid injections. Furthermore, all patients had suffered from back and leg pain for more than 7 months, and the average duration between the onset of symptoms and the caudal epidural PRF procedure was 24.66 months. Considering the prognosis and characteristics of FBSS, although only about one-third of our patients experienced clinical benefits in the management of pain after US-guided caudal epidural PRF, the results of this present study can be considered meaningful.

PRF stimulation is an alternative method to conventional radiofrequency ablation, with the advantage of avoiding the side effects related to conventional radiofrequency, such as neuritis and deafferentation pain [10]. What is clearly attracting the interest of clinicians is the investigation of the mechanism of action in PRF stimulation and its impact on the final outcome of therapy in patients with chronic pain syndromes. Although the efficacy of PRF has been documented clinically, its mechanism of analgesia is still under investigation. Currently, studies have reported that PRF has temperature-independent biological and physical effects on nerve morphology, neuromodulation, and pain signal pathways [8,9,31,32]. It is also assumed that the high-intensity electric fields inducing transmembrane potentials are the main factor among the modes of action of PRF. The induced transmembrane potentials can cause disruption of ion channel function and alterations in resting and threshold potential [33]. Recent studies have demonstrated the ultrastructural axonal changes, including the disorganization of microtubules and microfilaments, and the swelling of mitochondria following PRF [8,34]. Besides morphological changes, biochemical enhancement of noradrenergic and serotonergic descending pain inhibitory pathways have also been observed, as well as effects on immune modulation via decreases in proinflammatory cytokines such as interleukin (IL)-1b, TNF-α and IL-6 by electric fields [35,36].

Several studies have reported the PRF stimulation applied to manage chronic pain by placing needle electrodes into the caudal epidural space, dorsal root ganglion, intraarticular space, interfascial planes and even non-nervous soft tissues [11,13,14,17,37]. In caudal epidural PRF stimulation, the active part of an electrode is placed into the caudal epidural space at the S2-3 intervertebral level. In a rat model, Cho et al. reported that caudal epidural PRF decreased microglia activity at multiple levels

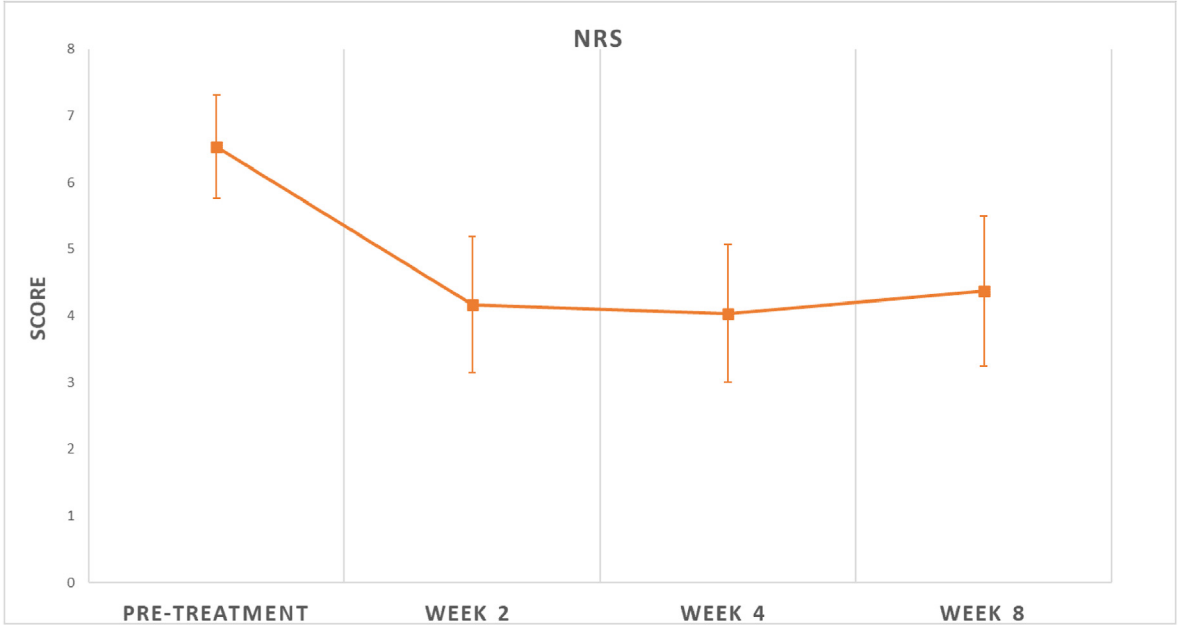

Fig. 2. Changes in Numerical Rating Scale (NRS) scores during the follow-up period.

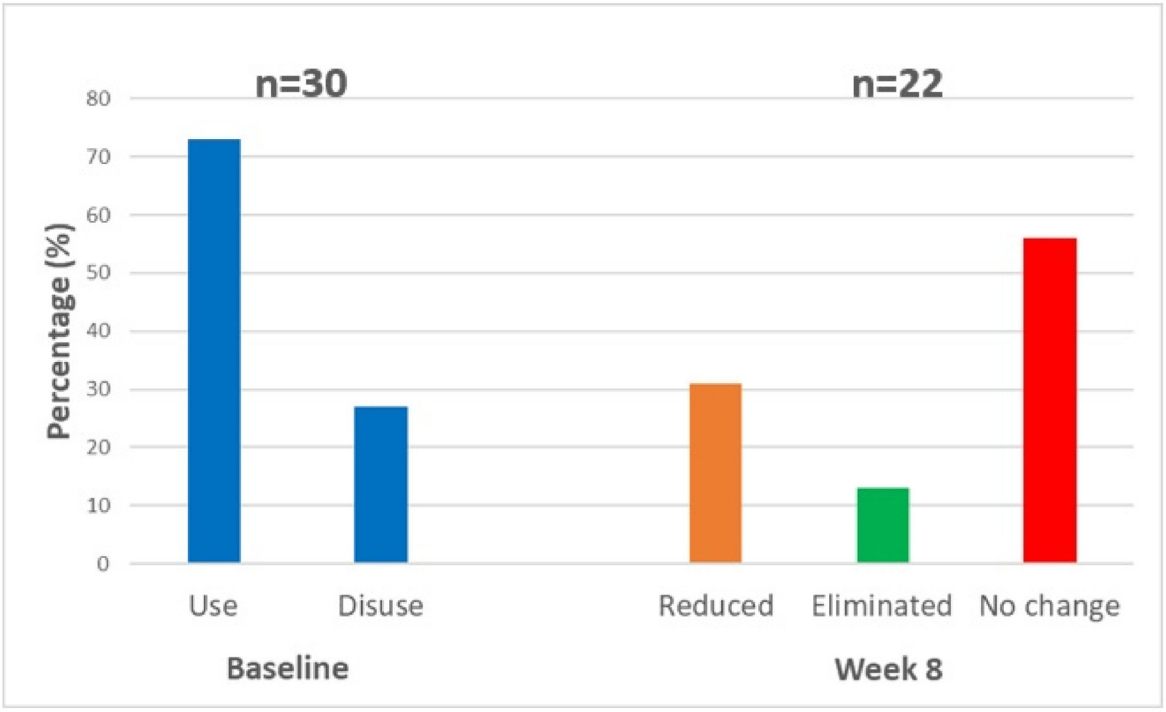

Fig. 3. Opioid use scores at baseline and at 2 months.
Data are as expressed as percentage of patients. The use of opioid at 8 weeks concerns the 22 patients using opioid at baseline* Reduction and discontinuation of opioid use was statistically significant compared to baseline at 2 months ($P < 0.001$).

Table 4
Outcomes of the caudal epidural pulsed radiofrequency.

	Pre-treatment	8 weeks	p
ODI	48.9 ± 10.1	31.6 ± 5.2	***< 0.001***
SF 36			
PCS	29.4 ± 5.9	38.5 ± 6.4	***< 0.001***
MCS	38.7 ± 11.2	44.7 ± 9.7	***0.030***

Values are presented as number or mean ± standard deviation.
p values were italicized and p values that are written in bold represent statistical significance.
PCS, physical component summary score of the Short Form-36 health survey (SF-36).
MCS, mental component summary score of the SF-36; ODI, Oswestry Disability Index.

Table 5
Patient- Reported Satisfaction as determined using a Likert scale.

Satisfaction	Number	Percent Total	
5 (very satisfied)	4	13.3%	Overall satisfied: 40%
4 (satisfied)	8	26.6%	
3 (neutral)	17	56.6%	
2 (dissatisfied)	1	3.33%	Overall dissatisfied: 3.33%
1 (very dissatisfied)	0	0.0%	

Data are given as number of patients.

of the lumbosacral spinal cord, from S1 to L3. Downregulation of microglial activity contributes to the pain relief, as microglial signaling in the spinal cord dorsal horn regulates chronic neuropathic pain by releasing pro-inflammatory cytokines such as interleukin-1β and tumor necrosis factor-α [20]. Additionally, Rohof et al. performed caudal epidural PRF in 3 patients with post-herpetic neuralgia. They reported that PRF stimulation successfully controlled pain in two of the patients with neuralgia in dermatomes L1-4 and T10- 11, respectively. In the latter case, the clinical effect of PRF stimulation was over more than 7 vertebral levels, from S3 to T11 [18].

In this study, we decided to use a PRF protocol based on higher voltage (55V), shorter pulses (5 ms) and higher pulse frequency repetition (5 Hz) instead of a standard clinical protocol (45 V pulses, 20 ms duration, 2 Hz repetition frequency) that has been shown to be effective and safe in previous studies [16,17,19]. Currently, pain physicians are focusing on improving PRF parameters to enhance its analgesic effects. A computer modelling study comparing the performance of two different PRF protocols has demonstrated that higher voltage and higher pulse frequency repetition significantly increase the magnitude of the electric field without raising the temperature [38]. Several clinical studies have reported that PRF at higher voltage leads to greater electric field strength, which may improve the analgesic effect of PRF [39–41]. The effects of caudal epidural PRF treatment reported in our study are similar to or slightly weaker than those of three previously published studies reporting a success rate of approximately 30% and 80% of caudal epidural PRF treatment with the same RF protocol. Atim et al. first introduced the application of caudal epidural PRF for coccydynia and reported that 80% of patients showed improvement in patient satisfaction and pain scores [16]. In another study, Lee et al. investigated the effect of caudal epidural PRF stimulation in 20 patients with refractory chronic idiopathic axonal polyneuropathy [17]. They reported that 3 months after PRF, half of the patients achieved meaningful pain relief and were satisfied with the treatment. Similar to our study, Chang et al. conducted caudal epidural PRF on patients with FBSS and found that the rate of successful pain relief was 32% after 3 months after treatment [19]. However, in this study, unlike previous studies, PRF treatments were performed under ultrasound guidance and prospectively. Additionally, this study evaluates the changes in opioid use, quality of life scores and disability level of patients with FBSS.

In patients with FBSS, it is recommended to prescribe an antidepressant or antiepileptic as first-line therapy. Opioid drugs such as tramadol or morphine are recommended for acute pain attacks [42]. Therefore, we advised patients to keep their prescribed drugs other than

opioids. Changes in opioid drugs were permitted throughout the study. We reported that 44% of the patients reduced their opioid drugs during the follow-up period, this outcome was considered meaningful, and caudal epidural PRF may have the potential to reduce opioid use.

US-guided caudal epidural procedures have been widely practiced in regional anesthesia and pain medicine. US enables clinicians to measure the depth of the sacral hiatus and the distance from the skin to the sacrococcygeal ligament. Furthermore, the US can identify anatomical variations such as closed or small sacral hiatus [21,22]. Kim et al. reported a patient with motor weakness and sensory deficits in the right leg due to a lumbar epidural hematoma after caudal epidural PRF stimulation [43]. In our clinical practice, we prefer ultrasonography, which allows us to visualize neurovascular structures and choose the proper needle length and diameter, eliminating the need for radiation exposure.

Some limitations of this study should be taken into account. First, there was a short follow-up period, with effects assessed at just 8 weeks. Second, while our study could be criticized for the lack of a sham group, it remains an ethical dilemma due to the Covid-19 pandemic. A placebo and nocebo effect on interventional treatments can be 13–30% and 3–8%, respectively [44]. In this study, all included patients did not respond to conventional therapies and repeated epidural steroid injections. Considering these observations and the progressive, degenerative nature of FBSS, we believe that our patients' pain had reached a plateau and that the experienced pain relief after intervention was a result of caudal epidural PRF and not due to natural recovery of lumbosacral radicular pain or placebo effect. Third, this study showed that caudal epidural PRF with 5 Hz and a pulsed width of 5-ms for 600 s at 55 V, was effective, but we did not investigate the effect of a higher pulse dose (by changing parameters such as pulse frequency, pulse width, or treatment time) or a relatively higher voltage (>55V) on efficacy.

We reported that persistent pain and opioid use in FBSS patients who were refractory to conventional treatments including physical therapy, medications, and repeated epidural steroid injections were significantly reduced after caudal epidural PRF. Improvement in functionality, quality of life and patient satisfaction were also observed. However, the rate of successful treatment outcomes related to pain relief at 2 months after caudal epidural PRF was only 36%.

5. Conclusions

In clinical practice, when epidural steroid injections are not effective to control the pain, there are several options such as adhesiolysis, neuromodulation and even reoperation to manage the FBSS. We suggest that US-guided caudal epidural PRF stimulation is worth considering as an alternative and safe treatment modality for patients with FBSS who are refractory to epidural steroid injections. Future studies with larger patient populations and all-around evaluations of treatment results are required to scrutinize the potential of US-guided caudal epidural PRF.

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Declaration of competing interest

The authors declare they have no competing interests.

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