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Effectiveness of Preemptive Analgesia Using a Frequency Rhythmic Electrical Modulation System in Patients Having Instrumented Fusion for Lumbar Stenosis

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Study Design: A randomized prospective study.
Purpose: To assess postoperative analgesic requirements after Phyback therapy preemptively in patients undergoing lumbar stabilization.
Overview of Literature: Frequency Rhythmic Electrical Modulation System is the latest method of preemptive analgesia.
Methods: Forty patients were divided into two groups. Patients who were to receive tramadol were allocated to "group A" and those who were to receive Phyback therapy were allocated to "group B." In patients with a visual analog scale score of >4 or a verbal rating scale score of >2, 75 mg of diclofenac IM was administered. The amount of analgesic consumption, the bolus demand dosage, and the number of bolus doses administered were recorded. Patient satisfaction was evaluated using the visual analog patient satisfaction scale.
Results: There were statistically significant differences in the visual analog scale and verbal rating scale scores in the fourth, sixth, 12th, and 24th hours. The number of bolus infusions was significantly lower in group B. The amount of analgesic consumption was higher in group A. There was a significant difference between the two groups in the number of bolus infusions and the total amount of analgesic consumption, and this comparison showed better results for group B.
Conclusions: Application of Phyback therapy reduced postoperative opioid consumption and analgesic demand, and it contributed to reducing patients' level of pain and increased patient satisfaction. Moreover, the application of preemptive Phyback therapy contributed to reducing preoperative pain which may have reduced patient anxiety.

Keywords: Spinal stenosis; Postoperative pain; Analgesics; Electric stimulation therapy; Preanesthetic medication

Introduction

Surgical treatment for lumbar spinal stenosis (LSS) has become increasingly popular in recent years. The underlying reasons for the increasing popularity of this approach are developments in diagnostic imaging methods, excellence in surgical techniques, and population aging. In addition, evaluation of the functional status of patients

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and consideration of this status as an aim of treatment by physicians has contributed to the use of surgical methods as a treatment modality. Improving the quality of life, increasing the walking distance, and eliminating pain and cramps in the patients are the main objectives of surgery for LSS [1].

Moderate and severe pain is seen in 75% of patients in the early postoperative period. Postoperative pain may continue for 3 years in 3% of patients and for at least 1 week in 27% of patients [2].

Preemptive analgesia can be used as a treatment for nociceptive pain. A painful stimulus is used to block central sensitization. If, prior to this, preemptive analgesia has been used, severe pain perception may develop postoperatively [3].

Electrical stimulation is an effective and noninvasive method to break pain cycles. It has no known adverse effects, nor does it have irreversible effects on the human body [4,5].

Frequency Rhythmic Electrical Modulation System (FREMS) is the latest method of preemptive analgesia that is based on the application of electrical stimulus. The aim of this study is to investigate the effectiveness of this preemptive method on postoperative pain scores and analgesic requirements in patients undergoing instrumented fusion for LSS.

Materials and Methods

This randomized prospective study was conducted in the neurosurgery and anesthesiology clinics. Forty consecutive patients undergoing short segment instrumented fusion for LSS were included in the study after obtaining the ethics committee approval. Informed consent was obtained from all patients.

Inclusion criteria

- Male and female patients between 30 and 70 years of age
- American Society of Anesthesiologists (ASA) class I-III group of patients
- Patients who were undergoing an operation for LSS

Exclusion criteria

- ASA IV patients
- Previous lumbar surgery for any reason
- Patients with diabetes mellitus, chronic obstructive pulmonary disease, renal failure, or any other serious systemic diseases
- Patients with cardiac pacemakers
- Patients who have any psychiatric or neurological disorders
- Pregnant patients

All patients were operated on by the same surgeon. Patients were randomly divided into two groups of 20 patients each. Group A comprised patients who were only given patient-controlled analgesia (PCA), and group B comprised patients who received preemptive analgesia with FREMS.

FREMS was administered with a Phyback device (PBK-2C, LMD Piccone, Bologna, Italy). FREMS therapy was administered preoperatively in five sessions of 20 to 30 minutes each for five days. The last session was given in the operating room just before the operation.

The Phyback treatment included modalities similar to those for lumbar contracture, antiphlogistic therapy for lumbar radiculitis, and activation of microcirculation and lumbar analgesia consecutively. All patients were administered 0.05 mg/kg of midazolam (Dormicum, Roche, Stockholm, Sweden) IM as premedication 30 minutes before the operation. After preoxygenation with 100% O_2 for 3 minutes, induction of anesthesia was performed with 2 mg/kg propofol (Pofol Injection, Dongkook Pharm, Seoul, Korea) IV and 1 μg/kg fentanyl (fentanyl citrate 2 mL sol., Antijen Pharmaceuticals, Dubulin, Ireland) IV in all patients. For facilitating endotracheal intubation, 0.1 mg/kg of vecuronium bromur (Blok-L iv flakon 10 mg, Mustafa Nevzat, Istanbul, Turkey) IV was used. Maintenance of anesthesia was performed with 50% O_2, 50% room air, and 5-6% desfluran (Suprane, Eczacıbaşı Baxter, Istanbul, Turkey) and with a 0.1 μg/kg/min remifentanyl (2 mg iv flakon, Ultiva, Glaxo Smith Kline, Verona, Italy) infusion.

All patients were given 10 mg of metoclopramid Hydroclorure (Primperan ampul, Biofarma, Istanbul, Turkey) IV 30 minutes before the end of operation to prevent nausea and vomiting. A PCA device (CADD-Legacy PCA pump, Smiths Medical, Dubulin, OH, USA) was inserted in the termination phase of the operation, and 50 mg of tramadol (contromal 100 mg/2 mL, Abdi İbrahim, Istanbul, Turkey) IV bolus was given.

After extubation, patients were transferred to the recovery room. Both of the groups were given a basal infusion of 5 mg/mL tramadol at a rate of 20 mg/hr. PCA devices were connected for 24 hours. Devices were programmed

Table 1. Demographic features

Parameters	Group I (n=20)	Group II (n=20)	*p*-value
Age (yr)	56.8±8.61	58.05±5.78	0.593
Sex			
Female	9 (45)	12 (60)	
Male	11 (55)	8 (40)	
Body mass index	28.34±2.64	29.32±4.67	0.422
American Society of Anesthesiologists Risk classification			0.698
I	5 (25)	5 (25)	
II	11 (55)	8 (45)	
III	4 (20)	6 (30)	

Values are presented as mean±standard deviation or number (%).

to stop after 20 minutes and to deliver 10 mL of the drug in one shot.

The patients' levels of pain were evaluated postoperatively by a 10-point visual analog scale (VAS) and a 5-point verbal rating scale (VRS) at 1, 2, 4, 6, 12, and 24 hours. If the VAS score was >4 or the VRS score >2, the patient was given 75 mg of diclofenac sodium (Voltaren 75 mg, 3 amp., Novartis, Istanbul, Turkey) IM. Timing and dose of extra analgesic needed were recorded. Overall patient satisfaction was evaluated by a 10-point visual analog patient satisfaction scale (VAPSS) at the 24th postoperative hour.

1. Statistical analysis

Analysis of data was performed by the SPSS ver. 13 (SPSS Inc., Chicago, IL, USA). Distribution of continuous variables was evaluated by the Shapiro Wilk test. Descriptive statistics were reported as mean±standard deviation and minimum-maximum value for continuous variables, and number and percent of cases for categorical variables.

One-way analysis of variance was used for the determination of difference in age between groups. Significance of differences between median values was evaluated by the Mann-Whitney U test for two groups and the Kruskal Wallis test for multiple groups. If the difference was significant, the determination of different groups was done by a nonparametric multiple comparison test.

Categorical variables were evaluated by the Pearson's chi-square test or Fisher's chi-square test. Correlation between continuous variables was investigated by Spearman's test.

Differences in the VAS and VRS scores between the preoperative and postoperative periods were evaluated by Wilcoxon's test.

The result was considered statistically significant when $p<0.05$.

Results

1. Demographic characteristics of patients

Groups were compared in terms of mean age, gender, body mass index (BMI), and ASA scores (Table 1). There was no significant difference in these parameters between the groups. *p*-value for mean age was 0.593, for gender was 0.429, for BMI was 0.422, and for ASA score was 0.698.

2. Postoperative VAS and VRS scores at different time intervals

Patients were evaluated postoperatively by means of the VAS and VRS at 1, 2, 4, 6, 12, and 24 hours. There was no significant difference in the 1- and 2-hour values between groups. At 4, 6, 12, and 24 hours, VAS (Fig. 1) and VRS (Fig. 2) scores in group B were significantly lower than those in group A.

3. Bolus infusion by the PCA device and supplementary analgesic needs

At 24 hours after the operation, the number of bolus infusions was significantly different between the two

groups. The number of bolus infusions in group B (3.1) was lower than that in group A (4.35). At the same time, supplementary analgesic demand in group B (0.65) was lower than that in group A (1.3). There was a significant difference (p<0.01) in the mean postoperative analgesic consumption between group A and group B; the mean postoperative analgesic consumption was 523.5±14.96 mg in group A and 511.0±9.67 mg in group B. Overall patient satisfaction evaluated by means of VAPSS was significantly higher in group B (7.5) than in group A (7,0) (p<0.004) due to the management of analgesia.

4. Side effects

There was no significant difference between groups in the number and type of side effects. The most frequently reported side effect was nausea in both groups. Sweating, dry mouth, fatigue, somnolence, dizziness, and hypotension were the most frequently reported side effects (Table 2).

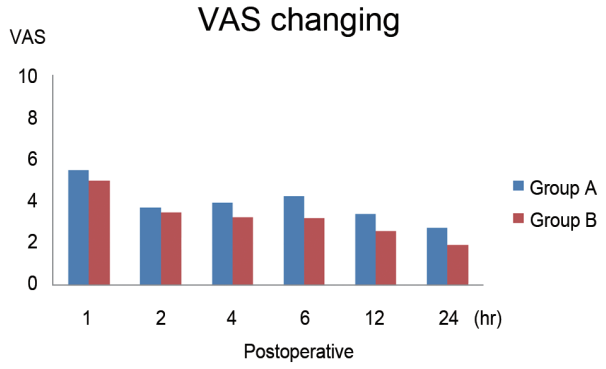

Fig. 1. Postoperative changes in the visual analog scale (VAS) scores.

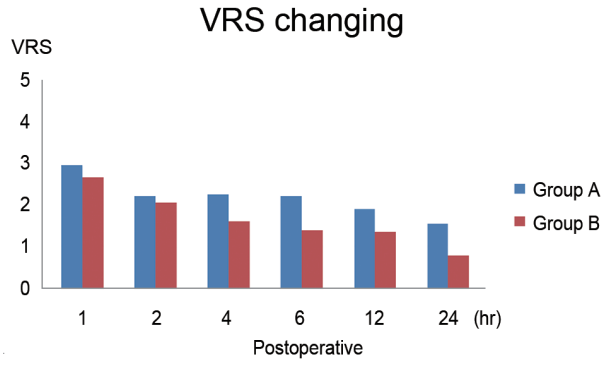

Fig. 2. Postoperative changes in the verbal rating scale (VRS) scores.

Table 2. Adverse effects

Adverse effects	Group I	Group II
Nausea	10 (50)	10 (50)
Sweating	3 (15)	4 (20)
Dry mouth	3 (15)	4 (20)
Fatigue	4 (20)	3 (15)
Drowsiness	5 (25)	4 (20)
Somnolence	3 (15)	3 (15)
Dizziness	5 (25)	5 (25)
Hypotension	2 (10)	2 (10)

Values are presented as number (%). p=0.959.

Discussion

Oral analgesics, bed rest, epidural injections, cryotherapy, electrical stimulation therapies, hot pack, manual therapies, biofeedback therapies, and trigger point injections are used for treating pain in degenerative LSS [5]. In this study, instead of classical electrotherapy, a FREMS technique that can produce a wave with a stable wave length (40–75 msec) and frequency (50–100 Hz) using the Phyback device was used. This system has three important advantages besides providing analgesia. It has a myorelaxant effect, anti-inflammatory effects, and a regulatory effect on the microcirculation.

According to Spratt et al. [6] the cause of pain in LSS is root compression or deformity. Morphologic changes like venous stasis, edema and intra- and perineural fibrosis develop under compression. Dysfunction of the roots develops with diminishing arterial flow. Mechanical compression can cause changes in the stimulus from the nerve roots. These stimuli are perceived as pain by the central nervous system (CNS) [7]. In this study, modalities for lumbar contracture, antiphilogistic therapy for lumbar radiculitis, activation of microcirculation and lumbar analgesia, were used in the patient group with this pathophysiology.

According to Postacchini [8], radicular pain and neurogenic claudication can be very easily improved by performing a decompression surgery. Decompression of more than one segment diminishes the expected benefits of the operation [8]. For this reason, patients who were undergoing short segment decompression and fixation were chosen for this study.

Increasing the release of opioid peptides from the CNS

and the peripheral nervous system is accepted as the mechanism of action of transcutaneous electrical nerve stimulation (TENS) [9,10]. Central sensitization and overstimulation occur immediately after making an incision and end with an increase in pain after the operation. If stimulation of the CNS can be suppressed by analgesic treatment, some benefits may be obtained in the short term (reduction in postoperative pain) and in the longer term (reduction in chronic pain) [11].

Today, treatment of acute postoperative pain is not as successful as expected, and 75% to 82% of postoperative patients suffer from moderate or severe pain [12,13]. Insufficient treatment of postoperative pain may result in thromboembolic or pulmonary complications and development of chronic pain. The use of unsuitable medication for postoperative pain may also result in respiratory and vascular depression, sedation, nausea and vomiting, urinary retention, itching, sleep disorder, and gastrointestinal symptoms [14]. Appropriate pain management is an important factor in patient recovery and for reducing the expenditure on treatment in the postoperative period [15].

Shealy et al. [16] showed experimentally that pain transmission to the upper centers decreases and the pain threshold increases by stimulating the dorsal spinal column. Melzack and Casey developed a gate control theory. They stated that stimulation of thick fibers promotes an inhibitory mechanism and changes neuronal activities of dorsal horn neurons [17]. Current functional magnetic resonance imaging studies indicate that TENS can prevent peripheral stimuli from reaching the sensorimotor cortex [18]. It has been shown that TENS blocks peripheral stimuli from reaching the cortex by the gate control mechanism, and this effect lasts for 35 minutes after TENS. Besides the gate control mechanism, TENS may have an effect by inhibiting nociceptors; blocking pain transmission in the afferent nerves, by sympathetic blockage or by increasing the release of endogenous opioids [18]. There are many studies on TENS, but there are few studies on FREMS in the literature. This situation may be because the FREMS device is new and expensive, and it is found in few centers.

Yip et al. [19] used high frequency and low amplitude TENS and synchronized electromagnetic millimeter waves in a group of patients with subacute low back pain. They showed that VAS scores during therapy were lower than those in the control group, but there was no statistical significant difference in VAS after treatment [19]. Cheing and Hui-Chan [20] used TENS only in a group of patients with chronic low back pain, and they observed a 63.1% decrease in VAS scores [20]. Marchand et al. [21] showed that TENS has a minimal effect on long-term low back pain, but it is an effective way to reduce short-term pain. Hsieh and Lee [22] found in a randomized controlled trial that TENS can provide rapid resolution of low back pain according to its region of application, duration, and frequency. Han [10] showed that application of different frequencies of TENS result in release of different neuropeptides.

There are contradictory conclusions on the use of TENS for postoperative pain in the literature. A meta-analysis by Carroll et al. [23] included 46 articles on the use of TENS in treating postoperative pain. Ten articles were excluded from the study for different reasons. In 17 of 19 nonrandomized studies, TENS was found to be effective in treating postoperative pain. Among these studies, there were studies of spine surgery. However, only two of 17 randomized controlled trials demonstrated that TENS was effective in treating postoperative pain. There were no studies of spine surgeries in this group of studies [23]. Bjordal et al. [24] found, in 21 randomized studies of 1,350 patients, that using TENS decreased the average postoperative analgesic consumption by 26.5%.

When the complex mechanism of pain and pain tract are considered, it is clear that more than one pain control method is needed for effective treatment of postoperative pain. The clinical practice guidelines for acute pain management by the Agency for Health Care Policy and Research emphasize that an effective approach in acute pain treatment must include both pharmacological and nonpharmacological methods and these methods should be applied at the same time [25].

In this study, the amount of analgesic consumption and the need for bolus infusion after 24 hours were found to be significantly less in group B than in group A. Supplemental analgesic need was also less in group B than in group A.

Conclusions

FREMS is a safe method for treatment of postoperative pain. It has almost no side effects. In addition, it may regulate the microcirculation. It can also provide long-term relaxation for patients. If FREMS is applied preemptively,

it can provide analgesia preoperatively which eliminates patient anxiety. The application of FREMS can reduce the need for opioids and supplemental analgesics in the postoperative period and can increase patient satisfaction.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

References

1. Yasar B, Simsek S, Er U, et al. Functional and clinical evaluation for the surgical treatment of degenerative stenosis of the lumbar spinal canal. J Neurosurg Spine 2009;11:347-52.
2. Stephens J, Laskin B, Pashos C, Pena B, Wong J. The burden of acute postoperative pain and the potential role of the COX-2-specific inhibitors. Rheumatology (Oxford) 2003;42 Suppl 3:iii40-52.
3. Kissin I. Preemptive analgesia. Anesthesiology 2000;93:1138-43.
4. Mannheimer JS, Lampe GN. Pain and TENS in pain management. In: Mannheimer JS, Lampe GN, editors. Clinical transcutaneous electrical nerve stimulation. Philadelphia: F.A. Davis Co.; 1994. p.7-27.
5. Rittenberg JD, Ross AE. Functional rehabilitation for degenerative lumbar spinal stenosis. Phys Med Rehabil Clin N Am 2003;14:111-20.
6. Spratt KF, Keller TS, Szpalski M, Vandeputte K, Gunzburg R. A predictive model for outcome after conservative decompression surgery for lumbar spinal stenosis. Eur Spine J 2004;13:14-21.
7. Olmarker K, Rydevik B, Holm S. Edema formation in spinal nerve roots induced by experimental, graded compression. An experimental study on the pig cauda equina with special reference to differences in effects between rapid and slow onset of compression. Spine (Phila Pa 1976) 1989;14:569-73.
8. Postacchini F. Management of lumbar spinal stenosis. European instructional course lectures. Vol. 2. Modena: University of Modena; 1995.
9. Fargas-Babjak A. Acupuncture, transcutaneous electrical nerve stimulation, and laser therapy in chronic pain. Clin J Pain 2001;17(4 Suppl):105-13.
10. Han JS. Acupuncture: neuropeptide release produced by electrical stimulation of different frequencies. Trends Neurosci 2003;26:17-22.
11. Carli F, Mayo N, Klubien K, Schricker T, Trudel J, Belliveau P. Epidural analgesia enhances functional exercise capacity and health-related quality of life after colonic surgery: results of a randomized trial. Anesthesiology 2002;97:540-9.
12. McHugh GA, Thoms GM. The management of pain following day-case surgery. Anaesthesia 2002;57:270-5.
13. Poisson-Salomon AS, Brasseur L, Lory C, Chauvin M, Durieux P. Audit of the management of postoperative pain. Presse Med 1996;25:1013-7.
14. Kehlet H, Holte K. Effect of postoperative analgesia on surgical outcome. Br J Anaesth 2001;87:62-72.
15. Mitchell RW, Smith G. The control of acute postoperative pain. Br J Anaesth 1989;63:147-58.
16. Shealy CN, Mortimer JT, Reswick JB. Electrical inhibition of pain by stimulation of the dorsal columns: preliminary clinical report. Anesth Analg 1967;46:489-91.
17. Wolf SL. Neurophysiologic mechanism in pain modulation, relevance to TENS. In: Mannheimer JS, Lampe GN, editors. Clinical transcutaneous electrical nerve stimulation. Philadelphia: F.A. Davis; 1984. p.41-55.
18. Mysiw WJ, Jackson RD. Electrical stimulation. In: Braddom RL, editor. Physical medicine and rehabilitation. Indianapolis: W.B. Saunders; 2000. p.464-91.
19. Yip YB, Tse HM, Wu KK. An experimental study comparing the effects of combined transcutaneous acupoint electrical stimulation and electromagnetic millimeter waves for spinal pain in Hong Kong. Complement Ther Clin Pract 2007;13:4-14.
20. Cheing GL, Hui-Chan CW. Transcutaneous electrical nerve stimulation: nonparallel antinociceptive effects on chronic clinical pain and acute experimental pain. Arch Phys Med Rehabil 1999;80:305-12.
21. Marchand S, Charest J, Li J, Chenard JR, Lavignolle B, Laurencelle L. Is TENS purely a placebo effect? A controlled study on chronic low back pain. Pain 1993;54:99-106.
22. Hsieh RL, Lee WC. One-shot percutaneous electrical nerve stimulation vs. transcutaneous electrical nerve stimulation for low back pain: comparison of therapeutic effects. Am J Phys Med Rehabil 2002;81:838-43.
23. Carroll D, Tramer M, McQuay H, Nye B, Moore A.

Randomization is important in studies with pain outcomes: systematic review of transcutaneous electrical nerve stimulation in acute postoperative pain. Br J Anaesth 1996;77:798-803.
24. Bjordal JM, Johnson MI, Ljunggreen AE. Transcutaneous electrical nerve stimulation (TENS) can reduce postoperative analgesic consumption. A meta-analysis with assessment of optimal treatment parameters for postoperative pain. Eur J Pain 2003;7:181-8.
25. Keskinbora K. Ameliyat sonrası agrı tedavisinde nonfarmakolojik yaklaşımlar (nonpharmacologic approaches in postoperative pain management). In: Yucel A, editor. Ameliyat sonrası analjezi postoperative analgesia). Istanbul: Mavimer Yay; 2004. p.77-8.