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ORIGINAL PAPER

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Effect of the frequency of transcutaneous electrical nerve stimulation on analgesia during extracorporeal shock wave lithotripsy

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Abstract In this prospective, randomised, sham controlled study, we set out to determine which transcutaneous electrical nerve stimulation (TENS) therapy modality (conventional vs acupuncture-like) is more effective as a supplementary analgesic regimen during extracorporeal shock wave lithotripsy (ESWL). Patients were prospectively randomised to one of three groups. In Group I ($n=22$), conventional TENS (impulse pattern: continuous at 80 Hz; intensity: 10–30 mA) was applied. In Group II ($n=22$) acupuncture-like TENS (impulse pattern: burst at 2 Hz; intensity: 15–50 mA) was applied. In Group III ($n=22$) (control group), stimulation was started at 1 mA and the intensity increased to no more than 10 mA until it produced a tickling sensation. Alfentanil was administered through a patient controlled analgesic device. Alfentanil consumption, hemodynamics and respiratory parameters, a 10-cm visual analogue pain scale, patient satisfaction, recovery and discharge times were evaluated. The consumption of alfentanil was significantly lower in Group I than in Groups II and III ($P<0.0001$). Pain scores were lower in Group I than in the other two groups ($P<0.05$). Patients in Group I were more satisfied with their analgesic medication than those in the other two groups ($P<0.05$). Both the time to an Aldrete score >8 and a modified post-anaesthetic discharge score >8 were significantly shorter in Group I (2.3 ± 1.8, 49.1 ± 14.6) than those of Groups II (4.6 ± 2.2, 60.2 ± 18.1) and III (4.9 ± 2.8, 58.4 ± 16.5) ($P<0.0001$ and $P<0.05$, respectively). We conclude that the use of conventional TENS is effective in decreasing the analgesic requirements and the incidence of alfentanil-related side effects during ESWL.

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Introduction

Extracorporeal shock wave lithotripsy (ESWL) has revolutionized the treatment of urinary stone disease because of its simplicity, efficacy, and minimal morbidity [1]. Second generation lithotripters offer immersion-free ESWL with less shock wave energy. However, ESWL without anaesthesia demands proper pain management to ensure success and patient satisfaction. Effective analgesia simplifies stone imaging and targeting by reducing patient movement during shock wave impact and allows the use of high acoustic energies which increase fragmentation efficiency.

Opioids seem to be a favourable analgesic during ESWL, however, opioid administration may be problematic, especially at high does, since ESWL is generally carried out in an outpatient setting. Therefore, different techniques have been tried for decreasing the dosage of opioids [2, 3].

Transcutaneous electrical nerve stimulation (TENS) is a method for the electrical stimulation of nerves through electrodes applied to the skin. When properly applied, the stimulation gives rise to nonpainful electric paresthesia in the area of the pain, called conventional TENS, or to muscle contractions in myotomes segmentally related to that area, called acupuncture-like TENS [4]. It has been postulated that there is an endogenously produced opioid-like substance acting as a mediator of pain relief in acupuncture-like TENS therapy [4]. The analgesic effect of the acupuncture-like TENS can be reversed with naloxone [4]. TENS is commonly used and achieves good results in both acute and chronic painful conditions caused by pathology in nervous structures, in the skeleton, and in muscles [4]. TENS is reported to decrease the need for

postoperative opioid [5, 6]. Reichelt et al. [2] suggested that TENS is an effective method of analgesia in ESWL. However, the effect of the location of the electrodes and the frequency of the stimulation on the opioid requirement has not been previously studied during ESWL.

This prospective, randomised, sham-controlled study was designed to determine which TENS therapy modality (conventional vs acupuncture-like) is more effective as a supplementary analgesic regimen during ESWL. The efficacy of TENS was evaluated by determining the consumption of alfentanil, and using a pain scale, and patient satisfaction. The effect of TENS on recovery and discharge times was also investigated.

Patients and methods

Patient selection and monitoring

After approval of the Dicle University Ethics Committee and the written, informed consent of the participant patients, we performed a prospective analysis of 66 patients with American Society of Anesthesiologists physical status I or II, 18–55 years old, and scheduled to undergo ESWL for kidney or ureteral stones. Exclusion criteria included hypertension, pregnancy, renal or hepatic insufficiency, cardiac pacemaker, drug or alcohol addiction, and allergic reactions to opioids.

The location and size of the stone had been determined by radiography and was verified on the screen of the lithotripter at the ESWL desk. Patients were instructed about the use of the visual analog scale (VAS; 0 = no pain, 10 = worst pain ever) [7] and the patient-controlled analgesia (PCA) device (Acute Pain Manager; Abbott, North Chicago, Ill.). A second generation lithotripter was used for ESWL (Direx Nova, Swag×1, Direx Systems, Israel). No premedication was given. At the ESWL desk, the patients were monitored by electrocardiography (ECG), and for non-invasive systolic and diastolic blood pressure (SBP, DPB), peripheral oxygen saturation (SpO_2), and end-tidal carbon dioxide pressure ($P_{ET}CO_2$) via a nasal cannula. After a routine preoperative evaluation and placement of the intravenous catheter, baseline measurements of blood pressure, heart rate, respiratory rate, SpO_2 and $P_{ET}CO_2$ were obtained.

PCA regimen

For the PCA device, 5 mg of alfentanil were diluted to 100 ml with isotonic saline. The PCA device was programmed to administer 5 ml/h with a bolus dose of 8 ml. The lockout time was 3 min. If patients suffered from severe pain (VAS > 5), the ESWL procedure was interrupted and another 8 ml bolus dose was administered.

TENS treatment and groups

A TENS device (Trio 300, ERP Group, Canada) and one electrode pairs (5 cm×9 cm) was used for electrical stimulation. By using computer generated random sequences, patients were randomly allocated to one of three TENS treatment groups each with $n = 22$. Electrode placement was shown in Fig. 1. In Group I, the conventional TENS mode was chosen. The active electrode (the cathode) was placed above the shock tube. The impulse pattern was continuous at 80 Hz and pulse width was 250 μs. Stimulation was started at 10 mA, and the intensity of stimulation was increased to the highest value that did not disturb the patient. In Group II, acupuncture-like TENS was chosen. The cathode was placed below the shock tube. The impulse pattern involved bursts at 2 Hz and the pulse width was 150 μs. Stimulation was started at 15 mA and the intensity of stimulation was increased until it produced visible muscle contractions in the shock tube placement area (external lateral oblique muscle). If the stimulation caused discomfort before muscle contractions, the electrode positions were adjusted slightly. In Group III (control group), the impulse pattern involved bursts at 2 Hz and the wave width was 150 μs. Stimulation was started at 1 mA and the intensity was increased to no more than 10 mA until it produced a tickling sensation.

ESWL procedure

After preparation of the patients, the PCA bolus dose was started. At 2 min after bolus dose administration,

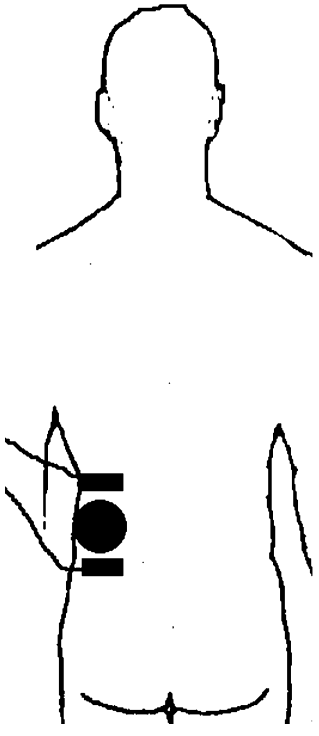

Fig. 1 Placement of the TENS electrodes

the shock waves were initially released at 9 kV, and then the voltage was increased to 24 kV with regular intervals. To approximate the total quantity of administered shock wave energy, a shock wave energy index SEI = $(n_1 \times U_1^2 + n2 \times U_2^2 + \cdots + n_n \times U_n^2)/(10^5 kV^2)$; n = number of shock waves, U = voltage (kV), was calculated as previously described [8].

Study parameters

Data were collected by an investigator blinded to the TENS therapy applied. SpO_2, $P_{ET}CO_2$ and heart rate were observed throughout the procedure. These variables were recorded at 5-min intervals. During the operation, when VAS > 3, the patients were asked to push the PCA button. Nausea or vomiting was recorded and treated with 4 mg of ondansetron as required. A modified Aldrete score [9] ≥9 was assessed at 1-min intervals after discontinuing the PCA. Patients who achieved an Aldrete score ≥9 on lithotripter suite were admitted directly to the postanaesthesia care phase II recovery area (step-down unit) (Table 1). Patients were considered to be ready for discharge when a modified postanaesthetic discharge score including five parameters (blood pressure, ambulation, nausea, pain and bleeding) was greater than 8 [10]. ESWL time, total alfentanil given, respiratory depression (apnea longer than 20 s or respiratory rate < 8 breath/min or SpO_2 < 90 during 30 s or $P_{ET}CO_2$ > 50 during 30 s), hypotension (SAB < 20% of first value or SAB < 100 mmHg), bradycardia (heart rate < 45 beat/min), nausea, vomiting and dizziness, and patient satisfaction (1 = poor, 2 = satisfactory, 3 = good, 4 = excellent) were all recorded.

Table 1 Modified Aldrete score

Criteria	Value
Oxygenation	
SpO_2 > 92% on room air	2
SpO_2 > 90% on oxygen	1
SpO_2 < 90 on oxygen	0
Respiration	
Breathes deeply and coughs freely	2
Dyspneic, shallow or limited breathing	1
Apnoea	0
Circulation	
Blood pressure ± 20 mmHg of normal	2
Blood pressure ± 20–50 mmHg of normal	1
Blood pressure more than ± 50 mmHg of normal	0
Consciousness	
Fully awake	2
Arousable on calling	1
Not responsive	0
Activity	
Moves all extremities	2
Moves two extremities	1
No movement	0

Statistical analysis

Statistical analyses were performed using SPSS 10.0 for Windows (SPSS, Chicago, Ill.). An a priori power analysis was performed to determine the number of patients per group sufficient to detect a decrease of 30% or more in the PCA alfentanil analgesic requirements during ESWL, based on the results of Gesztesi et al. [11]. With a power of 80% and type 1 error of 5%, it was estimated that 22 patients were required per group. Data were analysed using analysis of variance for repeated measures. Post hoc comparisons were conducted by using the Tukey HSD test. The χ^2-test was used to compare the frequency of side effects, location of the stones and sex distribution. The Kruskal-Wallis test was used to analyse VAS and satisfaction score between the groups. Data were expressed as means (SD) or numbers (proportion) as appropriate, and P values < 0.05 were interpreted as being statistically significant.

Results

The three groups were comparable with respect to demographic data, localization of the stone, and operation time (Table 2).

Mean intensity of the stimulation was 18.4 ± 6.2 mA in Group I, 25.2 ± 9.6 mA in Group II and 3.3 ± 2.1 mA in Group III. The VAS pain scores were significantly lower in Group I than in the other two groups, particularly at high energy levels (Fig. 2). The consumption of alfentanil was significantly lower in Group I than in the other two groups ($P < 0.0001$) (Table 2). The satisfaction score was 3 (2–4) in Group I and 2 (1–4) in Groups II and III ($P < 0.05$). Both time to the modified Aldrete score ≥9 and time to the modified postanaesthetic discharge score ≥9 were significantly shorter in Group I than in the other two groups (Table 3). Patients in Group I had a lower incidence of both nausea and

Table 2 Characteristics of patients, localization of the stone and operation time. Data are mean ± SD or number

	Group I	Group II	Group III
n	22	22	22
Age (years)	37.7 ± 11.9	41.4 ± 12.96	39.4 ± 14.1
Weight (kg)	73.9 ± 10.7	75.4 ± 10.3	76.3 ± 12.5
Sex (female:male)	12:10	16:6	14:8
Location of stone			
Upper calyceal	9	6	5
Lower calyceal	4	2	6
Renal pelvis	9	14	11
Time of ESWL (min)	29.4 ± 5.4	27.2 ± 6.3	29.3 ± 6.3

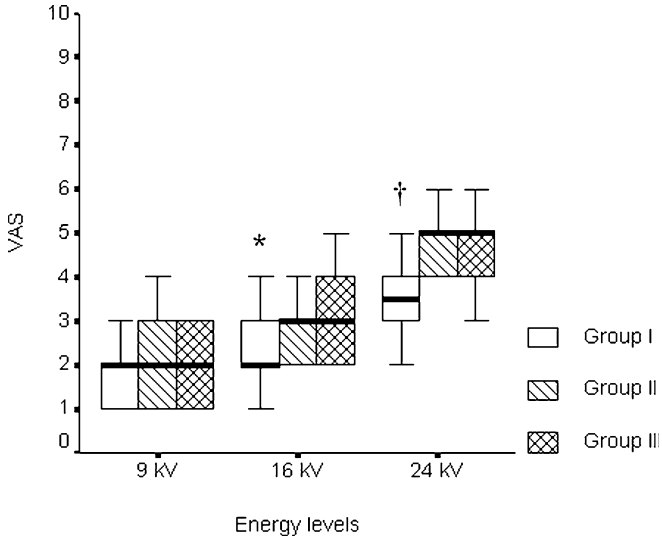

Fig. 2 VAS pain scores at different energy levels. The *box* represents the 25th –75th percentiles; the *dark line* is the median; the *extended bars* represent the 10th–90th percentiles. The *asterisk* indicates Group I vs Groups II and III ($P < 0.05$). The *cross* indicates Group I vs Group II and III ($P < 0.001$)

dizziness ($P < 0.05$) (Table 4). No serious complications, such as respiratory depression, bradycardia, or hypotension, occurred during the study period.

Discussion

The pain occurring during ESWL appears to be a function of the high-energy distribution of the administered shock waves. Other than the factors related to the patient, the generation and focusing of the lithotripter, the voltage energy and the number of shock waves, cavitation effects, stone location, shock wave peak pressure, area of shock wave entry at the skin and other similar factors are related to the pain [2]. Pain does not occur only at the skin surface, but also close to the tissues and organs where the machine focuses. New generation ESWL machines operate with low energy shock waves due to modifications in the aperture size of the shock wave source, thus ESWL with second or third-generation lithotripters is less painful, and the need for general or regional anaesthesia is decreased. Although anaesthesia is not applied to most patients, analgesic demands by the patients still continue. Effective analgesia during the procedure allows the use of high acoustic energies, which increase fragmentation efficiency and reduce the number of treatment sessions [8]. The lithotripter in our hospital is of the second-generation. Pethidine IV was administered for analgesia during ESWL at our hospital before this study. Because ESWL was carried out in an outpatient setting, we preferred alfentanil, a short acting opioid. Our results showed that alfentanil administered through PCA provided sufficient analgesia for ESWL. Furthermore, even at high energy levels, more satisfactory analgesia could be obtained by the administration of conventional TENS. Bjordal et al. [12] suggested that a meaningful change may not be observed in pain scores during TENS therapy when patients are given free access to analgesics by PCA. However, we observed a significant reduction in the VAS pain score in the conventional TENS group and were able to deliver high shock wave energy levels without interruption to all patients in this group.

TENS is a non-invasive, safe, and simple treatment method, which does not have any systemic side effects. We did not observe any difficulties in the use of TENS. Previous studies have also reported that TENS can be used easily during ESWL [2, 13].

The results of studies using TENS for acute pain control are inconsistent [14]. This may be related to a variety of factors including the stimulation site, frequency, intensity and duration of electrical stimulation, as well as the patient's psychological profile. Acupuncture-like TENS analgesia is reversed by naloxone, and therefore acts through links utilizing endorphins [4]. In contrast, conventional TENS analgesia is not reversed by naloxone, indicating that opioids utilizing μ receptors are not involved [15]. We were not able to clarify why conventional TENS analgesia was superior in our study. However, conventional TENS has been reported effective after laparotomy, thoracotomy, laminectomy, hernioplasty, reconstructive orthopaedic surgery, and low back surgery [14, 16, 17]. A meta-analysis demonstrated that the median stimulation frequency in trials with stimulation parameters within the assumed optimal dose range was 85 Hz for conventional TENS [12]. Reichelt et al. [2] reported that

Table 3 Shock wave energy index (SEI), alfentanil consumption and recovery times. Data are mean ± SD. MPDS: modified postanaesthetic discharge score, ** $P < 0.0001$ Group I vs Groups II and III, * $P < 0.05$ Group I vs Groups II and III, † $P < 0.001$ Group I vs Groups II and III

n	Group I 22	Group II 22	Group III 22
SEI	13.8 ± 2.1	12.8 ± 1.8	13.1 ± 1.4
Alfentanil consumption (μg)	956 ± 650**	1916 ± 615	1856 ± 554
Time to Aldrete score ≥9 (min)	2.3 ± 1.8†	4.6 ± 2.2	4.9 ± 2.8
Time to MPDS score ≥9 (min)	49.1 ± 14.6*	60.2 ± 18.1	58.4 ± 16.5

Table 4 Side effects. Data are number of the patients. *n* is 22 for all groups. * $P < 0.05$ Group I vs Groups II and III

	Group I	Group II	Group III
Nausea	6*	12	14
Vomiting	1	3	4
Dizziness	7*	16	15

TENS significantly reduced pain during ESWL performed with a third generation lithotripter. They used a dual channel TENS device and placed two pairs of electrodes both paravertebrally (L_1) and near the shock tube. We did not prefer parvertebral stimulation only at the L_1 level, since the shock tube placement area was innervated by more than one segment. Hamza et al. [6] found no difference between low (2 Hz) and high frequency (100 Hz) electrical stimulation. We did not observe any differences between the low frequency and control groups. This may be explained by differences between the characteristics of postoperative and ESWL pain. However, further investigation is required on this topic.

It is difficult to design a true control group in studies investigating the efficacy of TENS. To solve this problem, it was recommended the use of a sham TENS device that appeared to be functioning normally but produced no perceptible electrical stimulation [5, 18]. However, in this condition, the study cannot be considered to be double blinded, because patients do not perceive any electrical stimulation. It is well known that effective analgesia cannot be obtained in acupuncture-like TENS if electrical stimulation does not produce visible muscle contraction [4]. A stimulus strength three to five times that at the sensory threshold, at least 15 mA, is required to produce muscle contraction [4]. Hence, we preferred low intensity current (< 10 mA) producing only a tickling sensation in the control group. In our study, the mean intensity of stimulus was 3.3 mA in Group II. This intensity is considerably lower than that suggested. We believe that this approach can be used to obtain a true control group.

Alfentanil is a frequently used opioid in ESWL due to the short onset and duration of its action and its low accumulation because of low lipid solubility [19]. However, alfentanil related side effects may appear when high doses are used. Our results showed that TENS is an effective method for reducing the consumption of alfentanil and alfentanil related side effects such as nausea and dizziness.

ESWL is a procedure carried out in an outpatient setting. Hence, the analgesic method and drugs used should not prolong recovery times. Gesztesi et al. [10] reported that the time to an Aldrete score ≥ 9 was 4 min when alfentanil was administered as an analgesic during ESWL. Our findings were compatible with this result except for those of Group I. This positive effect of conventional TENS on recovery times reported in Table 3 is important for us, since ten patients are admitted daily to our ESWL unit of one lithotripter.

In conclusion, our findings demonstrate that TENS is a safe and useful supplementary analgesic method during ESWL. While acupuncture like TENS is not effective in reducing alfentanil consumption, conventional TENS effectively reduces alfentanil consumption and alfentanil related side effects. By using conventional TENS during ESWL, the recovery time can be shortened and patient satisfaction can be increased.

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