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Transcutaneous Electric Nerve Stimulation (TENS) for pain relief during Extracorporeal Shock-Wave Lithotripsy (ESWL)

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ABSTRACT

Background: Anesthesia for ESWL must provide good analgesia, rapid recovery with least side effects. Opioids are commonly used analgesics during ESWL, but are not devoid of side effects. TENS is a non-pharmacological, non-invasive analgesic technique, which has been recommended for pain control in many clinical settings.
Methods: Sixty patients scheduled for ESWL were randomly assigned to group-A (30 patients): received IV fentanyl 1µg/Kg with the application of conventional TENS. Group-B (30 patients) received IV fentanyl 1µg/Kg. IV increments of 20 µg of fentanyl were given if VAS was≥3 in both groups. Fentanyl consumption, discharge time, adverse effects, and satisfaction score for patients were compared.
Results: VAS was lower among group-A than group-B throughout the procedure but that was statistically non-significant. There was significantly lower fentanyl consumption in group-A compared to group-B (P-value < 0.001). Discharge time was significantly shorter among group-A (36.2 ± 0.6 min) than group-B (47.2 ± 0.8 min). Adverse effects were significantly less frequent in group-A compared to group-B. Incidences of O_2 desaturation, nausea and vomiting were higher in group-B compared to group-A. Patients' satisfaction was significantly higher among group-A than among group-B.
Conclusion: TENS is an effective and safe practice in controlling pain during ESWL, it decreases fentanyl consumption and its side effects, with greater patients' satisfaction. It decreases discharged time compared to fentanyl so it is ideal for outpatient procedures.

1. Introduction

Pain during extracorporeal shock-wave lithotripsy (ESWL) may lead to patient movement and can cause increased respiratory movement, both resulting in decreased hit rate with reduced stone fragmentation and a lower stone clearance. Additionally, pain may lead to a higher rate of kidney haematomas as a result of a rise in blood pressure [1].

The ideal anesthesia technique for ESWL must provide good analgesia, sufficient sedation, and rapid recovery with minimal side effects [2,3]. Opioids are commonly used analgesics during ESWL. Fentanyl is a potent synthetic narcotic, which has rapid onset and a short duration of action, it offers an acceptable analgesia during ESWL but has a noticeable respiratory depression [4,5].

Transcutaneous electrical nerve stimulation (TENS) is a method in which low voltage electrical impulses transmit through electrodes attached to the skin over a painful area. It is usually used to relieve a variety of painful conditions [6]. A TENS unit contains an electrical signal generator, a battery in addition to a set of electrodes. The TENS is small, programmable and the generator can deliver stimuli with different current intensities, pulse rates, and pulse width [7].

The mechanism of analgesia by TENS has been explained by many theories. The gate control theory by Melzack and Wall [8] stated that "when an electrical current is applied to a painful area, transmission of pain through small diameter fibers is inhibited by the activity of the large diameter, fast-conducting proprioceptive sensory fibers, closing the gate to the pain perception to the brain". Another mechanism suggested is activation of descending inhibitory pathway, via the release of endogenous opioids [9].

It has been postulated that conventional TENS is the optimal treatment for pain relief during ESWL [10], this is achieved by a median stimulation frequency (pulse rate) of 85 Hz [11], pulse rate can range from 1 or 2 Hz to 200–250 Hz [7], and the current intensity ranges from 1–100 mA, which is raised gradually to a level at which the patient perceives the stimulation with no pain, and the pulse width adjusted to 50–250µsec [12].

This study was designed to evaluate the usage of transcutaneous electrical nerve stimulation (TENS) during extracorporeal shock-wave lithotripsy (ESWL), for pain relief and the possibility of decreasing opioids consumption.

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2. Patients and methods

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Approval of ethical committee and written informed consent from the participant patients were done. This prospective, randomized, comparative, clinical study was done in ESWL unit in Ain-Shams University hospitals and included 60 patients scheduled for ESWL.

Inclusion criteria: patients having solitary renal stone 6–15 mm, patients aged 21 to 75 years old, ASA physical status I – II, with BMI 18–28.

Exclusion criteria: patients with bleeding and coagulation disorder, hypertension, pregnancy, patient with demand pacemaker, dermatological lesions at the site of ESWL, e.g. eczema or dermatitis, and drug or alcohol addiction.

Routine preoperative evaluation and investigations were done for all patients. Upon the arrival of patients to ESWL unit, baseline arterial blood pressure (ABP), heart rate (HR) and peripheral oxygen saturation (SpO2) were measured. All patients received 500–1000 ml of Ringer acetate solution over 30 min during the procedure. No premedication was given to any patient. Patients were randomly allocated into two equal groups using a computer-generated random list, and 60 sealed envelopes were prepared and coded (30 envelopes for each group).

Group A (30 patients): received IV fentanyl 1μg/Kg with the application of conventional TENS (Model 120Z, ITO Japan) dual channel TENS device, in which constant mode was chosen. Patients in this group were educated about TENS application before the procedure. One channel was used, in which two stimulator electrodes were applied paravertebrally just above and below the lithotripter shock tube. Stimulation frequency of 85 Hz and pulse width of 200 μs were selected. The current intensity was started at 10 mA and increased gradually till the patient perceived prickling sensation with no pain, at that moment shock waves were started.

Group B (30 patients) received IV fentanyl 1μg/Kg. Shock waves were started after 2 min from injecting fentanyl. In both groups number of shock waves was 3000 to 3500 shocks, frequency of 90–120/min, and voltage intensity was started at 1 kV and then increased gradually until a maximum of 4–6 kV.

Assessment of pain for all patients was done using visual analogue scale (VAS) every 5 min; patients were instructed to mark the line with a pencil (0 = no pain 10 = worst pain). In both groups, at any time during the procedure, if VAS ≥ 3 this indicated giving IV increments of 20 μg of fentanyl. The total dose of requested and received fentanyl was calculated and recorded. All patients were monitored for heart rate, arterial blood pressure, respiratory rate, and peripheral oxygen saturation, during and after the procedure until they were ready for discharge.

After the procedure, patients were transferred to the recovery area, where they were observed until the time they were ready for discharge, when fulfilling discharge criteria more than 8 according to Modified Post-Anesthetic Discharge Scoring System; which is a five-category score including vital signs, activity, nausea and vomiting, and pain and surgical bleeding [13]. Discharge time was considered as the time from the end of ESWL till patients were ready for discharge.

Any adverse effect during or after the procedure was recorded and treated, e.g. respiratory depression which was diagnosed by decreased oxygen saturation ≤ 90% and/or decreased respiratory rate ≤ 8 breathe per minute was treated by supplemental oxygen mask 5–10 L/min (O2 mask was not used routinely in both groups as patients were conscious and well monitored). Nausea and vomiting were treated with 1 mg granisetron slow IV. Any other side effect of using fentanyl-like dizziness was recorded.

Before discharge patients were asked to rate their overall satisfaction about the control of pain (0, inadequate; 1, fair; 2, good; or 3, excellent).

3. Sample size

Using PASS program, setting alpha error at 5% and power at 95%. According to a previous study done by Chia et.al [4] for fentanyl group, the total consumption of fentanyl was 130 ± 30 with 30 μg difference. Assuming that among group receiving TENS, the fentanyl requirement will be 100 ± 30 μg (for sample size calculation). Based on this, the needed sample size was 27 cases per group, rounded to 30 per group.

3.1. Statistical methods

The collected data were coded, tabulated, and statistically analyzed using IBM SPSS statistics (Statistical Package for Social Sciences) software version 22.0, IBM Corp., Chicago, USA, 2013.

Descriptive statistics were done for quantitative data as minimum& maximum of the range as well as mean±SD (standard deviation) for quantitative normally distributed data, while it was done for qualitative data as number and percentage.

Inferential analyses were done for quantitative variables using Shapiro–Wilk test for normality testing, independent t-test in cases of two independent groups with normally distributed data. In qualitative data, inferential analyses for independent variables were done using Chi-square test for differences between proportions and Fisher's exact test for variables with small expected numbers. The level of significance was taken at P value < 0.050 is significant, otherwise is non-significant.

4. Results

Figure 1 CONSORT flow diagram, 72 subjects were randomized; 12 subjects (from both groups) were excluded due to either that they did not meet inclusion criteria or refused to participate in the study.

The primary objective of this study was to determine the efficacy of TENS for controlling pain during ESWL. The secondary objective was to evaluate TENS in reducing fentanyl consumption, and fentanyl side effects (such as nausea, vomiting, respiratory depression, and desaturation).

No significant differences between the studied groups regarding demographic data and ESWL duration and characteristics were found. (Table 1)

Visual analogue scale values for pain assessment were lower among group-A (TENS group) than among group-B throughout the procedure but that was statistically non-significant. (Figure 2). Table 2 shows that there was a significantly lower total fentanyl dose that was given to the patients during the procedure in group-A compared to group-B (P-value < 0.001). Patients in group-A did not request more than the initial dose of fentanyl, except one patient who needed a single dose of fentanyl (20 μg).

Discharge time was significantly shorter among group-A (mean of 36.2 ± 0.6 min) than among group-B (mean of 47.2 ± 0.8 min) as shown in Table 2.

Table 3 shows that adverse effects were significantly less frequent among group-A compared to group-B. Ten patients developed O_2 desaturation and were in need of oxygen mask in group-B compared to one patient in group-A (P-value = 0.003). More patients complained from nausea and vomiting in group B (five patients) in contrast, no patients developed nausea and vomiting in group A. Patient's satisfaction was significantly higher among group-A than among group-B. (Figure 3)

5. Discussion

There are no exact guidelines for pain relief during ESWL, a variety of practices and drugs are being used. Conventionally, nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, and local anesthetics are being used frequently. Different combinations via different routes are used. More side effects would be anticipated from using opioids than simple analgesics or NSAIDs. [14,15]. Still, there is no consensus on the
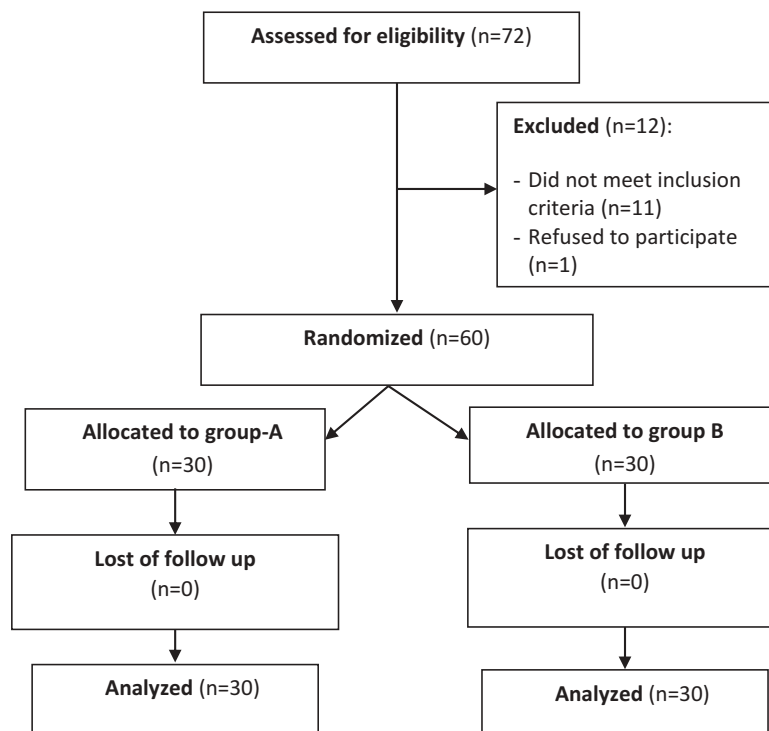
Table 1. Demographic and ESWL characteristics among the studied groups.

Variables	Measures	Group-A (N = 30)	Group-B (N = 30)	P
Age (years)	Mean ±SD	44.0 ± 2.2	46.8 ± 2.2	0.374
	Range	24.0–71.0	23.0–73.0	
Sex (n, %)	Male	16 (53.3%)	18 (60.0%)	0.602
	Female	14 (46.7%)	12 (40.0%)	
BMI (kg/m^2)	Mean ±SD	23.2 ± 0.3	23.9 ± 0.3	0.135
	Range	18.6–27.2	19.9–27.0	
ASA (n, %)	I	22 (73.3%)	20 (66.7%)	0.573
	II	8 (26.7%)	10 (33.3%)	
Duration (min)	Mean ±SD	34.0 ± 0.4	33.1 ± 0.4	0.106
	Range	29.0–40.0	27.0–38.0	
Shocks (number)	Mean±SD	3370.0 ± 48.0	3266.7 ± 44.8	0.121
	Range	2900.0–4000.0	2800.0–3900.0	

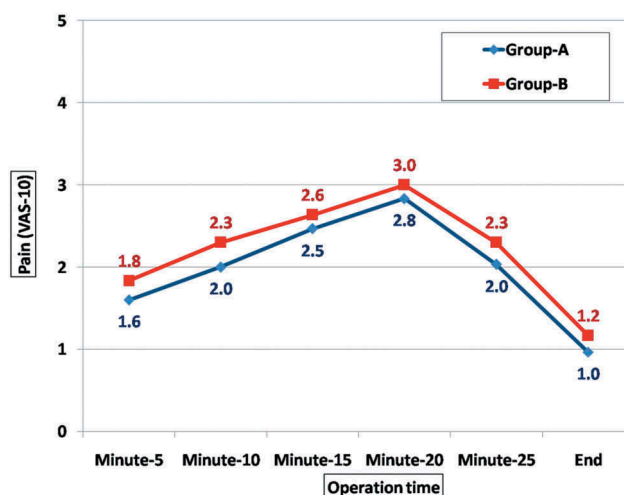**Figure 1.** CONSORT, patient flow chart.

Figure 2. Pain among the studied groups.

Table 2. Total fentanyl dose and discharge time among the studied groups.

	Group A	Group B	P[a]
Total fentanyl dose (µg)			
Mean±SD	87.0 ± 2.3	152.3 ± 4.9	**<0.001***
Range	70.0–110.0	120.0–220.0	
Discharge time (minutes)			
Mean±SD	36.2 ± 0.6	47.2 ± 0.8	**<0.001***
Range	31.0–44.0	37.0–58.0	
Value of group-A over group-B			
		Value	**95% CI**
Total fentanyl dose reduction		65.3 ± 5.4	54.5–76.2
Discharge time shortening		10.9 ± 1.0	9.0–12.9

[a]Independent t-test, CI: Confidene interval, *Significant

standard analgesic regimen for controlling pain during ESWL.

The pathogenesis of pain from ESWL is not evidently defined. It is suggested to be due to stimulation of nociceptors in skin, renal capsule, parietal peritoneum, or muscles [16].

Factors affecting analgesic requirement in ESWL are age, amount of energy, site and size of the stone, and type of lithotripter [17]. The introduction of new models of lithotripters led to conversion of the trend of anesthesia from general and regional anesthesia to sedative analgesic technique [16]. Efficient analgesia during ESWL lead to well targeting and effective fragmentation of the stone, as increased respiratory movement compromises shockwave delivery [18].

In our hospital ESWL unit, the shock waves are released at a maximum intensity of 4–6 kV. In our study, we preferred using fentanyl as it has short half-life which is better for outpatient procedures. Trying to be impartial, the number of shock waves and the duration of ESWL were comparable in both groups.

Transcutaneous electrical nerve stimulation (TENS) is described as non-pharmacological, non-invasive and inexpensive analgesic technique, which has been practiced for pain control in many clinical settings including post-operative pain, chronic back pain, and labor pain [19].

Different types of TENS techniques are used in clinical practice. Conventional TENS using high frequency, low-intensity current with continuous stimulating pattern produces rapid onset, rapid offset segmental analgesia localized to the dermatome. Acupuncture TENS using low frequency, high-intensity current activates small diameter fibers arising from muscles and produces non-painful muscle contraction over the myotome which

Table 3. Adverse effects and satisfaction among the studied groups.

Items	Group-A (N = 30)	Group-B (N = 30)	P	RR (95% CI)
Adverse effects				
O$_2$ desaturation	1 (3.3%)	10 (33.3%)	**0.003*[a]**	0.15 (0.02–1.01)
Nausea and vomiting	0 (0.0%)	5 (16.7%)	**§0.024***	–
Dizziness	1 (3.3%)	3 (10.0%)	§0.612	0.48 (0.09–2.69)
Satisfaction				
Inadequate	0 (0.0%)	0 (0.0%)	**0.011*[b]**	For excellent versus fair&good 2.0 (1.32–3.04)
Fair	1 (3.3%)	6 (20.0%)		
Good	19 (63.3%)	22 (73.3%)		
Excellent	10 (33.3%)	2 (6.7%)		

[a]Chi square test, [b]Fisher's exact test, RR: Relative risk, *Significant, CI: Confidence interval
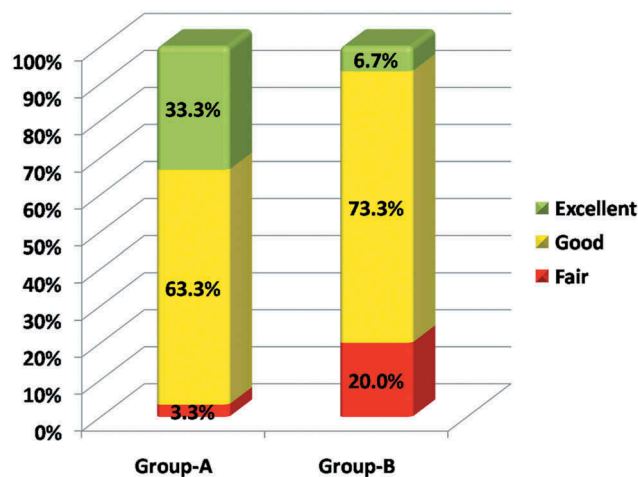
Figure 3. Patient's satisfaction among the studied groups.

causes pain. Intense TENS using high intensity and high-frequency current that patient can tolerate, this type of TENS activates small diameter Aδ nerve fibers [7].

Karamaz and colleagues [10] set out to define which TENS modality (conventional versus acupuncture-like) is more effective as an additional analgesic regimen during extracorporeal shock-wave lithotripsy (ESWL). They proved that conventional TENS was more effective than acupuncture-like TENS in reducing alfentanil consumption, and alfentanil-related side effects.

In the present study using conventional TENS in ESWL produced lower VAS values among group-A (TENS group), than group-B throughout the procedure, but were statistically insignificant. Group-B patients consumed more fentanyl than group-A, subsequently, adverse effects were less frequent among group-A compared to group-B. There were significantly more patients developed O_2 desaturation and nausea and vomiting in group-B compared to group-A, also discharge time was significantly shorter among group-A compared to group-B.

Consistent with our findings Ozsaker, and Diramali [20] applied TENS for analgesia during ESWL, they used two applications for the same patient in two ESWL sessions: one with conventional TENS and the other without TENS. They concluded that TENS decreased patients' intensity of pain, and reduced remifentanil consumption. In contrast to our study, they added two more electrodes at the level of lumbar vertebra (L1) in both sides, we favored using one pair as in Karamaz's study [10], which was effective in controlling pain during ESWL. Karamaz did not prefer paravertebral stimulation at the L1 level, they interpreted that by, the shock tube placement area is innervated by more than one segment, and so stimulation of L1 may have no role in controlling pain.

The results of our study are in agreement with many studies that used TENS for different acute pain management. Many studies used TENS for post-operative pain relief, they used it by different intensities and for variable periods of time. Some used TENS continuously for

48 h [21] while others applied it intermittently at different time intervals. The electrodes were applied around the surgical incision or, in some studies, at the corresponding acupoints [22–24]. All studies concluded that TENS is effective in reducing post-operative pain after many surgeries as a part of multimodal analgesia. The actual current intensity, site of electrodes and the frequency of stimulation were the common studied parameters in those studies [22–24].

A meta-analysis by Bjordal et al. [11] stated that selection of ideal TENS parameters for controlling post-operative pain is essential for its efficacy, parameters comprised of effective current intensities, position of electrodes and frequencies of stimulation.

Solak et al. [25] compared continuous TENS with intermittent TENS in post-operative pain management after coronary artery bypass graft, they concluded that both were equal in reducing pain, though continuous TENS led to more reduction in consumption of analgesics.

Fiorelli et.al [26]. studied TENS for post-thoracotomy pain, they found that TENS is a valuable strategy to lessen post-thoracotomy pain with decrease in cytokine production and in morphine consumption, and had positive effects on ventilation functions.

Limitations of our study: first the study was not blind, second pain during ESWL is variable and depends on the amount of energy used which is influenced by BMI of the patient, size and site of the stone. We tried to equalize these factors by a good selection of patients.

Conclusion: TENS is an effective and safe practice in controlling pain during ESWL, as it provides good analgesia and well tolerability. It leads to decrease in fentanyl consumption and its side effects, with greater patients' satisfaction. It decreases discharged time compared to fentanyl so it is ideal for outpatient procedures.

Disclosure statement

No potential conflict of interest was reported by the authors.

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