Özgün araştırma / Original research

Intravenous paracetamol versus oral tramadol for pain control during shockwave lithotripsy: a prospective randomized comparative study

Şok dalga litotripsi sırasındaki ağrı kontrolünde intravenöz parasetamole karşın oral tramadol: prospektif, randomize, karşılaştırmalı çalışma

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Abstract

Objectives: Shock wave lithotripsy (SWL) is a simple, effective, and minimally invazive treatment option for urinary tract stone disease. Nevertheless, pain during the SWL procedure is one of the most common restriction factor for this treatment modality.We aimed to compare the efficacy and adverse effects of intravenous (IV) paracetamol and oral (tablet) tramadol for pain control during SWL procedure.

Material and Methods: We enrolled 54 patients with the indication of SWL therapy in this prospective randomized comparative study. 1 g IV paracetamol infusion was applied to group I (n:28) and 100 mg oral tramadol was applied to group II (n:26). The pain was measured by 10-point visual analog scale (VAS). 1 mg/kg of body weight intramuscular pethidine (meperidine) was applied when supplemental analgesia required.

Results: The mean VAS score was significantly lower in group I patients than in group II at 5, 10, 15, 30, 40th minutes during lithotripsy (P=0.011, P=0.009, P=0.001, P=0.000, P=0.000, respectively). Supplementary analgesic requirement was higher in group I than group II which received more shockwaves or higher voltages. However, this difference was not statistically significant (P=0.199).

Conclusions: This is the first study comparing the analgesic effects of IV paracetamol

Özet

Amaç: Şok dalga litotripsi (SWL) üriner sistem taş hastalığının tedavisinde kolay, etkili ve minimal invaziv bir tedavi seçeneğidir. Bununla beraber, SWL işlemi sırasında hastanın duyduğu ağrı bu tedavi seçeneğini kısıtlayan en önemli faktördür. SWL işlemi sırasındaki ağrının kontrolü için intravenöz (IV) parasetamol ile oral (tablet) tramadolün etkinliğini ve yan etkilerini karşılaştırdık.

Gereç ve Yöntemler: Bu prospektif randomize karşılaştırmalı çalışmaya SWL tedavisi endikasyonu olan 54 hasta dahil edildi. Grup I (n:28)' deki hastalara 1 g IV parasetamol infüzyonu uygulanırken grup II (n:26)' deki hastalara 100 mg oral tramadol verildi. Ağrı düzeyi 10'luk vizüel analog skala (VAS) ile ölçüldü. Ek analjezi gereksinimi olduğunda 1 mg/kg dozunda intramüsküler petidin (meperidin) uygulandı.

Bulgular: Litotripsi işlemi sırasında 5, 10, 15, 30 ve 40. Dakikalardaki ortalama VAS skorları grup I'deki hastalarda grup II'deki hastalara kıyasla anlamlı olarak daha düşüktü (sırasıyla, P=0.011, P=0.009, P=0.001, P=0.000, P=0.000). Ek analjezik gereksinimi, daha fazla şok dalgasına ve voltaja maruz kalan grup I'deki hastalarda grup II'dekilerden daha fazlaydı. Fakat bu fark istatistiksel olarak anlamlı değildi (P=0.199).

Sonuç: Bu çalışma SWL işlemi sırasında IV parasetamol ile oral tramadolün analjezik etkinliğini karşılaştıran literatürdeki ilk araştırmadır.

and oral tramadol for pain control during SWL in the literature. IV paracetamol provides better analgesia than oral tramadol with minimal side effects. However, a minimal increase in supplemental analgesia requirement should be considered in patients who will receive more shockwaves or higher voltages.

Key Words. Analgesia; extracorporal shockwave lithotripsy; paracetamol; tramadol; pain

IV parasetamol, minimal yan etki ile oral tramadolden daha iyi analjezik etkinlik göstermektedir. Bununla birlikte daha fazla şok dalgası ve daha yüksek voltaj uygulanacak hastalarda az da olsa ek analjezik ihtiyacı olabileceği göz önünde bulundurulmalıdır.

Anahtar Kelimeler: Analjezi; vücut dışı şok dalga litotripsi; parasetamol; tramadol; ağrı

Introduction

Shock wave lithotripsy (SWL) has revolutionized the treatment of urinary stone disease because of its simplicity, efficacy, and minimal morbidity (1). Nevertheless, pain associated with SWL remains one of the most common restrictions for this treatment modality (2). Clinical outcomes and success as measured in terms of stone-free rate after SWL is strongly correlated to pain experienced during treatment (3). Pain during SWL treatment may lead to defocussing through voluntary or involuntary patient movement and can cause increased respiratory motion, both resulting in a reduced hit rate with a reduced stone fragmentation and a lower overall stone clearance (4). The improvement in technology has increased the efficacy of SWL with minimal morbidity and also made it possible to perform SWL in an outpatient setting without need for general or spinal anesthesia (5, 6). A relaxed cooperative patient is crucial in maintaining stone targetting for optimal fragmentation. This clearly requires effective pain control (7). Many analgesic medications, including opioids, nonsteroidal anti-inflammatory drugs (NSAIDS), local anesthetic agents, and a number of combinations have been used during SWL by various techniques, such as general and regional anesthesia, subcutaneous and intravenous injections, patient-controlled analgesia (PCA), and monitored anesthesia care (7-10). In the literature there are only two studies comparing the analgesic effects of paracetamol and tramadol (2, 11). However, in both studies intravenous (IV) forms of the drugs had been compared and found that IV paracetamol had no superiority against IV tramadol for pain control during SWL noting that tramadol had possible side effects.

In this prospective and randomized trial, we aimed to compare a simple drug with minimal side effects-IV paracetamol with a weak opioid drug with strong analgesic effects-oral Tramadol. Oral form of tramadol instead of IV form had been investigated in order to minimize possible side effects of IV tramadol. In the literature, it is the first study that compares these drugs during SWL procedure for the treatment of urinary tract stones.

Materials and Methods

A total of 54 patients of the American Society of Anesthesiologists (ASA) physical status I and II, aged 18–75 years, who underwent elective SWL for renal and ureteral stones, were enroled in this prospective, randomised study. Approval was received for this study from the ethics committee of Pamukkale University, Faculty of Medicine and written informed consent was received from patients who participated in this study. All patients were preoperatively evaluated by anamnesis, physical examination, urinalysis, urine culture, coagulation profile, serum creatinine level tests, and urinary system ultrasonography or intravenous urography.

Patients with the age less than 18 or more than 75 years, weight less than 50 kg or more than 100 kg, a history of SWL, serious cardiovascular, renal, or respiratory diseases, peptic ulcer disease, neurologic conditions (such as spinal cord injury, epilepsy, and multiple sclerosis etc.) bleeding disorders, active urinary infection, allergy to the study drugs, analgesic/narcotic or alcohol dependency, chronic use of some drugs (such as antidepressants, histamine blockers, anxiolytics or antiaggregants/ anticoagulants), and those who did not accomplish to mark the pain scoring system were excluded from the study.

Before the procedure patient demographics (age, sex, body mass index (BMI)), stone characteristics (side, size, site, prior ureteral stent placement), and treatment details (total number of shockwaves delivered maximum voltage used during session) were recorded.

An intravenous 18-gauge catheter was inserted into the dorsum of the hand and 2-4 ml/kg/h of 0.9% NaCl was infused. All patients received 2-4 l/min oxygen via nasal cannula. Then the patients were randomized into two groups using a computer-generated table based on

Table 1. Patient demographics, stone characteristics and treatment details.

	Group I (n=28) (IV paracetamol)	Group II (n=26) (oral tramadol)	P value
Sex, n (%)			0.761
Male	21 (75)	18 (69.2)	
Female	7 (25)	8 (30.8)	
Age (years), mean ±SD	44.52±15.36	49.84±12.23	0.146
Weight (kg), mean ±SD	75.31 ± 14.63	75.88 ± 14.54	0.981
BMI (kg/m^2), mean ±SD	26.30±4.07	26.43±3.92	0.960
ASA, n (%)			0.686
ASA I	19 (67.8)	16 (61.5)	
ASA II	9 (32.2)	9 (38.5)	
Voltage (kV), mean ±SD	18.10 ± 1.08	18.56± 1.16	0.278
Number of shocks (n), mean ±SD	2493.10± 183.10	2568.00± 247.86	0.334
SWL duration (min), mean ±SD	42.24 ± 5.60	41.60 ± 4.73	0.749
Stone size (cm), mean ±SD	1.59± 0.5	1.44 ± 0.5	0.577
Stone location, n (%)			0.523
Right kidney	12 (42.9)	9 (34.6)	
Left kidney	9 (32.1)	6 (23.1)	
Right ureter	1 (3.6)	3 (11.5)	
Left ureter	6 (21.4)	8 (30.8)	
Prior ureteral stenting, n (%)	6 (21.4)	5 (19.2)	0.555

randomized block design. Group I patients (n:28) received 1 g IV paracetamol within 15 minutes, 60 minutes before the SWL and group II (n:26) patients received 100 mg oral (tablet) tramadol, 60 minutes before SWL. When clinically indicated, 1 mg/kg of body weight intramuscular pethidine (meperidine) was applied as a supplemental analgesic medicine. The investigator who recorded all study data and the patients were blinded as to which drug being administreted. All patients were treated by the same urologist and the same anesthesiologist. Simultaneously, the vital signs including electrocardiogram, noninvasive blood pressure and pulsoxymeter and also nausea, vomiting, gastrointestinal irritation, and allergic reactions such as pruritis were followed and recorded during and after the procedure. All emergency measures including the intubation equipment were kept ready at the SWL room.

Table 2. The comparison of the groups in terms of visual analog scale and supplemental analgesia requirement.

	Group I (n=28) (IV paracetamol)	Group II (n=26) (oral tramadol)	P value
VAS score by time (0-10 points), mean ±SD			
5th minute	4.61±2.15	5.81±0.94	0.011
10th minute	4.64±2.02	5.85±1.05	0.009
15th minute	4.18±2.36	5.85±0.93	0.001
30th minute	3.61±2.42	6.04±1.08	0.000
40th minute	3.57±2.55	6.38±1.13	0.000
Supplemental analgesia required, n (%)	4 (14.3)	1 (3.8)	0.199

Table 3. The comparison of the groups in terms of vital signs (mean ±SD).

	Group I (n=28) (IV paracetamol)	Group II (n=26) (oral tramadol)	P value
Mean blood pressure (mm Hg)			
5th minute	98.82±10.80	103.88±9.63	0.076
10th minute	103.93±10.94	107.38±10.32	0.239
15th minute	103.50±11.78	108.46±10.76	0.113
30th minute	102.43±13.18	109.19±9.36	0.035
40th minute	102.82±10.22	107.92±10.78	0.080
Heart rate (beats/minute)			
5th minute	81.89±12.72	84.12±11.50	0.505
10th minute	80.54±14.50	81.58±11.17	0.770
15th minute	77.79±11.70	81.27±11.57	0.277
30th minute	73.25±12.58	76.73±11.41	0.293
40th minute	72.57±11.63	75.19±10.72	0.394
Oxygen saturation (SPO_2)			
5th minute	97.29±1.36	96.73±1.22	0.121
10th minute	96.89±1.50	96.65±1.47	0.557
15th minute	97.11±1.32	96.73±1.31	0.298
30th minute	97.43±1.23	96.77±1.28	0.059
40th minute	97.64±1.28	96.81±1.36	0.024

SWL was performed as a day-care procedure by the same physician using the EMD Lithoshock® (EMD, Ankara, Turkey) lithotripter, an electrohydraulic unit that permits us to use X-ray for stone focussing. The pulse rate of shockwaves was adjusted between 90-100/min for all patients. SWL therapy is usually started at a low voltage of 14 kV until the patient becomes accustomed to the shocks, and then the voltage is gradually increased to a maximum of 23 kV.

The pain was measured by 10-point visual analog scale (VAS) during the procedure (in 5, 10, 15, 30, 40th minutes). According to VAS scoring system, pain felt by the patient is referred as such; 0 point no pain, 1-3 points mild pain, 3-5 points moderate pain, 5-7 points severe pain, 7-9 points very severe pain, and more than 9 points intolerable pain.

For statistical analysis, SPSS version 15.0 (SPSS Inc., Chicago, IL) was used. Parametric variables were analysed with one-way ANOVA and non-parametric variables were tested with chi-square test. P values <0.05 were accepted as statistically significant.

Results

A total of 54 consecutive patients were enrolled in the study. Of the patients, 15 (27.8%) were female and 39 (72.2%) were male; with a mean age of 46.98±14.12 years (range 24 to 75). Both groups were comparable regarding the demographic parameters, stone characteristics and treatment details (Table 1).

The mean VAS scores were significantly lower in group I patients than in group II in the 5th minute (4.61±2.15 versus 5.81±0.94, P=0.011), 10th minute (4.64±2.02 versus 5.85±1.05, P=0.009), 15th minute (4.18±2.36 versus 5.85±0.93, P=0.001), 30th minute (3.61±2.42 versus 6.04±1.08, P=0.000) and in the 40 th minute (3.57±2.55 versus 6.38±1.13, P=0.000) (Table 2). Mean VAS scores was 4.12 in group I and 5.99 in group II. According to VAS scoring system, while patients in group I felt moderate pain, those in group II felt severe pain.

Supplementary analgesic requirement was higher in group I than group II (Table 2). Although 4 patients (14.3%) in group I received supplemental analgesic, in group II only 1 patient (3.8%) required supplemental

Table 4. The comparison of the groups in terms of side effects of the drugs.

	Group I (n=28) (IV paracetamol)	Group II (n=26) (oral tramadol)	P value
Nausea, n (%)	3 (11.5)	7 (25.0)	0.179
Vomiting, n (%)	0	0	
Gastrointestinal effects, n (%)	0	2 (7.7)	0.227
Pruritis, n (%)	0	0	
Recovery time, (min) mean ±SD	29.11±5.45	30.00±0	0.408
Discharge time, (min.) mean ±SD	71.61±9.13	71.92±4.92	0.876

analgesia. However, the difference between the groups regarding the supplementary analgesic requirement was not statistically significant (P=0.199) When we compared the patients which required supplemental analgesia in group I with others, regarding the patient demographics, stone characteristics and treatment details, they had received more shockwaves (2375 versus 2200, P=0.015) and higher voltages (17.5 kV versus 15 kV, P=0.000) during the SWL than the others.

All monitored vital parameters of the patients such as mean blood pressure, heart rate and oxygen saturation were within normal values and remained unaltered during the procedure in both groups. Comparing the two groups, there was no significant difference in vital parameters at all time intervals (P>0.05) (Table 3).

During the procedure no major complications were observed due to the SWL, and none of the patients needed hospitalization after lithotripsy. The complication rates regarding the side effects of paracetamol and tramadole were shown in Table 4. Nausea was seen in 7 patients (25%) in group II versus 3 patients (11.5%) in group I. But this difference was not statistically significant (P=0.179). Gastrointestinal effects were observed only 2 patients (7.7%) in group II versus none in group I (P=0.227).

Discussion

SWL has become the first-line treatment for renal and ureteral stones of 20 and 15 mm or less, respectively (8). Although SWL has noninvasive nature, efficacy, and minimal morbidity, it may cause severe pain during the procedure. It has been reported that the majority of patients who undergo SWL do not tolerate this procedure without analgesia or sedation (11). There are numerous factors influencing the amount of analgesia required during SWL, such as type of lithotriptor, the patient age and sex, the number and voltage energy of shock waves, the stone burden and location, and the patient's pain threshold (1). Although newer generation SWL devices are less painful, an adequate pain control is still an inevitable part of effective SWL treatment (3, 12-14).

Shock-wave induced pain is usually described as stinging and sharp (4). Its patogenesis is not yet totally understood, but cavitation seems to play a key role, rather than direct mechanical effects on nociceptive nevre endings (15, 16). Formation, movement, and implosion of the shock wave generated microbubbles in body fluids or tissues lead to stimulation of the superficial nociceptors in the skin as well as the deeper, visceral nociceptors in the renal capsule, periost, pleura, peritoneum, and muscles (16, 17). A second component of shock-wave related pain is the movement of the stone caused by the impact of the shock wave (18).

To date, various analgesic agents, including opioids (morphine, pethidine, fentanyl), NSAIDS (diclofenac, propofol, ketorolac, piroxicam), local anesthetic agents, and a number of combinations have been given during SWL using a variety of techniques (bolus subcutaneous/ intravenous injection, patient controlled analgesia, cutaneous creams, infiltrative analgesia) (19-23). Even sophisticated techniques that utilize nevre stimulation by acupuncture, chemoacupuncture, and transcutaneous electric nevre stimulation (TENS) were also reported in the literature (3, 13, 14, 24). Despite numerous studies, to date, guidelines for pain management during SWL have not been well established, and for this reason, the search for the ideal analgesic drug continues. The optimal analgesia technique should be easy to use, cheap and have a high efficacy and minimal side effects that permits a rapid discharge. In our study, we compared IV paracetamol

which is a simple drug with minimal side effects with oral tramadol which is an opioid drug with strong analgesic efficiency. In the literature there are only two studies comparing the analgesic effects of paracetamol and tramadol (2, 11). However, in both studies intravenous (IV) forms of the drugs had been compared and found that IV paracetamol had no superiority against IV tramadol for pain control during SWL noting that tramadol had possible side effects. To the best of our knowledge, the present study is the first randomized trial comparing the efficacy of intravenous paracetamol and oral tramadol in the literature.

Paracetamol is a derivate of p-aminophenol. It is not counted to the NSAIDS because it has no anti-inflammatory effect. It is commonly used for pain control after surgical procedures (4). Paracetamol has a central analgesic effect that is mediated through activation of descending serotonergic pathways (25). The mechanism of action of paracetamol, however, is still not completely understood. There is only two studies in the literature proving the efficacy of paracetamol in SWL. Akcalı et al. reported that paracetamol provides relatively efficient pain control similar with lornoxicam and tramadol (2). However, Ozkan et al. demonstrated that mean VAS scores and analgesic consumption were lower in lornoxicam used patients compared with paracetamol used and tramadol used patients (11). This study also showed that additional administration of analgesics was decreased with intravenous lornoxicam in comparison with paracetamol and only tramadol. These studies have demonstrated that IV paracetamol has not a superiority against IV tramadol for pain control during SWL. In contrast to these studies, our study presented that IV paracetamol provided better analgesia than oral tramadol.

Tramadol is a relatively weak, central active opioid analgesic, acting as an agonist at the μ-opioid receptors, inhibiting the reuptake of noradrenalin and releasing 5-hydroxytryptamine (serotonin) (26). Recent studies showed that for a dose of 100 mg tramadol IV provides efficient pain control during SWL, despite relatively higher rate of side effects (27, 28). However, Akcali et al. found that 8 mg lornoxicam was similar to 1 mg/kg tramadol, in pain control during SWL (2). In all abovementioned studies, tramadol was administered intravenously. In order to avoid the side effects of IV tramadol we used oral form instead of IV form of tramadol. To the best of our knowledge, the present study is the first, which oral tramadol was used for pain management during SWL.

The mean VAS scores were significantly lower in group I patients than in group II at all times of lithotripsy procedure. According to these mean values while patients in group I were felt moderate pain, those in group II felt severe pain. In our study, supplemental analgesia requirement was higher in paracetamol group than the tramadol group, however, this difference was not statistically significant (P=0.199). Supplemental analgesia was required in patients who received more shockwaves or higher voltages during the SWL.

Despite the effectiveness of the analgesics, their adverse effects during the SWL range between 3%- and 11% in different studies (29). It has been reported that tramadol has caused a high incidence (25%) of nausea and vomiting (30). The actual mechanism of nausea and vomitting remains unclear and is assumed to be related to its central effects on opioid receptors (18). And also, very convenient side effect profile makes paracetamol very interesting, through the analgesic component (5). Akcalı et al. observed vertigo in 10% and 16.7% and nausea in 3.3% and 6.7% of the patients in paracetamol and tramadol groups, respectively (2). Ozkan et al. demonstrated that nausea was seen 9.7% and 6.3% of the patients in paracetamol and tramadol group, respectively (12). Our study revealed that both of the drugs have tolerable side effects. None of the vital signs such as mean blood pressure, heart rate, and oxygen saturation showed instability during the procedure in both groups. Nausea was seen 11.5% and 25% of the patients in group I and II, respesctively, however, the difference was not significant ($P > 0.05$).

The potential limitations of this study should be considered. The major limitation was the sample size is small because of selective study groups. Despite the small sample size, we were able to show both safety and efficacy. Second, although we compared IV infusion and oral medication, analgesic drugs were in different classes. Oral administered drug was a weak opioid, infused one was a paracetamol.

In conclusion, in the literature, there are not any

studies comparing the effectiveness of intravenous paracetamol versus oral tramadol during SWL for urinary stones. According to our results, IV paracetamol provides better analgesia than oral tramadol with minimal side effects. However, a minimal increase in supplemental analgesia requirement should be considered in patients who will receive more shockwaves or higher voltages during the SWL.

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