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ORIGINAL PAPER

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Effectiveness of electro-acupuncture compared to sedo-analgesics in relieving pain during shockwave lithotripsy

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Abstract The aim of this study was to compare the clinical efficacy of electro-acupuncture (EA) with the combination of tramadol + midazolam (TM) for pain relief during outpatient extracorporeal shockwave lithotripsy (ESWL). A total of 35 patients (20 men, 15 women) with stones located in the pelvicalyceal system of the kidney were randomized prospectively to undergo lithotripsy with a third generation lithotriptor (Stone Lith, smart PCK) after receiving either EA ($n = 17$) or TM ($n = 18$) for sedation and analgesia. EA treatment was applied to patients by the same licensed acupuncturist 30 min prior to ESWL in group EA. Tramadol (1.5 mg/kg) 30 min before the start of lithotripsy and midazolam (0.06 mg/kg) 5 min prior to ESWL were given as a sedo-analgesic intravenously to group TM. During ESWL, blood pressure, heart rate, pain and sedation levels were measured at baseline and every 15 min thereafter. The pain intensity perceived during lithotripsy was evaluated using a visual analog scale (VAS). There was no statistical differences in the diameters of the stones and age of the patients between groups ($P = 0.590$; $P = 0.568$, respectively). In the EA group, the median of maximum energy level achieved was 16.0 kV (range 10–23 kV), while it was 18.0 kV (range 10–20 kV) in the TM group. There was no statistically significant difference between the maximum energy levels applied to the patients during ESWL ($P = 0.613$). The median numbers of shockwaves were 2,114 (range 1,100–3,800) and 2,200 (range 1,500–3,200) in the EA and TM groups, respectively. In the TM group, the numbers of shockwaves used were higher than in group EA during ESWL. However, this difference was not significant ($P = 0.732$). VAS scores were consistently lower in the EA group compared with the TM group throughout the ESWL procedure. The median VAS score was 5.0 (range 1–10) in the EA group while it was 8.0 (range 2–10) in the TM group. The patients who underwent EA had lower median scores of VAS than patients who took only conservative treatment, but this difference was not significant ($P = 0.245$). When both groups were compared for stone-free rates, no significant difference was found [82.3% (14/17) for group EA, 88.8% (16/18) for group TM] ($P = 0.658$). Durations of ESWL procedures were similar in both groups [median 27.4 min (range 15.7–34.3) in group EA vs 27.1 min (range 16.1–33.6) in group TM] ($P = 0.517$). No side effects was seen in any patient who received EA. Side effects such as mild orthostatic hypotension and dizziness occurred in patients given sedo-analgesia, but these were not severe enough to require any patient to be excluded from the study. Our study shows that EA is an effective method for inducing sedation with analgesia without any demonstrable side effects.

Keywords Electro-acupuncture · Extracorporeal shockwave lithotripsy · Sedo-analgesia · Side effect · Nephrolithiasis

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Introduction

The management of urinary calculi has undergone changes with the introduction of extracorporeal shockwave lithotripsy (ESWL). The goal of stone management is to achieve maximum stone clearance with minimum morbidity to the patient. Although ESWL is an effective method for the treatment of urinary calculi,

it may cause severe pain during the procedure. When ESWL first began in 1980, it was performed with the patients under epidural or general anaesthesia [1, 2]. Many forms of analgesia have been tried since this time, ranging from local anaesthesia to intravenous opioids. Nowadays, third-generation lithotriptors are used, which cause less pain than their predecessors as they produce lower shockwave energies. Thus, simpler forms of analgesia can be used [3, 4, 5].

We therefore conducted the current prospective trial to compare the effects of electro-acupuncture (EA) and conventional analgesic agents used during ESWL.

Patients and methods

The goal of this study was to objectively assess the effect of EA on the pain perceived during ESWL. A total of 35 patients suffering from nephrolithiasis were prospectively randomized (20 men, 15 women). The study took place between September 2003 and March 2004. Exclusion criteria included age less than 18 years, weight less than 50 kg or more than 100 kg, a history of drug or alcohol abuse, chronic use of drugs such as antidepressants, histamine blockers and anxiolytics, and allergy to one of the study medications [6]. These outpatients underwent ESWL using a third generation lithotriptor (Stone Lith, smart PCK) and received EA or midazolam + tramadol (TM) for sedation and analgesia. EA treatment was applied to 17 patients by the same licensed acupuncturist 30 min prior to ESWL in group EA. Patients were requested to lie in a prone position on the bed and 0.30×40 mm sterile filiform acupuncture needles were inserted 3–4 cm to the urinary bladder points 20, 21, 22, 23 and 52. It took only 3–4 min to deploy the needles. These acupuncture points were at the levels of the tips of the spinous processes of the 11th and 12th thoracic and the 1st and 2nd lumbar vertebrae, respectively (Fig. 1). The needles were stimulated manually until the patient felt the sensation of qi as numbness in that region. Then electrical stimulation with 2–4 Hz frequency with an intensity up to the tolerance level of each patient was given and the needles were retained in the body for 20 min. The levels of the points correspond well with the anatomical surface projection of kidneys (one vertebra lower). The needles were taken out after 20 min and then ear acupuncture needles were embedded to ear points shenmen, kidney and kladder. The patient was advised to press and stimulate the ear needles when he/she felt discomfort.

Conservative treatment with tramadol (1.5 mg/ kg) 30 min before the start of lithotripsy and midazolam (0.06 mg/kg) as sedo-analgesic 5 min before ESWL were given intravenously to group TM (18 patients) and served as the control group. During ESWL, blood pressure, heart rate, pain and sedation levels were measured at baseline and every 15 min thereafter. The pain intensity was evaluated by visual analog scale (VAS) [7, 8].

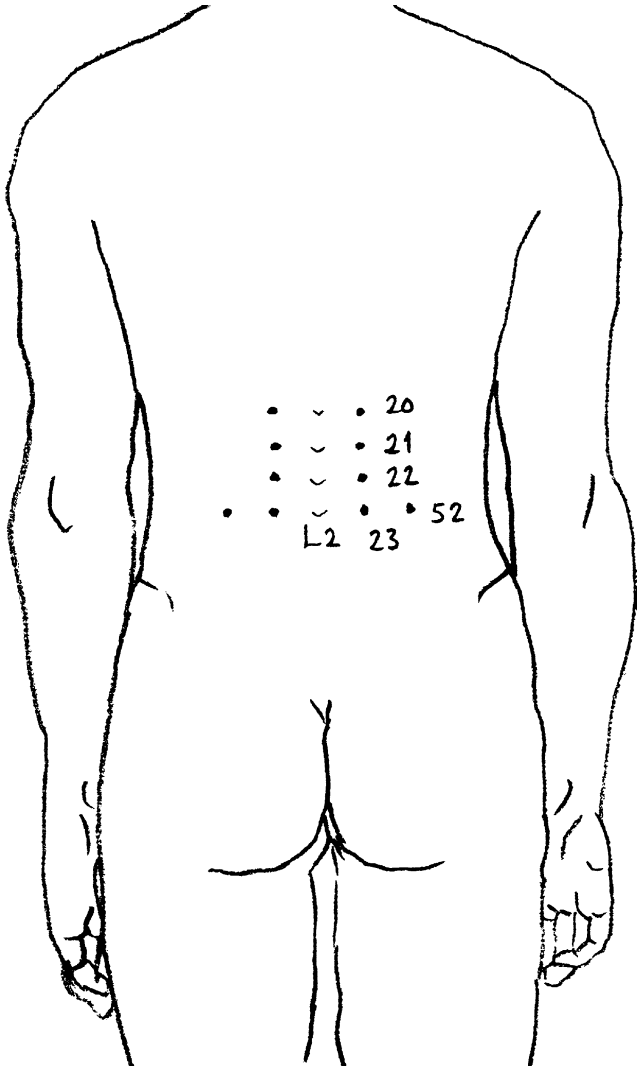

Fig. 1 The locations at which the body surface was punctured using filiform acupuncture needles. *L2*: urinary bladder meridian. Note that *23* and *52* are located at the level of the tip of the spinous process of the second lumbar vertebra. *22*, *21* and *20* are located on the same meridian and one vertebral level above the other respectively

The patient was requested to define the least pain he felt as 0 and unbearable pain as 10. The patient's discharge time was also documented.

The data collected were stone location, number of shockwaves given, treatment duration, discharge voltage achieved, pain score and incidence of side effects.

The institutional ethics committee approved this study, and all of the participants read and signed an informed consent form. An explanation was made to the patients in group EA including the reasons for and how we performed acupuncture before ESWL and their approval was taken.

For all patients, side effects of EA and TM were also evaluated.

ESWL was applied to patients by the same physician. Initial shockwaves were started at 8 kV and increased

gradually to the maximum tolerable levels. The patient was requested to tell us when he/she felt unbearable pain and the power of the shockwaves was not further increased.

All variables were expressed as median and range or as numbers of patients and percentages. The stone diameter and age, which were evaluated as potential confounding factors, were similar in both groups. Therefore, instead of using a multivariate analysis method, differences between the two groups were tested using the Mann-Whitney U-test and Fisher's exact test. A P value less than 0.05 was considered significant. Analyses were performed by using SPSS software, version 9.0 for Windows (SPSS, Chicago, Ill.).

Results

Group TM consisted of eight females and ten males with a median age of 43 years (range 18–55), while group EA included seven females and ten males with a median age of 35 years (23–58). The stone was in the left kidney in 19 (54.2%) and the right kidney in 16 of the patients (44.7%).

The diameters of stones ranged from 7 to 23 mm for both groups. There were no significant differences between the groups for the diameters of stones, ages, and gender distributions ($P=0.590$; $P=0.568$; $p=0.289$, respectively) (Table 1).

In the EA group, the median of maximum energy level achieved was 16.0 kV (range 10–23 kV) while in TM group, it was 18.0 kV (range 10–20 kV). There was no statistically significant difference between the maximum energy levels applied to the patients during ESWL ($P=0.613$). The median numbers of shockwaves were 2,114 (range 1,100–3,800) and 2,200 (range 1,500–3,200) in the EA and TM groups, respectively. In group TM, the number of shockwaves was higher than group EA during ESWL. However, this difference was not significant ($P=0{,}732$) (Table 1).

VAS scores were consistently lower in the EA group compared with the TM group throughout the ESWL procedure. The median VAS score was 5.0 (range 1–10) in the EA group and 8.0 (range 2–10) in the TM group. The patients who underwent EA application had lower scores of VAS than patients who underwent only conservative treatment, but the difference was not significant ($P=0.245$) (Table 1).

Both treatment regimens produced satisfactory sedation and analgesia and allowed the maximum number of shockwaves to be given. When both groups were compared for to stone-free rates, no significant difference was found [82.3% (14/17) for group EA, 88.8% (16/18) for group TM] ($P=0.658$) (Table 1).

The durations of the ESWL procedures were similar in both groups [median 27.4 min (range 15.7–34.3) in group EA vs 27.1 min (range 16.1–33.6) in group TM] ($P=0.517$) (Table 1).

No side effect was seen in any patient who received EA treatment.

Although side effects such as mild dizziness (11 patients), and mild orthostatic hypotension (two patients) occurred for 0.5–2 h in patients who were given sedo-analgesia, no significant side effect requiring exclusion from the study was seen. Medical intervention was not required for any of the patients for these minimal side effects (Table 1).

When the blood pressure and heart rate were compared at baseline and after 15 min, there was no significant difference between the groups (Table 2).

EA provided sufficient analgesia for ESWL and was associated with higher patient and urologist satisfaction when compared with a TM combination.

Table 1 Demographic data, distribution of stones, features of treatment and analgesic requirements. † Side effects such as nausea and vomiting, mild orthostatic hypotension and dizziness. * Eleven patients experienced mild dizziness and two patients experienced mild orthostatic hypotension

	Acupuncture	Midazolam + tramadol	*P*
Number of patients	17	18	
Number of patients according to sex (male: female)	10:7	10:8	0.289
Median (range) age (years)	35 (23–58)	43 (18–55)	0.568
Median (range) weight (kg)	68.2 (55–97)	70.3 (53–93)	0.603
First ESWL/repeat ESWL	17/none	18/none	
Diameter of stone (range) (mm)	12.4 (7–23)	12.3 (8–22)	0.590
Stone location			
Upper calyx	-	1	
Middle calyx	5	4	
Lower calyx	5	6	
Renal pelvis	4	2	
Upper ureter	3	5	
Median (range) energy level (kV)	16.0 (10–23)	18.0 (10–20)	0.613
Median (range)number of shock waves	2,114 (1,100–3,800)	2,200 (1,500–3,200)	0.732
Median (range) ESWL duration (min.)	27.4 (15.7–34.3)	27.1 (16.1–33.6)	0.517
Median (range) VAS (max. 10)	5.0 (1–10)	8.0 (2–10)	0.245
Number of side effects†	none	13*	
Stone-free rates	14/17 (82.3%)	16/18 (88.8%)	0.658

Table 2 Blood pressure and heart rate levels were measured at baseline and 15 min thereafter during ESWL

	Acupuncture median (range)	Midazolam + tramadol median (range)	*P*
Baseline systolic blood pressure (mmHg)	110 (95–140)	115 (100–150)	0.213
15 min systolic blood pressure (mmHg)	115 (100–140)	119 (95–145)	0.305
Baseline diastolic blood pressure (mmHg)	80 (70–95)	82 (70–100)	0.279
15 min diastolic blood pressure (mmHg)	80 (75–95)	80 (75–95)	0.618
Baseline heart rate	76 (70–88)	77 (72–92)	0.509
15 min. heart rate	79 (75–92)	80 (70–94)	0.722

Discussion

Although the development of new generation lithotriptors has decreased pain during ESWL, some form of sedation and anaesthesia may still be required to provide adequate patient comfort and effective treatment [9]. The pathogenesis of pain in ESWL is still not clearly known. Whether the origin of pain perceived is due to cutaneous or deep visceral afferent stimulation is debatable. Ganapathy et al. reported that EMLA cream (lidocaine 2.5% and prilocaine 2.5%) was not effective in reducing the pain of lithotripsy when used as a local anaesthetic. They suggested that it did not reduce the opioid requirement at the energy level of shockwaves commonly used during ESWL. In their opinion, the major component of the pain of lithotripsy arose from deeper visceral structures rather than from the skin [5]. The pain is reportedly due to cavitation mediated stimulation of nerve fibres. The intensity of pain perceived during ESWL depends on the energy level of shockwaves passing through the tissues [5]. However, Loening et al. suggested that there was a cutaneous component to the pain induced by the lithotriptor [10]. Supporting this finding, Bierkens et al. also reported that the opioid requirement was reduced when EMLA cream was used as a supplement during lithotripsy [11].

Non-steroid anti-inflammatory drugs, especially tenoxicam, piroxicam and diclofenac sodium, have been used for ESWL [6, 12]. Fredman and colleagues compared diclofenac sodium with placebo. He found that diclofenac sodium was an effective analgesic without causing hemodynamic and respiratory side effects [12]. Recently, intravenous sedative analgesics (such as midazolam and fentanyl) have been used to provide pain control during lithotripsy. These drugs provided safe and effective sedation and analgesia, but transient oxygen desaturation (<90), nausea and vomiting were seen frequently because of their opioid nature [13]. We use intravenous midazolam (0.06 mg/kg) + tramadol (1.5 mg/ kg) in daily ESWL practice. Midazolam, a benzodiazepin, is used to provide sedation and tramadol HCI, a narcotic analgesic, is used to provide pain control. Its efficacy is explained by two mechanisms: the first, its being an agonist at all types of opioid receptors with some selectivity to μ receptors, and the second, inhibition of neuronal noradrenalin uptake and serotonin release, the transmitters of which are in descending inhibitory pathways that enhance analgesia [14]. A single dose of 100 mg i.v. tramadol is satisfactory in the first postoperative hour, since the onset of analgesia is evident and its halflife is 6 h. Therefore, we administered tramadol i.v. half an hour prior to ESWL. When opioid analgesics are used, discharge of the patient is occasionally delayed due to persistent dizziness/vertigo and nausea [5]. Any adjuvant agent to reduce opioid dosage or side effects, or an exclusive form of analgesia to reduce pain and shorten recovery period will be beneficiary in many aspects.

Pain is subjective and initial shockwaves should be started after the patient is informed about the procedure. This condition eliminates the surprise factor, increases patient adaptation, and decreases the probability of patient movement. Therefore, cooperation with the patient during the procedure is essential for a maximum success rate and rapid recovery following ESWL. Apart from patient-related factors, several physical variables including shockwave generation and focusing, configuration of the shockwave front, cavitation effects, size of the focal zone and area of shockwave entry at the skin may be responsible for the perception of pain [3].

Our usual routine is to start lithotripsy at the lowest energy level (8 kV) and gradually increase the energy during the procedure. The use of lower levels of energy prolongs the duration of time required to fragment the stones as well as increasing the probability of unsuccessful treatment. We noted that the most discomfort, however, was at the start of lithotripsy.

For years, several different techniques have been tried to overcome the pain experienced during ESWL, such as local anaesthesia, paravertebral block, and various sedative and analgesic drugs. There appears to be no consensus on the type of analgesics to be used. At present, intravenous opioids, with or without sedation, seem to be most common, but they have adverse effects such as nausea and vomiting, mild orthostatic hypotension, dizziness and the risk of respiratory depression.

Contrary to all those applications, Rasmussen and Dahl reported no difference in the pain scores between patients given intravenous fentanyl and those who received intravenous saline [15]. Also, it may be argued that some patients can complete ESWL treatment with no analgesia, but it is not known which patients will actually need some form of pain relief prior to the procedure. The degree of dysfunction caused by routine medications for ESWL, while manageable, renders most

patients incapable of returning to work for some time. Acupuncture, as an alternative method, is associated with far less morbidity and still allows intravenous sedation should acupuncture prove inadequate (which, as it turns out, is uncommon) [16]. Quatan and coworkers reported that the result of acupuncture treatment during ESWL in place of standard analgesia in three patients who had previously failed ESWL was satisfactory [17]. They suggested that acupuncture may be effective in the acute pain setting and should be considered in appropriate patients. They did not propose that acupuncture is a technique suitable for all, merely one that should be offered to people who would not otherwise be suitable for outpatient ESWL services or those who request it. Their results show that good outcomes can be achieved with acupuncture in patients undergoing ESWL.

Acupuncture is well known and accepted for alleviating many sorts of pain, including the lower abdominal, testicular and perineal regions [18, 19, 20]. In a recent publication on the effects of acupuncture for chronic pelvic pain syndrome (prostatodynia) with intrapelvic congestion, three important domains of chronic prostatitis including pain, voiding symptoms and quality of life were evaluated according to NIH Chronic Prostatitis Symptom Index (NIH-CPSI) and the International Prostate Symptom Score (IPSS). Subjective symptoms were quantified by the use of NIH-CPSI and IPSS, and the pain and discomfort were found to be decreased from 11.6 before acupuncture to 8.8 after acupuncture ($P < 0.05$). With respect to quality of life, the number of patients who replied that they felt terrible or mostly dissatisfied decreased from eight to three after the treatment [20].

Pain during ESWL can be intense even though its source, whether from cutaneous or from deeper visceral afferents, is debatable. Various combinations of analgesic and sedative agents have been given to patients undergoing ESWL in different controlled trials. Since EA is an effective way of relieving pain, we performed this method prior to ESWL on some of our patients according to their preference and compared its effectiveness with traditional sedo-analgesia.

Acupuncture points of the urinary bladder 20, 21, 22, 23 and 52 were selected in the study since they all have analgesic effects on hypochondriac pain from various sources as well as being fairly in accordance with the segmental innervation of the kidneys. Moreover, UB23, which is the back-shu point of kidney, and UB52 both have specific tonifying effect on the functions of kidney, which in turn is responsible for the functions of lower back according to the theory of Chinese medicine [21].

Acupuncture needles inserted into the skin and underlying muscles activate sensory receptors inside the muscle. Small diameter myelinated type II and III muscle afferent nerves carry this impulse to the spinal cord and synapse onto an anterolateral tract cell which in turn projects to three centers to block pain transmission through endorphins: the spinal cord, the midbrain and the pituitary-hypothalamic complex [18]. During EA, stimulation at low frequency and high intensity activates all of these centers. By this means, acupuncture is able to block pain sensation from urinary calculi whether its origin is from the skin or from the deeper structures.

Electrical stimulation with 2–4 Hz frequency with an intensity up to the comfortable tolerance level of each patient was given to the retained needles for 20 min in order to enhance the effect of each point. Thus, the onset of analgesia was a little later with this kind of electrical stimulation, however, its effect was prolonged for many hours [18].

In the present study, there was no difference between the two groups. Neither patient comfort nor the length of hospital stay differed. However, patients undergoing EA experienced no side effects. In the EA group, nausea and dizziness did not occur, even though they received no anti-emetics. Similarly, Quatan and coworkers reported no side effects in patients who underwent acupuncture [18].

Patient satisfaction was moderate with the two sedo-analgesic techniques. The patients in the TM group experienced mild dizziness and needed the help of another person to return home, and most patients were incapable of returning to work for some time. In the TM group, we did not observe any respiratory depression, although this adverse effect of narcotic analgesics (tramadol) is potentiated by sedation with benzodiazepines (midazolam) [22]. On the other hand, patients who received EA stood up after ESWL without any dizziness and left the hospital on their own to go to their jobs.

TM and EA both provided good anesthesia for ESWL. Nevertheless, EA had less side effects than TM and provided rapid recovery.

Our study demonstrates that EA is an effective method for inducing sedation with analgesia and had no demonstrable side effects. However, a different experimental design and other studies with a much larger population would be required to establish its safety.

Conclusion

EA may provide sufficient analgesia for ESWL of urinary tract stones and is a good alternative to other forms of anesthesia and analgesia.

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References

1. Stoller ML (2000) Extracorporeal shock wave lithotripsy. In: Tanago EA, McAninch JW (eds), Smith's general urology, 15th edn. Mc Graw-Hill, San Francisco, p 321
2. Chaussy C, Schmiedt E, Jocham D, Brendel W, Forssmann B, Walther V (1982) First clinical experience with extracorporeally induced destruction of kidney stones by shock waves. J Urol 127: 417

3. Chin CM, Tay KP, NG FC, Lim PH, Chng HC (1997) Use of patient-controlled analgesia in extracorporeal shockwave lithotripsy. Br J Urol 79: 848
4. Ozcan S, Yilmaz E, Buyukkocak U, Basar H, Apan A (2002) Comparison of three analgesics for extracorporeal shock wave lithotripsy. Scand J Urol Nephrol 36: 281
5. Ganapathy S, Razvi H, Moote C, Parkin J, Yee I, Gverzdys S, Dain S, Denstedt JD (1996) Eutectic mixture of local anaesthetics is not effective for extracorporeal shock wave lithotripsy. Can J Anaesth 43: 1030
6. Aybek Z, Turan T, Yonguc T, Bozbay C, Atahan O, Tuncay OL (1998) Requirement of analgesia for extracorporeal shock wave lithotripsy and efficacy of a nonsteroidal antiinflammatory drug: piroxicam. 34: 207
7. Jensen MP, Chen C, Brugger AM (2000) Interpretation of visual analog scale ratings and change scores: a reanalysis of two clinical trials of postoperative pain. J Pain 4: 407
8. Jensen MP, Karoly P, Braver S (1986) The measurement of clinical pain intensity: a comparison of six methods. Pain 27: 117
9. Tauzin-Fin P, Delort-Laval S, Krol-Houdek MC, Maurette P, Bannwarth B (1998) Effect of balanced analgesia with buprenorphine on pain response and general anaesthesia requirement during lithotripsy procedures. Eur J Anaesthesiol 15: 147
10. Loening S, Kramolowsky EV, Willoughby B (1987) Use of local anesthesia for extracorporeal shock wave lithotripsy. J Urol 137: 626
11. Bierkens AF, Maes RM, Hendrikx JM, Erdos AF, De Vries JD, DebruyneFM (1991) The use of local anesthesia in second generation extracorporeal shock wave lithotripsy: eutectic mixture of local anesthetics. J Urol 146: 287
12. Fredman B, Jedeikin R, Olsfanger D, Aronheim M (1993) The opioid-sparing effect of diclofenac sodium in outpatient extracorporeal shock wave lithotripsy (ESWL). J Clin Anesth 5: 141
13. Monk TG, Rater JM, White PF (1991) Comparison of alfentanil and ketamine infusions in combination with midazolam for outpatient lithotripsy. Anesthesiology 74: 1023
14. Hennies HH, Friderichs E, Wilsmann K, Flohe L (1982) Effect of the opioid analgesic tramadol on inactivation of norepinephrine and serotonin. Biochem Pharmacol 31: 1654
15. Rasmussen YH, Dahl C (1994) Analgesic requirements for ESWL treatment. A double blind study. Scand J Urol Nephrol 28: 225
16. Johnstone PA, Issa MM (2004) Acupuncture in conventional practice. J Endourol 18: 127
17. Quatan N, Bailey C, Larking A, Boyd PJ, Watkin N (2003) Sticks and stones: use of acupuncture in extracorporeal shockwave lithotripsy. J Endourol 17(: 867
18. Stux G, Pomeranz B (1988) Basics of acupuncture. Springer, Heidelberg Berlin p 4
19. NIH Consensus Development Panel on Acupuncture. (1998) JAMA 280 : 1518
20. Honjo H, Kamoi K, Naya Y, Ukimura O, Kojima M, Kitakoji H, Miki T (2004) The effects of acupuncture for chronic pelvic pain syndrome with intrapelvic congestion. Int J Urol 11: 607
21. Yin G, Liu Zhenghua (2000) Advanced modern chinese acupuncture therapy. New World Press, Beijing
22. Dawson C, Vale JA, Corry DA, Cohen NP, Gallagher J, Nockler IB, Whitfield HN (1994) Choosing the correct pain relief for extracorporeal lithotripsy. Br J Urol 74: 302