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How painful are shockwave lithotripsy and endoscopic procedures performed at outpatient urology clinics?

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Abstracts Our aim was to investigate the subjective pain felt by patients during shockwave lithotripsy (SWL) and endoscopic procedures such as cystoscopy, retrograde ureteral stenting, retrograde pyelography (RGP), and ureteroscopic lithotripsy performed in an outpatient clinic, and to identify how severe pain during such procedures is. We estimated subjective pain in 984 patients after SWL (186), cystoscopy (489), retrograde ureteral stenting (127), RGP (97), and ureteroscopic lithotripsy (85) performed by a single expert in an outpatient clinic using a prospective questionnaire with a ten point visual analog scale between January 2001 and December 2003. There was no premedication in any procedure except ureteroscopic lithotripsy for which an intramuscular injection of analgesics (pethidine HCl 50 mg) was used. The pain scale score in SWL was 6.62 ± 2.27 , the highest among the procedures ($P < 0.05$). Pain scores for endoscopies were 4.48 ± 2.07 in retrograde ureteral stenting, 3.81 ± 2.06 in ureteroscopic lithotripsy, 3.72 ± 1.75 in RGP, and 3.08 ± 1.95 in cystoscopy. In this study, we observed that patients feel most pain in SWL without anesthesia, and that pain during ureteroscopic lithotripsy under local anesthesia is not high, compared with other endoscopic procedures.

Keywords Shockwave lithotripsy · Endoscopy · Pain · Anesthesia · Outpatient

Introduction

Shockwave lithotripsy (SWL) and endourologic procedures such as cystoscopy, retrograde ureteral stenting,

and retrograde pyelography (RGP) are often performed in an outpatient setting. In addition, ureteroscopic lithotripsy, which is considered to be an operating room procedure, is categorized as an outpatient procedure in selected cases [1, 2, 3].

When these urologic procedures were introduced, they required general or regional anesthesia because early instruments and techniques were highly invasive and painful. Further development of instruments for SWL and endoscopy, and improved skill have changed the anesthetic methods used from general or regional anesthesia to local or even no anesthesia, and made these procedures performable in an outpatient clinic setting. Consequently, the subjective pain that patients feel during these procedures is not only one of the most important factors that urologists should bear in mind, but is also what patients are most nervous about.

Many centers have investigated the pain that patients feel during such procedures [3, 4, 5, 6, 7, 8, 9], but they do not inform urologists precisely on the type of patient most vulnerable to pain during these procedures. Moreover, the findings of these investigations cannot be used to inform patients on how painful the procedures are, because most of the studies are case-controlled and compare different anesthetic methods and/or instruments to identify the least invasive technique. In fact, no study has been undertaken to compare the severity of pain and to identify how painful these procedures are.

In this study, we investigated subjective pain during SWL and endoscopic procedures in our outpatient clinic in order to determine how much pain patients experience and to identify those factors affecting pain

Materials and methods

Patients

The local ethics committee granted approval for the study. We designed a prospective study of pain experienced during SWL, cystoscopy, retrograde ureteral

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stenting, RGP, and ureteroscopic lithotripsy using a visual analogue pain score to evaluate subjective pain during the outpatient procedures. We included only adult patients 18 years or older who were undergoing these procedures for the first time, but excluded those who had severe coexisting disease. A total of 186, 489, 127, 97, and 85 patients who respectively underwent SWL, cystoscopy, retrograde ureteral stenting, RGP, and ureteroscopic lithotripsy between January 2001 and December 2003 were entered into the study. In SWL, all patients had only one urinary tract stone, and none of them had undergone SWL treatment before. All cystoscopy was performed on patients with gross or microscopic hematuria. The main reason for retrograde ureteral stenting was a relief of urinary obstruction due to renal stones, ureter stones, postoperative complications after pelvic surgery, and pelvic cavity mass, etc. Some patients underwent retrograde ureteral stenting preoperatively in order to identify the ureter easily during surgery. RGP was done for the work-up of hematuria and urinary obstruction. We performed ureteroscopic lithotripsy in patients with only distal ureter stones between the distal edge of the sacroiliac joint and the ureterovesical junction.

Questionnaire study

After the procedure, patients were asked to complete a ten item self-administered questionnaire. The items contained the degree of pain rated by the patient using a ten point linear visual analog scale (VAS), subjective tolerance of patients (yes or no to the question whether they considered themselves pain tolerant), requirements

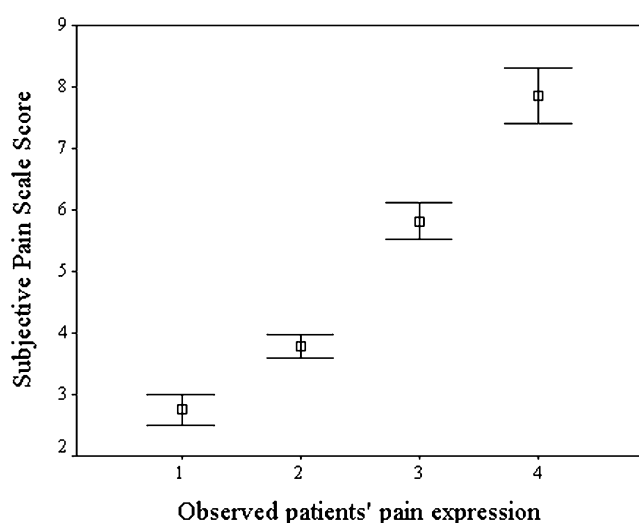


Fig. 1 The mean pain score for each scale (1, 2, 3, 4) of observed patients' pain expression by the operator. Pain scale scores were positively correlated with the observed patients' pain expression, indicating that the pain scores were reliable. 1 the patient seems to feel no pain, 2 the patient seems to feel mild pain, 3 he or she seems to feel severe pain but tolerate it well, 4 the patient needs to take a rest during the procedure or receive analgesics due to severe pain

for analgesic premedication, and economic status, education level, and residence. The operator also recorded observed pain expression severity scaled from 1 to 4 after the procedures (Fig. 1).

Procedure, technique and instruments

All endoscopic procedures and SWL were performed by one operator (H.H.K.). No premedication was administered to any groups except for ureteroscopic lithotripsy in which analgesics (pethidine HCl 50 mg) by intramuscular injection was used. In all male patients who underwent endoscopic procedures, 10 ml of 2% lidocaine gel was instilled into the urethra and retained for 10–15 min. All procedures were done with informed patient consent.

The lithotripsy machine used for SWL was a Nova Ultima (Direx, Israel) with an electrohydraulic shock-wave source. The aperture, focal zone, and peak pressure at the focal point of the machine were respectively 18.1 cm, 13×48 mm, and 400–1,100 bar. All patients underwent one session of SWL. All patients were treated on an outpatient basis and were not premedicated for pain relief. Urinary stones were treated at a power setting of 16–20 kV and 2,800–3,500 shockwaves were applied.

Ureteroscopic lithotripsy was performed with a rigid, tapered 6–7.5 F scope (Wolf, Germany). For fragmentation of calculi, various modalities (pneumatic, electrohydraulic and holmium:YAG laser) were used. Basket retrieval of calculi fragments was carried out as necessary.

We used a 17 F rigid cystoscope (Storz, Germany) whilst performing cystoscopy, and a 22 F cystoscope (Storz, Germany) whilst performing RGP under fluoroscopic guidance using a standard method [10].

Retrograde ureteral stenting was performed under fluoroscopic guidance using a 22 F cystoscope with the following sequence: cystoscope insertion, placement of a hydrophilic guide wire (Terumo, Japan) into the pelvis, cystoscope removal, insertion of an open ended ureteral catheter with a round tip (Microvasive, USA) into the pelvis, change of guide wire from a hydrophilic to a superstiff guide wire (Microvasive), and placement of a 6 F 24 or 26 cm double-pigtail catheter (Microvasive).

In the study, we did not use a flexible ureteroscope and cystoscope because rigid instruments still prevail in our country.

Statistical analysis

The pain score was analyzed and correlated with several clinical factors. Statistical comparisons of continuous data for each procedure were performed using one way ANOVA and categorical variables were compared using a χ^2 or Armitage test.

To evaluate factors influencing pain, odds ratios (ORs) for high pain score, that is greater than 4 (chosen as the cutoff based on the series mean pain score) with respect to sex, age, tolerance, education, economic status, residence and *P* values for trend were estimated by multivariate logistic regression analysis in 984 patients. Associations between these parameters and pain score were described using maximum likelihood estimates of relative risk and 95% confidence intervals (CIs) based on the multiple logistic regression model.

A 5% level of significance was used for all statistical testing and all statistical tests were two-sided. SPSS 10.0 (SPSS, Chicago, Ill.) was used for all statistical analyses.

Results

Table 1 shows the distributions of age, sex, education, income, residence, and tolerance in patients in relation to the procedure used. All patients who underwent ureteroscopic lithotripsy had distal ureter stones with a mean size of 7 mm (range 3–15 mm). In SWL, the mean

size of kidney and ureter stones was 8.3 mm (± 4.5 SD) (right side 88 and left side 98).

A strong, significant positive relationship was obtained between patient pain score and the severity of pain as assessed by an operator, indicating that the pain scores were reliable (Fig. 1).

The mean pain scores of each group were 6.62 ± 2.27 for SWL, 4.48 ± 2.07 for retrograde ureteral stenting, 3.81 ± 2.06 for ureteroscopic lithotripsy, 3.72 ± 1.75 for RGP, and 3.08 ± 1.95 for cystoscopy in decreasing order. SWL was highest, and cystoscopy lowest for pain ($P < 0.05$). When cystoscopy, ureteroscopic lithotripsy, retrograde ureteral stenting, and RGP were categorized into one group (the endoscopy group) and analyzed, the mean pain score for this group was 3.46 ± 2.02 , which was significantly lower than SWL ($P < 0.05$).

There was no significant difference in pain between males (4.09 ± 2.30) and females (4.02 ± 2.25) among the 984 patients. When the comparison of pain by sex was made in the endoscopy and SWL groups, the male pain score (3.52 ± 1.96) showed little difference from the female score (3.39 ± 2.09) for endoscopies, but the female

Table 1 Patient characteristics

	Cystoscopy	Ureteroscopic lithotripsy	Retrograde ureteral stenting	RGP	SWL	Total (%)
Mean age (range)	57.1 (18–87)	51.1 (19–75)	52.6 (19–71)	51.2 (18–78)	50.3 (18–76)	54.1 (18–87)
No. sex (%)						
Male	270 (55)	52 (61)	55 (43)	53 (55)	116 (62)	546 (56)
Female	219 (45)	33 (39)	72 (57)	44 (45)	70 (38)	438 (44)
Education level (%), college						
Not graduated	289 (59)	50 (59)	66 (52)	44 (45)	112 (60)	561 (57)
Graduated	200 (41)	35 (41)	61 (48)	53 (55)	74 (40)	423 (43)
Income (%)						
Lower than average	221 (45)	42 (49)	55 (43)	49 (51)	102 (55)	472 (48)
Higher than average	268 (55)	43 (51)	72 (57)	48 (49)	84 (45)	512 (52)
Residence (%)						
Urban	298 (61)	57 (67)	72 (57)	70 (72)	154 (83)	649 (66)
Rural	191 (39)	28 (33)	55 (43)	27 (28)	32 (18)	335 (34)
Tolerance (%)						
No	117 (24)	21 (25)	34 (27)	24 (25)	26 (14)	226 (23)
Yes	372 (76)	64 (75)	93 (73)	73 (75)	160 (86)	758 (77)
No. of patients	489	85	127	97	186	984

Table 2 Mean pain score for men and women and analgesic requirements for each procedure. * Taken together with cystoscopy, ureteroscopic lithotripsy, retrograde ureteral stenting, and RGP

	Mean pain score \pm SD			No. analgesics requirement (%)		
	Total	Male	Female	Yes	No	Total
Cystoscopy	3.08 ± 1.95	3.06 ± 1.85	3.09 ± 2.08	68 (14)	421 (86)	489
RGP	3.72 ± 1.75	4.04 ± 1.81	3.34 ± 1.60	31 (32)	66 (68)	97
Ureteroscopic lithotripsy	3.81 ± 2.06	4.10 ± 1.93	3.36 ± 2.19	24 (28)	61 (72)	85
Retrograde ureteral stenting	4.48 ± 2.07	4.71 ± 1.97	4.31 ± 2.13	46 (36)	81 (64)	127
SWL	$6.62 \pm 2.27^{\dagger}$	$6.20 \pm 2.22^{\ddagger}$	$7.33 \pm 2.17^{\ddagger}$	65 (35)	121 (65)	186
Endoscopies*	$3.46 \pm 2.02^{\dagger}$	3.52 ± 1.96	3.39 ± 2.09	207 (26)	591 (74)	798
Total	4.05 ± 2.41	4.09 ± 2.30	4.02 ± 2.25	276 (28)	708 (72)	984

$^{\dagger}P < 0.05$ between endoscopies and SWL, $^{\ddagger}P < 0.05$ between male and female in SWL

pain score (7.33 ± 2.17) was significantly higher than the male pain score (6.20 ± 2.22) for SWL ($P < 0.01$). A total of 276 (28%) of the 984 patients indicated that analgesic premedication was necessary. The percentages of patients answering that analgesic premedication would be required for SWL and retrograde ureteral stenting were 35% and 36%, respectively, being higher than for the other procedures. Meanwhile, only 14% answered that analgesic premedication would be needed for cystoscopy, which was the lowest score recorded (Table 2).

In the SWL group, 119 stones were located in the kidney and 67 in the ureter (upper 41, mid 12, lower 14). The subjective pain score during the procedures was not affected by patient age, laterality, or size of the stone, but was affected by sex ($P = 0.012$) and the location of stone ($P = 0.014$) (Table 3).

To evaluate the factors related to pain, logistic regression analyses were performed. Univariate analysis indicated that age and residence were possible risk factors. ORs (95% CIs between the high and low scores) for high pain levels were more frequent in patients younger than 40 years than in those older than 40 years, namely 2.67 (95% CIs 1.64–4.43) and for patients resident in an urban area than in those living in a rural area, 1.58 (1.05–2.36). Multivariate logistic regression was used to determine the independent predictors of a high pain score. In the 984 patients who underwent the procedures, age and residence were independent predictors. Patients younger than 40 years had a 2.6-fold higher risk (OR, 2.60; 95% CI, 1.53–4.45) of a high level than those 40 years or older. Patients in urban areas had a 1.7-fold higher risk (OR, 1.70; 95% CI, 1.11–2.62) of a high pain level than those in rural areas (Table 4).

Discussion

Anesthetic methods along with the operative instruments and techniques are thought to be the main factors affecting the levels of pain which patients experience during SWL and various endourologic procedures. Most studies have investigated the pain associated with anesthetic methods and/or instruments and/or techniques [3, 4, 5, 6, 7, 8, 9]. But, pain is so subjective and individu-

Table 3 Comparison of pain scores during shock wave lithotripsy according to variables. ^a Student's *t*-test

Variables		Number of patients	Mean pain score \pm SD	<i>P</i> ^a
Age (years)	≤ 40	80	7.0 ± 2.0	0.052
	> 40	106	6.3 ± 2.4	
Sex	Male	116	6.2 ± 2.2	0.012
	Female	70	7.3 ± 2.2	
Size of stone (cm)	< 1.0	129	6.5 ± 2.3	0.364
	≥ 1.0	57	6.9 ± 2.2	
Laterality of stone	Right	88	6.8 ± 2.1	0.338
	Left	98	6.5 ± 2.4	
Location of stone	Kidney	119	6.9 ± 2.3	0.014
	Ureter	67	6.1 ± 2.2	

Table 4 Multivariate logistic regression analysis of the influence of covariates on a pain greater than 4

	Mean pain score	Adjusted OR (95%CI)	<i>P</i>
Age			0.000
40 or older	4.1 ± 2.4	1.00	
Younger than 40	5.2 ± 2.1	2.60 (1.53–4.45)	
Sex			0.464
Male	4.2 ± 2.0	1.00	
Female	4.4 ± 2.7	1.16 (0.78–1.74)	
Tolerance			0.426
No	4.0 ± 2.3	1.00	
Yes	4.4 ± 2.4	1.21 (0.76–1.95)	
Education level			0.428
Low (non-graduation of college)	4.3 ± 2.4	1.00	
High (graduation of college)	4.3 ± 2.3	0.84 (0.55–1.23)	
Economic status			0.987
Lower than average income	4.3 ± 2.4	1.00	
Higher than average income	4.2 ± 2.3	1.00 (0.66–1.52)	
Living area			0.015
Rural	3.8 ± 2.5	1.00	
Urban	4.6 ± 2.3	1.70 (1.11–2.62)	

alized that it may vary according to a patient's demographics, e.g., age, sex, income, education level, residence, and tolerance. To our knowledge, this study is the first of its kind to investigate the levels of pain and the demographic factors affecting pain during SWL without anesthesia and during endoscopic procedures like ureteroscopic lithotripsy under local anesthesia, cystoscopy, RGP, and retrograde ureteral stenting undertaken in the outpatient setting.

The results of our study show that pain during SWL without anesthesia was higher than pain during endoscopic procedures. When SWL began in the mid 1980s, the first model HM-3 lithotripter (Dornier Medical System) required that patients be under general or regional anesthesia because of the severity of the pain [11, 12]. With the development of second and third generation lithotriptors, anesthetic requirements were reduced from general to local anesthesia or no anesthesia [13, 14, 15]. SWL is performed using various local anesthetic methods, e.g., NSAIDs, opioids, patient control anesthesia, or intravenous sedation. Some centers have even attempted SWL without anesthesia [4, 5, 6, 7], however, little consensus has been reached on the proper form anesthesia for SWL.

In this study, we performed SWL without anesthesia on 186 patients whose mean pain score was significantly higher than that of cystoscopy patients (6.62 vs 3.08), and even higher than ureteroscopic lithotripsy under local anesthesia (6.62 vs 3.81). Moreover, 35% of these patients indicated that anesthesia would be needed for SWL, whereas only 14% of cystoscopy patients answered in such a way. Although this study was not comparative for the various anesthetic methods and shockwave lithotriptors in SWL, our results suggest that

SWL without anesthesia is painful and intolerable compared with cystoscopy.

Recently, ureteroscopic lithotripsy under local anesthesia has been performed as an outpatient procedure to prevent complications associated with anesthesia and because of its low cost and ease of use. We have already reported the efficacy, patient tolerance, and safety of ureteroscopic lithotripsy under local anesthesia [16]. Nevertheless, it has not been popular because it is considered that a patient's sudden movements due to pain during the procedure may lead to complications such as mucosal damage or ureteral perforation, and that patients may not tolerate the procedure [3, 17, 18]. In the present study, the average pain score for ureteroscopic lithotripsy (3.81) was not significantly different from that of cystoscopy (3.08, $P=0.1$), was similar to that of RGP (3.72), and was even lower than that of retrograde ureteral stenting (4.48), showing that pain may no longer be a contraindication for local ureteroscopic lithotripsy for distal ureter stones.

It has been reported that male pain during urologic endoscopies is higher than female pain, due to anatomic urethral differences [8]. Therefore, the majority of urologists have used a lidocaine gel injection into the urethra before endoscopic procedures in men. Interestingly, our results showed no significant difference between the pain experienced by men and women (3.52 ± 1.96 vs. 3.39 ± 1.96) during endoscopy, which may suggest the efficacy of lidocaine gel in men. However, a significant difference in pain was found between men and women for SWL (6.20 vs 7.33). An explanation for this difference may be due to body weight, size, skin thickness, and/or subcutaneous fat content differences. Differences in body habitus could theoretically result in different shockwave energy delivery to nociceptive structures. There were no significant differences found for the location and size of stones, shockwave number, and maximum energy level between men and women.

In many studies that have investigated discomfort and pain during cystoscopy, age was found to be negatively correlated with pain in male patients [9], but some studies in female patients reported that age is not related to pain [8]. We observed a significant negative relationship between age and pain score in all patients irrespective of sex or procedure. In particular, patients under 40 years tended to be more sensitive to pain, suggesting that urologists should be cautious about performing procedures on young patients, or that they should consider using a complementary anesthetic method.

Unfortunately, the present study has several limitations. It would be difficult to objectively compare the levels of pain experienced during various procedures since the techniques involved, level of difficulties for performing each procedure, and characteristics of individual patients may vary.

Although our results show a relatively higher level of pain experienced by patients during SWL without

anesthesia but a lower level of pain during local ureteroscopic lithotripsy, these results are only from a comparison using procedures like cystoscopy, RGP, and retrograde ureteral stenting, and not with other SWL conditions or with ureteroscopic lithotripsy using other forms of anesthesia.

However, we are able to conclude that compared with cystoscopy, SWL without anesthesia is more painful and that local ureteroscopic lithotripsy for distal ureter stones is tolerable.

Conclusions

As a result of our study, we know that among SWL without anesthesia, cystoscopy, retrograde ureteral stenting, RGP, and ureteroscopic lithotripsy under local anesthesia performed at outpatient clinic, SWL without anesthesia is the most painful and cystoscopy is the least painful method. In addition, ureteroscopic lithotripsy under local anesthesia is as tolerable as cystoscopy. Considering factors affecting the pain patients experience during the procedures, age and residence are possible risk factors. The younger the patients are, the greater the pain, and those living in an urban area experience more pain than those living in a rural area. Thus, we suggest that analgesics or anesthetic methods should be used for SWL, and caution is necessary in performing these procedures, especially in younger and urban patients. Finally, we conclude that local ureteroscopic lithotripsy for distal ureter stones can be performed tolerably.

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