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TREATMENT OF BLADDER STONES WITHOUT ASSOCIATED PROSTATE SURGERY: RESULTS OF A PROSPECTIVE STUDY

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ABSTRACT

Objectives. To assess the effectiveness of noninvasive bladder lithiasis treatment without associated prostate surgery to know whether bladder lithiasis is an absolute indication for prostate surgery.

Methods. Fifty patients with bladder lithiasis were entered in a prospective trial and were treated with extracorporeal shock wave lithotripsy if lithiasis was smaller than 4 cm^2. Independent of the presence or absence of bladder outlet obstruction, in no case was prostate surgery associated. The variables studied were the effectiveness of the treatment, changes in the International Prostate Symptom Score (IPSS), and the subsequent need for desobstructive prostate surgery. The statistical study was performed using Student's *t* test and the proportional hazards model.

Results. Bladder lithiasis was successfully eliminated in 93% of the cases (in 77% of them with a single extracorporeal shock wave lithotripsy session). The mean IPSS decreased from 17.7 to 9.7 points ($P = 0.0001$) after lithiasis elimination. After a mean follow-up of 22 months, a mere 8% of the patients needed subsequent prostate surgery because their IPSS had increased to 20 points or more. The sole prognostic factor for the need for ensuing prostate surgery was the pretreatment IPSS score ($P = 0.042$).

Conclusions. Noninvasive management of bladder lithiasis with no associated prostate surgery is highly efficient and results in marked symptomatic improvement. Furthermore, the number of patients needing subsequent prostate surgery was very low at mid-term follow-up. Because of all of the above, the existence of bladder lithiasis is not an absolute indication for prostate surgery. UROLOGY **66:** 505–509, 2005. © 2005 Elsevier Inc.

In the past, the standard management of bladder lithiasis consisted of the surgical removal of the stone plus de-obstructive prostate surgery, because the etiology of bladder lithiasis was thought to be the existence of bladder outlet obstruction (BOO). Later, the development of endourology brought about lithiasis fragmentation and prostate de-obstruction by transurethral endoscopic resection. More recently, and continuing with this trend toward less-invasive therapy, several groups have started managing bladder lithiasis with extracorporeal shock wave lithotripsy (ESWL), sometimes adding some fragment removal or prostate de-obstruction method.[1–12] A retrospective study performed by our group showed the high effectiveness of ESWL in the treatment of 183 cases of bladder lithiasis with no associated de-obstructive maneuvers.[13] Obtaining bladder lithiasis fragmentation and expulsion without the need to perform de-obstructive prostate surgery challenged the dogma that the presence of bladder lithiasis is an absolute indication for prostate surgery, because it is always associated with BOO. A prospective trial was designed with the purpose of definitely confirming these preliminary results; 50 patients with bladder lithiasis underwent urodynamic study before and after bladder lithiasis treatment. In this trial, all bladder lithiasis smaller than 4 cm^2 were managed with ESWL, and no prostate de-obstructive maneuver was done, independent of the presence or absence of BOO. The first part of the study, which dealt with the urodynamic findings, showed that only one half of the bladder lithiasis were associated with BOO and that those results were not altered by the existence of bladder lithiasis.[14] We report the second part of the prospective trial. Its purpose was to evaluate thoroughly the mid-term

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effectiveness of the noninvasive management of bladder lithiasis using ESWL, with no associated prostate surgery. The ability of the treatment to fragment and expel lithiasis, the improvement of the patient's symptoms after the disappearance of the lithiasis, and the subsequent need to perform de-obstructive prostate surgery were assessed.

MATERIAL AND METHODS

Patients

A total of 50 patients were included who had received a diagnosis of bladder lithiasis in the course of a prospective trial. Their characteristics and the inclusion and exclusion criteria have been previously published.[14]

Patient Treatment

The following explorations were performed at the inclusion visit: plain radiology and ultrasonography; urinalysis and prostate-specific antigen measurement; the International Prostate Symptom Score (IPSS)[15]; and two physiologic uroflowmetry studies and one urodynamic study to assess whether the patient had BOO. Immediately after these measurements were taken, the patients were divided into two treatment groups according to stone size. Stones smaller than 4 cm^2 in diameter (squared surface on an x-ray) were treated by ESWL with a Lithostar Ultra machine by ultrasound focalization. Stones larger than 4 cm^2 were managed by surgery. Independent of the existence of BOO, no benign prostatic hyperplasia (BPH) treatment was added. If the bladder calculi were transparent, an alkaline treatment was added. The patients again underwent plain radiology and ultrasonography 3 weeks after stone treatment to evaluate the treatment effectiveness. If the ESWL was not effective, two more sessions were allowed. One month after the bladder was rendered stone free, IPSS and two physiologic uroflowmetry studies with a urodynamic study were performed. Pharmacologic BPH therapy (finasteride or terazosin) was only given to patients with obstruction whose IPSS increased after the first stone-free visit. Transurethral resection of the prostate was offered to patients with obstruction taking pharmacologic BPH therapy and whose IPSS increased to 20 points or more. Furthermore, if significant clinical and urodynamic vesical instability was present, oxybutynin was administered.

Variables

The main variables of the study were the pretreatment and posttreatment IPSS values, the number of patients who subsequently required prostate surgery, and the time to such prostate surgery. A descriptive study of these variables, including the percentages and mean values, was performed.

Statistical Analysis

The mean differences between the pretreatment and posttreatment IPSS were evaluated by using a paired Student's *t* test. The life-table method was used to estimate the cumulative incidence of prostate surgery. The patients were censored at the date of prostate surgery. The association of risk with the prespecified baseline covariates (mean pretreatment maximal flow rate, mean pretreatment IPSS, prostate volume, and stone size) was evaluated using a proportional hazards model. The analyses were two sided, with $P = 0.05$, and 95% confidence intervals (CI).

TABLE I. *Baseline data*

Variable	Value (95% CI)
Mean age (yr)	65 (61–69)
Mean pretreatment IPSS	17.7 (15.1–20.3)
Mean pretreatment QOL score	4 (3.5–4.5)
Mean baseline Qmax (mL/s)	11 (9.6–12.5)
Mean baseline PSA (ng/mL)	2.94 (2.41–3.47)
Mean baseline prostate volume (cm^3)	64 (54–74)

Key: CI = confidence interval; IPSS = International Prostate Symptom Score; QOL = quality of life; Qmax = peak urinary flow rate; PSA = prostate-specific antigen.

RESULTS

Baseline data are presented in Table I. According to the bladder lithiasis size, 3 patients were treated with transurethral endoscopic lithotripsy, 2 with cystolithotomy, and the rest with ESWL; in no case was BPH surgery performed. The patients treated with ESWL received a mean 4158 impulses (95% CI 3440 to 4875) at a 7.44 kV energy peak (95% CI 6.8 to 8). Of the patients undergoing ESWL, 77% of patients needed only one session, 18% needed two, and 5% needed three. Complete elimination of lithiasis was thus obtained in 93.2% of patients.

The mean pretreatment IPSS in the presence of bladder lithiasis was 17.7. After bladder lithiasis elimination, the posttreatment IPSS decreased to 9.7, a mean reduction of 8 points and statistically significant ($P = 0.0001$, Student's *t* test; Fig. 1). In contrast, the mean quality-of-life score decreased from 4 to 1.9 with treatment. This mean reduction of 2.1 points was also statistically significant ($P = 0.0001$, Student's *t* test; Fig. 1). Because of this great symptomatic improvement, only 12 patients (24%) required pharmacologic treatment of their BPH after treatment of bladder lithiasis (11 with finasteride and 1 with terazosin).

After a mean follow-up of 22.3 months (95% CI 19.9 to 24.7), lithiasis recurred in only 2 patients (4%), and 4 patients (8%) required prostate surgery, because their symptoms had not definitely improved despite pharmacologic treatment. When the possible variables regarding the need for subsequent prostate surgery were examined, the only statistically significant factor was the pretreatment IPSS ($P = 0.042$; Table II). No relationship was found between the pretreatment mean maximal flow, size of the bladder lithiasis, or initial prostate volume and the need for prostate surgery (Table II). In contrast, all 3 patients with a pretreatment IPSS greater than 30 needed subsequent prostate surgery, but only 1 patient of all those with a pretreatment IPSS less than 30 needed surgery.

COMMENT

Since 1990, several works have been published on the management of bladder lithiasis using

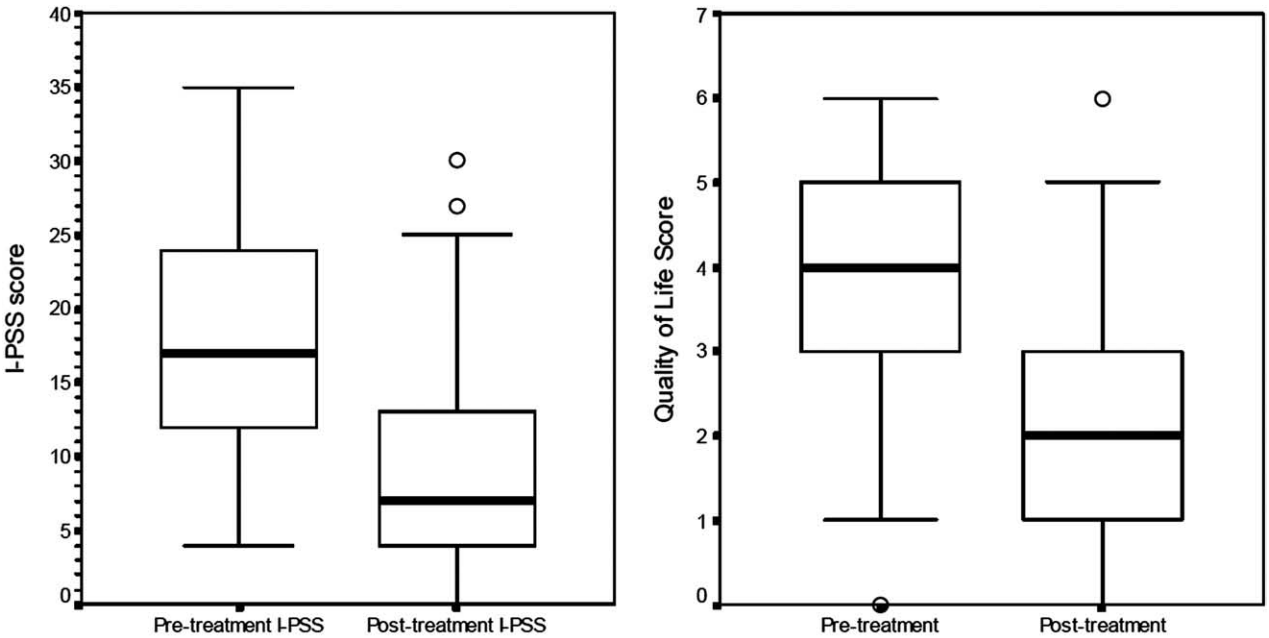

FIGURE 1. *Symptom modification after bladder lithiasis treatment. (A) IPSS (P = 0.0001, Student's t test): pretreatment mean 17.7 (95% CI 15.1 to 20.3); posttreatment mean 9.7 (95% CI 7.3 to 11.9); mean difference 8 (95% CI 5.5 to 10.5). (B) Quality-of-life score (P = 0.0001, Student's t test): pretreatment mean 4 (95% CI 3.5 to 4.5); posttreatment mean 1.9 (95% CI 1.4 to 2.4); mean difference 2.1 (95% CI 1.5 to 2.6). Open circles are outlier values.*

TABLE II. ***Proportional hazards model (dependent variable is prostate surgery)***

Independent Variable	B	Significance	Exp (E)	95% CI for Exp (B)
Stone size	−0.043	0.862	0.958	0.591–1.553
Prostate volume	0.042	0.068	1.043	0.997–1.091
Pretreatment IPSS	0.179	0.042	1.196	1.006–1.422
Pretreatment Qmax	−0.415	0.136	0.660	0.383–1.139

B = B coefficient; Exp (E) = risk; other abbreviations as in Table I.

ESWL.[1–13] However, some differences exist regarding the types of treatment and the kinds of machine used. Some patients were treated with a Siemens Lithostar lithotriptor,[1,2,4,6,7,13] others with a Dornier HM3,[3,8] a Dornier MPL 9000,[5,10–12] or a Dornier HM4.[9] Our group used the Siemens Lithostar Ultra lithotriptor whose ultrasonography focalization allows transparent and opaque bladder stone treatment without anesthesia in the supine decubitus position after physiologic bladder repletion.[13] In contrast, studies that examine potential prognostic factors for good results with ESWL in the management of lithiasis are scarce, perhaps because they often only had a small number of cases. The multivariate analysis of our previous study, however, showed that the sole prognostic factor was the initial stone size. It was significantly greater in those patients in whom ESWL failed (3.88 cm^2) than in those with a satisfactory result (1.87 cm^2).[13] To obtain a satisfactory result with ESWL, similar to other locations, the concurrence of two facts is necessary: lithiasis fragmentation and fragment expulsion ability. The ability to expel the bladder lithiasis fragments had traditionally been called into question, because it was generally accepted that all bladder lithiasis was associated with BOO.[16–18] For this reason, the presence of bladder lithiasis was considered an absolute indication for prostate surgery. However, the results of the first part of this study proved that only one half of the patients had obstruction.[14] This finding questions the absolute indication for prostate surgery in the presence of bladder stones. Thus, the second objective of this study was to evaluate the effectiveness of treating bladder lithiasis only, with no associated prostate surgery. From the results of a previous retrospective study,[13] we resolved to treat, with ESWL, all lithiasis smaller than 4 cm^2. This treatment pattern has provided high effectiveness (93%), with a single session of ESWL necessary in 77% of cases. Additionally, remarkable symptom improvement was achieved, because the mean IPSS decreased from 17.7 to 9.7 points and the quality-of-life score decreased from 4 to 1.9

(Fig. 1). This mean 8-point reduction in the IPSS is quite superior to the improvements seen in major studies on the treatment of BPH with alpha-blockers or alpha-5-reductase inhibitors.[19–23] Because of this remarkable improvement in symptoms, only 24% required subsequent pharmacologic treatment of their BPH. To accept the effectiveness of the noninvasive management of bladder lithiasis, the positive initial results obtained with ESWL should be maintained over time, because if a large number of patients should eventually need prostate surgery in the short term, this would challenge the suitability of ESWL without prostate surgery for treating bladder lithiasis. However, after a mean follow-up of almost 2 years, bladder lithiasis recurred in only 4% of our patients and, better yet, only 8% required prostate surgery for a clinical worsening of symptoms despite the elimination of bladder lithiasis and BPH pharmacologic treatment. This low percentage has confirmed that the initial effectiveness of noninvasive treatment of bladder lithiasis persists in the mid-term and constitutes additional support of our therapeutic proposal and opposes the theory that the presence of bladder lithiasis is an absolute indication for prostate surgery. Even though the percentage of patients who eventually needed prostate surgery was low, it was also interesting to determine whether any prognostic factor could predict for the need for surgery. Although we should be cautious concerning the low number of events (four prostate operations), the multivariate analysis showed that the only prognostic factor predictive of the need for prostate surgery was the pretreatment IPSS (Table II). The 3 patients with a pretreatment IPSS greater than 30 eventually needed prostate surgery, but only 1 patient of all those with a pretreatment IPSS less than 30 did so. These findings indicate that patients with bladder lithiasis and a pretreatment IPSS greater than 30 should also undergo prostate surgery or should be advised that if only their bladder lithiasis is treated, they have a high risk of needing prostate surgery in less than 2 years.

CONCLUSIONS

One of the most significant aspects of this study was that our patients were treated with ESWL only, without an invasive procedure and without anesthesia. We achieved a 93% effectiveness rate using a purely physiologic, noninvasive approach, with neither previous nor ensuing endoscopic maneuvers. This method has been shown to obtain complete expulsion of the stone fragments. The results of our study have shown that it is not necessary to add surgical treatment of BPH. Thus, the existence of bladder lithiasis should no longer be considered an absolute indication for prostate surgery.

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