

A Retrospective Study Evaluating the Efficacy and Tolerability of Intra-abdominal, Once-yearly Histrelin Acetate Subcutaneous Implants in Patients with Advanced Prostate Cancer

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ABSTRACT

Introduction: Luteinizing hormone-releasing hormone (LHRH) agonists are an androgen deprivation therapy used in advanced prostate cancer. The LHRH agonist histrelin is available as an implant of histrelin acetate for once-yearly subcutaneous administration into the upper arm. A single-center, clinical retrospective chart review was performed to characterize the safety and efficacy of abdominal insertion of the histrelin acetate implant.

Methods: Data were collected retrospectively from the charts of 64 patients aged ≥ 45 years with prostate cancer who received the histrelin acetate implant subcutaneously inserted into the abdomen at a single center. Of these, 37 patients received a second implant after 1 year.

Results: Following the first implant, mean serum testosterone levels were 0.38 nmol/L (10.89 ng/dL) at 6 months ($n = 19$) and 0.52 nmol/L (14.96 ng/dL) at 12 months ($n = 33$); serum testosterone level was ≤ 1.04 nmol/L (≤ 30 ng/dL) in 94.7 and 90.9% of patients at 6 and 12 months, respectively. Mean serum prostate-specific antigen levels were 6.56 $\mu\text{g/L}$ (6.56 ng/mL) at 6 months ($n = 23$) and 4.58 $\mu\text{g/L}$ (4.58 ng/mL) at 12 months ($n = 40$). Efficacy was maintained in patients who received a second implant. Adverse events occurred in 3 patients. Eleven patients died during the chart review period; these deaths were deemed unrelated to histrelin acetate implant use.

Conclusion: Insertion of the histrelin acetate implant into the abdomen appears to be an effective and generally well-tolerated alternative administration method.

INTRODUCTION

Prostate cancer is a leading type of cancer among men in the United States. The American Cancer Society estimates that in 2010 there will be over 217 000 new cases of prostate cancer (representing 28% of new cancer cases in men in the U.S.) and over 32 000 deaths caused by the disease (representing 11% of cancer-related deaths) [1]. Prostate cancer growth is stimulated

by testosterone, and androgen deprivation therapy (ADT) is frequently used for the treatment of advanced prostate cancer. Androgen deprivation therapy may be achieved surgically (bilateral orchiectomy) or by medical means, including via administration of luteinizing hormone-releasing hormone (LHRH) agonists [2].

Following an initial transient flare in testosterone levels

KEYWORDS: histrelin acetate, implant, prostate cancer, subcutaneous

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following initiation of LHRH agonist therapy [2,3], patients attain castration level within approximately 3 weeks of commencing therapy [3]. The achievement of a serum testosterone level $< 1.21\text{--}1.74$ nmol/L (< 35 to 50 ng/dL) is considered adequate for patients with prostate cancer [2,3]. LHRH agonists are a mainstay of therapy for patients with advanced prostate cancer [4]. The decision to initiate ADT should be made individually for each patient after considering all relevant clinical risk factors [4].

The LHRH agonist histrelin is available as a sustained-release hydrogel implant of histrelin acetate for once-yearly administration [5]. The histrelin acetate implant is 3.5 cm long by 3 mm in diameter and is administered subcutaneously into the inner aspect of the upper arm in a minor in-office surgical procedure [5]. In the pivotal open-label, single-arm study of the histrelin acetate implant in 138 patients with prostate cancer, mean serum testosterone showed minimal flare at week 1; in addition, serum testosterone levels were reduced to < 1.74 nmol/L (< 50 ng/dL) (indicative of medical castration) in all evaluable patients by week 4, and suppression was maintained for 52 weeks in $> 99\%$ of patients [6]. In an extension of this study, in which patients received once-yearly histrelin acetate implants, testosterone levels were maintained at < 1.74 nmol/L (< 50 ng/dL) for up to 208 weeks [7].

The histrelin acetate implant has been studied when placed in the inner aspect of the upper arm, but its placement in other sites has not been formally evaluated. The purpose of this retrospective chart review was to characterize the safety and efficacy of the histrelin acetate implant when placed in the abdomen.

METHODS

Subjects and Treatment

Data were collected retrospectively during the period of June 2007 to August 2009 from the charts of all patients who received the histrelin acetate implant inserted into the abdomen at a single center. Patients included in the analysis were aged ≥ 45 years, had a diagnosis of prostate cancer, and were deemed appropriate candidates for ADT.

Patients received histrelin acetate delivered using a sterile, diffusion-controlled reservoir drug delivery system (VANTAS; Endo Pharmaceuticals, Chadds Ford, PA, USA). The implant contains a 50 mg histrelin acetate drug core inside a nonbiodegradable cylindrical hydrogel reservoir and releases the drug at ~ 50 $\mu\text{g/day}$ [5]. During an aseptic office-based

surgical procedure, the histrelin acetate implant was inserted subcutaneously into the abdominal area approximately 2 finger-breadths below the costal margins in the mid-axillary (nipple) line, and roughly in-line with an inferior/superior line at the proximal aspect of the iliac crest, using the insertion device supplied with the implant.

Statistics

Qualitative data are presented as the number of patients and the percentage of the total population. Quantitative data are summarized using descriptive statistics, including mean, standard deviation (SD), and standard error.

RESULTS

Retrospective chart data were analyzed from 64 patients. The mean (\pm SD) age was 78.4 (10.7) years, mean (\pm SD) weight was 89.0 (18.3) kg, and mean (\pm SD) height was 174.0 (5.8) cm. Of the 42 patients for whom race was recorded, 37 (88.1%) were Caucasian, 4 (9.5%) were African American, and 1 (2.4%) was Hispanic. The majority of patients (38/64; 59.4%) had been treated with LHRH agonist therapy prior to administration of the histrelin acetate implant, with the most common agent being leuprolide acetate. Among the 58 patients with available serum prostate-specific antigen (PSA) levels prior to administration of the histrelin acetate implant, the mean level was 9.13 $\mu\text{g/L}$ (9.13 ng/mL), and 26 of 58 patients (44.8%) had PSA levels ≥ 5 $\mu\text{g/L}$ (≥ 5 ng/mL). Among the 16 patients with available serum testosterone levels prior to administration of the histrelin acetate implant, the mean level was 2.65 nmol/L (76.43 ng/dL), and 7 out of 16 patients (43.8%) had testosterone levels ≤ 1.04 nmol/L (≤ 30 ng/dL). The patients receiving prior LHRH agonist therapy in the chart review population received the histrelin acetate implant at the prescribed end of their prior LHRH agonist administration, and continued LHRH agonist therapy was indicated. The testosterone levels in these patients were subject to the clinical variability in the waning of the therapeutic effect from previous depot injection formulations (clinical observation).

A total of 37 patients received a second implant after 1 year, 11 patients died, the implant was not removed from 6 patients, and 1 patient discontinued therapy for financial reasons. None of the deaths were judged to be related to use of the histrelin acetate implant. Nine patients did not receive a second histrelin acetate implant for reasons that included not being implanted to downstage their prostate cancer prior to radiation therapy, requesting intermittent ADT, and not wishing to have ADT.

Figure 1. Mean (\pm standard error) serum testosterone levels during one year following the first histrelin acetate implant, and during a second year in patients receiving a second implant. To convert ng/dL to nmol/L, multiply by 0.0347.

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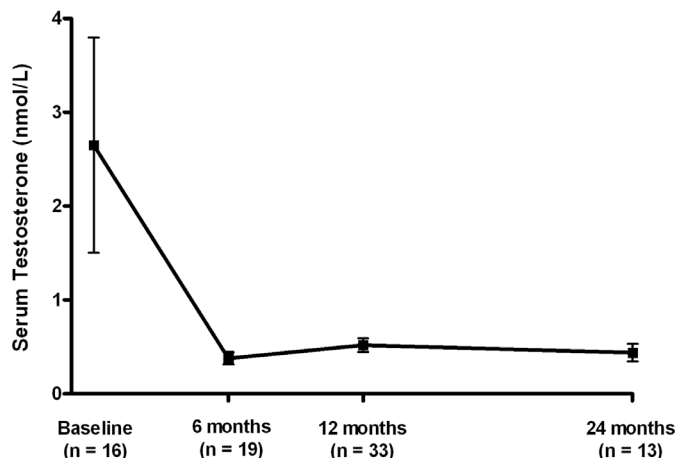
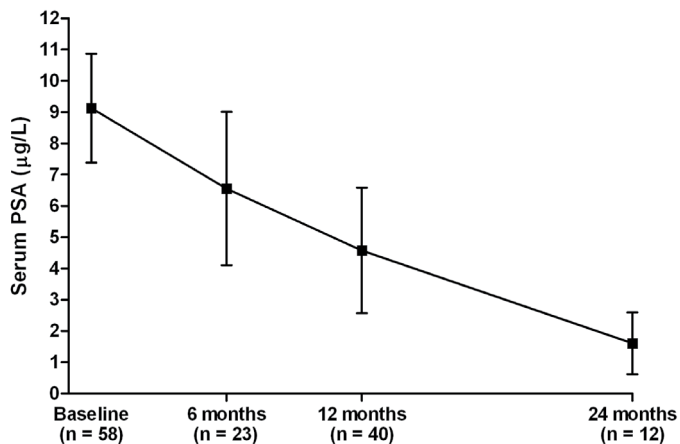


Figure 2. Mean (\pm standard error) serum prostate-specific antigen (PSA) levels during 1 year following the first histrelin acetate implant, and during a second year in patients receiving a second implant. To convert ng/mL to μ g/L, multiply by 1.

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Efficacy

Following insertion of the first implant into the abdomen, the mean serum testosterone level was 0.38 nmol/L (10.89 ng/dL) at 6 months ($n = 19$) and 0.52 nmol/L (14.96 ng/dL) at 12 months ($n = 33$; Figure 1). The proportion of patients with a serum testosterone level ≤ 1.04 nmol/L (≤ 30 ng/dL) was 94.7% (18/19 patients) at 6 months and 90.9% (30/33 patients) at 12 months. In addition, the mean serum PSA level decreased to 6.56 μ g/L (6.56 ng/mL) at 6 months ($n = 23$) and 4.58 μ g/L (4.58 ng/mL) at 12 months ($n = 40$; Figure 2).

Continued efficacy was seen in patients who received a second implant at 1 year. The mean serum testosterone level at 2 years was 0.44 nmol/L (12.76 ng/dL) ($n = 13$; Figure 1), with all 13 patients assessed at this time point having a serum testosterone level ≤ 1.04 nmol/L (≤ 30 ng/dL). The mean serum PSA level at 2 years was 1.61 μ g/L (1.61 ng/mL) ($n = 12$; Figure 2). Among the 9 patients who had received prior LHRH agonist therapy and had serum testosterone levels recorded, 7 patients had a decrease and 2 patients had an increase from baseline in this parameter.

Safety

At the time of reimplantation, the previous implant could not be located for removal in 4 patients, and in 1 additional patient ultrasound was used to locate the implant. In another 4 patients, the clinical decision was made not to remove the previous implant. In 1 patient, the implant was reinserted after unintended expulsion < 1 month after insertion. Subsequent clinical follow-up on this patient indicated maintenance of androgen suppression.

Three patients experienced adverse events: in 1 patient, the second implant protruded through the skin approximately 14 months after implantation and was replaced; 1 patient experienced redness and irritation around the implant removal site; and 1 patient experienced pain at the implant site 1 week after implantation (considered to be due to a muscle strain and unrelated to the implant), and hot flashes. Eleven patients included in this analysis died after ≥ 1 year of evaluation; none of the deaths were deemed related to use of the histrelin acetate implant.

DISCUSSION

There is clinical interest in the suitability of the abdomen as an alternative insertion site for the VANTAS implant, as this site may incur less irritation and environmental contamination. The main finding of this retrospective chart review is that implantation of the histrelin acetate implant into the abdomen instead of the upper arm appears to be effective at reducing serum testosterone to anorchid levels and is well tolerated in patients with advanced prostate cancer.

The patient population reviewed was similar to that enrolled in the pivotal study evaluating the histrelin acetate implant [6]. In the current analysis, the mean age was 78 years, 88% of patients were Caucasian, and 45% had a PSA level ≥ 5 $\mu\text{g/L}$ (≥ 5 ng/mL). A major difference was that approximately 60% of patients in the current chart review had previously received an LHRH agonist. Interestingly, the pivotal study reported by Schlegel excluded patients who had undergone bilateral orchiectomy or had received hormonal agents (including androgen receptor blockade, androgen ablative therapy, or systemic corticosteroid therapy) in the previous year [6].

The current chart review demonstrated that following subcutaneous administration of the histrelin acetate implant in the abdominal area (as described) mean serum testosterone was reduced to below castration levels (< 1.74 nmol/L [< 50 ng/dL]), with mean values of 0.38 nmol/L (10.89 ng/dL) and 0.52 nmol/L (14.96 ng/dL) at 6 and 12 months, respectively. These levels are similar to those reported by Schlegel and colleagues in the pivotal study in which the histrelin acetate implant was inserted into the upper arm [6]. All of the 134 evaluable patients in the Schlegel study attained chemical castration by week 4, and over 99% of patients maintained this throughout the 52-week study duration [6]. In the current chart review, 90.9% of patients achieved chemical castration in the first year, and 100% of patients who received a second implant after 1 year achieved chemical castration at 2 years. In this population, continuous and uninterrupted long-term ADT may be clinically important. Furthermore, the results of the chart review support other recently reported data [7], which show that androgen suppression is maintained with the histrelin acetate implant over successive yearly cycles of insertion and removal without interruption following reimplantation.

The corresponding decrease in serum PSA levels was similar in patients receiving the histrelin acetate implant in the abdomen compared with those who received the implant in the upper arm. In the current chart review, mean serum PSA level was 6.56 $\mu\text{g/L}$ (6.56 ng/mL) at 6 months and 4.58 $\mu\text{g/L}$ (4.58 ng/mL)

at 12 months. In the Schlegel study, the mean serum PSA level was 4.43 $\mu\text{g/L}$ (4.43 ng/mL) at 16 weeks [6]. Histrelin acetate appeared to be active in patients who had received prior LHRH agonist therapy, and thus may represent a treatment option in patients unresponsive to or intolerant of previous LHRH agonist therapy, or who prefer an agent that is administered once yearly.

Intra-abdominal administration of histrelin acetate was well tolerated by the patients represented in the current chart review, with minimal adverse events reported. The adverse events that occurred were insertion site reactions and hot flashes. These adverse events are similar to those previously reported with insertion of the histrelin acetate implant into the arm [6].

CONCLUSIONS

This retrospective chart review indicates that subcutaneous insertion of the histrelin acetate implant into the abdomen, as an alternative method to subcutaneous insertion into the inner aspect of the upper arm, is effective at reducing serum testosterone below castration levels and reducing serum PSA levels. This alternative technique also appears to be generally well tolerated.

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Sean Woolen, Knox Beasley, and Joseph Zahn declare no conflicts of interest.

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A Survey on the Effect of Anticholinergic Therapy on Post-Void Dribbling

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ABSTRACT

Purpose: Post-void dribbling (PVD) is a type of incontinence defined as the involuntary loss of urine immediately after passing urine and rising from the toilet. The purpose of this study was to evaluate whether anticholinergic therapy reduces symptoms of PVD in women placed on therapy for overactive bladder (OAB).

Methods: A survey was administered via telephone to patients being treated for OAB with anticholinergic medications who also carried a diagnosis of PVD. Patients were asked whether PVD symptoms had worsened, were unchanged, or had improved on anticholinergic therapy. Variables such as drug response to OAB symptoms, non-drug treatments for incontinence, and compensatory behaviors to avoid PVD symptoms were included. Other symptoms and variables of voiding dysfunction and medical comorbidities were collected from the medical record. Standard descriptive statistics, Wilcoxon rank sum, and Fisher's exact tests were used to describe the data.

Results: Sixty participants completed the survey. Of the eligible patients, 82% consented to participate in the survey. Of those, 72% (95% CI: 59%-83%, $p < 0.01$) improved PVD symptoms on anticholinergic therapy. The response rate for OAB was also 72%. No difference was found between the response to PVD and OAB ($p = 1$). No other variable measured affected improvement in PVD symptoms on anticholinergic therapy.

Conclusions: In our survey, anticholinergic medications appeared to be effective in treating PVD with an efficacy similar to that of OAB. Additional studies are needed to confirm these findings.

INTRODUCTION

Post-void dribbling (PVD) is a type of incontinence defined as the involuntary loss of urine immediately after passing urine and rising from the toilet [1]. Urinary incontinence is a common condition affecting 1 in 20 American women [2], many of whom complain of PVD as part of their symptoms. A prior study evaluating urinary incontinence found the prevalence of PVD among incontinent women in the general population to be

16.2% [3]. Coyne et al. reported on the prevalence of lower urinary tract symptoms (LUTS); they evaluated a cross-section of the population and found that 15.9% of women over 40 years had reported PVD sometimes, and 9.4% reported PVD symptoms often [4]. In our prior study [5], we noted PVD in 44% of women with overactive bladder (OAB). We also found OAB more common in women with symptoms of PVD; 85% of women with PVD had symptoms of OAB. The primary aim of this study was to evaluate the effect of anticholinergic therapy on PVD

KEYWORDS: Incontinence, overactive bladder, post-micturition dribble, survey, urge incontinence, women

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symptoms in patients being treated for OAB. We hypothesized that patients with PVD on anticholinergic therapy would have improvement of their PVD symptoms.

MATERIALS AND METHODS

IRB approval was obtained prior to the initiation of the study. We administered a survey to a cohort of female patients being treated for OAB with anticholinergic medications who also carried a diagnosis of PVD.

Potential subjects were identified using a medical record query, and were prescreened. This cohort was mailed an introductory letter and contacted approximately 1 week later. The study was described and subjects were then screened for eligibility. Eligible subjects were invited to participate in the survey.

Inclusion criteria included: female patients between 18 and 89 years of age with PVD symptoms at least twice per week; patients were on anticholinergic therapy or had been on anticholinergic therapy within the past 30 days. Exclusion criteria included: pregnancy, conditions which would prevent participation in a survey, including non-English speech, dementia, and mental illness.

An electronic medical record database query was run at the University of Wisconsin School of Medicine and Public Health in March of 2009. We searched for the diagnosis of PVD and the presence of anticholinergic drugs on an active medication list within a single urogynecology clinic. Anticholinergic medications for the treatment of OAB included solifenacin, darifenacin, oxybutynin, tolterodine, and trospium. Information was extracted from the medical record to prescreen for eligibility; the diagnosis of PVD and the use of anticholinergic medications within the past 30 days were confirmed. To receive the diagnosis of PVD in the medical record, the patient had to complain of symptoms of urine leakage after voiding and rising from the toilet, both on their written urinary history questionnaire and at their initial interview visit. Patients were asked "After urinating, do you have dribbling of urine when you stand up?" in a urinary history questionnaire mailed to the patient prior to the new patient visit. At the new patient visit, the patients were asked "Do you ever leak urine after urinating and have risen from the toilet?" If the answer was yes on both questions, and it occurred more than 2 times per week, a diagnosis of PVD was entered into the medical record. Patients were excluded if they were 90 years or older, 17 years or younger, pregnant, non-English speaking, or not competent to answer questions due to mental illness/dementia.

An information sheet describing the study was sent to prescreened patients approximately 1 week prior to contact. Two members of the research team contacted the patients by telephone. Potential subjects were asked to confirm the presence of PVD. If they denied having symptoms of PVD prior to treatment they were not included in the study. They were also specifically asked if they had been on anticholinergic medications in the past 30 days. If they had not been on medications for the past 30 days they were excluded from the study. After screening, eligible patients verbally consented and were asked several scripted questions.

The survey's script asked for the name of the medication being taken. Subjects were asked if the medication helped with OAB symptoms. They were also asked if they have had any additional treatments for incontinence, such as Kegel exercises, InterStim therapy, sling procedures, and estrogen therapy. Further, they were asked if their PVD symptoms had resolved, had improved, or if they remained unchanged since starting therapy. Finally, subjects were asked if they do anything to avoid episodes of PVD, such as waiting on the toilet after voiding for a "second void," or changing position during or after voiding to elicit additional urine.

Medical records were reviewed in this cohort of patients to gain additional demographic information, including body mass index, diabetes, recurrent urinary tract infection (UTI), multiple sclerosis, urethral diverticulum, prior prolapse surgery, prior incontinence surgery, pelvic organ prolapse, nocturnal enuresis, pelvic pain, dysuria, dyspareunia, stress incontinence, OAB and urodynamic testing information, maximum urethral closure pressure, and post-void residual.

The data were compiled and summarized by standard descriptive statistics, which included means, standard deviations, ranges for variables on a continuous scale, and frequency tables for variables on a categorical scale. For the comparison of patients' characteristics between responders and non-responders, Wilcoxon rank sum test and Fisher's exact test were used for continuous variables and categorical variables, respectively. In addition, a McNemar's test was used to examine 2 paired response rates for PVD and OAB. The number of patients initially planned was 68 in order to test the null hypothesis that the true response rate was 35% versus the alternative hypothesis that it was at least 50%, with 80% power and a 5% significance level. We used a lower response rate than that seen for OAB, based on the assumption that this treatment would be less effective for PVD. We chose these parameters based on the published response rates to anticholinergic medications [6].

Table 1. Continuous variables.

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Variables	Post Micturition Dribble		p Value
	No response (n = 17)	Response (n = 43)	
Mean age ± SD (Median, range of values)	57.58 ± 13.94 (60, 33-82)	57.97 ± 12.63 (58, 31-85)	0.94
Mean BMI ± SD (Median, range of values)	33.93 ± 9.08 (32, 22.02-47.3)	33.51 ± 9.13 (34, 17.52- 60.23)	0.93
MUCP ± SD (Median, range of values)	96.93 ± 51.65 (75, 44-225)	98.22 ± 44.12 (90, 16-200)	0.63
PVR ± SD (Median, range of values)	47.06 ± 53.15 (30, 5-220)	37.64 ± 36.15 (20, 1-130)	0.6

SD: Standard deviation

BMI: Body mass index

MUCP: Maximum urethral closure pressure

PVR: Post-void residual

RESULTS

We contacted 73 eligible subjects to participate in the study. Thirteen declined to participate. The total number of subjects available to participate in this study was 60. Anticholinergic medications were effective in treating PVD, with a response rate of 72% (95% CI: 59 to 83%, $p < 0.01$). When patients who declined to participate in the study were included in the "non-responder" group during data analysis, the response rate fell to 59% (95% CI: 47 to 70%); however, the response rate was still greater than 35% (our null hypothesis), with statistical significance. We noted an almost complete concordance in response to medication; if patients responded to their anticholinergic medication for OAB they also responded for PVD. The converse was true; if they did not respond to anticholinergic medications for OAB they did not respond for PVD either. Statistical significance was not found in the difference between the responses to PVD and OAB ($p = 1$).

We reviewed the medical history of the study subjects and found no difference in symptoms or medical conditions between those who responded and those who did not respond

to anticholinergic medications. See Tables 1, 2, and 3.

DISCUSSION

In our survey, anticholinergic medications were effective in treating PVD. The response rates mirrored those of anticholinergic medications for OAB symptoms in the literature, typically ranging from 60 to 70%. Response rates to a placebo in urge incontinence studies are approximately 35% [6].

PVD is an important type of incontinence; it is relatively common and negatively affects quality of life. Temml et al. [3] found the prevalence of PVD in 16.2% of incontinent women (at least 1 episode in 4 weeks). They also noted PVD significantly decreased quality-of-life scores; 14.4% of incontinent women had a moderate to severe decrease in quality of life due to PVD. These findings underline the importance of PVD as a type of female lower urinary tract dysfunction. Coyle et al. [4] reported similar findings for prevalence and quality of life.

PVD can occur in women without OAB symptoms. In our prior study [5], we examined women evaluated for lower urinary tract symptoms ($n = 161$). Of patients examined, 41% had PVD ($n = 68$) and 15% of the patients with PVD did not have urge incontinence ($n = 10$). This 15% would go untreated without knowledge of the relationship between PVD and anticholinergic meds. Women with OAB, in theory, may have their PVD incidentally treated when they are being treated for OAB. This is the first report of the therapeutic effect of anticholinergic medications on PVD symptoms.

OAB and PVD are considered distinct clinical entities, each with its own formally recognized definition. Interestingly, there is no overlap of symptoms in their definitions, which would imply a common condition. PVD in women was defined in 2002 by the International Continence Society as "involuntary loss of urine immediately after passing urine and rising from the toilet." OAB is defined as "urgency with or without urge incontinence, usually with frequency and nocturia" [1].

We noted an almost complete concordance in response to medication; if patients responded to anticholinergic meds for OAB they likely responded for PVD. The converse was true; if they did not respond to anticholinergic medications for OAB they did not respond for PVD either.

The mechanism for how anticholinergic medications improve PVD symptoms in women is unknown, as is the relationship between OAB and PVD. Research in this area is ongoing [7-11]. It is likely that PVD is caused by some type of abnormality in

Table 2. Categorical variables.

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Variables	Post Micturition Dribble		p Value
	No response (n = 17)	Response (n = 43)	
Non-drug treatment			
sling (%)	6 (35%)	15 (35%)	1
no sling (%)	11 (65%)	28 (65%)	
Compensatory behaviors			
prolonged void (%)	5 (29%)	13 (30%)	1
no prolonged void (%)	12 (71%)	30 (70%)	
OAB response			
yes (%)	1 (6%)	42 (18%)	< 0.0001
no (%)	19 (94%)	1 (2%)	
Pelvic organ prolapse			
yes (%)	1 (6%)	5 (12%)	0.67
no (%)	19 (94%)	38 (88%)	
Prior surgeries			
Other incontinence/prolapse (%)	3 (18%)	13 (30%)	0.53
TVT/TOT (%)	5 (29%)	9 (21%)	
none (%)	9 (53%)	21 (40%)	
Stress incontinence			
yes (%)	13 (76%)	34 (%)	1
no (%)	4 (24%)	9 (21%)	
Nocturnal enuresis			
yes (%)	6 (35%)	16 (37%)	1
no (%)	11 (65%)	27 (63%)	
Pelvic pain			
yes (%)	2 (12%)	2 (5%)	0.32
no (%)	15 (88%)	41 (95%)	
Dysuria			
yes (%)	1 (6%)	1 (2%)	0.49
no (%)	16 (%)	42 (98%)	
Dyspareunia			
yes (%)	2 (12%)	5 (12%)	1
no(%)	15 (88%)	38 (88%)	

OAB: Overactive bladder

TVT: Tension-free vaginal tape sling

TOT: Transobturator sling

the micturition reflex, which is corrected on anticholinergic therapy.

One of the weaknesses of this study is that all patients received treatment for their PVD symptoms, thus no control group was used. We also used a survey for data accrual, which exposes

Table 3. Medical comorbidities.

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Variables	Post Micturition Dribble		p Value
	No response (n = 17)	Response (n = 43)	
Diabetes melitus			
yes (%)	4 (24%)	7 (16%)	0.71
no (%)	13 (76%)	36 (84%)	
Recurrent UTI			
yes (%)	3 (18%)	7 (16%)	0.7
no (%)	14 (82%)	36 (84%)	
Multiple sclerosis			
yes (%)	0	2 (5%)	1
no (%)	17 (100%)	41 (95%)	
Urethral diverticulum			
yes (%)	1 (6%)	0	0.28
no (%)	16 (94%)	43 (100%)	

UTI: Urinary tract infection

the data to recall bias. In an attempt to minimize this bias we only included women who were actively on medication or had discontinued medications within the last 30 days [12]. We also used scripted telephone interviews to collect our data so that all patients received the same information in the same way. Another weakness of this study is that all patients had OAB symptoms; therefore, we do not know how women without OAB would respond to therapy.

A review of the literature reveals that only 42% of potential candidates participate in surveys using a single mode. In this study, we used 2 modes of contact: an introductory letter, followed by a phone call. It is likely that this combination of contact methods resulted in 82% of our eligible patients consenting to participate in the survey. Only 13 subjects (18%) contacted declined to participate. This is well above the national standards for survey response rates. There were an additional 7 subjects identified via the medical records query who appeared eligible in the prescreening that we were unable to contact. It is not known whether they would have been eligible to participate in the study after screening was complete.

This study did not discriminate between anticholinergic medications. We assumed that all of the anticholinergic medications would be equally effective in treating PVD since they all have similar efficacy for treating OAB. Although all of

the drugs used in this study are of the same class and have the same mechanism of action, their chemical structures do differ somewhat. The structural differences don't affect the mechanism of action but can alter their pharmacokinetic and side-effect profiles [13,14]. This study design allowed us to have a larger sample size and therefore increased the power of the study. It also improved the generalized and relevant findings. Finally, this study design enabled us to quickly and inexpensively take a "first look" at patient response to anticholinergic medications for PVD. Future studies involving randomized controlled trials are needed to confirm the findings of this initial study.

CONCLUSION

The results of this initial study showed that in our cohort, anticholinergic medications were effective in treating PVD with an efficacy similar to that of OAB. Further research evaluating the effects of anticholinergic medications on PVD symptoms and quality of life are needed.

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Epidemiological Study on Urinary Incontinence and Overactive Bladder in Primary Care, and the Prevalence of Risk Factors (URO-RISK Study)

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ABSTRACT

Introduction: The assessment of risk factors for urinary incontinence (UI) can help the physician detect patients with UI. Apart from traditional risk factors, specifically related to stress UI, other factors such as medications and drinking habits can influence urge micturition. The present study analyzed the prevalence of risk factors for UI in a population treated in primary care centers, with at least 2 urinary symptoms.

Methods: This is an epidemiological, cross-sectional, multicenter, nonprobabilistic study with a consecutive inclusion of cases. For our case, 2 276 physicians recruited primary care patients over 18 years old with at least 2 urinary symptoms, excluding those with urethral catheters.

Results: In the 4 674 patients, with a mean age of 64.7 years, most were women (72.6%), and the most prevalent urinary symptoms were frequent urination, urgency, and nocturia. More than 90% of patients had 3 or more symptoms of UI. The most important risk habits were the intake of coffee or tea (32.3%), followed by liquid intake such as water, juice, or soft drinks (29.9%). Of our patients, 73% were taking medication, which could affect micturition. The most prevalent pathological antecedents were those linked to gender, followed by recurrent urinary infections, and diabetes.

Conclusion: Despite a high prevalence of UI in the adult population, there's a low demand for health care. Moreover, the majority of these patients have habits and risk pathologies that could be solved or at least eased with medical advice that could result in improved quality of life.

INTRODUCTION

One of the major problems in carrying out an epidemiological study focused on a disease defined by symptoms is the disparity between the definitions and the criteria of the pathology; i.e., urinary incontinence (UI). The International Continence Society defined UI as "the condition in which the involuntary loss of urine is objectively demonstrable and is a social or hygiene

problem." This definition is totally acceptable theoretically speaking; however, it poses serious problems in its practical application as it neither establishes different types of UI nor takes into account different quantities of loss [1].

Poor social awareness of this problem, together with a lack of conceptual uniformity and great clinical variations, make it difficult to ascertain UI prevalence in the general population.

KEYWORDS: Epidemiological study, health care demand, overactive bladder, quality of life, urinary incontinence

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The embarrassment and social taboo associated with this problem, as well as the idea that UI is inherent to aging [2,3], are the main causes for the lack of demand for health care. There is a suspicion that less than 50% of patients with UI consult their family doctors.

Although, in general, UI is not a serious clinical problem, its high prevalence, symptoms, and socioeconomic connotations [4-6] are the cause of an important decline of quality of life [7] by reducing autonomy and self-esteem [8,9]. It is the doctor's task to detect the problem, determine its intensity and importance, and offer the best therapeutic options.

Although exact figures are not available, the high occurrence of UI is well known. Some studies [10] observed a UI prevalence of nearly 25% in populations over 40 years old.

Despite having a great impact on patients' quality of life, most UI remains undiagnosed. Social embarrassment is one of the causes; patients do not easily comment on this problem with their family doctors. Many people also think UI is usually an age-related problem and therefore it cannot be solved. Thus, doctors must be proactive in searching for UI among their patients [11].

The assessment of risk factors for UI can help the physician detect people with UI. Apart from traditional risk factors, especially related to stress UI (age, deliveries, abdominal surgery), other factors, such as medications and drinking habits, can influence urge micturition [12].

The present study analyzed the prevalence of risk factors for UI in a population treated in primary care centers, with at least 2 urinary symptoms.

METHODS

This is an epidemiological, cross-sectional, multicenter, nonprobabilistic study with the consecutive inclusion of cases. During a 6-month period, 2 276 physicians in primary care units included the first 2 patients over 18 years old, with at least 2 UI/OAB symptoms. Those patients with a urethral catheter or without signed informed consent were not included in the study. The following symptoms were selected in order to clinically detect UI/OAB [13]: frequent micturition (the need to urinate more than 8 times in 24 hours [polyuria] or with intervals of less than 2 hours [low periodicity]), nocturia (waking up to urinate more than once at night), urgency (an uncontrollable and urgent sense of needing to urinate), urgency incontinence (sudden urine leakage preceded by urgent sensation), stress

incontinence (urine leakage when doing physical exercise such as lifting weight, jumping, or running, or physical exertion such as sneezing, coughing, or laughing), and nocturnal enuresis (bedwetting or urine leakage when sleeping).

We studied triggering and aggravating factors of UI symptoms including an increased intake of liquid or diuretic substances and smoking, pathological antecedents that could be responsible for bladder disorders, and medical treatments, both pharmacological and nonpharmacological, that could alter diuresis.

Descriptive statistics were carried out with the statistical package SPSS version 11. The χ^2 test was used to determine the existence of statistically significant gender differences in previous consultations for UI, and the Mann-Whitney test was used to establish gender differences in urinary infection (UTI) frequency and the duration of diabetes.

RESULTS

From a total of 4 853 recruited patients, 179 did not meet the inclusion criteria. The final number of participants was 4 674. Of those, 72.6% women, had a mean age of 64.7 years (SD 10.4), and a mean body mass index (BMI) of 27.6 kg/m² (SD 3.7 kg/m²).

The frequency of urinary symptoms is shown in Figure 1. The most repeated symptom was micturition frequency, followed by micturition urgency, nocturia, and urgency incontinence. Stress incontinence and enuresis were less prevalent. Over 90% of the patients showed more than 2 UI symptoms: 32.9% had 4 symptoms, 25.3% 3 symptoms, 21.1% 5 symptoms, and finally 11.2% had 6 symptoms. Of those, 23.4% had never visited their physician for UI, of which 810 were women (24.2% of the women in the study) and 269 were men (21.2% of the men in the study). This difference is statistically significant (χ^2 test; $p < 0.05$) (Figure 2).

To study the UI associated risk factors, the clinical antecedents were divided into 4 categories: risk habits, pharmacological treatments, related illnesses that could be the cause of secondary UI/OAB, and risk factors related to gender. Among the risk habits, the intake of 3 or more cups of coffee a day in 32.3% of patients was noteworthy; furthermore, 29.9% did not limit their intake of liquids (water, juice, non-cola soft drinks) and were drinking 6 or more glasses a day. These results are shown in Figure 3.

The frequency of risk treatments in patients with urinary symptoms is shown in Table 1. Of our patients, 73.2% had a

Figure 1. Frequency of micturition dysfunction systems.

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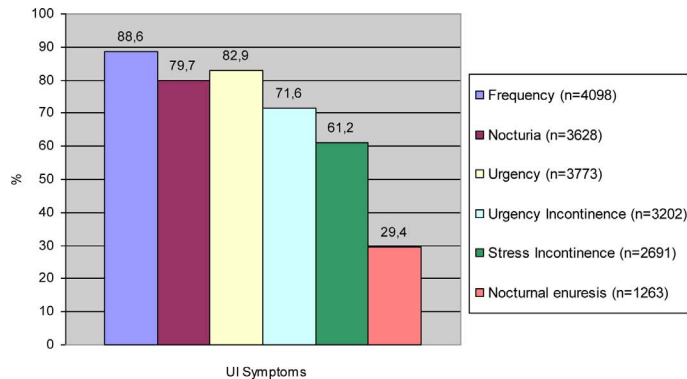
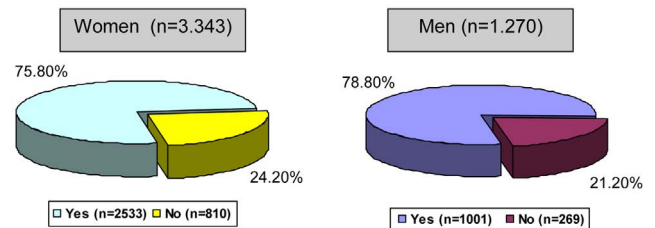


Figure 2. Patients who asked for health care for urinary incontinence and patients who did not, according to gender.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.10f2>



*We found statistically significant differences (χ^2 test ; $p < 0.05$).

pharmacological treatment that could alter diuresis. With respect to diseases that could cause secondary UI/OAB, the most frequent ones were recurrent urinary tract infection (UTI) (34.6%, mean 3.1 infection/year; SD 1.7), with a significantly higher frequency in women (Mann-Whitney test, $p < 0.05$), and diabetes mellitus (23.1%). According to the Mann-Whitney test ($p > 0.05$) there were no statistically significant differences in gender with regard to the duration of diabetes (Table 2). Of our patients, 13.2% had digestive pathologies and 12.4% had undergone a urological or gynecological operation. The less prevalent risk pathologies were neurological diseases (7.3%) and digestive surgery (5%) (Figure 4). Pathological antecedents related to gender were noteworthy; 52.5% of women had had 3 or more pregnancies while 61.7% of men had been diagnosed with benign prostatic hyperplasia.

It should be noted that the results could be biased as patients were recruited from primary care only; therefore, these results may not be representative of the general population.

DISCUSSION

Urinary continence is the result of the urinary bladder and urethra working in perfect coordination, as micturition and continence are the result of 2 opposing forces: intravesical and intraurethral pressure. The neurological mechanisms that make continence possible are still not understood, which makes controlling incontinence all the more complex [10]. Anything that affects the process at any point can lead to a dysfunction resulting in urinary incontinence (UI).

There are multiple sets of symptoms depending on the underlying disorder. Clinical disparity together with great variability in its intensity and lack of awareness among some patients is responsible for the unknown prevalence of UI. Current medical literature offers a wide range of levels of prevalence. For example, in Spain it is estimated that between 25 and 45% of women over 20 years old and between 7 and 11% of men of the same age suffer from UI. American guidelines indicate a prevalence of 15 to 35% among those over 60 [11]. In the present study, the number of women who had never before visited their doctors (24.2%) in comparison with men (21.4%) is notable (Figure 2). Moreover, this figure varies in gender depending on age. The study UrEpik showed that young men had less prevalence of UI symptoms while the proportion was reversed in the elderly [12]. But there are other factors that influence UI such as treatments, pathological antecedents, and lifestyle choices (smoking, alcohol intake, dietary habits).

The prevalence of UI in women varies according to different studies. The cause seems to be a lack of homogeneity in populations, with differences in age range, type of UI, and the patient. In the most recent works, we found a mean prevalence of 25 or 26% according to Hannestad [14] and Temml [15], respectively, but also much lower estimations by Bortolotti (11%) [16] or notably higher by Moller (72%) [17]. The main types of UI, mostly associated with women, are stress UI, urgency incontinence or mixed urgency-frequency, and mixed UI, which includes all the aforementioned.

Among all women with incontinence, stress UI had a mean prevalence of 49% (range between 24 to 75%), urgency UI

Table 1. Risk habits in patients with micturition dysfunction symptoms.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.10t1>

	n	%
Sedatives/hypnotics	1568	33.5%
Antidepressants	1245	26.6%
Calcium antagonists	995	21.3%
Diuretics	796	17%
Anticholinergics	694	14.8%
Alpha-blockers	418	8.9%
Beta-blockers	315	6.7%
Antipsychotics	177	3.8%
Chemotherapy	55	1.2%
Radiotherapy	50	1.2%
Total patients with risk treatments	3422	73.2%
Total patients in study	4674	100%

21%, (7 to 49%), and mixed UI of 29% (11 to 61%) [18]. In this study, which included patients with 2 or more symptoms of UI/OAB, the prevalence of stress UI was 61.2%, with no difference in gender.

Different types of UI in women had different age distributions. Stress UI is frequent in young and middle-aged women but decreases at about 50 to 59 years of age, while urgency and mixed UI gradually increase with age [15]. Also, UI severity varies according to different types. In the EPICONT study [14], mild UI accounted for 53% of stress, 39% of urgency, and 31% of mixed UI. In all types, severity increases with aging.

UI epidemiology in men has been much less researched. All studies have confirmed a lower prevalence of UI compared to women, at a rate of 1:2. Besides, the age distribution, types of UI, and the associated risk factors are completely different due to anatomical and etiopathogenic differences. As with women, the UI prevalence in men varies according to different studies but the differences are milder. Values range from 3% in Feneley [19], 5% in Schulman [20], 9% in Thomas [4] and Malmsten [21], and 11% in Yarnell [22]. The most prevalent UI in men is urgency UI (40 to 80%), followed by mixed UI (10 to 30%), and stress UI (less than 10%) [18]. There is an increase of UI with aging but the rise is more gradual than in women, and most new cases are urgency UI.

Figure 3. Risk habits in patients with micturition dysfunction symptoms.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.10f3>

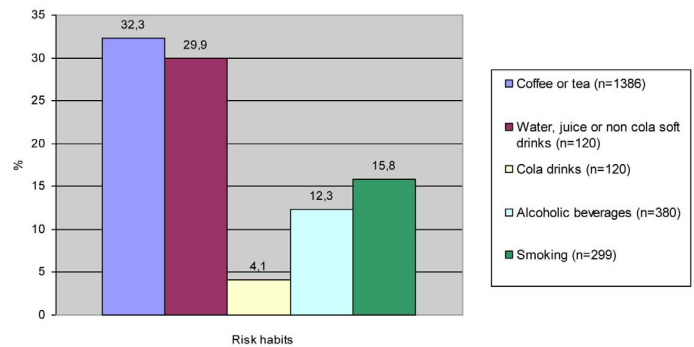
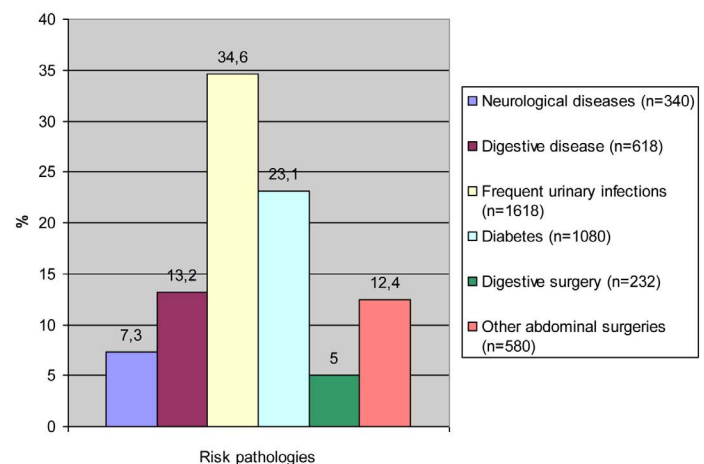


Figure 4. Risk pathologies in patients with symptoms of micturition dysfunction.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.10f4>



Ueda [23] shows an increase in prevalence from 0.7% in the 50- to 59-year age range, 2.7% in 60 to 69 years, and up to 3.4% in those older than 70. In relation to stress UI, the same author established prevalence levels of 0.5%, 0.5%, and 0.1% for the same age ranges, respectively. In the present study, the most important urinary symptoms were micturition urgency

Table 2. Characteristics of risk pathologies according to gender.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.10t2>

	Men			Women			Total			p*
	Mean	SD	n	Mean	SD	n	Mean	SD	n	
Number of urinary infections a year	2.8	2.1	298	3.2	1.6	1160	3.1	1.7	1458	< 0.001
Duration of diabetes (years)	6.1	5.5	204	5.8	5.2	514	5.9	5.3	718	0.469

* Mann-Whitney test

(82.9%), frequency (88.6%), urgency UI (71.6%), and nocturia (79.7%). These high percentages were due to the fact that they were present in almost all men of the study, but they were also found in women because one of the inclusion criteria was to have at least 2 urinary symptoms.

UI symptoms are especially frequent in the elderly. It is estimated that 15% of those over 65 suffer from UI. This percentage increases to 30 to 40% in case of hospital admission due to acute process, and it reaches its maximum (50 to 60%) in geriatric patients. Such high prevalence has reinforced the idea that UI symptoms are a normal part of the aging process. However, nowadays urinary continence is a basic function that healthy elderly people should maintain, independent of age, and its loss has to be taken as a symptom of a dysfunction and not as a normal consequence of the aging process [24]. Physiological alterations associated with aging do not have enough impact to cause UI. The high UI prevalence in the elderly is better explained in relation to multiple pathologies and combined therapies, which, together with mental and physical deterioration, are the most directly related factors to UI in the elderly [25].

Along with aging, other risk factors are associated with incontinence. Some habits can increase micturition volume in different ways.

Liquid, coffee, tea, and alcohol intake, as well as smoking, can alter the micturition volume and aggravate or rush UI. One of the most frequent habits is coffee/tea intake, present in 32.3% of patients at elevated doses (> 3 cups a day), and it highlights the room for improvement in many patients merely with dietary advice. Somewhat similar is the problem with pharmacological treatments, which can affect diuresis. The most frequent ones were sedatives/hypnotics (33.5% of patients in the study), antidepressants (26.6%), calcium antagonists (21.3%), and diuretics (17%). The combination of several pharmacological

treatments, each of them able to affect micturition, can exponentially increase urinary symptoms. This is one of the key points where the intervention of the physician, by leaving out unnecessary treatments, substituting drugs or reducing doses, can improve not only the patients' quality of life but also possible urological complications [25].

The most important pathological antecedents associated with UI are those related to gender. Many studies have shown the relation between UI and childbirth, increasing the severity of UI with the number of deliveries [4,26]. In our study, 52.5% of women had had 3 or more pregnancies. Childbirth may weaken and loosen pelvic floor muscles or harm perineal muscles or nerves. Other antecedents associated with female UI are menopause, due to genital trophic changes secondary to oestrogen depletion, and hysterectomy, due to possible nerve lesions and alterations to the bladder muscular fascia and pelvic wall [18].

Almost 2/3 of men in the study had antecedents of benign prostatic hyperplasia. The blockage of the lower urinary tract generates, over time, a hypertrophy of the detrusor urinae that can aggravate urgency UI [5]. Once the blockage is present, urine retention increases the risk of infection, which might aggravate symptoms and even lead to acute retention, sometimes clinically shown as overflow UI [18].

Among risk factors not related to gender, UTI was the most frequent (34.6%), suffered to a greater extent by women (Mann-Whitney test, $p < 0.05$). Thus, micturition disorder is, in many patients, the main cause for infections, generally because of traces of urine. These infections aggravate symptoms because of an increase in urgency symptoms and pollakiuria. This condition is usually associated with genital dystrophia secondary to hypoestrogenism during menopause in women. The frequency of urinary infections is 3.1 episodes a year (TD 1.6)

and they are favored by the concurrence of other alterations that can act as risk factors (neurological disorders, abdominal surgery, and especially diabetes). Lesions of the urological structures are the main cause of UI in patients undergoing abdominal surgery, and more frequently in gynecological and urological surgery. Radical prostatectomy is the operation with the highest rate of micturition dysfunction (5 to 60%), although it usually subsides in intensity during the first 2 years after surgery [27,28]. Due to the neurological complexity of micturition, neurological lesions are normally involved in UI, both central (neurovascular accidents, Parkinson's disease, etc.) and peripheral, among which the most frequent is diabetes-related neurogenic bladder [18].

Therefore, diabetes is, after urinary infections, the most prevalent (23.1%) pathological risk factor in the present study, with a mean duration of 5.9 years with no differences in regards to gender. With these patients, the physician has another line of action through the strict control of glycemia and proper monitoring of the diabetic patient, which will allow the prevention, or at least early detection, of possible urological complications that can result from long-term diabetes.

CONCLUSION

Disparity of UI definitions, clinical varieties, and, most important, the low rate of consultation for this problem are all factors that make it difficult to accurately determine UI prevalence in the general population. In the present study, the most relevant urinary symptoms have been frequency and urgency. Most patients had 3 or more symptoms related to this dysfunction. In spite of the symptoms, almost a third of patients do not limit their liquid intake and even claim to regularly take diuretic substances. One explanation of this fact could be that patients are unaware of the impact that fluid intake has on their symptoms. This indicates that education and behavioral modification would have a potential impact on the urinary symptoms of these patients. The most important aggravating or triggering factors in this study have been pharmacological treatments, present in up to 73% of patients, and gender-related factors, such as childbirth in women—more than half of whom had had 3 or more pregnancies—and benign prostatic hyperplasia in men, with more than 60%.

The physicians' task to ease or eliminate UI symptoms can be carried out on different levels: the detection of patients who have the problem but do not consult, advice on changing risk habits, the adjustment of pharmacological treatments, and the control of associated pathologies and specific treatments depending on the type of symptoms. All the above should lead

to the most important goal, namely to increase the quality of life of these patients.

Doctors should adopt a proactive attitude to find and help patients with urinary incontinence and overactive bladder because most micturition habits, treatments, and risk pathologies could be solved with the doctor's advice, thus improving quality of life.

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Shock Wave Lithotripsy Re-treatment Rates Among 3 Different Lithotripters

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ABSTRACT

Purpose: There is controversy as to whether electromagnetic (EM) lithotripters are associated with higher fragmentation and lower re-treatment rates when compared with electrohydraulic (EH) lithotripters. Therefore, the aim of the present study was to compare SWL re-treatment rates of two EH lithotripters (the Siemens LITHOSTAR and Philips Litho Diagnost M) together with an EM mobile lithotripter (the Storz MODULITH SLX-F2) at a single center.

Methods: A retrospective review of a SWL database was performed for patients with radio-opaque stones between July 2001 and February 2010. A total of 6 434 SWL treatments were included (2 824 with Siemens, 3 136 with Philips, and 474 with Storz). Patients presenting for SWL re-treatment of the same stone were considered SWL failures. Clinical follow-up information was available only for patients treated by the Storz lithotripter.

Results: The Storz lithotripter had a significantly lower re-treatment rate (14.7%) when compared with the Siemens (18.8%, OR = 1.34, $p = 0.04$) and the Philips (19.6%, OR = 1.41, $p = 0.01$). However, on multivariate analysis, the Storz significantly differed only from the Philips (OR = 1.36, $p = 0.02$). When compared with renal pelvic stones, stones in the upper calyx were associated with significantly lower re-treatment rates (OR = 0.65, $p = 0.02$), whereas distal ureteral stones were associated with significantly higher re-treatment rates (OR = 1.30, $p = 0.01$). The Storz lithotripter was associated with higher fluoroscopy time (2.4 ± 1.3 min) when compared with the Siemens (1.74 ± 0.8 min) and the Philips (2.13 ± 1.1 min, $p = 0.001$).

Conclusion: In the present retrospective study, the EM Storz SLX-F2 lithotripter was associated with significantly lower re-treatment rates compared with the Philips EH lithotripter, but not the Siemens.

INTRODUCTION

Since the early 1980s, shock wave lithotripsy (SWL) has been established as a minimally invasive procedure for the treatment of urinary stones. In 1982, Chaussy and colleagues installed

the first electrohydraulic (EH) lithotripter, Human Model 2, in Munich while the first widely distributed clinical lithotripter, the Dornier HM3, was introduced to the United States 2 years later [1]. Since then, several generations of different types of lithotripters have been developed to improve patient comfort

KEYWORDS: Shock wave lithotripsy, lithotripters, retreatment rate

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ACRONYMS AND ABBREVIATIONS

EH: Electrohydraulic
EM: Electromagnetic
SWL: Shock Wave Lithotripsy

N/A: Not applicable
OR: Odds ratio

Table 1. Specifications of the 3 lithotripters.

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Variables	Siemens	Philips	Storz
Energy source	EH spark-gap electrode	EH	Dual focus EM
Coupling system	Water cushion	Water cushion	Water cushion
Aperture diameter	12 cm	20 cm	30 cm
Imaging system/localization	X-ray and separate ultrasound	X-ray and ultrasound	In-line fluoroscopy/in-line ultrasound
Focal zone (W x L)	5 x 80 mm	8 x 38 mm	Dual focus (6 x 28 to 9 x 45 mm)
Focal distance	11.3 cm	15 cm	16.5 cm
Date of installation	1984	September 2004	June 2009

and safety, optimize handling, reduce costs, and provide multifunctional use. This treatment comfort is a trade-off for less effective stone disintegration and a higher re-treatment rate when compared with the gold standard, the Dornier HM3 [2-5]. In addition to stone- and patient-related factors, the type of lithotripter used affects fragmentation and re-treatment rates [6]. Currently, it is controversial whether or not electromagnetic (EM) lithotripters are better than the original electrohydraulic (EH) lithotripters. Some authors found that EM lithotripters had higher re-treatment rates when compared with EH lithotripters (63% versus 55%) [7]. However, there was no difference in stone-free rates (83% versus 84%) [7]. Others reported significantly lower re-treatment rates for EM lithotripters when compared with EH lithotripters (34% versus 51.6%, $p < 0.001$), with significantly higher success rates (88.5% versus 82.4%, $p = 0.03$) [8]. Therefore, the aim of the present study was to compare re-treatment rates of 2 EH lithotripters; the Siemens LITHOSTAR and the Philips Litho Diagnost M with a Storz MODULITH SLX-F2 EM lithotripter at a single center.

METHODS

A retrospective review of a SWL database using 3 different lithotripters was performed. The Siemens LITHOSTAR (Siemens Medical Solutions, Erlangen, Germany) and the Philips Litho Diagnost M (Philips Healthcare, Eindhoven, The Netherlands) had EH generators, whereas the Storz MODULITH SLX-F2 (Storz Medical, Kreuzlingen, Switzerland) was a mobile EM lithotripter with dual focal zones. The specifications of these lithotripters are presented in Table 1. For each SWL treatment, stone size, and location, fluoroscopy time (in minutes) and fragmentation as assessed by fluoroscopy was recorded. A total of 1 195 treatments with incomplete data were excluded; 533, 616, and

46 treatments were recorded for Siemens, Philips, and Storz, respectively. In addition, 377 (5.5%) treatments for radiolucent stones were excluded (163, 198, and 16 for Siemens, Philips, and Storz lithotripters, respectively). Therefore, a total of 6 434 SWL treatments for radio-opaque stones were included (2 824 with Siemens [July 2001 to August 2004], 3 136 with Philips [September 2004 to May 2009], and 474 with Storz [June 2009 to February 2010]). In all lithotripters, shock waves were coupled to the patient by water-filled cushions directly abutting the patient with an ultrasound-compatible jelly interface. Intravenous sedation was used in most patients. Patients were treated at a rate of 2Hz, whereas SWL re-treatments were treated at a rate of 1Hz.

Treatment outcomes were assessed by intraoperative fluoroscopy at the end of the SWL session. SWL re-treatment was defined as repeat SWL sessions for the same stone; therefore, patients presenting for re-treatment of the same stone were considered SWL failures. Patients who failed treatment with a particular lithotripter, and were subsequently treated with another lithotripter for the same stone, were considered a re-treatment session for the original lithotripter. Patients with SWL failures were referred for a second SWL session rather than more invasive procedures such as ureteroscopy or percutaneous stone extractions. For the Siemens and Philips lithotripters, patients who failed 2 SWL sessions and underwent subsequent ureteroscopy were not captured in the current database. Clinical and radiologic follow-up, including auxiliary procedures, were only available for the Storz lithotripter.

Data analysis was done using the commercially available Statistical Package of Social Sciences for Windows (SPSS, Chicago, IL), version 17. Descriptive data were presented

Table 2. Stone location among the 3 lithotripters.
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Stone location	Siemens	Philips	Storz	p value	Total
Renal	1 466 (51.9%)	1 674 (53.4%)	270 (57%)	0.11	3 410
Upper calyx	148 (5.2%)	165 (5.3%)	21 (4.4%)	0.78	334
Middle calyx	155 (5.5%)	233 (7.43%)	52 (11%)	< 0.001	440
Lower calyx	566 (20%)	596 (19%)	117 (24.8%)	0.02	1 279
Renal pelvis	597 (21.1%)	680 (21.7%)	80 (16.9%)	0.054	1 357
Ureteral	1 358 (48.1%)	1 462 (46.6%)	204 (43%)	n/a	3 024
Proximal ureter	718 (25.4%)	722 (23.02%)	112 (23.6%)	0.10	1 552
Mid ureter	188 (6.7%)	224 (7.14%)	13 (2.7%)	< 0.001	425
Distal ureter	452 (16%)	516 (16.5%)	79 (16.7%)	0.86	1 047
Total	2 824	3 136	474	n/a	6 434

in terms of numbers, percentages, means, and standard deviations. Continuous variables were compared using an analysis of variance (ANOVA), while the Fisher's exact test was used to compare categorical variables where a 2-tailed p value of < 0.05 was considered statistically significant. Multivariate logistic regression was performed to compare re-treatment rates among the 3 lithotripters.

RESULTS

Left-sided stones represented 55.8, 56.4, and 52.7% of stones for the Siemens, Philips, and Storz lithotripters, respectively ($p = 0.34$). There was no significant difference in the percentage of renal stones treated among the 3 lithotripters: Siemens (51.9%), Philips (53.4%), and Storz (57%) ($p = 0.11$). In terms of stone location, the most common stone location was the proximal ureter in the 3 lithotripters (25.4, 23, and 23.6%), followed by the renal pelvis for Siemens and Philips lithotripters (21.1 and 21.7%, respectively), and the lower pole calyx for Storz (24.8%) (Table 2). When all 3 lithotripters were compared, Storz had a significantly higher percentage of stones in the middle and lower calices ($p < 0.001$ and $p = 0.02$, respectively) and a significantly lower percentage of midureteral stones ($p < 0.001$) (Table 2). In terms of mean stone size, there was a significantly larger mean stone size with Philips (10.3 mm \pm 3.2) when compared with Siemens (9.6 mm \pm 3.4) and Storz (9.7 mm \pm 3.0) ($p = 0.001$). The Storz lithotripter was associated with a significantly higher fluoroscopy time (2.4 \pm 1.3 minutes) when compared with Siemens (1.74 \pm 0.8 minutes) and Philips (2.13

Table 3. Re-treatment rates among the 3 lithotripters.
<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.05t3>

Variables	Siemens	Philips	Storz	p value
Re-treatment rates	18.8%	19.6%	14.7%	0.04*
Mean stone size (mm)	9.6 \pm 3.4	10.25 \pm 3.18	9.73 \pm 3	0.001*
Mean fluoroscopy time \pm SD (min)	1.74 \pm 0.78	2.13 \pm 1.07	2.4 \pm 1.3	0.001*
Energy \pm SD	4.46 \pm 0.99	21.9 \pm 3.22	7.03 \pm 2.63	n/a

\pm 1.1 minutes) ($p = 0.001$). Furthermore, the mean \pm SD energy levels used for each of the lithotripters are reported in Table 3. Since these energy levels were not comparable (different units), statistical analysis was not applicable.

The re-treatment rates for renal and ureteral stones were 18.3 and 19.4% for Siemens, 17.7 and 21.7% for Philips, and 15.2 and 14.2% for Storz (Table 4). The Storz lithotripter had significantly lower re-treatment rates (14.7%) when compared with Siemens (18.8%, OR = 1.34, $p = 0.04$) and Philips (19.6%, OR = 1.41, $p = 0.01$). On the multivariate analysis, the Storz lithotripter significantly

Table 4. Re-treatment rates by location among the 3 lithotripters.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.05t4>

Variable	Siemens	Philips	Storz	Total
Renal	268 (18.3%)	297 (17.7%)	41 (15.2%)	606 (17.8%)
Upper calyx	16 (10.8%)	24 (14.5%)	2 (9.5%)	42 (12.6%)
Middle calyx	25 (16.1%)	37 (15.9%)	6 (11.5%)	68 (15.4%)
Lower calyx	113 (20%)	111 (18.6%)	26 (22.2%)	250 (19.6%)
Pelvis	114 (19.1%)	125 (18.4%)	7 (8.8%)	246 (18.1%)
Ureter	263 (19.4%)	317 (21.7%)	29 (14.2%)	609 (20.1%)
Proximal ureter	130 (18.1%)	136 (18.8%)	17 (15.2%)	283 (18.2%)
Mid ureter	43 (22.9%)	48 (21.4%)	3 (23%)	94 (22.1%)
Distal ureter	90 (19.9%)	133 (25.8%)	9 (11.4%)	232 (22.2%)
Total	531 (18.8%)	614 (19.6%)	70 (14.7%)	1 215 (18.9%)

differed only from Philips (OR = 1.36, $p = 0.02$). On the multivariate analysis, when compared with renal pelvic stones, stones in the upper calyx were associated with significantly lower re-treatment rates (OR = 0.65, $p = 0.02$) and stones located in the distal ureter were associated with significantly higher re-treatment rates (OR = 1.30, $p = 0.01$) (Table 5).

DISCUSSION

Since the introduction of the Dornier HM3 more than 2 decades ago, efforts have been made to design a lithotripter capable of maximizing stone fragmentation while minimizing pain and renal injury. More attention has been given to reduce the focal point size by increasing the aperture, thus increasing the peak-point pressure to reduce the patient's discomfort and renal injury. However, newer designs have demonstrated higher re-treatment rates owing to the difficulty of keeping the stone in the smaller focal zone [9]. This SWL failure may be lithotripter dependent, stone related (size, location, density), patient related (skin-stone distance, musculoskeletal deformities), or attributable to intrarenal anatomy and drainage [10]. Controversy exists about the superiority of modern EM energy sources over that of EH lithotripters. EM sources have the advantages of delivering several hundred thousand shock waves before servicing, thereby eliminating the need for frequent electrode replacement as with EH lithotripters. Direct comparisons of lithotripter efficacy are quite difficult because of the difference in study populations and treatment protocols. A prospective randomized study would require the simultaneous

presence of more than 1 lithotripter at a single center, which is impractical [6]. In the present retrospective study, SWL re-treatment rates among the 3 different lithotripters at a single center were reviewed. The Storz MODULITH SLX-F2, an EM lithotripter, was found to be associated with significantly lower re-treatment rates (14.7%) when compared with 2 EH lithotripters, the Siemens LITHOSTAR (18.8%, OR = 1.34, $p = 0.04$) and the Philips Litho Diagnost M (19.6%, OR = 1.41, $p = 0.01$). Upon multivariate analysis, there was a significant difference between the Storz and Philips lithotripters (OR = 1.36, $p = 0.02$) (Table 5). It is important to note that for the present study, auxiliary procedures for the Siemens and Philips lithotripters were not available. Therefore, once these auxiliary procedures are added, the re-treatment rates for both lithotripters would increase the difference between the EM Storz and these 2 EH lithotripters.

In a previous study, both the EH and EM lithotripters were found to be equally efficacious with comparable stone-free rates (83% versus 84%) and re-treatment rates (55% versus 63%) [7]. In another study, a second generation EH lithotripter had similar results when compared with a fourth generation EM lithotripter in terms of stone-free rates (64.5% versus 61.1%, $p = 0.07$) and re-treatment rates (3.6% versus 4.5%, $p = 0.21$) [11]. In another study, comparing EH and EM sources at a single center revealed that the EH lithotripter was associated with significantly higher stone-free rates when compared with the EM lithotripter (77% versus 67%, $p = 0.01$) but also with a significantly higher rate of auxiliary procedures (56%

Table 5. Univariate and multivariate analysis of re-treatment rates.

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Variable	Re-treatment rate No (%)	Univariate analysis		Multivariate analysis	
		OR (95% CI)	p value	OR (95% CI)	p value
Stone location					
Upper calyx	42 (12.6)	0.65 (0.46 - 0.92)	0.02	0.65 (0.46 - 0.93)	0.02
Middle calyx	68 (15.4)	0.82 (0.61 - 1.10)	0.19	0.84 (0.63 - 1.13)	0.25
Lower calyx	250 (19.6)	1.11 (0.90 - 1.34)	0.35	1.13 (0.93 - 1.38)	0.22
Renal pelvis	246 (18.1)	1	Reference	1	Reference
Proximal ureter	283 (18.2)	1.01 (0.83 - 1.22)	0.94	1.02 (0.84 - 1.23)	0.86
Mid ureter	94 (22.1)	1.28 (0.98 - 1.68)	0.07	1.29 (0.99 - 1.69)	0.06
Distal ureter	232 (22.2)	1.29 (1.05 - 1.57)	0.01	1.3 (1.06 - 1.59)	0.01
Stone size	n/a	1 (0.98 - 1.02)	0.88	1 (0.99 - 1.02)	0.74
Fluoroscopy time	n/a	0.98 (0.92 - 1.05)	0.61	0.99 (0.93 - 1.06)	0.73
Siemens	18.8	1.34 (1.02 - 1.75)	0.04	1.3 (0.99 - 1.72)	0.06
Philips	19.6	1.41 (1.07 - 1.84)	0.01	1.36 (1.04 - 1.79)	0.02
Storz	14.7	1	Reference	1	Reference

versus 47%, $p = 0.04$) [12]. Although the EH lithotripter was associated with a higher SWL re-treatment (40% versus 10%), this was not significant ($p = 0.21$) [12]. Similarly, in a prospective randomized trial comparing the EH with the EM lithotripter, the EH lithotripter was associated with significantly higher re-treatment rates (51.6% versus 34%, $p < 0.001$) and significantly lower stone-free rates (82.4% versus 88.5%, $p = 0.03$) [8]. These findings are comparable to the results of the present series where the Storz EM lithotripter was associated with a significantly lower SWL re-treatment rate when compared in the multivariate analysis with the Philips EH lithotripter.

In another study, 2 EH lithotripters were compared with an EM lithotripter [4]. Although there was no significant difference in terms of stone-free rates at 3 months (87, 80, and 81%, $p > 0.05$), the EH lithotripters were associated with significantly lower re-treatment rates (4, 13, and 38%, ($p < 0.05$) [4]. However, in this study, authors followed patients on the postoperative day with plain X-rays and ultrasonography, and they may have had re-treated stones that would have passed spontaneously after the EM lithotripsy.

In the present study, the Storz lithotripter was associated with significantly higher fluoroscopy time (2.4 ± 1.3 minutes) when

compared with Siemens (1.74 ± 0.8 minutes) and Philips (2.13 ± 1.1 minutes) ($p = 0.001$) (Table 3). This may be due to the fact that the Storz lithotripter is a mobile lithotripter that had to be used with a mobile C-arm fluoroscopy unit. Furthermore, the higher fluoroscopy usage also reflects the initial training with this new lithotripter.

The Storz lithotripter was only used for 6 months to treat 20% of patients in the database while the Siemens and Philips lithotripters were used for over 50 months each. Therefore, 1 of the limitations of the present study is the small sample size for the Storz lithotripter. Perhaps with a larger sample size, there would have been a significant difference between the Storz and Siemens lithotripters on the multivariate analysis. Another limitation of the study is that only the SWL re-treatment was captured in the database. Follow-up information regarding stone-free rates, stone composition, or auxiliary procedures such as ureteroscopy were not captured because patients were referred to this tertiary care center for SWL, and were then cared for by the referring urologist. Furthermore, at the time of acquisition of the Storz lithotripter, a dedicated endourologist (SA) was hired. This may have contributed to the lower SWL re-treatment rates with the Storz lithotripter. The sequential acquisition of the 3 lithotripters may introduce bias in terms of

changes in patterns of referral and practice over time.

CONCLUSION

Retrospective analysis of the SWL database at a single lithotripsy center showed that SWL re-treatment rates significantly varied depending on the type of lithotripter used and stone location. The EM Storz SLX-F2 lithotripter was associated with significantly lower re-treatment rates compared to the Philips EH lithotripter, but not the Siemens EH lithotripter.

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The Era of Tubeless Percutaneous Nephrolithotomy

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ABSTRACT

Objective: To prescribe our experience in performing tubeless percutaneous nephrolithotomy and how we diagnose its indication, safety, and effectiveness.

Methods: Two hundred and fifty-three patients with renal stones were enrolled for a tubeless percutaneous nephrolithotomy with an externalized ureteric catheter. Their ages ranged between 4 to 80 years old, and of the sample, 168 were male and 85 were female. The stones ranged from 15 to 80 mm in size and were located in different areas of the pelvicalyceal system. The majority of the procedures were conducted in the prone position while 24 cases were supine. The majority of the patients were treated with a single puncture, 20 patients were treated with double punctures, and 2 patients required 3 punctures. Hemostatic substances were used in only 50 of the patients, with no significant differences when compared to 50 who were treated without. In addition, 40 patients had a history of previous ipsilateral renal surgery, 20 had renal impairments, and 15 had a solitary kidney.

Results: The mean operative time was 44.34 minutes, the mean stent time was 1.1 days, and the mean hospital stay was 1.6 days. The mean drop in Hb levels was 1.67gm/dl, with 3.95% of the patients needing blood transfusions and 12.65% needing postoperative analgesia. The stone-free rate was 91.76% while the overall success rate was 97.25%. Complications were encountered in 7.9% of the patients, most of which were minor and were managed conservatively. One patient suffered from a colonic injury and 2 patients suffered from hydrothorax.

Conclusion: In the era of tubeless percutaneous nephrolithotomy, nephrostomy tube insertion should only be used for large residuals that need a second look. Tubeless percutaneous nephrolithotomy should be extended to include large stones, multiple numbers, multiple punctures, prone or supine positions, sub- or supracostal approaches, recurrent cases, solitary kidneys, renal impairment, extended time, and bilateral simultaneous cases. It's safe and effective, and it decreases postoperative pain, discomfort, the need for analgesia, and the length of hospital stay.

KEYWORDS: Percutaneous, nephrolithotomy, tubeless, ureteric, catheter

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Table 1. Patient demographic data and stone characteristics.
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Gender	
Male	168
Female	85
Total	253
Age (years)	
Minimum	4
Maximum	80
Mean	39.7
Renal units	
Right	136
Left	119
Total	255
Stone size (mm)	
Minimum	15
Maximum	80
Mean	37.68
Stone site	
Pelvis	85
Pelvis + lower calyx	75
Pelvis + upper + lower calyx	27
Pelvis + upper calyx	18
Pelvis + middle calyx	17
Pelvis + middle + lower calyx	13
Lower calyx	11
Upper calyx	5
Pelvis + upper calyx	4

INTRODUCTION

Goodwin's description of percutaneous nephrostomy (PCN) in 1955 and Fernstrom and Johansson's first publication of percutaneous nephrolithotomy (PNL) in 1976 are considered some of the most important milestones in the history of percutaneous renal surgery [1,2]. Wikchamen conducted trials omitting the placement of a nephrostomy tube in 100 patients as early as 1984 [3]. However, premature nephrostomy

tube removal by Winfield, which led to more complications such as serious hemorrhaging, marked urinary extravasation necessitating transfusion, internal stenting, and prolonged hospitalization made urologists adherent to the policy of nephrostomy drainage [4]. Bellman and associates challenged the requirement for the routine placement of a nephrostomy tube after PNL and were the first to use the term tubeless PNL [5]. Since then there have been increased reports of tubeless PNL utilization [6-11].

In this study we present our experience with tubeless PNL, with very limited exclusion criteria as part of the new era of percutaneous renal surgery.

PATIENTS AND METHODS

Two hundred and fifty-three patients (255 renal units) with renal stones of different sizes, at different locations, were enrolled and underwent tubeless percutaneous nephrolithotomy (TPNL) in the Urology and Nephrology Center in the period between July 2004 and September 2010. Stone size was determined by measuring the greatest dimension of the stone in plain film. The demographic data of the patients and stone characteristics are shown in Table 1. In the majority of the cases, the procedure was done under general anesthesia as 1 stage TPNL in the prone position; in some cases the supine position was used. Operative time was measured from the moment of puncturing the calyx up until the suturing of the puncture site. The time limit was not considered exclusive criteria. Cases of multiple punctures, unilateral or bilateral, solitary kidney, renal impairment, bleeding to any degree, or pelvicalyceal system injury were not excluded from the study as the bleeding was stopped by deeply suturing the wound (Figure 1, Figure 2, Figure 3) or using a hemostat, in addition to the normal hemostatic function of the body.

Simultaneous bilateral TPNL was performed in 2 patients with 2 punctures in one side and 1 in another side (Figure 4). The procedure was done via the insertion of a 6 Fr ureteric catheter in which opacification of the pelvicalyceal system is performed, as well as puncturing the kidney by the urologist under fluoroscopy guidance. Classic dilatation of the tract using Alkenes serial metallic dilators was performed in the first 100 cases. In the remaining cases, acute dilatation using a facial scalpel then an Amplatz 30 Fr dilator over a central rod was used, followed by the insertion of a 34 Fr Amplatz sheath. A 24 Fr working nephroscope was used, followed by stone disintegration using a pneumatic lithoclast (Swiss lithoclast EMS). Finally, the fragments were removed with 3-jaw, grasping forceps.

Figure 1. Amplatz sheath at the end of the procedure.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.04f1>



Figure 2. After removal of the Amplatz sheath.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.04f2>



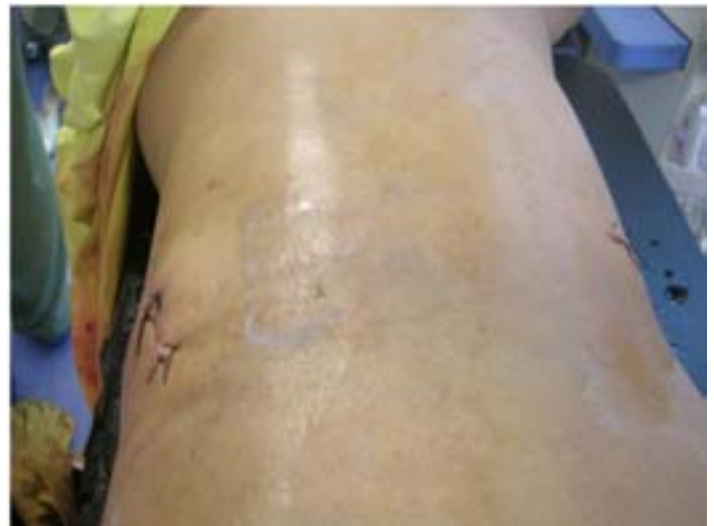
Figure 3. After taking a deep 0 silk stitch.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.04f3>



Figure 4. Bilateral simultaneous TPNL; 2 punctures in left and 1 in the right.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.04f4>



After removing all the stone fragments, careful endoscopic and fluoroscopic inspection of the system to check for any significant

residual fragments was performed. The nephroscope was then removed, and the sheath was withdrawn to the periphery

Table 2. Treatment details.
<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.04t2>

Criteria	
Position	
Prone	229
Supine	24
Approach	
Subcostal - lower calyx	220
Subcostal - middle calyx	17
Supracostal - middle calyx	12
Supracostal - upper calyx	10
Puncture number	
Single	233
Double (20)	40
Triple (2)	6
Total	279
Operative time (minutes)	
Minimum	15
Maximum	100
Mean	44.34
Stent time (hours)	
Minimum	7
Maximum	72
Mean	26.65 (1.1 days)
Hospital stay (hours)	
Minimum	12
Maximum	96
Mean	38.34 (1.6 days)
Blood transfusion	
No/total	10/253
Rate	3.95%
Analgesia (declofinac sodium 75 mg/IM)	
One injection	19
Two injections	10
Three injections	3
Total	32 (12.65%)
Stone-free rate no. (%)	
Stone free	234 (91.76%)
Insignificant residual stone (< 5 mm)	14 (5.49%)
Significant residual stone (> 5 mm)	7 (2.75%)
Success rate	97.25%

of the calyx. A retrograde pelvicalycography was performed to ascertain the integrity of the collecting system, and the sheath was withdrawn after applying SURGICEL, Spongstan, or GELFOAM, which was inserted in a sample of 50 patients. In the rest of the study group, only the deep stitch technique was completed, which stopped the bleeding at once. The patients were left with an inserted ureteric catheter only. Hemoglobin level was measured after 12 hours, and on the next day, all patients were evaluated by plain X-ray and an abdominal ultrasound. If they were found to be stone free, with no perinephric collection or hematoma, and their urine was clear, the externalized ureteric and Foley catheters were removed and the patients were discharged. Details of the treatment procedures are provided in Table 2.

RESULTS

The mean operative time was 44.34 minutes, the stent time was about 1.1 days, and the mean hospital stay was 1.6 days. The mean drop in hemoglobin levels was 1.67 gm/dl (range 0.3 to 5 gm/dl) with a blood transfusion rate of 3.95%. The majority of the patients needed a single puncture, but some needed double or triple punctures. Only 12.65% of the sample needed analgesia. A stone-free rate of 91.76% and overall success of 97.25% were achieved (Table 2).

Previous ipsilateral renal surgery was noted in 40 patients, solitary kidney in 15 patients, and renal impairment (creatinine 1.5 to 2.5 mg/dl) in 20 patients. Hemostatic substances were used in 50 patients (first group), and when compared to another 50 patients (second group) where it was not used we found that the Hb drop in both groups was 0.3 to 4 gm (mean 1.2 gm) and 0.3 to 5 gm (mean 1.7 gm), respectively, with no significant difference, as the p value was 0.455.

No intraoperative complications were observed. Postoperative complications were recorded in 20 patients (7.9%) (Table 3). The majority of them were minor, in the form of a perirenal collection of different amounts, urine leakage, high-grade fever, and postoperative bleeding, which was managed conservatively or by insertion of a double J stent. Major complications came in the form of 1 colonic injury in the supine position, managed conservatively, and hydrothorax in 2 patients, 1 managed conservatively and the other by insertion of a chest tube.

DISCUSSION

Naturally, the greatest work begins small with insignificant progress but is then enlarged by the hard work of scientists. This is truly what happened in Bellman's case in 1997 when he

began to omit the insertion of the nephrostomy tube at the end of PNL and left only a ureteric stent in the form of the double J stent [5]. Initially the condition was limited and restricted to a small stone burden no greater than a 25 mm, single puncture, intact pelvicalyceal system with non-considerable bleeding and stone-free results without the need for a second look [11-15]. After continuous work and observation researchers observed no serious complications with this idea. On the contrary, they observed the advantages of decreased postoperative pain and discomfort, the need for analgesia, and a decrease in hospital stay [6-8,10], and cost [16]. However, the drawback was the need for re-cystoscopy, which is more invasive and may need general anesthesia. There are also irritative symptoms and bleeding caused by the double J stent [5,17]. An externalized ureteric catheter that can replace the double J stent and stay for 12 to 24 hours solved the previous problem [7,10,18], which made the situation more acceptable. Then the era of TPNL won more support and became widely known, and the inclusion criteria became more and more unlimited with the introduction of patients with previous ipsilateral renal surgery [19], solitary kidney [20], renal impairment, multiple accesses, controllable bleeding, supracostal approaches, and the option of supine or prone position. Time is also no longer a limiting factor [6,20-22]. Trials using hemostatic substances like a gelatin matrix, SURGICEL, a sponge stain, or the use of coagulant on bleeding site were conducted to control bleeding, but most of the studies proved insignificant and lacks benefit if the tract is without these auxiliary procedures [23,24]. Finally, limited studies with a limited number of patients started what is known as tubeless and stentless PNL, with extended restricted criteria such as being stone-free or a 2 cm stone or less without any residual stones, which could not be guaranteed with more or less acceptable manipulation [25-27]. Fear of postoperative pain, obstruction, leakage because of the passing of small fragments, or clots should be considered, and more studies are needed.

From this study, results show that it is the time for the new era of tubeless PNL. It provides more availability to all varieties and situations of PNL with a large number (253 patients) of different stone sizes, locations, numbers, positions (prone, supine), approaches (supracostal, subcostal), tracts (single, double, triple), with previous ipsilateral surgery (40 cases), solitary (15 cases) renal impairment (creatinine 1.5 to 2.5 mg/dl in 20 patients), and simultaneous bilateral TPNL (2 patients). The need for analgesia was decreased markedly (12.65%), hospital stay was also decreased (1.6 days), and the utilization of an externalized ureteric catheter for a short period of time (26.65 hours) is also an advantage, without the need for additional intervention.

Table 3. Postoperative complications.
<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.04t3>

Perirenal collection	
< 50 cc	4
50 - 300	4
300 - 500 cc	2
Total	10
Leakage	
Treated by double J stent	1
Spontaneous passage of fragment	1
Total	2
Posoperative fever	
	5
Colonic injury	
	1
Hydrothorax	
	2
Total	20 (7.9%)

Hemostatic substances like SURGICEL, GELFOAM, and Spongstan to secure the bleeding site were used in 50 patients and were compared to another 50 patients with whom these substances were not used. The Hb drop was 0.3 to 4 gm (mean 1.2 gm) and 0.3 to 5 gm (mean 1.7 gm) with no significant difference as the p value was 0.455. Complications occurred in (7.9%) of the patients and were mostly minor, with a minimal number of major complications; they were managed conservatively (Table 3). Blood transfusions were needed in 3.95% of the sample, which is acceptable. We took a deep stitch of 0 silk to control the bleeding after the removal of the sheath, and in multiple puncture cases we kept the sheath or tube temporarily in place until the end of the procedure.

CONCLUSION

The era of nephrostomy tube post PNL should be halted to give the era of TPNL a chance to take priority. Only cases with big residuals, which need a second look, should use the older method. TPNL should be extended to include big stones, multiple stones, multiple punctures, prone or supine positions, subcostal or supracostal, recurrent cases, solitary kidneys or with increased serum creatinine, bleeding, bilateral simultaneous procedures. TPNL is safe and effective, with acceptable complications and many advantages such as decreased postoperative pain, decreased analgesia, and decreased hospital stay.

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A Case of Recurrent Nephrocutaneous Fistula Treated with Partial Nephrectomy

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ABSTRACT

Nephrocutaneous fistula is a distressing clinical condition. The fistula can be very difficult to treat and has a high chance of recurrence. The standard treatment of a recurrent fistula is nephrectomy along with the excision of the fistula. We present a case with recurrent nephrocutaneous fistula along with a hypofunctional contralateral kidney. This was a difficult clinical scenario as any compromise of the affected kidney could have resulted in renal failure. The patient was treated with a left upper polar partial nephrectomy and excision of the fistulous tract.

INTRODUCTION

Nephrocutaneous fistula is a rare complication of renal surgery. It may be associated with nonfunctional kidneys, staghorn calculi, renal trauma, renal tumors, or chronic urinary tract infections. The fistula can be very difficult to treat as there is a high chance of recurrence. The standard treatment, in case of recurrence, is nephrectomy along with the excision of the fistula [1-3]. We present a case with recurrent nephrocutaneous fistula along with a hypofunctional contralateral kidney. This was a difficult clinical scenario as any compromise of the affected kidney could have resulted in renal failure.

CASE REPORT

A 56-year-old man with a history of open pyelolithotomy done in 2003 presented with a complaint of intermittent seropurulent discharge from a wound in his left flank over the last 5 years. He was previously diagnosed as having a nephrocutaneous fistula,

and had an excision of the tract done in 2010, but after an asymptomatic period of 6 months, the discharge returned. On examination there was a 1 cm x 1 cm opening in the left flank with pouting granulation. His urea was 51 mg/dl and creatinine was 2.1 mg/dl. The urine culture was sterile. An MRI revealed hydronephrosis of the upper pole of the left kidney with evidence of perinephric inflammation, but a fistula could not be visualized (Figure 1a). It also revealed a shrunken right kidney (Figure 1b). The biopsy of the tract was suggestive of chronic inflammation. Urine examination performed for 3 consecutive days on 2 separate occasions did not reveal any acid-fast bacilli. There was no evidence of malignancy or tuberculosis. A 99mTc Diethylenetriaminepentaacetic acid (DTPA) scan was done, which revealed a total glomerular functional rate of 35 ml/min, the majority contributed from the left kidney (88%). A retrograde pyelogram was performed but failed to reveal any lesion or calculi. Though there was upper polar hydronephrosis, there was no infundibular narrowing. A double j stent was inserted on the left side but the patient continued to have fistula discharge; therefore, surgical intervention was planned.

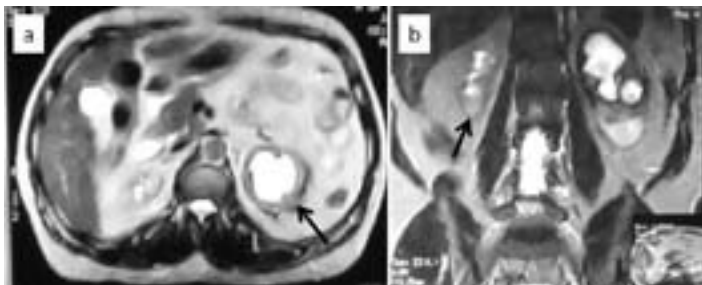
KEYWORDS: Fistula, kidney, cutaneous

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Figure 1. (a) MRI (T2 weighted) revealing left upper polar hydronephrosis with perinephric inflammation (arrow). (b) The shrunken right kidney (arrow) is also seen.

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As the right kidney was shrunken to prevent the patient from renal compromise from a left nephrectomy, a left partial upper polar nephrectomy was performed. As the patient already had 2 open explorations, the kidney was approached from the bed of the eleventh rib. The kidney could be reached with significant difficulty due to dense adhesions. There was an abscess cavity in the outer aspect of the renal parenchyma, which was in continuation with the fistulous tract. An upper polar partial nephrectomy was performed under cold ischemia along with the excision of the tract. The patient recovered well in the postoperative period. There was a mild elevation of serum creatinine in the post operative period but after 3 weeks, the level returned to the preoperative level of 2.1. At a follow-up of 10 months, the patient is doing well and is free of any recurrence.

DISCUSSION

Nephrocutaneous fistula is a rare but serious complication of renal surgery. The incidence ranges between 1 to 2%. The nephrocutaneous tracts usually heal spontaneously once the distal drainage from the kidney is ensured but in rare cases they may persist. The usual causes for persistence are distal urinary obstruction, malignancy of the tract, tuberculosis, and chronic nonspecific inflammation [2-6]. The possible cause of recurrence of the nephrocutaneous fistula in the case presented above was the persistence of renal infection due to inadequate resection of the tract during the previous surgery.

The diagnosis of a nephrocutaneous fistula usually requires direct antegrade or retrograde pyelography or fistulography,

because underlying renal disease usually precludes sufficient contrast medium opacification for the visualization of a fistula on intravenous urography. The diagnosis can occasionally be made by CT or MRI [2,5,6].

To treat the patient, an etiology should be sought. Nephrectomy is usually considered to prevent recurrence. Since these lesions occur most often in kidneys with hypofunctionality, nephrectomy is the preferred solution. The case presented here was a difficult clinical scenario. The patient already had 2 open surgeries making re-exploration a technically difficult procedure. Moreover, his contralateral kidney was shrunken with low functionality. Performing a nephrectomy would have been a more feasible option to prevent further recurrence but would have created renal compromise and even the need for lifelong dialysis. Partial nephrectomy, though technically challenging in a revisited scenario, was the best option for the patient and could be performed successfully.

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A Rare Feminizing Adrenocortical Carcinoma: A Case Report

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ABSTRACT

Adrenocortical carcinoma (ACC) is a rare tumor that accounts for only 0.02% of all cancers. About 60% of patients present with symptoms of excessive hormone production. However, ACC is usually nonfunctional when it occurs in adults. Its presentation with only virilizing symptoms is extremely rare. We report a case of a huge functional, virilizing ACC of the right adrenal gland that measured 14 cm by 9 cm by 6 cm and weighed 600 gm, which was successfully extirpated.

INTRODUCTION

Adrenocortical carcinoma (ACC) is a rare tumor that accounts for only 0.02% of all cancers [1]. About 60% of patients present with symptoms of excessive hormone production. However, ACC is usually nonfunctional when it occurs in adults. Its presentation with virilizing symptoms is extremely rare. We herein report a case of a huge functional, virilizing ACC of the right adrenal gland that measured 14 cm by 9 cm by 6 cm and weighed 600 gm, which was successfully extirpated.

CASE REPORT

An 18-year-old male presented with complaints of dull, vague abdominal pain localized to the right upper quadrant for a 6-month duration. The pain was not associated with vomiting, fever, or any other systemic complaint. Other complaints were bilateral breast enlargement, striae over axilla, and breast, thigh, and facial puffiness for 4 years. A physical examination

revealed hypertension with a typical Cushingoid appearance, including a plethoric moon face, truncal and centripetal obesity, and abdominal cutaneous striae (Figure 1).

An abdominal examination revealed a large lump of about 10 cm by 15 cm located in the right hypochondrium. It was smooth, firm to hard in consistency, and was not moving with respiration. Laboratory testing revealed no anemia, normal white blood cell counts, and normal differential counts. His fasting blood sugar was 98 mg/dL, and his serum creatinine 1.2 mg/dl, with normal serum electrolytes. Liver function tests were normal. Urinalysis was normal. Ultrasonography revealed a solid mass at the upper pole of the right kidney. The chest radiograph did not reveal any abnormality. An MRI of the abdomen showed the organ of origin was the right adrenal gland, which was heterogenous with hemorrhagic areas within (Figure 2).

The liver and the opposite adrenal were normal. Functioning of

KEYWORDS: Adrenocortical carcinoma, functional, virilizing

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Figure 1. Physical appearance at presentation.

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DISCUSSION

ACC is a rare, aggressive tumor that affects only 1 to 2 persons per million [1]. It represents 0.02% of all cancers and has a poor prognosis, causing 0.2% of all cancer deaths. Most series show a female preponderance, but our case is an 18-year-old male. ACC can be functional or nonfunctional, depending on the production of corticosteroids, androgen, estrogen, or mineralocorticoids by the tumor [2]. The functioning tumors may secrete excessive glucocorticoids (Cushing's syndrome), mineralocorticoids and their precursors, including androgens (virilization) and/or estrogens (feminization), as well as aldosterone causing hypertension as in our case which had elevated cortisol and DHEA. Most of the carcinomas (60%)

Figure 2. An MRI showing a right adrenal mass.

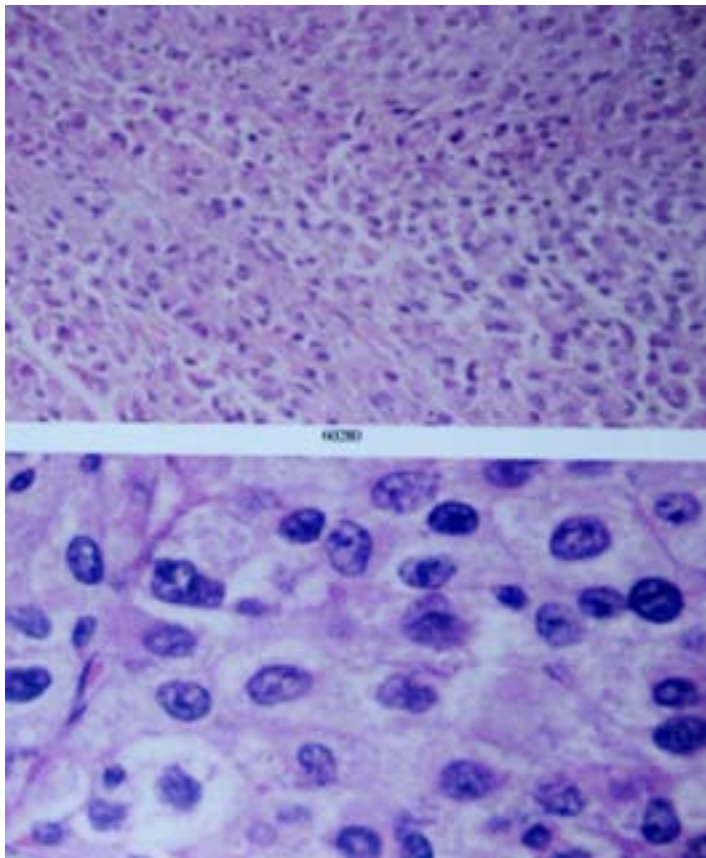
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both kidneys was normal. His serum cortisol (42.08) and DHEA (832.7) levels were elevated. A 24-hour urinary catecholamine was normal. The patient was subjected to right radical adrenalectomy. The right kidney could be preserved. The tumor mass was abutting the IVC and there was involvement of the posterior surface of the liver. Histopathological examinations of the excised specimen confirmed the diagnosis of adrenocortical carcinoma (Figure 3) with a mitotic figure of 8-9/50hpf, an extracapsular extension, lymphovascular invasion, positive peripheral margins with tumor necrosis, cystic degeneration hemorrhage, and focal calcification. Postoperative recovery was uneventful. The Cushingoid features improved gradually within 3 months after the surgery. The patient is alive with no metastases 1 year after the surgery. His blood pressure and electrolyte levels remain normal.

Figure 3. Microsections showing adrenocortical carcinoma.

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are functional, and the first manifestation is usually Cushing's syndrome. They are typically large, with imaging features of malignancy, including heterogeneous density, central necrosis, and calcification requiring histological evaluation. They can also be biochemically active, prompting imaging evaluation for mass detection.

Estrogen-secreting tumors, which can cause feminization, are rare. However, ACC with virilizing syndrome is a rare presentation that was seen in our case, and by looking at the presentation of the patient, combined with biochemical and imaging studies, ACC becomes the most suitable diagnosis without any differentials. Prompt regression of Cushingoid fascia and cutaneous manifestation were observed after the tumor extirpation. Such a large mass should be closely followed over a lifetime as chances of recurrence, after many years of

treatment, are very high due to its characteristics. Mitotane (adrenocortical cytotoxin) is usually reserved for these cases and also for inoperable ones. There may be local tumor invasion, including the potential for tumor thrombus formation, which can embolize, or hormone excess syndromes and paraneoplastic syndromes upon follow-up.

The detection of tumors at an early clinical stage is crucial for curative resection, and total resection offers the only prospect for a cure. Patients with functional ACC may have a better prognosis because they present earlier, unlike patients with nonfunctional variants who invariably present when the tumors are very large or are associated with distant metastasis. Estimates of the overall 5-year survival rate are approximately 20 to 35%. For cases where total surgical resection is achieved, this rate is estimated to be approximately 32 to 47%. In those cases where total surgical extirpation has not been possible, the 5-year survival rates are 10 to 30%. Even after apparently complete surgical resection, local or distant relapse occurs in nearly 80% of cases. Patients who show no response to mitotane or who relapse are probably best served by a referral to a major cancer center where they can be enrolled in one of several ongoing combination chemotherapeutic/radiation and/or surgical resection protocols. The size of the adrenal tumor on CT or magnetic resonance imaging (MRI) is considered the best indicator of malignancy [3]. This case is reported due to the rarity of its presenting features.

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Acute Penile Prosthesis Insertion in the Delayed Presentation of Ischemic Priapism

Yeng Kwang Tay, Dan Spernat, Sree Appu, Christopher Love

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ABSTRACT

Ischemic priapism is an organ-threatening event. It presents as a rigid and painful erection despite the absence of any sexual stimulation. In up to 60% of cases of ischemic priapism no precipitating factor is identified. However, medications such as intra-cavernosal agents, anti-psychotics, anti-hypertensives, as well as illicit drug use and hematological disorders have been implicated in ischemic priapism. Management of a prolonged priapism is challenging. It is usually refractory to aspiration, intra-carvenosal phenylephrine, and even surgical shunting. The corpora carvenosa can be irreversibly replaced by dense fibrosis after 6 hours of ischemia. This may result in a shortened, indurated, non-erectile penis. We present and describe the surgical technique of a case of prolonged ischemic priapism treated with early implantation of penile prosthesis.

INTRODUCTION

Ischemic priapism is an organ-threatening event. It presents as a rigid and painful erection despite the absence of any sexual stimulation. Ischemic priapism is commonly associated with intracavernosal agents to treat erectile dysfunction [4]. Less commonly, anti-hypertensives, anti-psychotics, illicit agents such as cocaine or medical conditions such as blood dyscrasias, and sickle cell anemia may cause it. The management of prolonged priapism (greater than 24 hours) is difficult. Irreversible damage is evident even after 6 hours of ischemia [4], and in our experience the priapism is usually irreversible by the time patients present to our tertiary referral center.

The sequelae of unresolved priapism are penile fibrosis and total erectile dysfunction, treatable only by later implantation of a penile prosthesis. This is a technically difficult procedure with a high complication rate and often leaves a cosmetically

and functionally poor result, particularly because of the severe shortening associated with the fibrosis.

CASE REPORT

A 51-year-old man presented to our tertiary referral center with an 8-day history of ischemic priapism. He had no history of erectile dysfunction nor had he had any previous episodes of priapism. There were no inciting events noted in the history. He had presented several days earlier at a peripheral hospital where aspiration was attempted. This failed to relieve his priapism and he was discharged home with analgesia.

When he presented to our tertiary referral center he was in severe pain and had no detumescence for 8 days. Initially, he was managed with attempt at aspiration and an injection of phenylephrine as per the American Urological Association guidelines. As this failed to relieve his priapism, a distal shunt

KEYWORDS: Priapism, penile prosthesis, early insertion

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(Winter shunt) was performed. Unfortunately, this also failed to relieve his priapism. The patient was admitted to the ward for analgesia and taken to theater the following morning for placement of a malleable penile prosthesis.

SURGICAL TECHNIQUE

Under a general anesthetic, the corpora were exposed via a penoscrotal incision. Bilateral 3 cm corporotomies were performed with minimal bleeding from the ischemic cavernous tissue. Dilatation was achieved with a single pass of a Furlow tool proximally and distally on each side, followed by a 12 Hegar dilator. Following this, 12 mm by 21 cm Coloplast (Minneapolis, USA) malleable rods were inserted. The procedure was uneventful, and even after 8 days of priapism there was minimal fibrosis and no difficulty dilating the corpora cavernosa. The total operative time was 20 minutes. Additionally, the previously performed Winter shunt did not impede the placement of the prosthesis. The patient was discharged home on postoperative day 2 with minimal pain. He was reviewed at 4 weeks postoperatively, and his wound has healed completely without any evidence of complications. The 6-month follow-up confirmed excellent patient satisfaction without any difficulties achieving successful sexual intercourse. The patient was offered placement of a 3-piece inflatable penile prosthesis; however, due to satisfaction with the malleable device the patient has declined this.

DISCUSSION

Of patients who have priapism lasting for more than 24 hours, 90% experience impotence [1,4]. Dense fibrosis of the corpora cavernosa occurs with extended priapism and complicates the later insertion of penile prostheses [1]. Early implantation before the development of dense fibrosis might give more satisfactory results [1]. Furthermore, the placement of a malleable prosthesis acts to prevent fibrosis and scarring of the corpora cavernosa, thus maintaining penile length [2]. Early implantation of penile prosthesis also permits early return of sexual activity [4]. As highlighted by Deveci et al., the loss of penile length is closely associated with lower satisfaction rates and lower International Index of Erectile Function scores [5]. An alternative would be to place an inflatable penile prosthesis acutely. However, regular cycling of the device is required to prevent fibrosis and penile deformity [6]. This may be difficult for the patient to perform due to pain and swelling.

Some studies have reported difficulties with migration of penile prostheses after aggressive Winter shunt with the potential for distal extrusion of the prosthesis necessitating additional

procedures [1]. Others, however, have reported no increased incidence of extrusion through the weakened tip of the corpora cavernosa [3]. To prevent this theoretical increased risk we recommend performing a Winter shunt with a "Tru-cut" biopsy needle as used for transrectal prostate biopsy to prevent loss of large areas of distal corpora cavernosa. Additionally, Ralph et al. have reported an increased infection risk (6%) in patients with shunt surgery [4]. Once the tissues have settled the patient can be considered for placement of an inflatable penile prosthesis. In fact, early penile prosthesis insertion is technically easier with low complication rates [4]. It can also prevent extended or double corporotomies, which is often unavoidable in cases with dense corporal fibrosis [4].

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Adult Wilms Tumor with Spinal Metastases

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ABSTRACT

Wilms tumor is rare in adulthood. The prognosis is poor when compared with children. Adults more frequently present with advanced disease stages, and chemotherapy has a moderate effect. The various protocols of chemotherapy and indications for surgery and radiotherapy are not yet precisely defined, mainly due to the rarity of the disease. Here we report a case of adult Wilms Tumor with spinal metastases who remains disease free for 3 years after undergoing multimodality treatment.

INTRODUCTION

Wilms tumor is the most common pediatric renal neoplasm, but its occurrence in adults is very rare. There is no morphological difference between adult Wilms tumor (AWT) and pediatric Wilms tumor (PWT), but the pathogenesis may be different [1]. The prognosis of AWT is poorer when compared to PWT, in part because adults frequently present with advanced disease stages. Clinical presentation of AWT is often indistinguishable from other more common adult renal tumors. Staging and treatment guidelines for adults are still lacking. Currently, the staging of both AWT and PWT is done in the same way, according to the National Wilms Tumor Stage Group (NWTSG) or the Society of Pediatric Oncology (SIOP) [2,3].

CASE REPORT

A 21-year-old female presented with complaints of severe low backache and radiating pain to her right lower limb over a 3-month duration. Ultrasound of the abdomen showed a 10.2

cm x 8.1 cm heterogeneous mass arising from the lower pole of her right kidney. Magnetic resonance imaging (MRI) of the abdomen and spine showed a mass lesion arising from the lower pole of the right kidney (Figure 1, Figure 2) with metastases in the lumbar spinal cord (Figure 3). CT-guided, fine-needle aspiration cytology (FNAC) showed renal cell carcinoma metastasizing to the spinal cord. A right cytoreductive nephrectomy was done, and the postoperative period was uneventful. The gross specimen showed a gray-white tumor that was 15 cm x 10 cm x 6 cm with areas of hemorrhage and necrosis. Histopathological examination of the kidney showed adult Wilms tumor (monophasic blastemal type) with neuronal differentiation (Figure 4). Immunohistochemical (IHC) markers cytokeratin, CD 117, S100, and neuron-specific enolase (NSE) were positive, and the vimentin, epithelial membrane antigen (EMA), leucocyte common antigen, synaptophysin, chromogranin, and PAS with diastase were negative. Postoperatively, the patient received chemotherapy and radiotherapy, and there was no recurrence of disease. The patient has been disease free for 3 years.

KEYWORDS: Adult Wilms Tumor, spinal metastases

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Figure 1. MRI abdomen showing a mass arising from the lower pole of the right kidney.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.11f1>

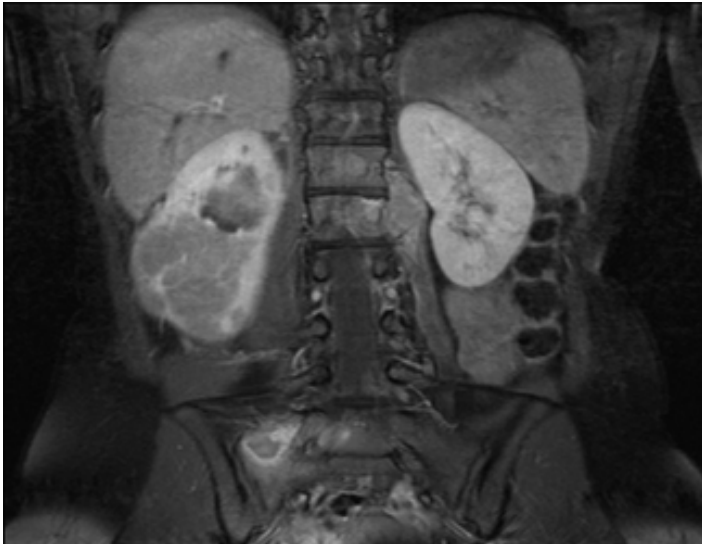
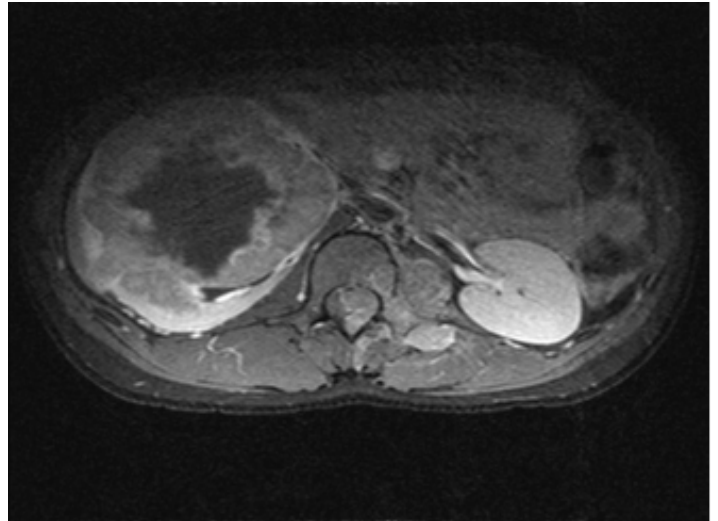


Figure 2. MRI abdomen showing a mass arising from the lower pole of the right kidney.

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DISCUSSION

Wilms tumor is an embryonal malignancy that arises from remnants of an immature kidney. Only 3% of Wilms tumors are diagnosed in adult patients [4]. Results from the California Cancer Registry [5] showed that AWT represents 30% of primary renal cancer in the second decade of life, and that patients have a mean age of 13.9 years. Because AWT is rare, its diagnosis is infrequently suspected in adult patients. Tumor symptoms are unspecific (e.g., flank pain, abdominal mass, hematuria), and it is not possible to achieve a safe diagnosis with imaging studies alone. Imaging only confirms the presence of a renal mass. Usually, the diagnosis is established after primary nephrectomy [4]. A fine-needle or true-cut biopsy may be a plausible approach in cases of primarily inoperable tumors or metastatic disease.

Histologically, AWT does not differ from PWT. The tumors are composed of blastemal, stromal, and epithelial cells that recapitulate normal kidney development. The proportions of the 3 cell components vary greatly [2,3]. In some cases diagnosis is difficult by morphology alone, especially in adults. Diagnosis of nephroblastoma is retained after the exclusion of other disorders that are more common to this age, such as renal cell carcinoma (RCC), renal sarcoma, and primitive neuroendocrine tumors (PNET) [4,6].

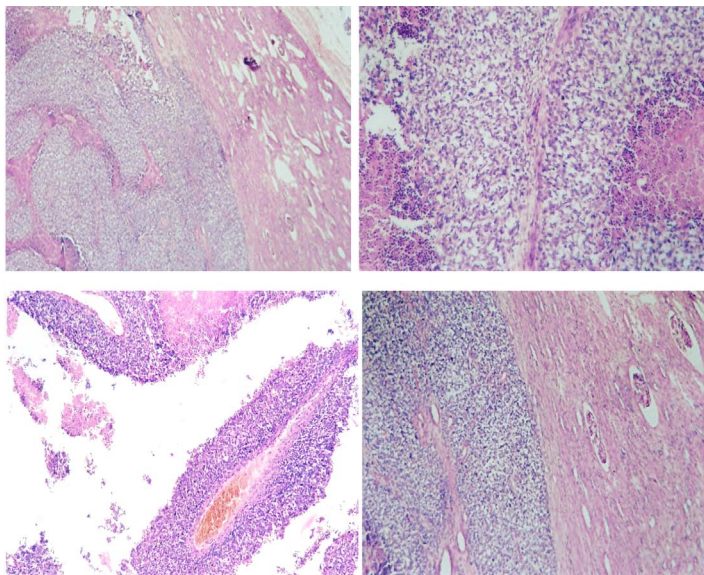
Figure 3. MRI of the spine showing lumbar spinal cord metastases.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.11f3>



Figure 4. Histopathological examination of the kidney showing an adult Wilms tumor (monophasic blastimal type) with neuronal differentiation.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.11f4>



AWT often shows anaplasia, which is associated with a more aggressive clinical behavior. Patients with anaplasia have a 5-year overall survival (OS) rate of 37%; patients without anaplasia have a corresponding OS rate of 65% [7]. The prognosis of AWT is poor when compared with children. Approximately 33 to 50% of adult patients have metastatic diseases at the time of diagnosis, and adults often have weight loss or a decline in their performance status that is not typically seen in children [2,4]. Adult Wilms tumor is diagnosed based on the criteria given by Kilton, Mathews, and Cohen [8]. These include: 1) the tumor under consideration should be a primary renal neoplasm, 2) the presence of a primitive blastemal spindle or round cell component, 3) the formation of abortive or embryonal tubules or glomerular structures, 4) no area of tumor diagnostic of renal carcinoma, 5) pictorial confirmation of histology, and 6) the patient's age is less than 15 years.

Recently, several markers have been identified as poor prognostic indicators, such as the loss of heterozygosity (LOH) at chromosomes 1p and 16q and telomerase expression level [2]. These factors should be investigated in patients with AWT. Molecular studies and gene expression profiling should be carried out to identify new prognostic factors and incorporate

them into treatment decisions.

In AWT, surgical treatment has the highest priority, and even the discovery of metastatic disease should not prevent exploration or the attempted removal of the primary tumor. If the primary tumor is initially inoperable, a second look laparotomy is worth consideration following chemotherapy [9]. Tumor debulking and removal of the primary tumor might carry an advantage over initial systemic therapy for patients with AWT, because standard chemotherapy used for patients with PWT is expected to be less effective in adults

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Ectopic Kidney

Muhammad Abdullah Rahman Alshwani

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ABSTRACT

This rare case is an unusual form of ectopic kidney in an unusual site in a 4-year-old male child presenting with a history of a lump on the dorsal shaft of the penis since birth. He had a history of repeated UTI and failure of growth. Lump size was small at birth, as mentioned by his parents, and increased in size gradually until the last days when there was a noticeable increase in size, with redness of the overlying skin and urine retention after complete investigations and full imaging studies. After a cystoscopy and surgical excision, the diagnosis of ectopic kidney on the penile shaft became clear.

INTRODUCTION

Simple congenital ectopy usually refers to a low kidney on the proper side that failed to ascend normally; its incidence is about 1/1 000 per newborn. It may lay over the pelvic brim or in the pelvis. It may rarely be found in the chest. It takes its blood supply from the adjacent vessels and its ureter is short. It is prone to ureteral obstruction and infection, which may lead to pain or fever. At times such a kidney may be palpable, leading to an erroneous presumptive diagnosis (e.g., cancer of the bowel, appendicular abscess). Excretory urography reveals the true position of the kidney. Hydronephrosis, if present, will be evident, and there is no redundancy of the ureter as in the case of acquired ectopy. Obstruction and infection may complicate simple ectopy and should be treated by appropriate means [1-2].

CASE HISTORY

A 4-year-old male child presented with a history of a lump on the dorsal shaft of the penis since birth and a history of repeated UTI and growth failure. The lump was small at birth as mentioned by the patient's parents and increased in size gradually until the last days when there was a noticeable increase in size, with redness of the overlying skin and urine retention. When seen by a general surgeon, he thought that the case seemed to be an abscess. After incision and drainage and insertion of a Foley catheter, the patient was referred to our urological unit. The child looked healthy. He was febrile with normal hemoglobin and renal function tests. The patient had an elevated WBC count of 10 000, and pyuria was obvious in the urine exam. The mass was on the dorsal side of the penile shaft and was freely mobile in all directions. An abdominal ultrasonography revealed no kidney in both loins and a solitary kidney at the pelvic brim while the mass on the penile shaft looked kidney-like. An intravenous urography revealed a solitary kidney that was centrally located over the pelvic brim, malrotated, with no

KEYWORDS: Ectopic kidney, congenital anomalies

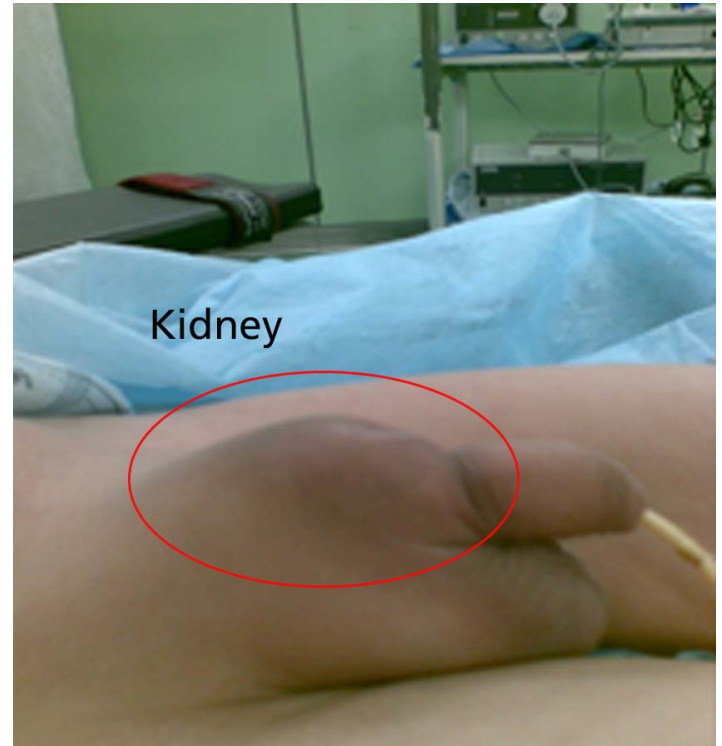
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Figure 1. IVU shows solitary ectopic kidney.
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Figure 2. Kidney on the dorsal penile shaft.
<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.08f2>



evidence of function in the mass. During cystourethroscopy, only the right ureteric orifice was identified while the left orifice was not found even in the urethra. A retrograde urography showed only 1 pelvic kidney. During exploration, the mass was attached to the corpora cavernosa and the suspensory ligament of the penis. A nehprectomy was performed without injury to the corpora and the suspensory ligament. The kidney was grossly and severely hydronephrotic with parenchymal thickness loss. The histopathology showed the mass was truly a kidney with signs of chronic pyelonephritis. The postoperative period passed smoothly, the Foley catheter was removed, and the patient passed urine normally.

DISCUSSION

It is possible for this condition to go unnoticed as it may not cause any symptoms and may remain undiscovered until the individual has some form of testing done, typically for another medical condition [3]. Many individuals do not experience any issues with this type of birth defect; however, others can

develop problems involving the urinary tract such as urinary stones, urinary blockage, or infections [4]. Treatment depends on the severity of the condition and what symptoms are present. If there is no blockage and the child is not developing stones or infections, no treatment is generally necessary. Surgery is necessary if there is an obstruction present or if kidney damage is severe [5-7]. Once renal ectopia is suspected or diagnosed, every attempt should be made to locate the contralateral kidney, as damage or removal of a solitary ectopic kidney may lead to renal insufficiency, which may necessitate dialysis or transplantation [8]. Gleason et al. [9] conducted a retrospective review of 77 patients with 82 ectopic kidneys. Out of 82 kidneys, 46 (56%) had hydronephrosis. Dilatation of the renal pelvis was the result of primary ureteropelvic or ureterovesical obstruction in 52%, grade 3, 4, or 5 vesicoureteral reflux in 26%, and extrarenal collecting systems with malrotation that produced apparent ureteropelvic junction obstruction in 22%. Bader et al. [10] reported that they have initially misinterpreted a case of ectopic pelvic kidney as bulky lymph node conglomerates in 2 different patients undergoing surgery for a gynecological

Figure 3. Retrograde pyelography showing solitary ectopic kidney.

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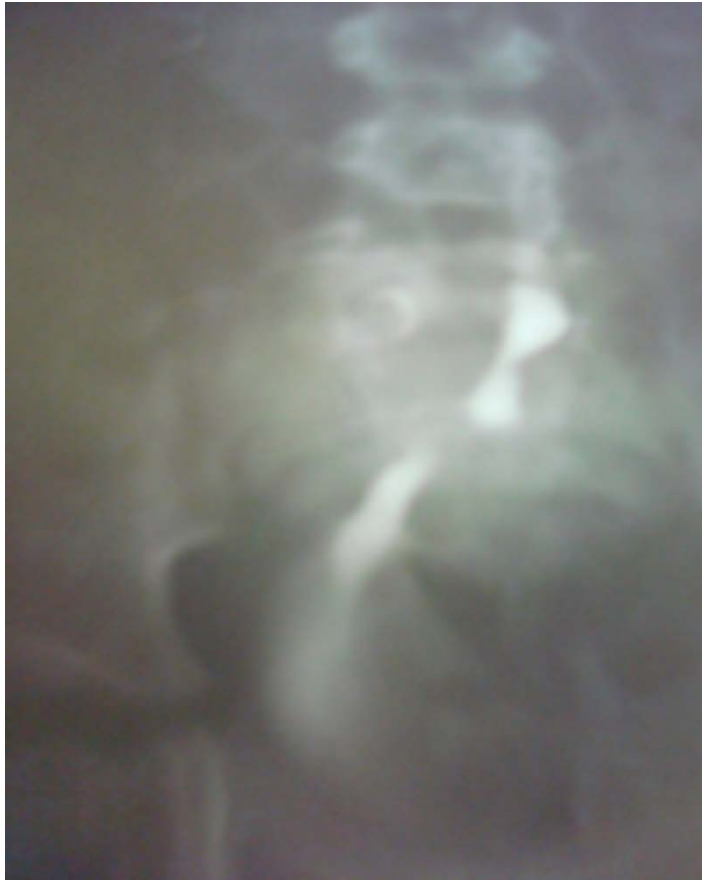
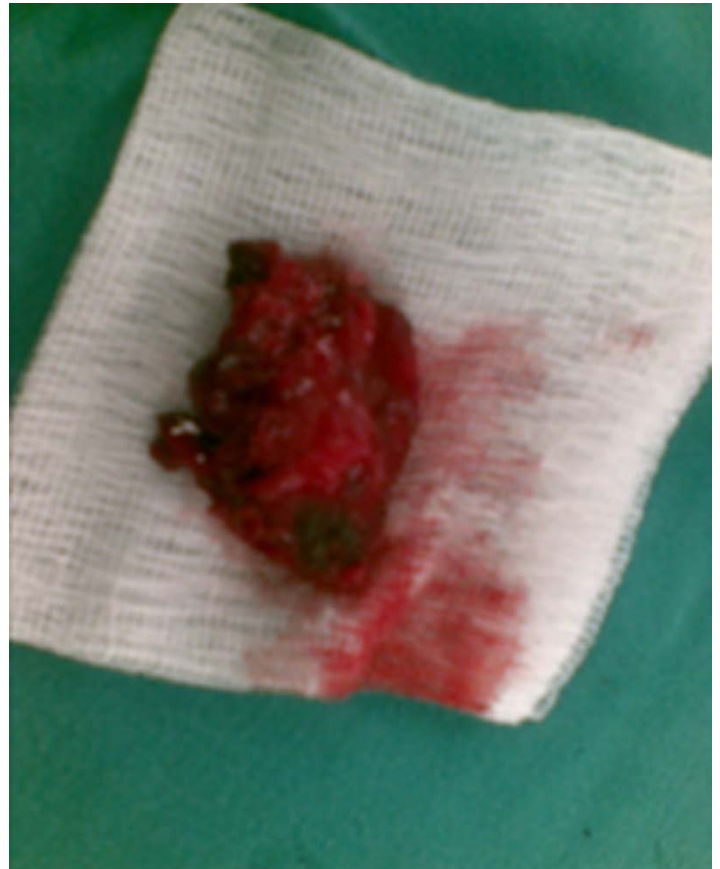


Figure 4. The specimen.

<http://dx.doi.org/10.3834/uij.1944-5784.2012.06.08f4>



malignancy. They stressed that initial exploration of the abdomen and pelvis after laparotomy should include manual confirmation that the kidneys are in the normal position.

The ectopic kidney is usually smaller than normal, and it may not conform to the usual reniform shape because of the retained fetal lobulations and the axis of the kidney medial or vertical, but it may be tilted as much as 90° laterally so that it lies in a true horizontal plane, so the renal pelvis is usually anterior to the parenchyma [9]. The ectopic kidney is more susceptible to the development of hydronephrosis or urinary calculus formation than the normally positioned kidney; this is in part a result of the anteriorly placed pelvis or an anomalous vasculature that partially blocks one of the major calyces or the upper ureter. In addition, there may be an increased risk

of injury from blunt abdominal trauma because the low-lying kidney is not protected by the ribcage [9,10].

In a review of the literature it was discovered that ectopic kidney may be found in a low position in the loin, pelvic beam, and pelvis, and extremely rare cases have been in the chest, but none til now reported a kidney in the penile shaft. It is possible this is the first reported case. Our colleague, who received the case for the first time before its presentation to our unit, believed he drained an abscess but really drained a hydronephrotic kidney. Ectopia of an organ has great importance, especially from a surgical point of view. The possibility of an ectopic kidney should be kept in mind in order to prevent the devastating consequences due to a missed diagnosis. Ectopic positioning and varied vasculature can predispose one to iatrogenic trauma during interventional radiological and surgical procedures.

Nephrectomy in our case was indicated because of repeated urinary tract infection and the site of the ectopic kidney, which was vulnerable to trauma.

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Encrusted Hairball in the Urethra: An Uncommon Complication of Hypospadias Repair

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ABSTRACT

We present an uncommon case of an encrusted urethral hairball in an adult patient who had hypospadias repair during childhood. The management of such a case is discussed briefly and suggestions are made to overcome this issue.

INTRODUCTION

In the case of hypospadiac repair, an encrusted hairball is not commonly seen. We present such a case and briefly discuss its management.

CASE REPORT

A 29-year-old man, with infertility and hypospadias, presented to another hospital with a scrotal mass along the midline, and with urethral fistulas he'd had for 10 years. The scrotal mass gradually increased in size but it was painless, and the patient mistook it as a testis. In addition, he was used to having a fistulous urinary stream for many years. He finally came to seek treatment for infertility as he was planning to start a family. The patient had multiple hypospadiac repair surgeries in various other health institutions when he was a child. He had been lost to follow-up after the last repair operation and was unable to recall details. On examination, both his tiny testes were barely palpable in the scrotum. The scrotal mass was situated along the midline, measured 2 x 2 cm, was hard in

consistency, mobile, and its margin was well-demarcated from the surrounding tissue. Also, there were a few fistula openings seen around the penoscrotal region. A computed tomography (CT) scan identified the mass as a stone.

The patient was referred to our hospital for further management. Surgical exploration revealed the presence of an encrusted hairball at the site of the neourethra constructed from the transpositioned scrotal skin. After removing the stone and trimming the hairs, the urethrotomy was primarily repaired. Postoperatively, the patient recovered uneventfully without any complications. Two months after the operation, he was still being followed up for the fistulae that were treated expectantly as well as the regrowth of hair in the urethra.

DISCUSSION

A urethral stone is an uncommon entity in urology practice, accounting for only 1% of all urinary stones [1]. The formation of encrusted hairballs or stones is also infrequently seen in hypospadiac surgery. Barbagli et al. reported an incidence of 1

KEYWORDS: Urethra, stone, hair

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Figure 1. A stone covered with hair was seen at the urethrotomy site.

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Figure 2. The stone measured 2 x 2 cm and the hairs were removed as well.

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in 60 patients with failed hypospadias surgery had developed stones in the urethra [2]. A search yielded only a minute amount of literature, the chief of which were just case reports. The largest series was a collection of 5 cases by Hayashi et al. [3]. Among these 5 cases, 4 had previously undergone Thiersch-Duplay repair, and the type of repair was not known in another case. At presentation, the stones were numerous but collectively they measured about 2 cm in diameter and were located in the neourethra. How could a diagnosis be made? Given the suggestive history of hypospadias repair and the easily palpable superficial location of the stone, we felt a clinical diagnosis could be confidently made. Otherwise, simple imaging studies such as a plain radiography or ultrasound should be sufficiently

conclusive. The use of a CT scan as in our case was unnecessary unless the mass was deep within the scrotum or if diagnosis was questionable in the simpler imaging studies aforementioned.

Various treatments had been suggested to overcome the issue of an encrusted hairball in these hypospadias patients. Giordano et al. proposed the use of extracorporeal shock wave lithotripsy to blast the urethral stone, but it was necessary to consider the potential mechanical damage delivered to the testes due to the proximity of these organs [4]. Lasers had been utilized to remove hairs as well as the urethral stone on the neourethra [5]. Singh and Hemal advocated the chemical epilation of hair by using thioglycolate at a thrice-monthly interval [6]. A simple measure described by Hayashi et al. was the use of self-catheterization of the urethra and this seemed promising since there had been no recurrence among patients until a 7-year follow-up after reparative surgery [3]. Even if one decided on a surgical treatment, it was also vital to consider the access of choice. In the era of endoscopy, the open method was still a chosen route for many [3,5-7]. The reasons likely being the difficulty in identifying clearly the border of the stone from the neourethra as well as the density of the hair impairing vision during endoscopic surgery, compounded by bleeding that potentially damaged the urethra [3]. Additionally, a stone of substantial size certainly would take a much longer

operating time if endoscopic method is employed. In fact, 2 out of 3 cases from Hiyashi et al. that underwent endoscopic lithotripsy developed recurrence [3]. The additional advantage of open surgery was clearly the opportunity to perform diverticulectomy, if any.

What could be the ideal in preventing the formation of hair and urethral stones in hypospadiac repair? Gil-vernet et al. suggested an epilation of hair follicles at the donor skin site before urethroplasty [3]. Although the use of apparently non-hair-bearing donor skin for the neourethra seemed to be the solution, unfortunately it had proved to cause a hairy urethra as well [8]. It has been reported that a hairy urethra has a complication rate of 5% [9]. Other types of urethral mucosal substitutions such as buccal mucosa and tunica vaginalis also had their own share of limitations, albeit with different success rates. In a review of 60 patients, with a mean follow-up period of 33.8 months, Barbagli et al. concluded that buccal mucosa was superior to skin as a urethral substitution. The success rate of buccal mucosa was 82% regardless of the number of stages needed to repair the hypospadias. However, the success rate of skin was 82% in 1-stage repair but it dropped to 50% in multistage repair [2]. Saphenous vein grafts had been reportedly used as a neourethra. In their case report of an 8-year-old boy with hypospadias, Shaer and El-Sadat claimed the superiority of the vein graft attributed to pre-tubularization, thus eliminating the longitudinal suture line and the risk of fistula, robustness as a graft due to the thick and multilayer nature of the vein, and the absence of hair. But the follow-up period of the patient was only 12 months and it was believed that a longer observation period was desirable [8].

Disregard of the type of tissue used, the alien nature of transplanted or transpositioned tissue, and the lack of vascularized spongiosum, a neourethra may not grow naturally or in tandem with the surrounding tissue [2]. It had been suggested that hypospadiac patients should be followed up until sexual maturation is attained [2]. Despite this, the complications of reparative surgery such as hairball formation could still occur later. Although most of the reported cases including ours occurred in the second or third decade of life, it had been reported in a patient in his sixth decade of life [3-7]. Therefore, we additionally felt that proper patient education is vital, and periodical self massage of the neourethra may prevent or detect early formation of a stone. Early medical attention in this regard was pivotal since it could serve to prevent the breakdown of a once successfully yet painstakingly reconstructed urethral passage.

CONCLUSION

Although hairball formation after hypospadias repair using hair-bearing skin as a neourethra was an uncommon entity, it was still reasonable to avoid using hair-bearing skin as urethral substitution given the potential damage. However, in situations where the use of skin is inevitable, such as a surgeon's familiarity with the technique or a lack of alternative substitution, a urethral hairball should be actively sought even many years after repair. In this regard, educating the patient in proper care would be beneficial in addition to long-term clinical follow-up.

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Retrocaval Ureter with Contralateral Renal Agenesis with Renal Failure: A Rare, Reversible Surgical Cause of Renal Failure

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ABSTRACT

Retrocaval ureter is a rare anomaly causing upper urinary tract obstruction, usually presented later in life as recurrent flank or abdominal pain and recurrent urinary tract infection. There may be associated abnormalities of other organ systems as well. We present a rare case of retrocaval ureter with contralateral renal agenesis with renal failure. Surgical correction with ureteropyelostomy was successful.

INTRODUCTION

Retrocaval ureter is a rare congenital anomaly associated with upper urinary tract obstruction due to the passage of the ureter posterior to the inferior vena cava (IVC). Many times it is associated with abnormalities of other organ systems as well. This anomaly is typically diagnosed by the fishhook shaped or the sickle shaped appearance of the upper ureter on intravenous urogram (IVU) and can be confirmed by a CT scan/MRI. We present a rare case of retrocaval ureter and contralateral renal agenesis with renal failure.

CASE REPORT

A 17-year-old female presented with intermittent right flank pain, dysuria, and intermittent fever for 2 months. Her physical examination was unremarkable except for a palpable, mildly tender right flank lump. Urine analysis showed 12 to 15 pus cells/HPF, and the urine culture/sensitivity showed *E. coli*, sensitive to amikacin and ciprofloxacin. The serum creatinine was 2.9 mg/dl. The renal ultrasound showed right gross hydronephrosis with internal echoes, a mildly dilated upper ureter, and empty left

renal fossa (Figure 1). Initially, the patient was managed with right percutaneous nephrostomy. The serum creatinine became normal 1 week following nephrostomy. The nephrostogram showed a grossly dilated right pelvicalyceal system with a curved upper ureter and abrupt cutoff at the L3 level (Figure 2[a]). The retrograde ureteropyelogram showed a medial deviation of the right upper ureter with a curved ureter at the L3 vertebra, from the medial to the lateral side, and narrow lumen (Figure 2[b]). The magnetic resonance (MR) urogram was suggestive of right retrocaval ureter. The DTPA scan showed right subrenal obstruction and an absent left kidney.

The patient was subjected to midline laparotomy. Prior to that cystoscopy and right ureteric catheterization was done. On exploration, the right upper ureter was retrocaval in position (Figure 3). The retrocaval portion of ureter was atretic, it was excised, and the proximal end of the ureter was spatulated. End-to-end ureteropyelostomy, over 6 Fr/26 cm double J stent, was performed. Her postoperative period was uneventful. The histopathology of the excised atretic segment of the ureter showed chronic inflammation and fibrosis. The double J stent was removed after 6 weeks. The DTPA scan 4 weeks following

KEYWORDS: Retrocaval ureter, ureteropyelostomy, surgical cause of renal failure

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Figure 1. Renal ultrasound showing: a) the right gross hydronephrosis with internal echoes and b) an empty left renal fossa.

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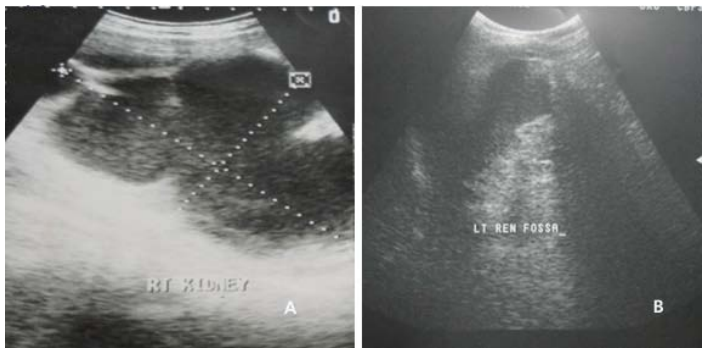


Figure 3. Operative photograph showing the right upper ureter coursing behind the inferior vena cava.

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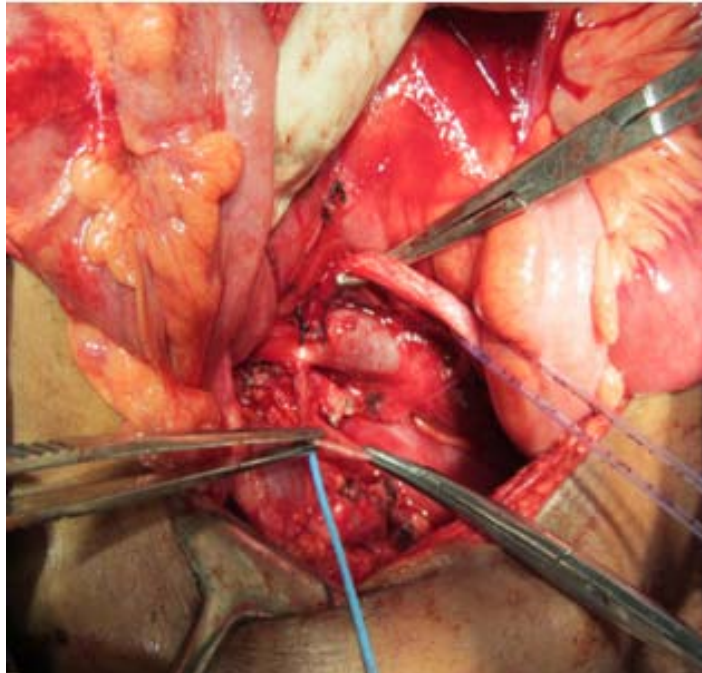
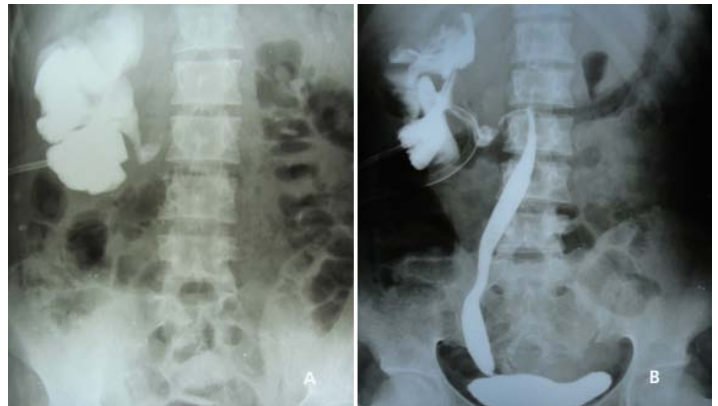


Figure 2. a) The right nephrostogram showing a grossly dilated right pelvicalyceal system with a curved upper ureter and abrupt cutoff at the L3 level. b) The retrograde ureteropyelogram showed medial deviation of the right upper ureter with a curved course of the ureter at L3 vertebra from medial to lateral side and narrow lumen.

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stent removal showed no subrenal obstruction. The patient is doing well in her last 1 year of follow-up.

DISCUSSION

Retrocaval ureter was first reported by Hochstetter in 1893 [1]. Its incidence is about 1 in 1 100 with a 2.8:1 male-female ratio [2]. Retrocaval ureter almost invariably involves the right side, but in patients with situs inversus, it can be on the left side.

Although the lesion is congenital, it is usually present by the third or fourth decade of life [3]. Retrocaval ureter results from altered vascular, rather than ureteric, development. Persistence of the posterior cardinal vein as the infrarenal IVC is the cause of the development of this anomaly [4].

The reported literature revealed that nearly 20% of retrocaval ureter cases present with concomitant abnormalities with preponderance from the cardiovascular system and the genitourinary tract. Various associated anomalies include congenital variations of inferior vena cava, brachial arch syndrome, horseshoe kidney, myelomeningocele, hypospadias, Turner syndrome, esophageal atresia, an abnormal left kidney (agenetic, ectopic, or malrotated), and cardiovascular anomalies such as situs inversus, supernumerary lumbar

vertebra syndactyly, and yolk sack tumor [5].

Patients with retrocaval ureter usually present with recurrent flank pain, recurrent urinary tract infection, and nephrolithiasis. This entity may be totally asymptomatic, too [6]. Based on the intravenous urogram (IVU) findings, Bateson and Atkinson classified retrocaval ureter into 2 clinical types: the more common, type I, has moderate-severe hydronephrosis and fishhook shaped deformities of the upper ureter. The less common, type II, has less angulated "sickle-shaped" deformities with milder/no hydronephrosis [7]. This anomaly is typically diagnosed by a fishhook shaped or a sickle shaped appearance of the upper ureter on IVU and can be confirmed by a CT scan/MRI. A spiral CT scan of the abdomen is the investigation of choice.

Surgical correction involves uretero-ureteral or ureteropelvic anastomosis with excision or a bypass of the retrocaval segment, either by an open or laparoscopic approach.

In our case, the patient had a solitary right kidney with retrocaval ureter and renal failure, initially managed by percutaneous nephrostomy, and, subsequently, a ureteropyelostomy was done. Based on our findings of retrograde ureteropyelogram and MR urogram, it was a type 1 retrocaval ureter. The renal failure in our patient was most likely was due to the infection and debris in the pelvicalyceal system, which would have aggravated the obstruction in an already obstructed (retrocaval segment of the ureter) system. The percutaneous nephrostomy was done to relieve the obstruction, which must have prevented the irreversible tubular damage. This is the most probable reason for the reversal of renal failure and stable serum creatinine over 12 months of follow-up.

CONCLUSION

Retrocaval ureter with contralateral renal agenesis presenting with renal failure is a rare condition. Initial percutaneous nephrostomy followed by ureteropyelostomy should be the treatment of choice.

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Hydatid Cyst of a Kidney in a Child: A Case Report

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ABSTRACT

Hydatid disease of the kidney is rare and constitutes only 2 to 4% of all cases of hydatid. Its occurrence in children is even more rare. It ranks third after liver and lung. In the urinary tract, kidneys are generally affected, usually together with multiple organ involvement. An isolated renal hydatid cyst of the kidney without other organ involvement is very rare. We hereby present a case of pure hydatid cyst of the left kidney in a child presenting with left flank swelling and renal colic. She also had episodes of fever on and off for 2 months. On the basis of imaging studies, a diagnosis of hydatid cyst of the left kidney was established. The patient was successfully managed by simple nephrectomy. The patient is doing well at an 8-month follow-up.

INTRODUCTION

A 9-year-old female presented with swelling in her left flank and colicky pain that increased with time for 2 months. There was also associated dysuria. On abdominal examination, there was a smooth, mobile lump with a well defined margin in the left lumbar region. A routine blood investigation and renal function tests were normal except for mild eosinophilia. The indirect hemagglutination test was negative. The ultrasonography of the abdomen revealed an enlarged left kidney with a large thick-walled cyst, with a floating membrane and fine-floating echoes. An intravenous urogram showed an enlarged left kidney with calyceal distortion and pooling of the contrast, which is persistent in post-void film (Figure 1). A computed tomography (CT) scan revealed a large cyst rising from the mid and upper poles of the anterior surface of the left kidney. The cyst was thick-walled with a modulating membrane

located in the center of the cyst (Figure 2). On exploration, the kidney was edematous, friable, and hugely enlarged in size, and it crossed the midline with marked and dense perinephric adhesion (Figure 3). Simple nephrectomy was performed. A thick-walled, single-layer cyst was seen on the cut section of the nephrectomy specimen (Figure 4). In the postoperative period, the patient was kept on albendazole (400 mg daily) for 3 months. The histopathological examination was consistent with hydatid disease.

DISCUSSION

A hydatid cyst is a parasitic infection caused by a larval form of *Echinococcus granulosus*. The adult worm is present in a dog's small intestine. Humans are an intermediate host of *Echinococcus granulosus* through the ingestion of water or vegetables contaminated by its eggs [1]. The ovum is digested

KEYWORDS: Renal, hydatid cyst, simple nephrectomy, floating membrane

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Figure 1. An intravenous urogram showed an enlarged left kidney with calyceal distortion and pooling of the contrast.

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Figure 2. Thick-walled cyst with a modulating membrane located in the center.

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in the duodenum and the parasitic embryo pass through the intestinal wall to reach the portal venous system [1].

Liver acts as first line of defence and is therefore the most frequently involved organ. In humans, the hydatid involves the liver in 75% of cases and the lung in 15% of cases. Hematogenous dissemination may be seen in almost any anatomical location [2]. Kidney involvement in echinococcus is extremely rare (2 to 3% of cases), even in areas where hydatid is endemic [3]. Hydatid is rarely seen in children and is usually encountered between patients aged between 30 and 50 years old [6]. Primarily, hydatid of the kidney occurs via the passage of embryos into the kidney by retroperitoneal lymphatics [2]. A hydatid cyst is closed if it contains all 3 layers

of the cyst: pericyst, ectocyst, and endocyst. If the third layer, pericyst, is lost, it becomes an exposed cyst. When the layers of the cyst rupture, resulting into free communication with the pelvicalyceal system, it is called a communicating cyst [7]. Renal hydatid cysts usually remain asymptomatic for many years. Presenting complaints are typically flank mass, hematuria, and pain. Hydatiduria occurring due to the rupture of a cyst in the pelvicalyceal system is a pathognomonic clinical sign [4,5]. Microscopic hydatiduria occurs in 10 to 20% of cases of a renal hydatid. Gross hydatiduria is very uncommon [4]. There is no serological and immunological pathognomonic test for hydatid disease. Eosinophilia, the Casoni test, the complement fixation test, and an indirect hemagglutination test may be helpful for the diagnosis of renal hydatidosis [8].

On a plain radiograph, a ring-shaped calcification can be seen, which may be linear, multilaminated, or amorphous. In our case, there was no calcification on a plain radiograph but a renal shadow was enlarged and extended from T11 to I5. Excretory urography may demonstrate calyceal distortion, caliectasis,

Figure 3. The kidney was edematous, friable, and hugely enlarged in size, and it crossed the midline with marked and dense perinephric adhesion.

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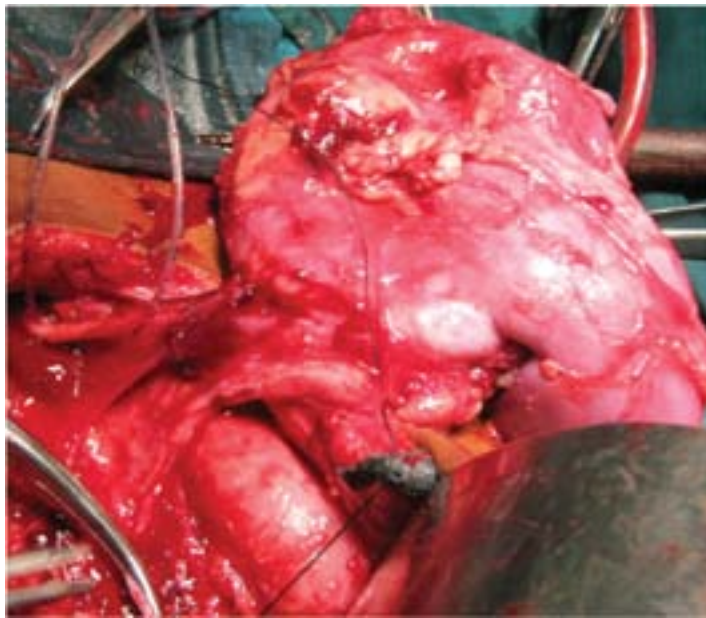


Figure 4. A thick-walled, single-layer cyst was seen on the cut section of the nephrectomy specimen.

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and a nonfunctioning kidney, possibly due to a mass effect of the cystic lesion [9]. Intravenous urography revealed calyceal distortion with caliectasis and pooling of the contrast in calyces, which persisted even in the postvoid film. Ultrasonography is usually the primary radiological investigation. Although abdominal sonography is helpful with the diagnosis, CT is more accurate and sensitive [10]. Sonographic findings may show anechoic lesions with well defined margins, while a CT may demonstrate a cyst with a thick or calcified wall, a unilocular cyst with a detached membrane, a multiloculated cyst with a detached membrane, or a multiloculated cyst with mixed internal density and a daughter cyst with lower density than the maternal matrix [2,11,12]. Computed tomographic findings in this case demonstrated a unilocular cyst with a floating membrane typical of hydatid disease. Magnetic resonance imaging delineates the cyst more accurately but offers no advantage over CT, and it is also expensive.

Treatment of a renal hydatid cyst is essentially surgical. Kidney sparing surgeries such as cystectomy and pericystectomy are carried out whenever possible. Nephrectomy is the treatment of choice for renal hydatid cysts but it should be reserved for destroyed kidneys (25%)[13]. In this case, nephrectomy was done because the kidney was hugely enlarged, oedematous, and friable, and during manipulation the kidney parenchyma ruptured and extruded pus. In addition, the upper ureter was suspected to have a daughter cyst due to its thick wall and beaded feeling on palpation along with the presence of hooklets in the pelvis. The surgeon must be careful to totally remove the cyst and avoid spilling its contents. There should be delicate manipulation with the use of abdominal packs soaked with hypertonic saline to reduce the risk of dissemination and prevent recurrence [14]. Preoperative treatment with albendazole decreases the tension in the cyst wall and renders the cyst nonantigenic.

The technique of percutaneous injection, aspiration, and re-aspiration has been described as a safe and effective treatment modality for a renal hydatid [15]. Cysts do not completely disappear with this technique but it can be useful for high-risk patients with symptomatic hydatid cysts [16].

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Robotic Partial Nephrectomy in a Morbidly Obese Patient: A Case Report

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ABSTRACT

Laparoscopic surgical management of obese patients can be challenging. Data is limited on the use of robotic-assisted laparoscopic nephrectomy and partial nephrectomy in the management of renal masses in the obese population. We report a case of a morbidly obese white male with a BMI of 56.6 kg/m² who underwent an uncomplicated robotic partial nephrectomy for 2 right-sided renal masses. We conclude that robotic partial nephrectomy is feasible for the management of renal masses in morbidly obese patients.

INTRODUCTION

Obesity is common in the United States; recent reports indicate a prevalence of 32.2% in adult men and 35.5% in adult women [1]. Evidence shows increased body mass index (BMI) is associated with an increased risk of renal cell carcinoma [2]. Surgical management of obese patients can be technically challenging and has been associated with increased complications. Mendoza et al. reported increased complication rates for markedly obese patients undergoing laparoscopic urologic surgery when compared to non-obese patients [3]. However, more recent literature reports surgery complication rates are no different for obese patients requiring laparoscopic nephrectomy when compared to non-obese patients [4,5]. Laparoscopic surgery has also been shown to be a safe option for obese patients undergoing partial nephrectomy [6]. Naeem et al. found robotic-assisted partial nephrectomy to be safe in obese patients (BMI 30.3 to 49 kg/m²) [7]. We report a case of a robotic-assisted partial nephrectomy for a renal mass in a

markedly obese patient with a BMI of 56.6 kg/m².

CASE REPORT

A 42-year-old morbidly obese white male with a BMI of 56.6 kg/m² (height: 73 in, weight: 495 lb) was referred for 2 right renal masses incidentally found on a nephrolithiasis work-up. The patient denied associated symptoms. On the computed tomography (CT) imaging, a 15 mm cystic lesion was seen in the superior pole and a 4.2 cm cystic lesion was seen in the inferior pole. Due to the patient's body habitus, the masses could not be completely characterized on CT in spite of the administration of intravenous contrast (Figure 1). A renal ultrasound was obtained, which confirmed the 4.2 cm complex, predominately cystic, exophytic lesion with septations in the inferior pole of the right kidney; however, the lesion in the superior pole was not visualized (Figure 2). Given the possibility of renal cell carcinoma, the patient was counseled on treatment options, including radical nephrectomy, partial nephrectomy,

KEYWORDS: Robotic partial nephrectomy, obese

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Figure 1. Abdominal CT without contrast with mass indicated by white arrows.

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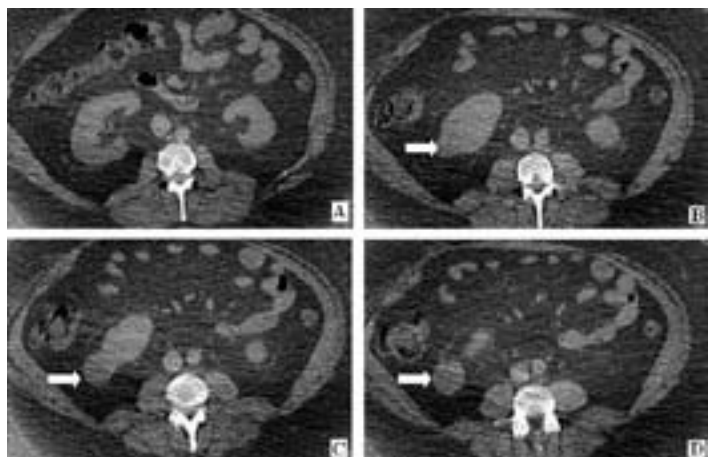


Figure 2. Renal ultrasound of right kidney showing 4.2 cm complex, exophytic lesion in the inferior pole.

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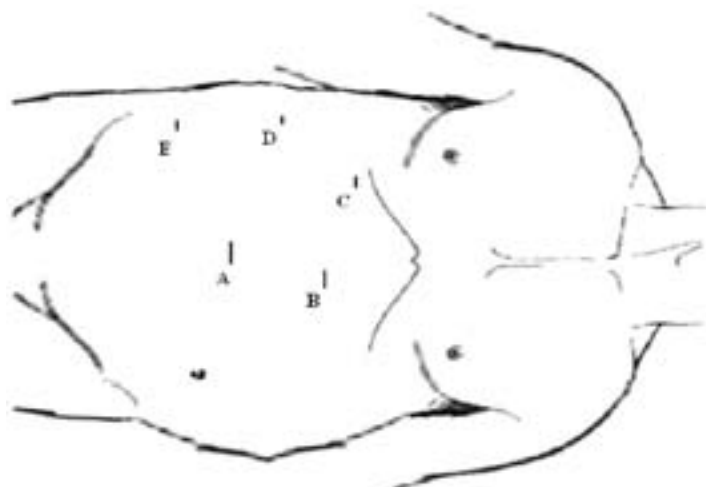
percutaneous management with renal cryoablation or radiofrequency ablation, biopsy, and observation with repeat imaging. We decided to observe and obtain a follow-up ultrasound within 6 months. Weight loss was emphasized to both decrease risk of perioperative morbidity if surgery was required, and to improve future imaging.

Six and 12 month follow-up ultrasounds showed a stable 4 cm lesion in the inferior pole of the right kidney. The patient opted for continued observation. Six months later the patient presented with right-sided flank pain. At this point he had lost 66 pounds (BMI: 56.6 kg/m²), and his ultrasound showed the mass was stable at 4.2 cm in its maximum diameter. However, given the new onset of pain, the patient elected to undergo right laparoscopic robotic-assisted partial nephrectomy.

Right robotic-assisted laparoscopic partial nephrectomy and cyst excision were performed. After induction of anesthesia, intubation, and oral gastric tube placement the patient was easily transferred from his hospital bed onto the operating table with the aid of an inflatable transfer mattress. Attachments to widen the operating table had to be placed to accommodate the patient. He was carefully positioned into the left lateral decubitus position. All pressure points were padded and an axillary roll was placed to avoid brachial plexus injury. The abdomen was prepared and draped in the typical sterile fashion. Veress needle insufflation was performed. Due to the patient's obesity, the laparoscopic ports were shifted laterally

Figure 3. Diagram of trocar placements; A. 12 mm camera port; B. 12 mm assistant port; C-E. Additional 8 mm ports. (Image modified from Kapoor et al. Figure 1 [4].).

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(Figure 3) and long robotic trocars were utilized. The patient

had a distended right colon, which occupied a significant portion of the abdominal space. In addition, there was a large amount of perinephric adipose tissue. After mobilization of the right colon along the line of Toldt, the kidney was retracted laterally and the lower pole was exposed. Intraoperative ultrasound was used to identify the lower pole renal mass. The mass was largely exophytic. While dissecting along the lower pole of the kidney, a plane between the mass and the kidney became apparent. Given the patient's obesity, gaining exposure to the hilum proved challenging. Also, to avoid prolonged warm ischemic time given the presence of 2 masses, we decided to further develop the plane between the mass and the kidney without hilar control. This plane was advanced, and the mass was enucleated from the kidney. Hemostasis was maintained throughout the resection of the mass. Once the mass was resected the base was thoroughly cauterized followed by placement of the Floseal. The mass was placed into an entrapment sack and placed out of the operative field.

The anterior aspect of the upper pole of the kidney was then exposed to examine the additional mass that was identified by the initial CT. The mass identified appeared to be a simple cyst by ultrasound, without an identifiable solid component. Given the presentation of abdominal pain, to minimize confounding factors in follow-up care, the decision was made to excise the cyst. The procedure was done entirely off clamp. The base of the defect was cauterized. The pneumoperitoneum was decreased to 5 mm Hg and the kidney was inspected to ensure hemostasis. The abdomen was inspected. The fascia was not closed at any port site. Skin was reapproximated with a stapling device. Total operative time was 2 hours and 46 minutes. There were no intraoperative complications, and he tolerated the procedure well. Blood loss was estimated to be 100 to 150 ml. The patient's hospital course was uneventful and he was discharged home postoperative day 1. At home, the patient's extraction incision opened, requiring home wound care. This was due to the patient removing staples from his incision without consulting the surgical team. He followed up 6 weeks after surgery and was doing well.

Final pathology was a 3.2 cm, T3a (tumor focally penetrated the capsule into perinephric fibroadipose tissue), Fuhrman grade II-III, clear cell carcinoma in the right, lower pole, and a 3.2 cm simple cyst in the right, upper pole.

DISCUSSION

Given the high prevalence of obesity in the United States and the increased risk of renal cell carcinoma (RCC) in obese patients, optimal surgical management for this patient population needs

to be defined. Historically, marked obesity was considered by some to be a relative contraindication to laparoscopic surgery [3]. In 1996, Mendoza et al. reported increased complication rates for markedly obese patients (mean BMI: 35.1 kg/m²) undergoing a variety of laparoscopic urologic surgeries when compared to non-obese patients [3]. Complications included conversion to open surgery, trocar injuries to abdominal wall vessels, bladder injury, peripheral nerve injury, DVT, wound seroma, nephrocutaneous fistula, and incisional hernia.

With technological advancement and increased surgeon experience, obesity is no longer considered a barrier for laparoscopic surgery. Recent literature on laparoscopic nephrectomy indicates that the procedure is not associated with increased complication rates for obese patients when compared to non-obese patients [4,5]. Rogers et al. demonstrated that robotic nephrectomy is recognized as a safe and feasible option for minimally invasive nephrectomy [8]. While not specifically studying obese patients, Rogers et al. had a relatively obese patient cohort with a mean BMI of 31 kg/m² and were successful with nephrectomy in patients with a BMI as high as 44 kg/m².

Several studies have indicated laparoscopic surgery is a reasonable option for nephrectomy in obese patients; however, these studies categorize patients as obese or not obese based on varying BMI cutoff points. It is important to consider the degree of obesity when evaluating the risks of surgery. Gong et al. were the first to study how the degree of elevated BMI affects laparoscopic renal surgery [9]. They found no statistical difference in outcomes for patients with increased BMI. Logistic regression analysis indicated there may be an association with the degree of obesity and an increase in both operation time and intraoperative complications. Therefore, patients in the extremes of obesity need to be counseled on potential increased risks of intraoperative complications and operative times, as well as conversion to an open procedure. In this case, to decrease the patient's risks of surgical complications it was beneficial to monitor the mass and allow the patient time to lose weight.

When appropriate, nephron-sparing surgery (NSS) is the preferred management of patients with RCC [10]. However, this may increase the complexity of an already difficult surgery in the obese population. Colombo et al. demonstrated laparoscopic partial nephrectomy as a safe option for obese patients [6]. Naeem et al. compared 49 obese patients with an average BMI of 36.2 kg/m² (range 30.3 to 49) to 48 non-obese patients with an average BMI of 25.7 kg/m² (range 20.5 to 29.7) who underwent robot-assisted partial nephrectomy. There were no differences in intraoperative or postoperative complications.

They found obese patients had a larger estimated blood loss (150 versus 100 ml) and an insignificant trend toward longer median operative time and median warm ischemia time [7]. To our knowledge there is no report of robotic-assisted partial nephrectomy in a patient with a BMI as high as 56.6 kg/m². This case demonstrates that even in morbidly obese patients, robotic-assisted partial nephrectomy is a reasonable therapeutic option. Long-term follow-up is necessary to assess an oncological outcome, but we anticipate that it would be similar to robotic partial nephrectomy in non-obese persons. Ten months after the surgery the patient has no evidence of tumor recurrence.

This case also demonstrates key modifications that must be made when approaching robotic-assisted surgery in obese patients. The aid of an inflatable mattress allows for easier transfer onto the operating table. Additional attachments can be helpful to widen the operating table. The patient is prepped in the lateral decubitus position, which leads to a lateral shift of the patient's pannus. Thus, trocar sites need to be shifted laterally, away from the umbilicus to account for this (Figure 3). Due to the patient's thick subcutaneous tissue layer and oftentimes larger abdominal cavity, longer trocars should be available to allow manipulation of deeper structures. Also, given the potential for longer operation time, care should be taken when positioning and securing the patient to prevent tissue necrosis and rhabdomyolysis. Our patient experienced minor wound complications at the extraction site during recovery. There is currently no consensus on closing port fascia in obese patients. Phillips et al. analyzed studies of obese patients who underwent bariatric procedures. They found some studies indicate closing the fascia predisposes patients to incisional hernias, while other studies show no difference in incisional hernias with or without fascial closure [11].

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Scrotal Swelling and Penile Fistula in a Patient with Crohn's Disease

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ABSTRACT

Crohn's disease often is detected in adolescents with nonspecific gastrointestinal complaints. Extraintestinal complications are common but usually follow the onset of the bowel complaints. We present an unusual case in which scrotal swelling was the first symptom in a patient discovered to have Crohn's disease. This is particularly unusual in that the patient presented as a case of urethral fistula.

INTRODUCTION

Crohn's disease (CD) may involve the perineum, but this complication most frequently follows gastrointestinal complaints. Genitourinary manifestations of CD are not common as presenting symptom [1].

We present an unusual case of scrotal and penile involvement of CD with a complete MRI exploration. To our knowledge, no prior reported cases of this entity with MRI were reported previously.

CASE REPORT

A 48-year-old man presented with a 2-month history of scrotal swelling and pain. He has a history of CD involving the small intestine and colon since 1989, confirmed by colonoscopy and rectal biopsy. He was operated on 2 times for ileal obstruction. Mesalazine was conducted thereafter. Under antibiotics, the swelling and pain decreased with the onset of purulent discharge.

A physical examination revealed 2 productive fistulas located in the scrotum and the perianal region. There was no evidence of induration or erythema. Compression adjacent to the orifice resulted in the expulsion of purulent material. The 2 testes were palpable without any clinical abnormality, and the digital rectal examination was unremarkable. Laboratory investigations, including hematologic and biochemical examinations, revealed no abnormalities, especially the white blood cell count, which was normal. The rectoscopy, performed to rule out an eventual subclinical rectitis, was normal. Scrotal ultrasonography found a normal aspect of the 2 testes without any deep collection.

MRI showed a complex perineal fistula with a sagittal trans-sphincteric tract involving the corpus cavernosum (Figure 1, Figure 2). There was no evidence of thrombosis within the corpora. There were 2 external openings, one in the scrotum and the other in the perineum, and at least 2 internal openings in the external anal sphincter. The low fistula into the anal canal had penetrated the root of the scrotum and the bulb of the urethra, extending into the penile shaft. There was no involvement of the lower urinary tract (bladder, prostate, and urethra). Urethroscopy didn't show any urethral narrowing

KEYWORDS: Crohn's disease, diagnostic, fistula, complication, penis, MRI, treatment

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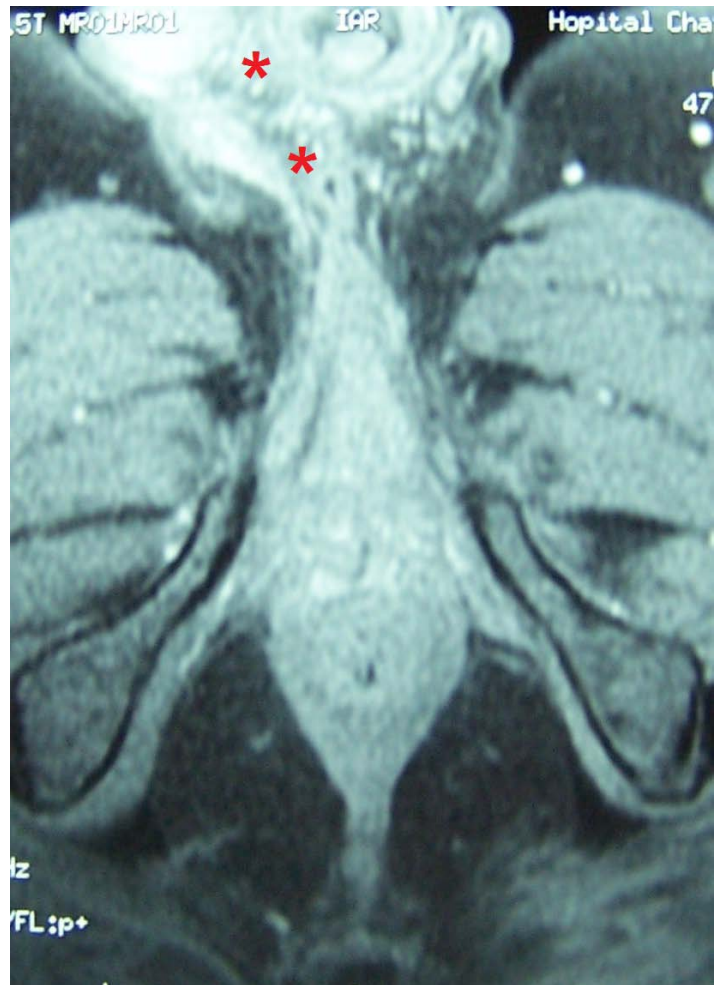
Figure 1. MRI of pelvis shows well-circumscribed abscess with central area of low attenuation and peripheral rim enhancement.

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Figure 2. MRI of the pelvis fitula within the left corpus cavernosum.

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or internal fistula opening. Thus, the diagnosis of complex fistulas with scrotal and penile involvement was made. Seton placement, associated with antibiotics as adjuvant treatment, was performed. Infliximab has been conducted thereafter because of the complex aspect of fistulas. The patient's symptoms resolved and he was discharged.

Six months after he remains in good health and has had no further relapses of his CD. The scrotal and perianal fistulae remain healed. He didn't report any gastrointestinal, voiding, or sexual complaints.

DISCUSSION

CD commonly presents in adults. Genitourinary manifestations of CD are rare and often secondary to gastrointestinal symptoms. Such complications occur in 5 to 20% of patients [1]. Two theories [2,3] were reported to explain genital involvement of CD in males:

1. Direct extension from the diseased bowel with transmural fistulization; it may affect all pelvic organs causing fistulas, abscesses, edema, and ulceration.

2. "Metastatic" deposit granulomas and abscesses involving the penis, scrotum, seminal vesicles, and prostate; they may form independently from the diseased intestine or in the absence of active bowel disease.

Metastatic CD was described for the first time by Parks et al. [4]. Clinically, it presents as ulcers, papules, nodules, plaques, or crusts located most frequently on the extremities, flexures, and genitalia. It is necessary to exclude other granulomatous diseases such as cellulitis, erysipelas, intertrigo, sexually transmitted diseases, hidradenitis suppurativa, lichenoid eruptions, erythema nodosum, and primary and secondary lymphedema.

Penile involvement in cutaneous CD is uncommon and manifests in the form of non-healing ulcers or erosions with or without oedema [5,6]. The ulceration can lead to considerable destruction and distortion of the surrounding soft tissues.

Pelvic MRI becomes the referenced technique in the evaluation of perianal CD. There is a high sensitivity and specificity of 100 and 86%, respectively, in the detection of a fistula's primary tracts, and a high sensitivity and specificity of 96 to 97%, respectively, in the detection of abscesses [7,8].

MRI is particularly useful for complex perianal fistulas to detect deep sepsis and their relationship with the sphincter and the genitalia [9]. MRI provides information about perianal disease activity and assess inflammatory changes in fistula tracks in response to treatment with Infliximab [10,11]. To our knowledge, this is one of the first reported cases of MRI findings for a patient with CD involving the penis.

Endoscopic exploration of the lower urinary tract is indicated in such cases to rule out any other cause of fistula or an associated complication, such as urethral stricture.

The treatment of perineal and genital cutaneous CD is controversial, and a number of therapies have been advocated. But first of all a rectoscopy should be performed to establish the existence of macroscopic inflammatory activity in the rectum [12]. Antibiotics are useful, although they have only been assessed in uncontrolled, open-label studies (evidence level 3; recommendation grade D) [13].

In recent years there has been a significant change in treatment with the incorporation of new drugs such as immunosuppressants (azathioprine), 6-mercaptopurine, methotrexate and cyclosporine, and more recently infliximab, which are combined with local surgical treatments (abscess

drainage and seton placement), such as our case, in order to preserve rectal anal function [14].

CD fistulae seem to be an operative challenge for the surgeon, as they tend to be associated with significant scarring and insufficient surrounding tissues to allow for a tension-free closure. For this reason, interposition of the tissue for good vascular supply is necessary to facilitate healing [15]. Fistulotomy will rarely be possible and, before establishing any surgical option, rectosigmoid intraluminal inflammatory bowel activity must be controlled [12]. In all cases, long-term medical treatment and follow-up are mandatory.

CONCLUSION

Genitourinary manifestations of Crohn's disease are rare. MRI can help determine disease activity in genitourinary locations and might be helpful in selecting a subpopulation of patients who should be monitored more closely for the development of more extensive disease.

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