Extracorporeal shock waves lithotripsy versus retrograde ureteroscopy: is radiation exposure a criterion when we choose which modern treatment to apply for ureteric stones?

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ABSTRACT

The aim of this study is to compare two major urological procedures in terms of patient exposure to radiation. We evaluated 175 patients, that were subjected to retrograde ureteroscopy (URS) and extracorporeal shock waves lithotripsy (ESWL) for lumbar or pelvic ureteral lithiasis, at two urological departments. The C-arm Siemens (produced in 2010 by Siemens AG, Germany) was used for ureteroscopy. The radiological devices of the lithotripters used in this study in the two clinical centers had similar characteristics. We evaluated patient exposure to ionizing radiation by using a relevant parameter, the air kerma-area product ($P_{KA;}$ all values in cGy cm^2), calculated from the radiation dose values recorded by the fluoroscopy device. P_{KA} depends on technical parameters that change due to anatomical characteristics of each case examined, such as body mass index (BMI), waist circumference, and stone location. For the patients subjected to ESWL for lumbar ureteral lithiasis the mean of P_{KA} (cGy cm^2) was 509 (SD=180), while for those treated for pelvic ureteral lithiasis the mean of P_{KA} was 342 (SD=201). In the URS group for lumbar ureteral lithiasis, the mean of P_{KA} (cGy cm^2) was 892 (SD=436), while for patients with pelvic ureteral lithiasis, the mean of P_{KA} was 601 (SD=429). The patients treated by URS had higher exposure to ionizing radiation dose than patients treated by ESWL. The risk factors of higher radiation doses were obesity, exposure time, and localization of the stones.

KEY WORDS: extracorporeal shock waves lithotripsy, retrograde ureteroscopy, radiation

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INTRODUCTION

Treatment of ureteric stones is nowadays performed by retrograde ureteroscopy (URS) and extracorporeal shock waves lithotripsy (ESWL). The most recent guidelines (2014) from EAU (European Association of Urology) [1] recommend (grade A) as the first treatment option (Table 1): ESWL for proximal ureteral stones <10 mm and ureteroscopy for distal ureteral stones >10 mm; URS and ESWL are considered equivalent options for proximal ureteral stones >10 mm and for distal ones <10 mm.

While the long debate about the effectiveness and aggressiveness of two procedures is still ongoing, radiation exposure during this treatment may represent a risk of subsequent malignancy [2,3]. Recent technological advancements in endourology have had a great influence on URS, which has led to changes in the practice guidelines accordingly. While in 1997 the American Urological Association (AUA) guidelines recommended ESWL for lithiasis of the lumbar ureter with a stone size below 1 cm as the first line treatment, and for stones

TABLE 1. Ureteral stones treatment choice.

Ureteral stone		Option	
Location	Size	First	Second
Proximal	<10 mm	ESWL	URS
	>10 mm	URS or ESWL	
Distal	<10 mm	URS or ESWL	
	>10 mm	URS	ESWL

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of the distal ureter either URS or ESWL, 10 years later the AUA and EAU guidelines suggested the superiority of ureteroscopy for all types of lithiasis regardless of the size or position, except for lumbar ureteral stone size below 1 cm. The aim of this study was to evaluate whether the two procedures, which dispute the supremacy for the treatment of lumbar and pelvic ureteral stones, expose the patient to a substantial radiation and if this aspect should be taken into consideration when establishing the therapeutic strategy.

MATERIALS AND METHODS

We prospectively evaluated 175 patients subjected to URS or ESWL for lumbar or pelvic ureteral lithiasis, admitted to two Departments of Urology (in Iași, Romania and Târgu Mureș, Romania) from 01.07.2013 to 01.01.2014. Both departments use C-arm Siemens (produced in 2010 by Siemens AG, Germany), for ureteroscopy and radiological focusing of stones, and the radiological devices of the lithotripters have similar characteristics, measured the same way. In our prospective survey all four urologists involved had a wide experience in URS and ESWL, with a positive impact on limitation of fluoroscopic exposure time, both urological centers involved having over 4,000 cases treated through these procedures in the last seven years, while open surgery has been performed only as a relatively rare exception. In the evaluation of our study the age and the gender of the patients were also analysed.

All the comparisons described below refer to the radiation dose recorded by the fluoroscopy device, expressed as the air kerma-area product (P_{KA}; cGy cm^2). P_{KA} depends on various technical parameters, changing for example due to anatomical differences among patients, such as: body mass index (BMI), waist circumference, and stone location. The fluoroscopy device assumes a total projection area of 100 cm^2 of the patient's skin during the entire procedure. We also recorded and compared the intraoperative radiation exposure time. The average size of stone was similar in ESWL and URS groups for both lumbar and pelvic ureteric stones.

In terms of BMI we divided patients according to the recommendations from the World Health Organization (WHO): normal weight (BMI<25 kg/m^2) and overweight to obese (BMI>25 kg/m^2). Although abdominal obesity has several different definitions, we considered the population criteria of the International Diabetes Federation (IDF) to be the best, adapted to the conditions of the study. According to these criteria the patients with abdominal obesity are those with a waist circumference longer than 90 cm in men and 80 cm in women. Depending on the location of stones we divided the patients into two groups: those with lumbar ureteral stones and those with pelvic ureteral stones. The exposure time was expressed in seconds. Additionally, we have to mention that the urologist was in control of the pedal all the time, being concerned about his own exposure to ionizing radiation. We used the last image hold technique, associated with maintenance of the pulse rates as low as possible. In our centers we developed the same protocol of fluoroscopic monitoring for the important moments of URS and uretero pyelography, position check for the guide wire, control of residual/migrated fragments, and the final position of the double J catheter.

For hypothesis testing we used Student's t-test, as performed by SPSS (v. 17.0, IBM Corporation), without adjustment for multiple testing and with nominal significance level defined as $p<0.05$. Continuous variables were described using the ANOVA test. Sample normality was proven as follows, the distribution in a data series was considered normal if simultaneously: (a) ~68% of the values are in the mean ± 1 SD range; (b) ~ 95% of them are in the mean ± 2 SD range. The respective values in this study were all higher than the specified limits (see a and b above):

- P_{KA} 84% vs. 68% and 100% vs. 95%;
- BMI 90% vs. 68% and 95% vs. 95%;
- waist circumference 83% vs. 68% and 98% vs. 95%.

RESULTS

From the total of 175 patients, in 92 of them we performed ESWL and the rest of 83 patients underwent URS. In terms of gender distribution this study comprised of 105 men and 70 women; sex ratio M/F=1.5. The patient age was ranged between 19 and 81 years, with a mean of 49.62 years (SD=15.61 years, 95% CI) and no significant difference between genders (p=0.864). One hundred and seven patients had BMI>25 kg/m^2 (65 men and 42 women) and 68 patients had BMI<25 kg/m^2 (40 men and 28 women). No significant differences of BMI mean were observed between the URS and ESWL groups. There were no significant statistical differences in terms of BMI between men and women ($p=0.847$, SD=4.8). 128 patients had abdominal obesity and 47 patients had normal waist circumference. Depending on the location of the calculi, 90 patients (51.4%) presented with lumbar ureteral stones (52 men and 38 women) and 85 patients (48.6%) pelvic ureteral stones (53 men and 32 women). The mean stone size was 6 (3-11) mm in the ESWL group and 7.1 (4-13) mm in the URS group; with no significant statistical difference ($p>0.05$) between these two groups.

Patient radiation dose was expressed in terms of total P_{KA} in cGy cm^2. Patients who underwent ESWL for lumbar ureteral lithiasis were exposed to an ionizing radiation dose between 154 cGy cm^2 and 890 cGy cm^2, with a mean of 509 cGy cm^2 (SD=180 cGy cm^2), while for those who were treated for pelvic ureteral lithiasis, the received dose was between 111 cGy cm^2 and 910 cGy cm^2, with a mean of

342 cGy cm² (SD=201 cGy cm²). In the URS group for lumbar ureteral lithiasis the radiation dose was between 200 cGy cm² and 2304 cGy cm², with a mean of 892 cGy cm² (SD=436 cGy cm²), while patients with pelvic ureteral lithiasis received a dose between 166 cGy cm² and 1765 cGy cm², with a mean of 601 cGy cm² (SD=429 cGy cm²). Patients with BMI <25 kg/m² subjected to ESWL received a dose between 122 cGy cm² and 890 cGy cm², with a mean of 316 cGy cm² (SD=177 cGy cm²) and those subjected to URS received a dose between 166 cGy cm² and 1207 cGy cm², with a mean of 416 cGy cm² (SD =289 cGy cm²).

In terms of average radiation dose the study groups presented the following differences. In patients suffering from pelvic ureteral stones, especially those with lumbar ones, the average radiation dose was higher in the URS group (***p***=0.001). In obese patients the average dose of radiation was higher in URS group (***p***=0.001), while in patients with normal weight the average radiation only tended to be increased in the URS group (***p***=0.089).

By comparing the groups in terms of BMI and waist circumference (Table 2) it is evident that all the groups with obese and abdominally obese patients received radiation doses higher than the normal weight group.

In terms of average exposure time depending on location of the ureteral stone, the studied groups presented the following differences (Table 3):

- In obese patients with lumbar ureteral stones, the average exposure was increased in the URS group (***p***=0.014) versus the ESWL group, with a similar observation in patients with abdominal obesity (***p***=0.036);
- The average exposure shows no differences between the URS and ESWL groups in patients with pelvic ureteral stones and with obesity or abdominal obesity.

TABLE 2. Influence of body mass index and waist circumference upon patient radiation.

Ureteral stone group	Air kerma-area product (cGy cm²)		*p*	Air kerma-area product (cGy cm²)		*p*
	BMI>25	BMI<25		Abd. obesity	Normal waist circ.	
Lumbar						
ESWL	567	386	0.001	555	392	0.002
URS	1089	544	0.001	1004	558	0.001
Pelvic						
ESWL	420	246	0.004	426	213	0.001
URS	815	338	0.001	663	303	0.018

TABLE 3. Influence of body mass index and waist circumference upon exposure time.

Ureteral stone group	Procedures	Exposure time (s)		*p*	Exposure time (s)		*p*
		BMI>25	BMI<25		Abd. obesity	Normal circum.	
Lumbar	ESWL	209	160	0.001	208	156	0.001
	URSR	286	153	0.016	268	148	0.054
	p	0.014	0.647	-	0.036	0.721	-
Pelvic	ESWL	207	185	0.567	209	179	0.444
	URSR	241	125	0.002	207	100	0.039
	p	0.414	0.061	-	0.943	0.130	-

DISCUSSION

In most studies success rate is, as expected, the main criterion for comparison between the two procedures. Many authors who compared the stone-free rate for ESWL versus URS revealed the superiority of the last one. In 156 patients of which 87 underwent URS and 69 ESWL, Hendrikx revealed a stone-free rate of 51% for ESWL compared to 91% for URS [4]. In a meta-analysis from 2012 Aboumarzouk revealed a stone-free rate lower for ESWL (7 trials; 1,205 participants), compared to URS (5 studies, 751 participants), but with a lower rate of complications [5]. According to EAU guidelines, the stone-free rate in the case of pelvic ureteral stones is ~82%, similar for ESWL and URS. In case of lumbar ureteral stones, the stone-free rate of 93% is in favor of URS compared to 74% for ESWL. Therefore urologists choose URS as a first line treatment for ureteral lithiasis. This option is confirmed by a study from Canada, Orduna et al. showing that ESWL decreased from 68.5% in 1991 to 33.7% in 2010, while URS increased from 24.6% to 59.5% (URS almost replaced ESWL) [6].

Both procedures may have complications, so that another criterion that can help in making the right decision is their comparative analysis from this point of view. For ESWL complications are practically insignificant and the procedure can be repeated after a few days in case of failure or partial success. In the case of URS, according to Geavlete et al, there may be mucosal injury (1.5%), ureteral perforation (1.7%), ureteral avulsion (0.1%), renal colic (2.2%) or sepsis (1.1%) [7]. Previous studies generally show that the incidence of infectious complications and renal colic is slightly higher with ESWL. However, Aboumarzouk believes that URS brings more serious complications, requiring prolonged hospitalization, despite the higher stone-free rate compared to ESWL [5]. The cost of medical treatment is always an important issue. Several authors have compared the cost of URS versus ESWL used for ureteral lithiasis treatment. While Francesca and Kapoor et al. indicated that URS is cheaper and more efficient than ESWL [8,9], Anderson et al. showed similar costs [10]. In our attempts to choose the right treatment procedure for each patient, we have to take into consideration the preference of every patient, who must have the best information we can provide. Pearle and Lee, on groups of 223 and 228 patients respectively, found that the patients have a higher satisfaction with ESWL versus URS [11,12].

The side effects of exposure to ionizing radiation are well known, with erythema being the first visible complication. In the case of single-delivery radiation the risk threshold is

20,000-50,000 cGy cm² for simple transient erythema and >150,000 cGy cm² for transient erythema with edema and acute ulceration [13]. The radiation doses for our patients treated by ESWL or URS were lower than the mentioned threshold for simple erythema and we emphasize that the results presented here are doses delivered along the entire surgical procedure (Table 4).

The increasing use of X-rays for the management of urinary lithiasis (diagnosis and treatment) could raise the question of radiation exposure of patients and urologists. The dose of radiation per patient has increased 6 times in the United States since 1980 and because of this there have been concerns regarding the increasing incidence of ionizing radiation-induced cancers [14,15].

Comparing ESWL and URS regarding the X-ray exposure of the patient, Rebuck et al., found no significant difference between the two procedures [16]. Nevertheless, we found a significant difference between these two groups, for patients with BMI>25 and lumbar stones (***p***=0.014) and for patients with abdominal obesity and the same location of stones in the ureter (***p***=0.036). Although our results show a significant difference between the two procedures, we agree that this information is relevant only for patients with recurrent stones who need repeated interventions, with the risk of cumulative exposures over time. In our opinion this is also relevant for the young patients with high potential of recurrent stones.

According to Preston et al. exposure to ionizing radiation at the age of 30 increases the incidence of cancers of parenchymal organs till the age of 70 by 35% per Gy for men and by 58% per Gy for women [17]. The conclusions drawn after some of these studies had been performed were that the medical team should be aware of radiation risks and, that improved urological techniques may decrease radiation exposure [18-20]. Given that younger patients are more frequently subjected to surgery under fluoroscopic guidance and also knowing that they are more susceptible to radiation-induced lesions than older patients [21], the kind of treatment we perform is important. From this point of view it is a challenge for urologists to perform the best treatments which lead to the stone free result, but meanwhile with lower doses of radiations for both the patients and the medical staff. Here we discuss separately the issue of patient irradiation during the procedure, both methods using X-rays for stone detection and fragmentation monitoring. We strongly believe that such a discussion is fully justified, for the reasons we present below. Patients with lithiasis are exposed to radiation for both diagnostic and therapeutic purposes. Babbin et al. calculated that patients are exposed to a dose of 5.3 mGy per lithiasic episode on average and this dose is increased by performing CT-scan or other interventions [22]. Both forms of treatment use X-rays for diagnosis, the patients are subjected to ionizing radiation irrespective of stone location and size, BMI or waist circumference; during urography this is similar, with an average of about 2.5 cGy cm² [22].

TABLE 4. Parameters that influence patient radiation via ESWL and URS.

Parameter	ESWL (cGy cm²)	URS (cGy cm²)	*p*
Lumbar ureteral stone	510	892	0.001
Pelvic ureteral stone	342	602	0.001
BMI>25	513	944	0.001
BMI<25	316	417	0.089
Abdominal obesity	507	803	0.001
Normal waist circumference	303	438	0.107
Total	441	728	0.001

The radiation dose received by the patient varies depending on many factors: size of the stones, operator experience, radio-opacity of the stones, patient's abdominal obesity, stone enclavation in the ureteric mucosa, intraoperative difficulties due to anatomical causes, etc. In addition, the patient is subjected to X-ray ionizing radiation in order to establish the diagnosis and for post-therapeutic control. Thus, a patient with ureteric stones during iv urography receives an average radiation dose of 2.5 cGy cm² (depending on the number of X-ray pictures made), and during the post-procedures they further receive an average of 0.7 cGy cm², depending on the number of radiographs necessary [22]. Patients undergoing ESWL may receive a radiation dose between 2.33 cGy cm² and 398 cGy cm², while for URS the dose is between 2.23 cGy cm² and 590 cGy cm² [23,24]. This varies depending on the patient's weight and on the stone size [25]. Obese patients can receive 3 times higher doses [26]. The urologist's knowledge regarding ionizing radiation is another important aspect, because urologists with more than 2 years of experience, who monitor the radiation dose during surgery, can decrease it by up to 55% [18]. Probably this is not the same for urologists with less experience. The average radiogenic risk for genetic defect associated to treatments of proximal and distal ureteral stones was found to be 2.5 and 24.4 per million of births, respectively. The radiation risk from a typical fluoroscopy guided ESWL treatment of ureteral stones is low [27]. Although the measured doses were infinitesimal, ESWL cannot be considered a safe treatment procedure, because of the cumulative effect due to the repetition of procedures in addition to pre and post-examination exposures [28].

Possible limitations of our study could be the following: absence of a non contrast-enhanced CT evaluation of stone density and of skin to stone distance, as well as the fact that no patient enrolled with ureteric stone and double J stent previously inserted (although Rebuck et. al) [16] did not demonstrate significant differences in terms of X-ray exposure between patients with or without double J catheter). Also, the URS procedure was not performed with the flexible ureteroscope in any of the centers.

CONCLUSIONS

Comparative evaluation of the level of ionizing radiation using air kerma-area product for a patient with the same lithiasis pathology (including stone location and size) treated with different therapeutic methods revealed higher values of air kerma-area product in patients subjected to URS versus ESWL, also confirmed by other studies. Patients with BMI>25kg/m^2 received higher radiation doses than those with BMI<25kg/m^2. However, all these ionizing radiation levels are low, so we consider that urologists must have these issues in mind when treating patients with recurrent urolithiasis, possibly requiring repeated X-ray guided endourological procedures. On the other hand, further research on the relation between re-treatment rate and radiation exposure, until the stone free status is reached, appear to be particularly of interest.

DECLARATION OF INTEREST

The authors declare no conflict of interest.

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