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Comparison of single-use flexible URS and re-usable flexible URS: Effectiveness, reliability, cost-efficiency analysis

Mustafa Erkoc[1], Huseyin Besiroglu[2]

[1]Beylikduzu State Hospital, Department of Urology, Istanbul,Turkey
[2]Catalca Ilyas Cokay State Hospital, Department of Urology, Istanbul,Turkey

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Abstract

Comparison of Single-use Flexible Ureterorenoscopy (SF-URS) with Reusable Fiberoptic Flexible Ureterorenoscopy (RF-URS) is one of the most popular subject in Endourology. Flexible Ureterorenoscopy (F-URS) is the gold standard method used in the treatment of kidney and ureteral stones smaller than 2 cm and together with ESWL.SF-URS has been widely used along with RF-URS. Our study aims to analyze retrospectively RF-URS and SF-URS in terms of effectiveness, reliability and cost. 200 patients who underwent F-URS due to renal stones were included in our study. Patients were divided into 2 groups: 100 patients who underwent SF-URS and 100 patients who underwent RF-URS. Mean age of the two groups was 49.58, 50.24 in the RF-URS and SF-URS groups, respectively. The presence of hypertension and diabetes, Body Mass-Index (BMI), and stone characteristics were recorded, and postoperative stone-free rates, duration of hospital stay, duration of operation, post-operative hemoglobin loss, postoperative urosepsis, and auxiliary procedures were evaluated. A cost effective analysis was carried out. The demographic data and stone characteristics of both groups were similar and there was no statistically significant difference ($p> 0.05$). The SF-URS group was found to be more advantageous in terms of the duration of operation ($p<0.05$). Other operational data were similar to each other and no statistically significant difference was found ($p>0.05$). The RF-URS group was found to be more advantageous after a cost-effective analysis ($p<0.05$). SF-URS has an advantage over RF-URS in terms of image quality, ease of use and duration of operation. RF-URS was found to be more advantageous in a cost-effective analysis. In terms of other operational data, both procedures were similar. Well-designed prospective randomized controlled trials are needed.

Keywords: Flexible URS, kidney stone, RIRS, stone

Introduction

Renal stone disease is one of the most common diseases in daily urology practice [1]. With the advanced technologies, minimally invasive procedures for kidney stones and ureteral calculi have become prominent. Although the treatment method for the stone depends on the size and location of the stone, percutaneous nephrolithotomy is recommended for the treatment of kidney stones greater than 2 cm, whereas ESWL (Extracorporeal Shockwave Lithotripsy) and Flexible Ureterorenoscopy (F-URS) are recommended as the gold standard for stones smaller than 2 cm. Especially in ESWL-resistant stones, the most important treatment method is F-URS [2-5]. Furthermore, F-URS can be used for all age groups, from pediatric patients to geriatric patients, thanks to its low complication rates and its less invasive intervention [4,5].

With the technological developments in laser systems, and considerable improvements in imaging methods, F-URS is also used for much larger stones [6].

Although the stone size of 1-2 cm has been specified as the optimal usage range in studies, Flexible URS can also be used for stones up to 3 cm [7]. Recently, Single-use Flexible Ureteroscopes (SF-URS) have been developed as an alternative to Re-usable Fiberoptic F-URS (RF-URS). While RF-URSs in our clinic use fiber-optic imaging systems, SF-URSs uses digital video imaging systems. This difference enables SF-URS to be more advantageous in terms of weight of the device and vision quality [8]. These two types of URS used in the treatment have been discussed in terms of effectiveness, reliability and cost, and have recently been a popular topic to popular publications [9]. Although there have been some studies on this subject in the literature, there is a need for more studies comparing these two groups. Reusable digital F-URS devices are also used in the treatment of renal and ureteric stones. There are studies about this device; however, it is not available in our clinic [10]. Accordingly, our study aims to analyze RF-URS and SF-URS in terms of effectiveness, reliability and cost.

***Coresponding Author:** Mustafa Erkoc, Beylikduzu State Hospital, Department of Urology, Istanbul,Turkey. E-mail: mustafa.erkoc@yahoo.com

Material and Methods

This study was carried out with the Okmeydani Training and Research Hospital Ethics Committee's approval dated 16.04.2019 and numbered 1234.Informed consent form was obtained from all patients.The type of the study was retrospective. Two hundred patients who underwent operations due to kidney and ureteral stones were included in the study. RF-URS was applied to 100 of the patients, and SF-URS was applied to the other 100. Patients between 20-70 years of age with renal pelvis or proximal ureteral stone size of 10-24 mm, and who did not receive prior surgical treatment, were included in the study. Patients who had previous surgical treatments, used anticoagulants, had serious additional comorbidities and had congenital kidney anomalies were excluded. All operations were performed by a single surgeon. Patients underwent a routine hemogram, biochemistry tests, INR and urine culture before the operation. Unenhanced abdominal computerized tomography was applied to all patients before the operation. In addition, contrast imaging methods were applied to the patients if necessary. Firstly, the urethra, bladder and ureter were observed by semi-rigid URS in all patients. Then, a guide-wire was left in the kidney. A ureteral access sheath (Navigator HD Boston Scientific 11-13 F) was introduced through guide wire. In patients in which ureteral access sheaths could not be placed, direct access was made through the guide. Double J(DJ) stents were placed in 40 patients, where it was not possible to enter the ureter and they were re-operated on 4 weeks later. The stone was found by F-URS. With a Holmium Yag laser (QUANTA Holmium; Yag laser litho DK30 watt) device, stones were pulverized. Laser settings were standard for all patients (1.2 Joule,8 Heartz,9.6 Watt).DJ stents were applied to all patients after the operation. The kidney and urinary system were monitored by using X-rays 24 hours after the operation. DJ stents were removed from patients two weeks later. The Storz Flex-X2 Flexible Ureteroscope was used as the RF-URS device. A total of 3 RF-URS devices were used in 100 patients. Since the first RF-URS device broke down after the 35th patient, and the second RF-URS device broke down after the 72nd patient, they were replaced with a new one. The AnQing Eu Single-Use Digital Flexible Ureteroscope(Shanghai AnQing Medical Instrument Co.,Shangai,China) was used for each patient as the SF-URS device.

The patients were classified into two groups, being RF-URS and SF-URS. The presence of hypertension and diabetes, Body Mass-Index (BMI), stone location, stone size, stone density and hounsfield unit (HU) score of all patients was recorded. Postoperative stone-free rates, length of hospital stay, operating time, loss of postoperative Hb loss, postoperative urosepsis, ESWL and the data on whether a second operation is needed or not were recorded. The stone-free rate was determined according to unenhanced abdominal computerized tomography applied 3 months after the operation. A cost-effective analysis of the operation was examined. The data were analyzed by using Statistical Package for the Social Sciences, V. 22.0 (SPSS; SPSS Inc, Chicago, IL, USA). Continuous variables were compared by independent samples t-tests in case the variables had normal distribution according to Kolmogorov-Smirnov test. Otherwise the Mann Whitney-U test was used. Categorical variables were compared by chi-square or Fisher exact tests, as appropriate. The value of ($p<0.05$) was considered as statistically significant.

Results

Demographic data and stone characteristics of the patients were analyzed. The age, gender, BMI, stone density at tomography, stone size, operation-side and stone locations were examined, and no statistically significant difference was found ($p>0.05$). The demographic and stone characteristics of the patients are shown in detail in Table 1.

Table 1. Demographic data and stone characteristics

Parameters	RF-URS(100)	SF-URS(100)	P value
Age(y) mean±SD	49.58±12.58	50.24±12.12	0.630
Sex n%			
Male	72(72%)	70(70%)	0.952
Female	28(28%)	30(30%)	0.782
BMI (kg/m²), mean ±SD	26.07±4.55	25.84±3.56	0.756
Stone CT density (Hu), mean ±SD	978.42±288.28	1012.52±290.48	0.236
Stone size (mm), mean±SD	15.84 ±5.15	16.18±5.32	0.872
Operation Side n%			
Right	60(60%)	58(58%)	0.932
Left	40(40%)	42(42%)	0.898
Stone Location			
Upper Calix	2	3	0.728
Mid Calix	3	3	1.000
Lower Calix	25	25	1.000
Pelvis	32	30	0.882
Proximal Ureter	38	39	0.920

The mean operation time was found as 72.48 ± 24.32 and 58.14 ± 18.68 minutes in the RF-URS and SF-URS groups, respectively, and statistically significant difference was found (p <0.05). Stone-free rates of the patients were 83 (83%), 85 (85%) in the RF-URS and SF-URS groups, respectively, and no statistically significant difference was found (p>0.05). Durations of hospital stay were found to be 1.92 ± 0.32 and 1.74 ± 0.28 days in the RF-URS and SF-URS groups, respectively, and no statistically significant difference was found (p> 0.05). Also, after analyzing the rates of hospitalization due to secondary intervention rates, postoperative hemoglobin loss, and postoperative urosepsis, no statistically significant difference was found (p >0.05). Operational data of the patients is summarized in Table 2.

Table 2. Operational data of patients and cost-effective analysis

Parameters	RF-URS(100)	SF-URS(100)	P value
Operating time (mn)	72.48±24.32	58.14±18.68	0.0098
Duration of hospital stay (day)	1.92±0.32	1.74±0.28	0.236
Stone free rate n%	83(83%)	85(85%)	0.732
Secondary intervention (ESWL,Operation) n%	17(17%)	15(15)	0.584
Postoperative hemoglobin loss (g/dl) mean ±	0.842±0.392	0.834±0.348	0.968
Postoperative urosepsis n %	2(2%)	2(2%)	1.000
Cost Effective Analysis Per Patient(USD)	465	1100	0,012

A cost-effective analysis on the patients was carried out for the F-URS costs only, since the patients' operation procedures were the same except for F-URS. Cumulatively, in the SF-URS group, the single-use URS cost in our country was USD 110.000, and the cost per patient was USD 1.100. A total of three F-URS devices were used for 100 patients in the RF-URS group. 35 patients used the first RF-URS device and 37 patients used the second RF-URS device. The study was completed without any failure in the 3rd device. The price of the RF-URS device we use in our country is around USD 15.000. There is no difference between the maintenance and exchange costs for the devices in our country. Therefore, the devices are exchanged. Sterilization of RF-URS is performed via the hydrogen peroxide device. In our hospital, each application costs 15 US Dollars. A total of 100 applications would create a sterilization cost of 1500 US Dollars. Cumulatively, the cost in the RF-URS group was USD 46.500. The cost per patient was approximately USD 465. A statistically significant difference was found (p<0.05).

Discussion

AF-URS plays an important role in the treatment of kidney stones smaller than 2 cm. After the use of F-URS devices as a treatment modality, they have become the gold standard method due to low stone-free rates and complication rates [11]. In a study consisted of 279 patients conducted by Elbir et al, stone-free rate was found to be 78.4%, therefore, it was found that F-URS was an effective and reliable method in proximal ureters and kidney stones [12]. In addition, there are studies that suggest that it may be an alternative to PCNL for kidney stones greater than 2 cm [13]. Furthermore, it has been demonstrated that F-URS can be used effectively in all age groups [4,5,14].

SF-URS devices have been recently preferred due to their easy portability and better image quality compared with RF-URS devices. Salvado et al. examined the effectiveness of SF-URS in 71 patients. Their stone-free rates were as follows: 97.9% in stones smaller than 10 mm, 95.4% in stones between 10-20 mm, and 78.9% in stones greater than 20 mm. They reported that SF-URS technique is a reliable and effective method in kidney stone surgeries [15]. Many studies are available comparing the effectiveness of SF-URS and RF-URS devices. Davis et al. found similar stone-free rates for both procedures in a systematic review of 11 studies including 466 patients. This study demonstrated that SF-URS devices are easier to use and have better image quality compared with RF-URS devices, but it was stated that a cost-effective analysis should also be done [16]. Qi et al. divided 126 patients into two equal groups and compared SF-URS and digital reusable F-URS differently other studies. They demonstrated that SF-URS can be used as a reliable and effective method like digital reusable F-URS [9].

With the emergence of the comparable outcomes of SF-URS in terms of the stone free and complication rates, and with more favorable ergonomic advantages compared with RF-URS, the two methods are starting to be compared in terms of cost-effectiveness. Hennessey DB et al. examined both procedures in terms of cost-effectiveness and demonstrated that RF-URS is more advantageous, especially in hospitals with a high number of patients [17]. In the systematic review in which Talso et al. and PETRA URO Group analyzed 19 studies to compare both procedures in terms of cost-effectiveness, they found that RF-URS was more advantageous, although both methods had similar effectiveness rates [18].

Unlike other studies, our study found that SF-URS is more advantageous than RF-URS in terms of operating time. It also revealed that both procedures have similar results and are consistent with the literature in terms of stone-free rates, duration of hospital stay, and postoperative hemoglobin loss. Additionally, in accordance with the literature, RF-URS is more advantageous in terms of cost-effectiveness. Despite the fact that the costs of SF-URS are high, it should be considered that it provides ease of learning without the fear of breaking down particularly in hospitals, which offer assistant training; and that the breakdown of RF-URS device would result in higher costs. In addition, it should be noted that a substitute device is required in hospitals where RF-URS device is used as a measure in the case of breakdown. The experience of the surgeon is of utmost importance in F-URS.

The studies have shown that RF-URS has an economic life of 24-44. Our study is in line with the literature [9,18]. We could also say that our surgeon, who implements the operation procedure, is experienced in the field [5].

There are various limitations in our study. Our study is retrospective, and the duration of fluoroscopy was not recorded. Furthermore, the high costs of the devices in our country should also be taken into consideration. In addition, it should be considered that the economic life of the RF-URS could vary based on the experience of the surgeon and localization of the stone. The operation period is approximately 20% shorter in the SF-URS group when compared to the other group. This does not affect the operation costs in the RF-URS group statistically; however, it may increase them to a certain extent. Considering that the consumables to be used in both procedures are similar, the cost of staff, cleaning and nursing services is 25 USD per operation in our country, which is negligible when compared to other costs [19]. It was not included in the data of the study as it was not recorded.

Conclusion

SF-URS devices were found to be more advantageous than RF-URS devices in terms of the ease of use, image quality [8] and operating time. RF-URS was found to be more advantageous in terms of cost-effectiveness. There is a need for better designed wide-range studies to support our results on this subject.

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Conflict of interests
*There is no conflict of interests between authors***.**

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Ethical approval
This study was carried out with the Okmeydani Training and Research Hospital Ethics Committee's approval dated 16.04.2019 and numbered 1234.

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