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Comparative medico-economic study of reusable vs. single-use flexible ureteroscopes

Khalid Al-Balushi[1] · Nathalie Martin[2] · Hélène Loubon[1] · Michael Baboudjian[1] · Floriane Michel[1] · Pierre-Clément Sichez[1] · Thomas Martin[1] · Eugénie Di-Crocco[1] · Sarah Gaillet[1] · Veronique Delaporte[1] · Akram Akiki[1] · Alice Faure[3] · Gilles Karsenty[1] · Eric Lechevallier[1] · Romain Boissier[1]

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Abstract

Purpose Reusable flexible-ureteroscopes (fURS) require personnel and budget for processing and repairing, whereas single-use fURS were recently developed. After exclusive reusable fURS since 2011, we experienced high repair costs and single-use fURS were therefore introduced in mid-2017. We aimed to evaluate economic and practical advantages and disadvantages of reusable versus single-use fURS.

Materials and methods First, we evaluated the incidence of breakage and repairs of reusable fURS in 2017. We assessed the overall operational costs of reusable fURS including purchase, processing, and repairing in our institution from 2011 to 2017. Following our experience, we created a model to compare operation costs/procedure of single-use fURS with reusable fURS depending on repair costs.

Results In 2017, repair costs of reusable fURS increased by 345% compared with the period 2011–2016, causing: a median unavailability per reusable fURS of 200 days/year (100–249), median number of functioning fURS 0/5–3/5 per operating day, while unavailability of reusable fURS had become the first reason for cancellation of procedure. Since it was introduced, single-use fURS accounted for 59% of the flexible ureteroscopy activity. Taking into account the costs of processing, maintenance and repair, in 2011–2016 versus 2017, the single-use fURS was cost-effective compared with the reusable fURS until the 22nd procedure versus the 73rd procedure, respectively.

Conclusions After years of exclusive reusable fURS, the rising incidence of breakage not only increased maintenance costs but also hampered daily activity owing to unavailability of the devices. The introduction of single-use with reusable fURS provided substantial help to maintain our activity.

Keywords Flexible ureteroscopy · Single-use ureteroscope · Optic fiber ureteroscope · Digital ureteroscope · Economic study

Introduction

The flexible ureteroscope is one of the most used instruments in urology. It allows minimally invasive diagnosis and treatment of a variety of upper urinary tract pathologies such as stones and upper urinary tract urothelial carcinomas (UTUC) [1–3]. The conventional flexible ureteroscope is a reusable instrument which requires certain procedures for disinfection and decontamination to be safely reused. Sterilization procedures take time and incur costs for products and materials as well as the cost of personnel [4–6].

With the increased use of fURS, urologists face challenges that can influence their performance. The lack of

✉ Romain Boissier
romain.boissier@ap-hm.fr

[1] Department of Urology and Kidney Transplantation, APHM, Conception University Hospital, Aix-Marseille University, 13005 Marseille, France

[2] APHM, Conception University Hospital, Central Pharmacy, Marseille, France

[3] Department of Pediatric Surgery, APHM, Timone University Hospital, Aix-Marseille University, Marseille, France

available fURS is a real problem in certain centers when fURS are being repaired or sterilized [7–10].

Single-use fURS have recently been developed (PUSEN Medical© Uscope®, Boston Scientific©, Lithovue®) [11–13]. These devices reproduce the characteristics of conventional reusable ureteroscopes: distal numeric image sensor, diameter from 7.7 to 9.5 Ch, bi-directional deflection of 270°, 3.6 Ch operator channel [14–16]. They have been manufactured to overcome the major inconveniences of reusable fURS which require decontamination and sterilization, availability in emergency situations, reduction of efficiency and life span with multiple use and complete sterilization procedures. In 2017, two models of single-use flexible ureteroscopes (PUSEN Medical© Uscope, Boston Scientific©, Lithovue®) were included in our endoscopic activities.

The aim of this study was to retrospectively report the real operating and repair costs of reusable fURS after an exclusive use since 2011, to evaluate the costs of single-use flexible ureteroscopes and their impact on our endoscopic activities in terms of decreasing the rate of cancellation/rescheduling.

Materials and methods

This is a single-center, retrospective study which included all flexible ureteroscopic procedures performed in our department from January 1 to December 31, 2017. These procedures were noted in the operating room registry. Flexible ureteroscopies were scheduled and performed by eight senior urologists for the following indications: kidney stones, management, diagnosis and conservative treatment of UTUC [17]. A ureteral sheath was used in all cases (Ch 9-10 Peel-Away Cook Medical®). A maximal intrarenal operating time of 1 h was respected for each procedure [18].

To evaluate the impact of single-use ureteroscope in our endoscopic activities, we collected all data regarding the causes of ureteroscopic procedure cancellation or rescheduling which included: inadequate preoperative management of infectious risk (i.e., preoperative urine culture not performed or not efficiently managed in case of urine infections), unavailability of a reusable flexible ureteroscope (breakdown, in repair) or the unavailability of other equipment (laser fibers, and fluoroscope).

The primary endpoint was the rate of procedure cancellation/rescheduling owing to the unavailability of reusable flexible ureteroscopes. The secondary endpoints were the availability of reusable flexible ureteroscopes assessed by the average number of flexible ureteroscopes available per operative day, the percentage of functioning flexible ureteroscopes and the average duration of repair (in days).

To evaluate the cost impact of single-use ureteroscopes compared with reusable flexible ureteroscopes, we conducted a retrospective medico-economic study that evaluated the costs of reusable ureteroscopes including the costs of operation, maintenance and repair over two periods: 2011–2016 versus 2017. We also evaluated the costs of single-use ureteroscopes.

Operating cost of reusable ureteroscopes

On January 1, 2017, our fURS included three fiber optic (Flex X, Storz®) and two digital ureteroscopes (Flex XC, Storz®). In the cost evaluation, we considered the costs of ureteroscope purchase, maintenance, repair and operating expenses. The cost of purchase was considered as depreciated after 5 years of utilization (Table 1).

Regarding reusable fURS repair, the following factors were taken into account: the duration of non-availability of a ureteroscope for repair (in days) and the costs of repairs (on the invoices supplied by the manufacturer). The costs of protocoled bacteriological examination before reutilization after repair were also included (Table 1).

Operating expenses involved the costs of decontamination, transport, and storage. After each procedure, a ureteroscope undergoes the first treatment in the operating room: wiping, aspiration, and tightness test. The second step in ureteroscope processing (sterilization and repacking) is carried out in the sterilization room, which involves: brush cleaning, rinsing, disinfection by soaking in peracetic acid, drying, and reconditioning. The third step in reusable fURS processing is transport from the decontamination room to the operating room. In all, the cost of materials and labor for the decontamination, repackaging and transport for each

Table 1 Characteristics of reusable ureteroscopes in December 31, 2017

Identification	Type	Price USD (Euros)	Year of purchase	Annual repair cost from purchase until 12/31/2016 USD (Euros)	2017 repair cost USD (Euros)	Unavailability in 2017 (days)
Ureteroscope 1	Fibered	12,530 (11,000)	2006	4126 (3621)	11,515 (10,105)	298
Ureteroscope 2	Fibered	14,300 (12,558)	2011	3898 (3421)	11,027 (9677)	286
Ureteroscope 3	Fibered	14,300 (12,558)	2012	4276 (3753)	10,545 (9254)	207
Ureteroscope 4	Numeric	17,452 (15,315)	2014	3490 (3063)	18,803 (16,500)	284
Ureteroscope 5	Numeric	17,452 (15,315)	2015	3063	6800	121

reusable ureteroscope was $71.67 (€62.89) per procedure. All of the costs for the operation of reusable fURS are presented in Table 2. Purchase of video equipment was not included in the medico-economic study since we considered that this equipment was not specific to flexible ureteroscopy.

The total cost of reusable fURS per procedure was calculated according to the following formula:

$$\text{Cost per procedure } (y) = (\text{cost of decontamination} + \text{repacking} + \text{transport per procedure}) + (\text{annual cost of repair}/\text{number of procedures per year}(x)).$$

The overall cost of flexible ureteroscopy activity based on the number of procedures was calculated by the formula:

$$\text{Overall Cost} = \text{number of procedure } (x) \times \text{cost/procedure } (y).$$

Cost of single-use ureteroscopes

Single-use fURS are provided in sterile packs which means they do not require decontamination or reconditioning before their utilization. Their only cost is for their purchase. Waste processing of single-use fURS was not taken into account, considering that incineration is also required for the waste of a flexible ureteroscopy performed with reusable fURS.

Table 2 Cost of sterilization, packaging, and transport of reusable ureteroscopes per procedure

	Cost USD (euros)
Consumables	
Pharmacy	22.78 (19.99)
Commissary	17.91 (15.72)
Other	
Water	0.14 (0.12)
Sterilization	12.6 (11.1)
Transport	5.29 (4.64)
Paramedical Staff	12.9 (11.3)

We therefore calculated the total cost of single-use fURS according to the following formula:

$$\text{Total cost } (y) = (\text{cost of purchase of each single use fURS} + 20\%\ \text{VAT}) \times (\text{number of procedures } (x)).$$

Statistics

Continuous quantitative variables are reported as mean ± standard deviation. Quantitative discontinuous data are reported in median [min–max]. Continuous data were analyzed by the Mann–Whitney test. A difference was considered significant if $P < 0.05$. Statistics were calculated with Xlstat® software version 2018.5 (Addinsoft, Paris, France).

Results

Causes of fURS cancellation or rescheduling

From January 1 to December 31, 2017, 390 fURS procedures were scheduled in our department. 104 (27%) of these interventions were canceled/rescheduled: 57 (55%) were canceled owing to the unavailability of fURS (broken, in repair), 35 (34%) were canceled owing to inadequate preoperative management of infectious risks, and 12 (12%) were canceled for other reasons (unavailability of laser, fluoroscopy, etc.) (Fig. 1).

In January 2017, the mean life span of our 5 fURS was 4 years [1–6]. The median number of fURS available was 1 per day with a maximum of 3 per day in March 2017, decreasing to 0 per day in May 2017. Due to multiple repairs per fURS in 2017, total unavailability of reusable fURS reached an average of 200 days per fURS [100-249]. The causes of unavailability of fURS are reported in Table 1.

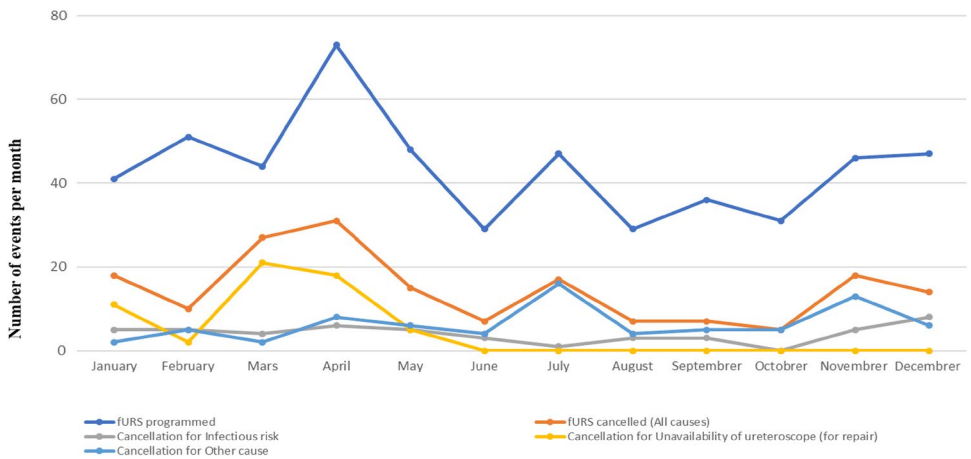

Fig. 1 Causes of rescheduling for flexible ureteroscopy in 2017

The introduction of single-use fURS in our department in June 2017 enabled us to reduce to 0% the risk of cancellation owing to unavailable equipment and increase the median availability of only 1 fURS/operating day. From June to December 2017, we performed a mean of 17 procedures per month with single-use fURS or 59% of our flexible ureteroscopy activity (Fig. 2).

Medico-economic study

The total annual cost of reusable fURS repair from 2011 to 2016 was $3859 ± $360 (€3384 ± €316)/year/ureteroscope vs. $11,938 ± $4216 (€10,470 ± €3698)/year/ureteroscope in 2017 ($p = 0.01$) (Table 1). The cost of reusable fURS repair from 2011 to 2016 was $55 (€48) per procedure versus $208 (€183) per procedure in 2017 ($p = 0.01$).

In 2017, the average repair cost for an optic fiber ureteroscope was $11,035 ± $7821 (€9678 ± €245)/year vs. $13,284 ± $7821 (€11,650 ± €6859 euros)/year for a digital ureteroscope ($p = 0.75$). Therefore, the total repair cost of the reusable ureteroscopes in 2017 was $83,435 (€73,173), representing a 345% increase in the annual repair cost compared with 2011–2016. In 2017, the total cost of protocoled bacteriological analyses of repaired fURS before reuse was $935 (€820), i.e., $187 (€164)/ureteroscope.

In 2017, our institution has acquired 98 single-use fURSs (93 Pusen units, 5 Lithovue units) for a total amount of $104,580 (€91,716) including 20% sales tax.

After calculations, we determined that the single-use fURS was more cost-effective compared with the reusable fURS up to the 22nd procedure for the period 2011–2016 vs. the 73rd procedure in 2017 (Fig. 3).

Discussion

In this single-center retrospective study of five reusable fURS (having an average life span of 4 years) we found that the unavailability of fURS owing to breakdown/repair was the main cause of cancellation/rescheduling in 2017. Despite the huge difference in repair costs of approximately 345% between the two periods (2017 vs. 2011–2016), reusable fURS were significantly more cost-effective for medium-to-high volume flexible ureteroscopic procedures. Single-use fURS would be more cost-effective in centers where there are low volumes of flexible ureteroscopic activity.

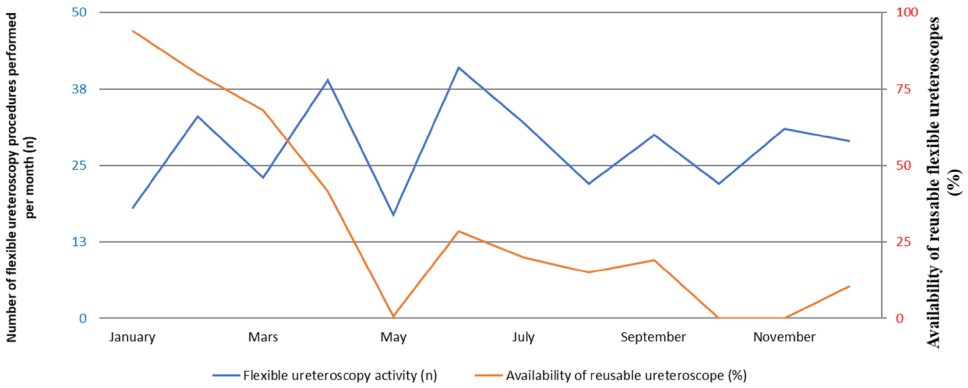

Fig. 2 Availability of reusable ureteroscopes and flexible ureteroscopy activity per month

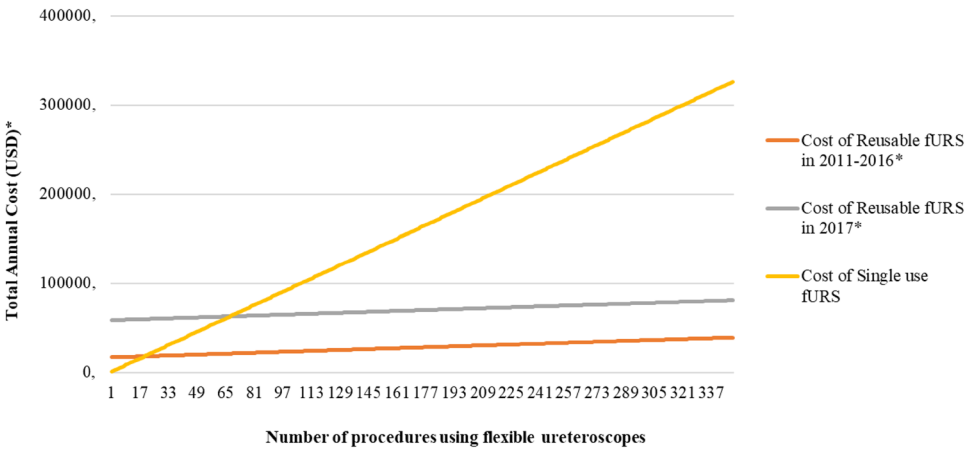

Fig. 3 Modeling of operating costs, maintenance and repair of reusable flexible ureteroscopes based on retrospective analysis of 2011–2016 (mean of 2011–2016 period) and 2017 versus single-use ureteroscopes according to the volume of activity. *Including cost of ureteroscope purchase, maintenance, repair and operating expenses

One of the main advantages of single-use fURS that we experienced are accessibility and availability since they do not require maintenance/repair and sterilization and the stock is controlled by the pharmacy [13, 14]. In 2017, the rate of breakdown/repair of reusable fURS resulted in a 15% rate of cancellation/rescheduling of flexible ureteroscopic activities in our institution [8, 19]. Despite a total of 5 reusable ureteroscopes, the median number of ureteroscopes available per operative day was only 1/5, with a minimum of 0/5. In addition, the time required for reprocessing reusable fURS (decontamination, sterilization, and transport) before reutilization must be considered [9, 10, 20]. In a single center, Carey et al. reported that a newly purchased ureteroscope provided 40–48 uses before the first repair was needed [8]. However, after a repair, the median number of uses before another repair decreased to 11.

In our institution, reusable fURS reprocessing involves at least 3 paramedical personnel and at least 1 h of labor (15 min pre-cleaning and transport, 35 min sterilization and repackaging, and 10 min transport) [4, 6]. Regarding a single-use fURS, the device is kept in sterile packaging and stored in the operating room. At the end of the procedure, the single-use is discarded and sent to an incinerator [21].

The reusable flexible ureteroscope is a thermo-sensitive instrument which cannot be sterilized by the autoclave process. Since our institution does not have Sterrad sterilization, reusable fURS is disinfected by a process involving detergent and disinfectants such as peracetic acid (22]. These products are highly reactive, irritating and potentially sensitizing molecules such as peracetic acid. All of that has an impact on personnel and the environment [21, 22].

On the other hand, single-use fURS do not require decontamination and sterilization which means that personnel are not exposed to detergents or disinfectants. Reduction of hospital waste by reducing the waste products of a high-level sterilization process is of great benefit to the environment [14]. In an analysis of the typical cycle life of reusable and single-use fURS, Davis et al. concluded that the carbon foot print per procedure of reusable vs. single-use fURS was equivalent (4.47 vs. 4.43 kg of CO^2/case, respectively) [21].

Despite the availability of international and national recommendations for the sterilization and decontamination processes of reusable endoscopes, the risk of cross-contamination and infection transmission exists. A recent study conducted by Ofstead & Associates analyzed 16 fURS in two different centers in the United States and showed that despite validated disinfection procedures, 100% of the fURS had visible irregularities and contamination by microbial growth, hemoglobin, a protein or a chemical indicating the presence of living cells [5]. On the other hand, there is no such risk with single-use fURS since a new ureteroscope is used for every patient.

Although it is usually a drawback, we consider that a retrospective study is an advantage for this medico-economic analysis. The reason is that a purely experimental economic model does not provide precise evaluation of real daily practice [23–25]. This is obvious in our study since the price of fURS processing remained nearly the same while there was a significant difference in repair costs between the two periods (2011–2016 and 2017) [8].

One limitation of this study is that we do not have an explanation for the increased rate of fURS breakdowns in 2017 compared with the period between 2011 and 2016. There were no changes in our practice over these periods [10, 23, 26, 27]. Breakdowns were principally perforations of fURS sheath, which was noted at the time of reprocessing during testing of the permeability of the operative channels.

In addition, the duration of the economic study was limited to 1 year and did not take into account the costs of decontamination room construction and maintenance which would probably increase the reprocessing costs of reusable fURS. Therefore, for institutions starting fURS activities, the expected costs of equipment earmarked for reusable versus single-use ureteroscopes would probably be different [28].

The equation to calculate the functioning cost of reusable and single-use fURS is debatable as it was specific to our institution for: the purchase of single-use fURS and the cost of processing (personals and materials). However, we evaluated that cost of transport, sterilization and re-packaging in 2017 accounted for 15% of the global annual cost of reusable fURS, highlighting that the main cost concerned repair that should be standard among institutions.

This study helped us to improve our practice using a hybrid strategy combining single-use and reusable fURS. Single-use fURS can replace the conventional reusable fURS in situations where there is a high risk of infection transmission or in cases of a high risk of ureteroscope damage (complex stones, stones in inferior calyx, urinary diversion, etc.) [7, 26, 29, 30]. In addition, it avoids cancellation of a procedure when reusable fURS are not available.

Conclusion

In conclusion, the unavailability of flexible ureteroscopes owing to breakdown and/or lengthy repairs was the main reason for cancellation/rescheduling of ureteroscopic procedures despite our being equipped with five reusable fURS. The arrival of single-use fURS has enabled us to maintain a standard level of flexible ureteroscopic activity and reduced the rate of cancellation owing to of fURS to 0%.

The medico-economic study demonstrated that despite the high costs of reusable fURS reprocessing and repair, they are more cost-effective than single-use fURS for centers with a high volume of ureteroscopic activity. However, single-use

fURS could be cost-effective for centers with a low volume of flexible ureteroscopic activity.

Therefore, the only obstacle to the spread of single-use fURS is the cost which is relative to the number of acts and the rate of repair of conventional fURS. A hybrid system combining single-use and reusable fURS is probably the most advantageous for centers with a large operating volume.

Author contributions Romain Boissier had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Protocol/project development: Boissier, Lechevallier. Data collection or management: Al-Balushi, Martin, Loubon, Baboudjian. Data analysis: Boissier, Al-Balushi, Lechevallier. Manuscript writing/editing: Al-Balushi, Boissier. Manuscript revision for intellectual content: Michel, Sichez, Martin, Di-Crocco, Gaillet, Delaporte, Karsenty, Akiki, Faure.

Compliance with ethical standards

Financial disclosures None.

Conflict of interest The authors report no conflicts of interest regarding this study.

Research involving human participants and/or animals Not applicable.

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