Original Article

The cost-effectiveness of reusable flexible ureteroscopes: An institutional audit

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ABSTRACT

Introduction: A flexible ureteroscope (FU) is an important tool in the urologist's armamentarium. This study aims to check the durability and cost-effectiveness of conventional FU.
Methods: The institution registry of damaged FU over the last 7 years was reviewed. A total of 17 flexible scopes were used. The data of 13 scopes (11 Storz fiberoptic and 2 Seesheen digital) are included in this study. A total of 1905 cases were performed. The cost of scope, duration of use, number of cases done by each scope, and nature of damage were evaluated. We compared the cost-effectiveness of conventional scopes with published costs on disposable scopes.
Results: The mean number of cases done by fiberoptic scope was 159 (range 25–334). The total cases done by 2 digital scopes were 135 and 25. The mean life of fiberoptic and digital scopes was 17 (range 4–31) and 8 months, respectively. The mean cost of fiberoptic scope was Indian Rupee (INR) 338,951 ($4082.7221) and INR 525,000 ($6323.7138) for digital scope. The cost per case for reusable scope is calculated by dividing the mean cost of FU by the mean number of cases done. The reprocessing cost of INR 527 was then added. Thus, the average cost per procedure for fiberoptic and digital FU was INR 2658.76 and INR 7089.50, respectively. We compared this cost with a projected cost of disposable FUbased on today's market data, which ranged from INR 60,000 to 107,427.
Conclusions: The reusable scopes are durable, cost-effective, and an excellent option for high case-load institutions.

INTRODUCTION

Over the past 30 years, flexible ureteroscopy has emerged as a key minimally invasive treatment in the management of upper ureteric and renal stones. This is made possible because of the advancements in scope design like improved optics, better ergonomics, and exaggerated active deflection. Moreover, the slimmer scope design and enhanced maneuverability with available thinner laser fibers for intracorporeal lithotripsy made it a critical tool in the urologist's armamentarium.

However, with the miniaturization of flexible ureteroscopes (FUs) and increasing indications for flexible ureteroscopy, the durability of these fragile instruments has come under scrutiny. A limited number of randomized control trials have concluded that FU is fragile with significant maintenance and repair costs.[1] To date, the durability and cost-effectiveness of FU remain unresolved problems.

"Disposable" FU was introduced by smart market strategies to eliminate maintenance requirements and the associated costs as well as durability issues such as deflection loss after multiple usages.[2] The disposable FU bypasses the sterilization as well as repair costs and hence is claimed to be more cost-effective as per the studies published in Western countries. The first commercially available

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disposable FU (LithoVue™) was introduced by Boston Scientific in October 2015. Pusen (China) introduced the next model (Uscope) and within 12 months, several other companies had released other versions. Comparable studies related to cost-effectiveness, maneuverability, and navigation between reusable FU and disposable FU are sparse. However, disposable scopes have become today's flavor because of the growing perception of cost-effectiveness in many Western countries. Thus, the efficacy, fragility, and cost efficiency of reusable versus disposable FU has been a topic of debate worldwide.

This institutional audit was done to assess some of these issues. The primary objective of the study was assessing the durability and cost-effectiveness of conventional FU in the Indian scenario. The secondary objective was to compare the cost-benefit ratio of conventional FU with disposable scopes.

MATERIALS AND METHODS

This is a single-institution audit. We reviewed our institution registry for the number and type of FU used over 7 years. During these 7 years, a total of 17 FU were used and condemned after being declared unfit for further usage [Figure 1]. The data of four damaged FU were not available. We could retrieve data for the remaining 13 scopes. A total of 1905 procedures were done using these 13 scopes by three senior consultants before these scopes were declared unfit. It is the institution's policy not to get damaged scopes repaired. Of the 13 scopes, 11 were Karl Storz™ (11278AU1) FLEX X2S FU and two were digital FU (Seesheen™ UR 1331). All conventional flexible scopes were reused. All the FU included in the study were in a good condition until the date of damage. We studied the date of occurrence and nature of damage of each scope from its initial use. The cost of each scope, duration of use, number of cases done with each scope, occurrence, and nature of damage to FU were evaluated. The authors confirm the availability of, and access to, all original data reported in this study.

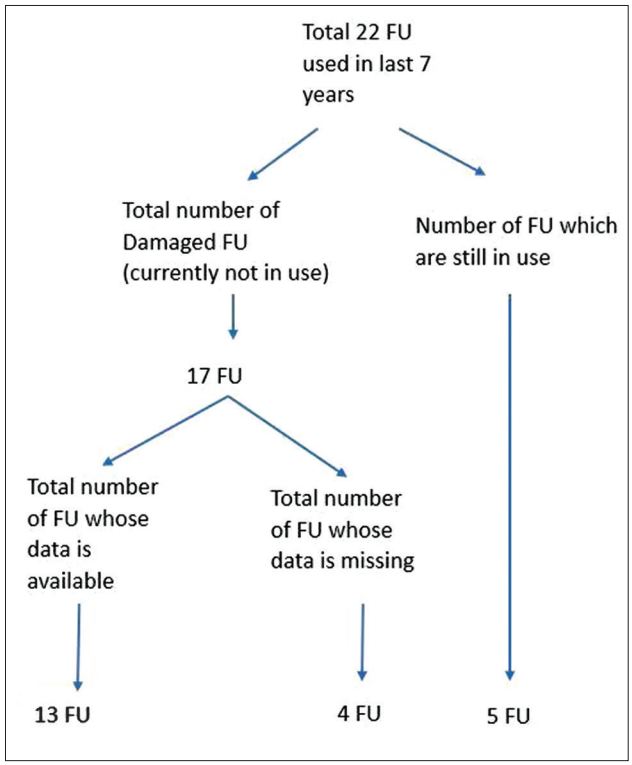

Figure 1: Consort flow

All the FU after the use were sterilized through a low-temperature hydrogen peroxide plasma sterilization method by STERRAD NX Sterilizer machine (S/N 0033090002). The reprocessing cost for each FU use was calculated. The cost per case for reusable scopes was calculated by dividing the mean purchasing cost by the mean number of cases done by scopes. This cost per case was calculated separately for fibreoptic and digital reusable scopes. The total cost per case was then estimated by adding the reprocessing cost to this cost per case. All cost expenditures were calculated in Indian Rupee (INR). We have compared this cost with the projected cost of disposable FU based on today's market data, which varies between INR 60,000 and INR 107,427.

Our reprocessing system comprises washing, drying, sterilization, and sterile double-packing. The cost of one box of five cassettes is INR 30,000/-. One cassette costs INR 6000/- and each cassette is used for five cycles. In one cycle, three FU and two rigid scopes were sterilized. Hence, the cost of one cycle was INR 1200 and that can sterilize three FU. Sterilization per case was, therefore, INR 400. This value is overestimated as two more rigid ureteroscopes were also sterilized in the same cycle. The plasma packaging roll costs INR 3000. Approximately 25 instruments can be packed with one packaging roll, and hence, the cost of one FU packing will be INR 120.

We have also calculated the expenditure on electricity usage by the plasma sterilizer. Sterrad™ machine consumes around 2400 watts/h. A unit of electricity is the amount of power required to use an appliance of 1000 W power rating for an hour. Thus 2400/h will consume 2.4 units/h. One cycle of Sterrard lasts for 28 min. In 1 h, it can do two cycles. Hence, 1.2 units were consumed per cycle. As we already mentioned, we sterilize 3 FU in one cycle. Thus, 0.4 units of electricity per case are utilized. One unit of electricity rate as per 2022 bill rates costs around INR 6.70 for an initial 500 units in commercial areas and INR 7.10 for above 500 units. For the case of calculation, we have kept the charge per unit of electricity at INR 7 per case. The total reprocessing cost was calculated by adding sterilization cost, packaging cost, and electricity cost, which is INR 527 per case.

RESULTS

Of the total 1905 procedures using 13 FU, the mean stone size was 12.55 mm (range 5–21 mm). The ureteral access

sheath was used in 94.4% of cases. We always prefer to use an access sheath whenever feasible to facilitate ureteroscopy and to protect the FU. The most common used access sheath was of size 11/13 Fr for the stented patient and 10/12 Fr for the nonstented patient. Sometimes, when the ureter was too tight even to pass a 9.5/11.5 Fr access sheath, we have used FU over a guidewire.

The mean number of cases done by fiberoptic scope was 159 (range 25–334). Total cases done by two digital scopes were 135 and 25 [Table 1 and Figure 2]. This is something to ponder about as the number of cases performed with the digital scopes is less expected. The mean life of scope was 17 months and 8 months for fiberoptic and digital scope, respectively. The maximum and minimum life of scope for which the scope was used was 31 months and 4 months, respectively. The life of two digital scopes was about 9 and 7 months. The most common cause for scope damage was fiberoptic damage. The limitation in deflection was the second-common cause which was seen, especially in the digital one. A positive leak test is one of the reasons for which scopes could be considered unusable. However, none of our scopes showed a positive leak test. The mean cost of fiberoptic scope was INR 338,951 and INR 525,000 for digital scope. The cost per case for reusable scope is calculated by dividing the mean cost of FU by the mean number of cases done. The cost per case for fiberoptic and digital FU was INR 2131.76 (338,951/159) and INR 6562.5 (525,000/80). The reprocessing cost of INR 527 was then added. Thus, the average cost per procedure for fiberoptic and digital FU was INR 2658.76 and INR 7089.50, respectively. We compared this cost with a projected cost of disposable FU based on today's market data, which ranged from INR 60000 to 107,427 [Table 2].

DISCUSSIONS

FUs have brought a paradigm shift in the treatment of upper tract conditions mainly caliceal stones and upper tract urothelial cancer. The introduction of disposable scopes may appear to be a logical step but it has wider implications on economics, cost-effectiveness, and carbon footprint. This audit was initiated to understand logistics for an institution and then extended to the utility of disposable scopes.

We found that most of the earlier literature was focused only on the repair costs. The longevity of the ureteroscope significantly reduces even after the repair.[3] Our senior consultants have observed significant breakage rates

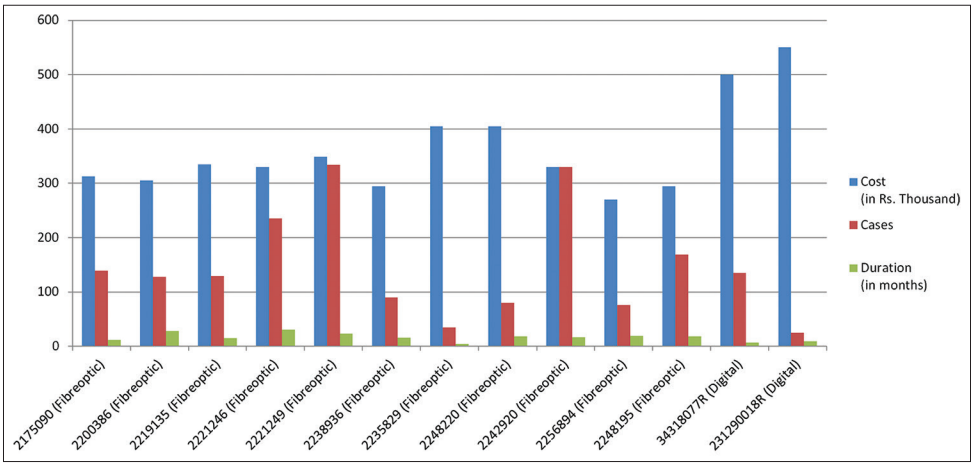

Figure 2: Graphical presentation of audit of flexible ureteroscope

Table 1: Audit of flexible ureteroscope at our center

Serial number of company product	Manufacturer	Date of opening	Date of damage	Duration (months)	Fiberoptic versus digital	Cases	Cost (INR)	Cause of damage
2175090	Storz	August 9, 2015	October 5, 2016	14	Fiberoptic	139	270,830	Deflection
2200386	Storz	January 8, 2016	April 5, 2018	28	Fiberoptic	128	305,900	Vision
2219135	Storz	May 20, 2016	August 29, 2017	15	Fiberoptic	129	335,675	Vision
2221246	Storz	October 17, 2016	May 11, 2019	31	Fiberoptic	235	330,489	Vision
2221249	Storz	August 29, 2017	July 17, 2019	23	Fiberoptic	334	349,888	Vision
2238936	Storz	November 20, 2017	March 12, 2019	16	Fiberoptic	90	295,000	Vision
2235829	Storz	April 24, 2018	August 1, 2018	4	Fiberoptic	35	405,675	Vision
2248220	Storz	December 12, 2019	March 5, 2021	15	Fiberoptic	80	405,000	Vision
2242920	Storz	May 7, 2018	July 7, 2019	14	Fiberoptic	330	350,000	Vision
2256894	Storz	October 9, 2018	March 29, 2020	18	Fiberoptic	76	385,000	Vision
2248195	Storz	May 10, 2019	November 30, 2021	30	Fiberoptic	169	295,000	Vision
34318077R	Seesheen	April 4, 2019	December 11, 2019	8	Digital	135	500,000	Vision + deflection
231290018R	Seesheen	October 3, 2022	June 28, 2023	9	Digital	25	550,000	Deflection

Table 2: Cost analysis

Our study	Mean of purchasing cost (INR)	Mean number of cases	Cost for FU per case (INR)	Reprocessing cost (INR)	Total cost for FU per case (INR)
Fiberoptic reusable FU	338,951	159	2131.76	527*	2658.76
Digital reusable FU	525,000	80	6562.5	527*	7089.5
To days cost of disposable FU	60,000–107,427	NA	60,000–107,427	0	60,000–107,427

*Isaacson *et al*. study showed reprocessing cost of INR 7934.77 per case. FU=Flexible ureteroscopy, NA=Not available

postrepair. This has led us to the conclusion that it is better financially to purchase a new ureteroscope than it is to maintain a ureteroscope, which has undergone major repair. The previous studies have not included the reprocessing cost which is an equally important factor in determining the cost efficiency.

According to Isaacson *et al*.,[4] processing a single FU costs 96 US dollars, with the cost of a single Sterrad™ sterilization cassette being responsible for 25% of the total cost. This study mentions that each reprocessing event requires a labor cost of around $36.88 per ureteroscope (INR 3056.95), which is much higher than in India. Our results of expenditure on reprocessing of reusable FU are different. A previous study showed the reprocessing cost of 100 dollars that is equivalent to Rs. 8000,[3] unlike in our center the cost was INR 527 per case. The basic principle of economic evaluations is related to the usability and cost per case. Cost efficiency arises when usability is maximized and cost per case is minimized. This is the main reason for the discrepancy in the cost per case in Indian and Western scenarios. In addition, the labor cost and sterilization costs in Western countries are high.

We have purposely not included the cost of the STERRAD NX Sterilizer machine because the machine is used for other equipment and such machinery is included in general sterilization or surgical expenses.

"Disposable FU" is disposable in the true sense. There is no vent port for leakage test for disposable scope. Reusable scopes are provided with a "Vent port," i.e. a "valve for pressure compensation and leakage tester connection." A leak test is performed with a leakage test connector through the "vent port" as recommended by the manual of reusable scopes. A pressure of up to 160–180 mmHg is used. This confirms the integrity of the scope thus preventing blood and body fluid contamination. The confirmation of integrity of the scope is a basic requirement before you proceed for the sterilization of scopes. As this port is not provided in the case of most disposable scopes, so the integrity of disposable scopes cannot be guaranteed when they are used multiple times.

The advantage of single-use FU is that it bypasses the sterilization process, thereby offering institutions potential savings on cost, time, and labor. In addition, surgeons have the advantage of always using a new device. Moreover, they are ergonomically lighter than fiberoptic scopes and have no need for sterilization procedures, thus theoretically reducing the risk of infections. However, considering the fact that the occurrence of complications related to ureteroscopy is relatively low compared to other procedures and is generally comprised of less severe Clavien–Dindo scores; this theoretical benefit is not a significant factor.[5-8]

Pietrow *et al*.[9] evaluated the performance of 4 Olympus™ 7.5 Fr FUs in a total of 109 flexible ureteroscopic procedures. The FUs had an average of 27.5 uses before being sent for repair. As per his study, nitinol devices, ureteral access sheaths, and 200-micron laser fibers were identified as new ureteroscopic accessories that helped to lessen the strain on the FU and extend ureteroscope longevity.

In the study of User *et al*.,[10] 14 urologists used 6 new FUs for a total of 102 uses in 7 months. The ureteroscopes were used an average of 10–34 times between breakages. The 8 Fr and 9 Fr ureteroscopes had higher durability scores than the smaller diameter models. The predominant cause of breakage noted was perforation of the working channel by laser energy. Carey *et al*.[3] studied four purchased FUs, representing three models from two manufacturers, lasting between 40 and 48 uses before the repair was needed. After returning from repair a median of three uses was achieved with these ureteroscopes before further repair was required. Their analysis showed that more damage usually occurs rapidly postrepair. He concluded that the cost of maintaining an older ureteroscope should be carefully considered in comparison to the cost of a new ureteroscope. Grasso and Bagley[11] found a maximum of 30 procedures between interval repair, while Afane *et al*.[1] found the need for repair between 6 and 15 uses. Hollenbeck *et al*.[12] report the average number of procedures before scope breakage to be 21. Bultitude *et al*.[13] reported maximum procedures done by FU is 36.

Martin *et al*.[2] analysis who had also included the repair cost, favored reusable FU over disposable FU, but that was dependent on case volume. Essentially, the break-even point between the two alternatives appeared to be 99 cases in his institution. If his institution performed <99 flexible ureteroscopies for that year, then a disposable FU would have been a better cost-effective alternative. Conversely from a financial standpoint, for a higher volume with his repair rate, a reusable FU would be a more favorable option.

However, the most critical finding from our results is that the maximum number of procedures done with conventional reusable FU remains at least 8–10 times higher than the maximum achieved in the published series [Table 3]. The reasons are multifactorial. The primary reason apparently is that the procedures were done by three senior urology consultants. Other possible reasons are strict maintenance of Six Sigma rules such as reprocessing by trained urological staff, preoperative leak test, movement of scopes rather than laser fibers, routine use of access sheath, avoiding unnecessary firing of laser fibers and of course the dedicated endourology theatre. All these findings mentioned maximal usability and minimal reprocessing cost have led us to the final cost-effectiveness outcome [Table 2].

Our study has the following limitations. Quantitative data regarding change of deflection and vision was not recorded. A comparison study with other disposable FUs is not available as we have used only demo disposable FUs for a few cases at our institute. Scopes from other manufacturers were not used. However, by doing this, it also eliminated variables introduced by studying multiple scopes. Despite the shortcomings, the large caseload over a 7-year period has enabled us to assess the durability of conventional reusable FUs.

Disposable scopes if we use one for each case will be faster but not be cost-effective. Moreover, after sterilising a disposable scope, the integrity of the scope is not known.

The disposable scopes could be cost-effective in scenarios where case-load is low and scenarios where a Sterrad®terrad machine is not available. More data are required to make decisions comparing purchase price, repair cost, warranty costs, and the expected lifetime of FUs that can formulate into an institutional policy for purchasing and maintaining ureteroscopes.

Apart from these factors, it is equally important to consider the environmental impact of FU during this study. On a global average basis, health-care systems account for over 4% of global CO_2 emissions[14] For most industrialized nations, that figure is closer to 10% of national emissions.

Table 3: Comparison with other studies

Various studies	Maximum number of cases done by single FU
Pietrow *et al*.[9]	27
User *et al*.[10]	34
Carey *et al*.[3]	48
Grasso and Bagley[11]	30
Afane *et al*.[1]	15
Hollenbeck *et al*.[12]	21
Bultitude *et al*.[13]	36
Our study	334

FU = Flexible ureteroscope

That is more than the aviation or shipping sectors. The total carbon footprint of the lifecycle assessment of disposable and reusable FU was 4.43 and 11.49 kg of CO_2 per scope, respectively.[14] The carbon footprint assessment per endourological case for disposable and reusable would be 4.43 and 0.0727 kg of CO_2, respectively. Thus, this small step of continuing to use of reusable ureteroscope rather than opting for disposable ones will take us toward a "Greener Urology."

CONCLUSIONS

The overall cost per case of a reusable FU is much lower than average cost per case of a disposable one. The reusable FU seems a more durable and cost-effective option for high case-load institutions. The cost of maintaining previously used FUs should be carefully considered in comparison to the cost of purchasing a new FU. Health-care providers should carefully consider the total cost of ownership of both types of FUs before making a choice on type of equipment.

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