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Early Outcomes of the Reprocessing and Reuse of Disposable Flexible Ureteroscope for Renal Stone Management: A Single-Center Study in Nepal

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Authors' contributions

This work was carried out in collaboration among all authors. Author MBA and AKS have designed the outline of the manuscript and the production of the first version. Authors BP and MBA have helped to collect data and bibliographic research and have supervised the work. Authors JK and SM have helped in data collection. All authors read and approved the final manuscript.

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ABSTRACT

Introduction: The use of disposable flexible ureteroscopy for the management of renal stone has become an established procedure since last few years however discarding the instrument after single use possess a financial burden to the patient in resource limited countries. Therefore, it's an attempt to assess the cost effectiveness and the safety profile of the procedure by reprocessing and reusing the disposable flexible Ureteroscope.
Methods: It was a hospital-based prospective observational cross-sectional study. LithoVue, Single Use Flexible Ureteroscope from Boston Scientific device was used for the procedure. Operative time, level of intra-operative performance alteration and fluoroscopic guided stone clearance were assessed. Early postoperative complications, durability of each scope, postoperative ultrasonographic stone clearance were also assessed. The cause of immature scope damage was also identified.
Results: Thirty-eight disposable flexible ureteroscope were used for 186 procedures of mean age

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of 42.67 ± 14.88 years. The mean size and average CT scan hardness of the stones were 14.65 ± 9.82mm and 1017 ± 340HU respectively. The number of disposable flexible ureteroscope and the patient ratio was found to be 1:5. The mean operative time was 44.26 ± 25.16 minutes. The immature damage of the scope was seen in 9 scopes. Five patients (2.76%) developed urinary tract infection. Sonography after 6 weeks following the procedure showed that 11 patients (6%) had Clinically Significant Residual Fragment (>5mm) whereas 32 patients (17%) had Clinically Insignificant Residual Fragment (< 5mm).

Conclusion: Reprocessing and reuse of disposable flexible ureteroscope is safe and cost-effective procedure with minimal probability of cross-infection and immature scope damage if reprocessing of the device is well supervised.

Keywords: Disposable flexible ureteroscope; early outcome; retrograde intra renal surgery; reprocessing; reuse.

1. INTRODUCTION

Retrograde Intra Renal Surgery (RIRS) has become a widely accepted procedure for the management of renal stones of less than 20mm size. Both reusable flexible ureteroscope (fURS) and disposable flexible ureteroscope are available worldwide and has been accepted by most of the reputed urology centres. The disposable device is also known as Single-Use Device (SUD). The reuse of Single-Use Devices (SUDs) began in the late 1970s for reducing cost [1]. SUDs are much cheaper than the reusable devices and if it can be reused with proper reprocessing techniques, it becomes economically viable and could be good alternatives in the resource limited centres.

The hospitals willing to control the costs of expensive medical instruments and reducing environmental waste should adopt this policy [2]. It is a common and growing practice worldwide. However, it can be associated with cross infections, performance alteration of the device and patient's safety [3,4]. Immediate cleaning may be insufficient and may leave residual contaminations on the device that alters the efficacy of high-level disinfection and sterilisation [5,6]. Reuse of SUDs has been extremely controversial for decades. Ethical, medico-legal and regulatory requirements are needed for the reuse of SUDs at the time of original manufacture [7].

From the beginning of clinical history, many disposable medical instruments are being reused in medical practice to reduce the burden of expensive healthcare. However, there is no standard protocol in Nepal to guide a healthy reprocessing of SUDs. The objective of our study is to assess the outcomes of reprocessing and reuse of disposable fURS for the management of renal stones in terms of safety, cost analysis, postoperative complications and identification of factors responsible for scope damage.

2. METHODOLOGY

It was a hospital-based prospective observational cross-sectional study at the Department of Urology, Nepal Mediciti Hospital, Bhainsepati, Lalitpur, Nepal from November 2018 to April 2021 (30 months). A total of 179 consecutive patients above the age of 15 years undergoing Retrograde Intra-Renal Surgery for the management of nephrolithiasis of all sizes of stones were included in this study by non-probability consecutive sampling method. The size, location and hardness of the stone were assessed by CT urography. Patients younger than 15 years, those with history of recent similar side endourological intervention for any reason within last 1 month, those with pregnancy and mental disorders unable to comply with the study protocol and those not willing to give the informed consent to participate were excluded from the study. Litho-Vue Single-Use flexible ureteroscope from Boston Scientific device of 9.5Fr external lumen diameter, and 240 minutes working duration was used to perform the procedure. Patients with positive urine culture status were treated accordingly with sensitive antibiotics. Preoperative negative urine culture status was confirmed in each patient. Single dose of Piperacillin and Tazobactum combination antibiotic (dose calculation on the basis of weight of the patient) was given 30 minutes before induction of anesthesia to each patient. Another 3 doses of same antibiotic was given intravenously in the post-operative period. The operative time of each procedure was noted from the time of scope negotiation to the end of scope removal. Laser lithotripsy was done with

Holmium 265 µm fiber using 20watts Swiss Laserclast. The immediate manual cleaning of the device was done with tap water. The water channel was flushed with 10 percent povidone iodine and then again flushed with tap water. Similarly, the scope was cleaned with scrub povidone iodine and flushed with tap water. The scope was allowed to dry in room temperature. Then repackaging of each instrument was done separately with a label including date, number of used time and time remaining in the system. Sterilisation of the scope was done with 2% Glutaraldehyde solution for 20 minutes before the surgery. Level of intra-operative performance alteration was assessed by asking the surgeon about the level of difficulties experienced while performing the subsequent procedure with the same instrument. Patients with no defined intraoperative and post-operative complications were discharged on first post-operative day with 3 days course of oral Ciprofloxacin. The postoperative fever in each patient was assessed for 7 days following the procedure. Similarly, the evidence of cross-infection was assessed by doing urine culture and sensitivity test among those who developed a postoperative fever. The durability of each scope was noted. The intra-operative stone clearance was assessed by real-time fluoroscopy, whereas postoperative stone clearance was assessed by ultrasonography kidney, ureter and bladder (USG KUB) for 6 weeks following the procedure. The double J (DJ) ureteral stent was removed 2 to 4 weeks following the procedure. Preopeartive and post-operative assessment of renal function test (serum creatinine, serum urea) were done in each patient. An assessment of the DJ symptoms was done while coming for the DJ removal. A set of closed-ended questionnaires was used to collect the data. The data analysis was done using Statistical Package for the Social Sciences (SPSS) software (Version 21.0). The descriptive statistics were interpreted in mean, frequency and percentage.

3. RESULTS

One hundred and seventy-nine patients with renal stone underwent RIRS from November 2019 to April 2021 at our department. The male and female ratio was 1.86:1 with a mean (SD) age of 42.67 ± 14.88 years (42.79 ± 14.85 for female and 42.82 ± 14.89 for male). There were 97 and 89 renal units in right and left side respectively, out of which 7 patients underwent bilateral RIRS for renal stone management. A majority of the patients were in their third to fifth decades of life. The mean (SD) size of the stones was 14.65 ± 9.82mm and the average (SD) CT scan hardness of the stone was 1017 ± 340HU. There were 38 disposable fURS used for the renal stone management of 179 patients with 186 renal units. The number of disposable fURS and the patient ratio was found to be 1:5. The mean (SD) operative time was 44.26 ± 25.16 minutes. Immature loss of 9 scopes was found during the study. Physical damage to the pulley during deflection, physical damage of camera chips while sterilisation and scope shaft damage were the causes identified. The gradual difficulty in scope deflection during subsequent procedure was noted in almost all the scopes specially if used after interval of more than 7 days. The average hospital stay of the patient was 1 day. Table 1 illustrates the findings.

Majority of the patients (58.6%) had solitary renal stone; whereas 18.4% had 2 stones and 23% had more than two stones. We assessed the surgeon's experience about the hardness of stone while fragmenting and dusting the stones with holmium laser. The hardness assessed by CT HU and surgeon's experience during the procedure was compared. As illustrated in Table 2, the stone hardness as shown by CT was 801 to 1200HU in 40% of cases which in contrast, surgeons experienced moderate hardness in 59%of cases.

Only four patients (2.24%) developed ipsilateral flank pain and gross haematuria for 2 days following the procedure. Five patients (2.76%) developed high-grade fever with chills and rigors for 2 days following the procedure. Urinary infection was confirmed with positive urine culture and sensitivity report. Unfortunately, 4 out of 7 post-operative urinary tract infection cases had undergone simultaneous bilateral procedure.

Both of our operating urologists confirmed that there is a gradual loss of deflection and performance alteration with the reuse of the disposable fURS scope. Intraoperative fluoroscopic clearance of the stone was ensured in all the cases. Post-operative USG KUB 6 weeks following the procedure showed Clinically Significant Residual Fragment (CSRF) of more than 5 mm size in 11 patients (6%), whereas Clinically Insignificant Residual Fragment (CIRF) of less than 5mm size were observed in 32 patients (17%).

The procedure was found successful with scope negotiation in first sitting in 162 cases (90.8%). Among them fURS was successfully completed by scope negotiation through ureteral access sheath in 96 cases (59.5%), whereas direct scope negotiation was done in 66 cases only (40.5%). There was failure of first sitting procedure in 17 cases (9.2%), where we could not negotiate the fURS scope either through UAS or directly. Those with failed first sitting were ended with double J stenting and were planned for second sitting procedure after 2 weeks. There were no significant changes in the pre-operative and post-operative renal function test status (serum creatinine and serum urea) of the patients.

Table 1. Variables and the findings

Variables	Findings
Total number of patients	179
Total number of RIRS	186
Gender	Male: 121 (65%) Female: 65 (35%)
Male Female Ratio	1.86:1
Age	42.67 ± 14.88 year Male: 42.79 ± 14.85 year Female: 42.82 ± 14.89 year
Laterality of RIRS intervention	
Right:	90 (50.2%)
Left:	82 (45.8%)
Bilateral:	7 (4%)
Size of Stone	14.65 ± 9.82mm
Location of Stone	
Upper Pole	26 (14%)
Mid Pole	20 (10.8%)
Lower Pole	56 (30.1%)
Renal Pelvis	22 (11.8%)
Pelvi-Ureteric Junction	30 (16.1%)
Upper ureteric calculus migrated to renal pelvis	31 (16.7%)
Hardness of Stone	1017 ± 340 HU
Scope and Patient Ratio	1:5
Operative Time	44.26 ± 25.16 minutes
Average Hospital Stay	1 day

Table 2. Categorical illustration of the size of the stone and their hardness

Variables	Category of data	Percentage
Stone Size	<10mm	29.2%
	11-15mm	39.5%
	16-20mm	23.2%
	>20mm	8.1%
Hardness of Stone (CT HU)	<600HU	8.6%
	601-800HU	19.4%
	801-1000HU	24.7%
	1001-1200HU	15.6%
	>1200HU	31.7%
Hardness of Stone (Surgeon's Experience)	Soft Calculus	10.2%
	Moderately Hard Calculus	59.8%
	Grossly Hard Calculus	30%

Table 3. Postoperative complications of disposable flexible ureteroscopic renal stone management

Postoperative Complications	Frequency	Clavien Dindo Score
Postoperative ipsilateral side severe flank pain and gross haematuria	4 patients (2.24%)	Grade II
Postoperative ipsilateral side pyelonephritis	5 patients (2.79%)	Grade II for 4 patients Grade IIIb for 1 patient

The study found immature damage of 9 scopes. Physical damage to the pulley deflection was seen in 5 scopes and physical damage of camera chips while sterilization was seen in 3 scopes. One of the scopes was found with damages to the shaft. Unfortunately, physical damage to the pulley deflection was observed in the first two scopes. We were able to perform 7 cases from first and second scopes. The first scope was damaged in 212 minutes of its use whereas the second was damaged in 118 minutes. We observed a similar type of damage in the other 3 scopes (8th, 11th and 29th scopes in 189 minutes, 162 minutes and 98 minutes respectively). The physical damage to the camera chips was seen in 3 consecutive scopes (13th, 14th and 15th scopes in 44 minutes, 64 minutes and 48 minutes of their use). Later, we came to know that improper technique of reprocessing was the cause behind these losses. Therefore, our learning curve deemed to be a responsible factor for this damage. Lack of knowledge about the proper cleaning and disinfection method of the assigned urology operation theatre nurse was the cause behind the physical damage of the device.

4. DISCUSSION

The number of disposable fURS and the patient ratio was found to be 1:5 in this study. Therefore, the cost of each device was divided into 5 patients. The cost of the procedure would have been very high and may not be economically possible if the scope is discarded after single use. The finding was consistent with that of a study done by Raval K et.al, which concluded that discarding SUDs in every case increases the final cost of surgery and adds a huge economic burden to the healthcare industry [8]. Another study from Nepean Hospital, Sydney, Australia (among 150 patients) concludes that disposable digital fURS have visibility, manoeuvrability and clinical outcome profiles approaching that of a more expensive reusable digital fURS [9]. It has been suggested that reprocessed devices are as good as the new ones [10.11]. There should be an established clear limit regarding the number of times an item can be reused.[3] A US market in 2016 randomized controlled trial study among 180 patients concluded that disposable fURS (LithoVue) represents a feasible alternative to reusable ureteroscopes with a low rate of scope failure comparable with reusable ureteroscopes. It was also found beneficial in terms of short procedure duration [12].

It is really difficult to identify the actual cause of scope damage. A comprehensive Medline search for related publications from the last 20 years was reviewed to identify common causes of fURS damage.[13] Intra-operative causes are loss of the deflection mechanism, damage to the working channel and fibreoptic bundle injury whereas; cleaning, sterilization and handling of the fURS during reprocessing are the non-operative causes [13]. A study done by Al-Balushi K et al, in 2017 represents repair costs of reusable fURS increased by 345%, a median unavailability per reusable fURS of 200 days/year (100–249) and the median number of functioning fURS 0/5–3/5 per operating day. The unavailability of reusable fURS had become the prime reason for the cancellation of the procedure. Disposable fURS provided substantial help to maintain the years of the problem caused by the rising incidence of breakage, increased maintenance costs and hampered daily activity owing to unavailability of the reusable fURS for renal stone management [14].

Regarding the postoperative complications, 4 patients (2.24%) developed ipsilateral side flank pain and gross haematuria for 2 days following the procedure. However, there were some confounders with them. Unfortunately, they had not been stented with double J stent postoperatively. They were known cases of Diabetes Mellitus under medications. One of them was recurrent stone former. They were readmitted and were managed with antispasmodics, pain killers, antibiotics and alfa blockers. Five patients (2.76%) developed high-grade fever with chills and rigors for 2 days following the procedure. There were some confounders with these patients also. One of them also had not been stented with double J stent postoperatively. She was readmitted, and E. coli was isolated in the urine culture and was treated with a sensitive intravenous antibiotic. On the 6th postoperative day, she was intervened under general anaesthesia for ipsilateral diagnostic ureteroscopy and retrograde double J ureteral stenting. A gush of frank pus was drained from the renal pelvis. Four of them had undergone bilateral RIRS for bilateral renal stone management in the same sitting. One of them was diabetic with uncontrolled preoperative blood sugar. Another patient had a history of culture-positive urinary infection (*E. coli*) treated 2 weeks preoperatively. *Pseudomonas auriginosa* was isolated in both cases. Since the isolated

organism was hospital-acquired, cross-infection was accepted.

The rate of complications in our study is significantly lower in comparison to that of other studies. In a study done by Yong Xu (2018) the total complication rate on the basis of Modified Clavien Classification System (MCCS) was 26.1% (MCCS: I = 67.7%, II = 22.7%, IIIb = 7.2%, IVb = 2.4%) [15]. Positive preoperative urine culture, operative time, irrigation rate, and stone burden were considered as significant factors affecting the complications. The rate of low grade clavien complications was common which is quiet similar with the finding of our study. A recent study by Sarwar Noori Mahmood (2021) also reported that overall complications was 24 % (MCCS-I, II = 20 %, MCCS-IIIb = 4 %) [16]. The procedures in both of the above cited studies were performed by reusable scope whereas; a study done by Jose A. Salvado et al, (2018) where the procedure was performed by single use disposable scope showed only two minor complications (9.1%) related to the ureteral access sheath used. There was no problem associated with the performance of the ureteroscope [17]. A prospective comparative study by Jonathan Kam et al, (2019) compared the outcomes between the groups undergoing retrograde intrarenal surgery done by single use ureteroscope and reusable ureteroscope. They reported that there was no difference in the complications between two groups [9].

These devices and supplies are often complex in design, and cleaning may be inadequate. It may compromise the product's performance status. The manufacturer may not be liable when a product is not being used according to the manufacturer's instructions [3.18]. Reprocessing disposable devices increases the risk of contamination with body fluids and exposure of healthcare workers to the chemicals used for sterilization [3].

US FDA confirms standard supervised guidelines for hospital-based in house reprocessing or outsourcing reprocessing with immediate cleaning and disinfection with 2% Glutaraldehyde for 20 minutes or ETO sterilization. We follow the same recommendation, although there is no guideline regarding the reprocessing of the fURS. We follow hospital-based in-house reprocessing of SUD, which is more often in practice nowadays [19]. We immediately clean the disposable fURS device with tap water and make sure that no visible residual organic contamination are left on the device. We do high-level disinfection of disposable fURS with 2% Glutaraldehyde for 20 minutes. The rest of the accessories like a ureteric catheter, ureteric dilator, ureteric access sheath, guide wires and the stone basket are sterilized with ETO after immediate cleaning with tap water. We remove the original manufacturer label from each device. We re-label the new reprocessed packaging with all the information including date of reprocessing and number of times of reuse.

With modern day practice, evidence is lacking either to support or rule out the reuse of the SUDs in terms of infection, performance status and adverse outcomes to the patients. Much of the literature has been found more on the theoretical basis for these concerns than any firm scientific evidence [20].

We do not have our own national guideline to practice reprocessing and reuse of SUDs in Nepal. We simply follow the recommendations from the US FDA that ensures the safe reuse of disposable devices by proper disinfection and sterilization [8] The US FDA considers reprocessing and reuse of SUDs equivalent to new manufacturing [3]. American Institute of Medicine considers the reuse of disposable masks (N95 respirator) during epidemics or pandemics [3]. Ethical, regulatory, and legal implications should be considered [3].

Reuse of SUDs has remained in debate for several decades worldwide. The practice continues in an unregulated manner in developing countries like Nepal and India due to a lack of monitoring from the concerned authorities [8]. Development of a "guidelines for reprocessing" is necessary for developing countries with poor health insurance facilities where the cost of surgical management is very important [2].

World Health Organization (WHO), Joint Commission International (JCI) and health authorities of some countries like China and many European countries do not allow the reuse of SUDs [18,21,22].

A study done by *Legemate JD* et. al. (2019) reported that microbial contamination of reprocessed ureteroscopes was found in an eight of all (389 cases) procedures. Uropathogenic microorganisms were discovered in a small proportion and their persistent contamination was only rarely encountered. They concluded that

reprocessing and reuse of ureteroscope was not associated with a higher probability of microbial contamination. Urinary tract infection symptoms did not develop in any of the patients who underwent ureteroscopic surgery with a uropathogen contaminated ureteroscope [23]. However; we could not collect the microbial samples from the ureteroscope shaft pre-operatively as *Legemate JD* et. al. (2019) did in their study.

5. CONCLUSION

Disposable fURS is a good alternative to reusable fURS for endoscopic management of nephrolithiasis. It is not inferior to reusable fURS in terms of availability, manoeuvrability and clinical outcomes. The reuse of disposable fURS can reduce the cost of the procedure and can ensure its availability all the time and very economical without comprising the safety and quality performance in the resource limited settings. The reuse of the disposable f URS scope can be recommended with proper, well supervised hospital-based in house reprocessing of the device.

CONSENT

As per international standard or university standard, Participants' written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

The authors have obtained all necessary ethical approval from Institutional Review Board (IRB). This confirms either that this study is not against the public interest, or that the release of information is allowed by legislation. All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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