

**NEW RESEARCH PROPOSAL**

by IRB - Security Forces Hospital Program in Holy Capital

<http://www.sfhm.med.sa/>**IRB number : 0535-301122****Protocol Title : Cost comparison of single-use versus reusable flexible ureteroscope****Protocol Version : 1.0****Principal Investigator : Suhail Anwarfathi Kalantan****Purpose of the project:**

Research project

Type of Project and activities involved:

Retrospective chart review

Is there any possibility that the study may involve any of the following vulnerable groups?

NO

Is the study a single or a multi-center study?

Single center

Has the study been previously reviewed by another ethics committee or IRB?

Yes and approved

- Security Forces Hospital - Makkah Institutional Review Board
- 0528-131122

Is there any co-investigators in this research ?

Yes

Name of co- investigators

Co-Investigators	Title/Position	Affiliation/Department	Study role
Waleed Alhozali	Senior Registrar	General Surgery / Urology	Record Review and Data Collection
Amr Mohamed Azzam	Registrar	General Surgery / Urology	Record Review and Data Collection
Abdelsalam Ammar Abdallah	Registrar	General Surgery / Urology	Record Review and Data Collection
Ali Hassan Abdelmagied	Registrar	General Surgery / Urology	Protocol Development
Ahmed Issam Abd ElAziz Ali	Consultant	General Surgery / Urology	Protocol Development

Anticipated starting Date :

2016-01-01

Expected duration :

2023-02-28

Total Fund Available (SR) :

0

Introduction and Background :

The flexible ureteroscope is one of the most used instruments in urology. It allows minimally invasive treatment of renal stones [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 include 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 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 that is acquisition and maintenance costs, breakages, ready availability, and reprocessing between procedures. [11–13]. These devices reproduce the characteristics of conventional reusable ureteroscopes [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. WiScope® Single-Use Digital Flexible Ureteroscope (OTU Medical Inc.) has recently been introduced with the promise of delivering equivalent clinical performance, but at a reduced cost. To date, the cost issue still remains one of the main barriers in the adoption of these novel technologies.

Research Question :

Cost comparison of single-use versus reusable flexible ureteroscope

Aim and Objective :

Retrospectively evaluate the costs of single-use flexible ureteroscopes and reusable flexible ureteroscope.

Literature Review :

Cost comparison of single-use versus reusable flexible ureteroscope: A systematic review. Eugenio Ventimiglia et al. "In high-volume centers, with proper training for reusable ureteroscopes management, the cost per case of reusable and single-use scopes are overlapping (\$1,212-\$1,743 versus \$1,300-\$3,180 per procedure)" Reusable, Single-Use, or Both: A Cost Efficiency Analysis of Flexible Ureterorenoscopes After 983 Cases. Dries Van Compernelle et al. " using rFURS is more cost-efficient than the constant use of sFURS after 155 to 274 cases "Comparative medico-economic study of reusable vs. single-use flexible ureteroscopes. Khalid Al-Balushi et al. "the single-use fURS was cost-effective compared with the reusable fURS until the 22nd procedure versus the 73rd procedure, respectively. " The Economic Implications of a Reusable Flexible Digital Ureteroscope: A Cost-Benefit Analysis. Christopher J Martin et al " It appears that a disposable ureteroscope may be cost beneficial at centers with a lower case volume per year. However, institutions with a high volume of cases may find reusable ureteroscopes cost beneficial. "

Methodology :

This is a single-center, retrospective study which included all flexible ureteroscopic procedures performed in our department from (Jan / 2016 till present). Flexible ureteroscopies were scheduled and performed by three senior urologists for treatment of renal stones. To evaluate the cost impact of single-use ureteroscopes compared with reusable flexible ureteroscopes, we conducted a retrospective study that evaluated the costs of reusable ureteroscopes including the costs of operation, maintenance and repair. We also evaluated the costs of single-use ureteroscopes. 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. We there fore calculated the total cost of single-use fURS according to the following formula: Total cost (y) = (cost of purchase of each single use fURS + 15 % VAT) × (number of procedures (x)). cost of reusable flexible ureteroscopes In the cost evaluation, we considered the costs of ureteroscope purchase, maintenance, repair and

operating expenses. 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 protocolized bacteriological examination before reutilization after repair were also included. 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, drying, and reconditioning. The third step in reusable fURS processing is transport from the decontamination room to the operating room. 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: $\text{Overall Cost} = \text{number of procedure (x)} \times \text{cost/procedure (y)}$. Patient demographic and clinical data such as age, gender, BMI, stone size, location and laterality were reported. Intraoperative data such as postoperative stenting, laser energy and frequency and complications were collected. Postoperative follow up imaging was reviewed to evaluate for late complication and stone free status.

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Other :

CONSENT FORM

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