f-URS – The Impact of the Learning Curve in Stone Free and Complication Rates

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ABSTRACT

Introduction and Objectives. Flexible ureterorenoscopy (f-URS) gained a lot of field in treating reno-ureteral lithiasis, with a clear indication for kidney stones smaller than 20 mm with an acceptable stone free rate (SFR) compared to its complications, but also with a specific learning curve. The goal of this study is to investigate the learning curve in f-URS and its impact on success and complication rates.

Materials and Methods. 60 patients from a tertiary care urology clinic who underwent f-URS were enrolled in this prospective study and divided into two study groups of 30 patients each based on the period of time the surgery was performed. Patients' and lithiasis characteristics, f-URS-related parameters, hospital stay time, SFR and complications were gathered into a database for comparison and statistical assessment of the differences.

Results. The two study groups were comparable, regarding the age, sex, BMI, stone location, stone density and stone sizes. Time passed till the introduction of the flexible ureteroscope was 18.5 minutes in group 1 versus 12.4 minutes in group 2 ($p = 0.001$). The fluoroscopy time was shorter in group 2 40.8 versus 83 seconds ($p = 0.001$). The operative time decreased significantly from 49.2 minutes to 32 minutes in the second group ($p = 0.001$). Complication rate and hospital stay showed no major difference between the two patient groups, but the SFR was significantly improved in the latest study group - 86.66% versus 66%.

Conclusions. Flexible ureteroscopy is a minimally invasive surgical intervention that requires experience and surgical skills gained after overpassing a specific learning curve. Our study shows that a good level of proficiency might be obtained after the completion of at least 30 cases in terms of operative time, fluoroscopy time, complication, and stone free rates. Further standardized prospective trials ought to be conducted to better characterize assess the precise learning curve.

Key-words: flexible ureteroscopy, f-URS, learning curve, SFR, stone free rate

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INTRODUCTION AND OBJECTIVES

Since its introduction and perfectioning as a surgical method at the beginning of the 1980s, flexible ureterorenoscopy (f-URS) gained a lot of field as the minimally invasive, endoscopic surgery used for the diagnosis and treatment of several pathologies of the upper urinary tract, with a main indication in treating reno-ureteral lithiasis. f-URS might be the endoscopic surgery of choice for kidney stones with the maximum dimension less than 20 mm, with better stone free rates (SFR) compared to Extracorporeal Shock Wave Lithotripsy (ESWL) and with lower complication rates than percutaneous nephrolithotomy (PCNL), according to the European Urology Association (EAU) Guidelines on Urolithiasis and several other studies published in the literature [1-3]. Stone location, stone density in Hounsfield Units (HU), urinary tract anatomy, and nevertheless the patient's preference are important factors for the treatment conduit [1, 4]. Like any other surgical procedure, it has a learning curve, defined as the period of time and/or the number of procedures an average surgeon requires in order to perform the surgery with acceptable success and complication rates according to the literature. Previous studies investigated the learning curve of several surgical procedures and some of them stated that different surgical procedures have unique learning curves [5-7]. The goal of this study is to investigate the learning curve in f-URS and its impact on success and complication rates.

MATERIALS AND METHODS

We conducted a prospective study in our tertiary care urology clinic of „Prof. Dr. Th. Burghele" Clinical Hospital, between 1st of October 2018 and 25th of August 2019, in which 60 patients with the indication of f-URS for renal lithiasis were enrolled. All f-URS surgery were performed by a single surgeon, mid-experienced in semirigid ureteroscopy and PCNL, after observing several cases and attending several surgical procedures as well as dry and wet-labs in urolithiasis expert centres in Europe. All the included patients presented with a stone burden of less than 20 mm, excluding at first the patients with renal malformations, untreated coagulopathies, previously operated patients (except the ones with previously mounted JJ stents) and patients with untreated urinary tract infections (UTI). Patients' characteristics (demographics), surgery related parameters, hospitalization time, complication rate and SFR were gathered into a database. Afterwards, the database has been divided into two study groups: Group 1 containing the first 30 operated patients and Group 2 the last operated ones. A comparison was made between the two study groups regarding the patients' demographics, preoperative data, several operative parameters, success, and complication rate. All cases were performed under general anaesthesia with Oro-tracheal intubation, with the patient placed in the lithotomy position. All cases had previously mounted JJ stent before the f-URS procedure and the semirigid ureteroscopy under guidewire was performed in all cases to ensure direct visualisation of the ureter and passive dilatation to ease the insertion of the ureteral access sheath (UAS). The same digital chip-on-the-tip flexible ureteroscope was used in all cases, while the laser lithotripsy was performed with two Ho:Yag laser device, same model and make year from the same producer. Stone retrieval was performed when necessary, with nitinol baskets. Following the surgery, JJ stent was inserted in all cases under fluoroscopic guidance. Final stone free status was assessed with non-contrast abdomen and pelvis computed tomography (CT) six months after the surgery. Successful surgery in terms of stone free rate was defined as the absence of renal and/or ureteral lithiasis on the follow-up CT. Statistical analysis was done by using Statistical Package for the Social Sciences version 20 (SPSS IBM Corp., Armonk, NY, USA). The comparison of continuous variables was performed by using one-way ANOVA test. Furthermore, Chi Square and Fisher tests were used for categorical variables and all the data's been analysed on a 95% confidence interval. A p value < 0.05 was considered statistically significant.

RESULTS

The total number of enrolled patients was divided into two study groups, each containing 30 patients – the first group who underwent f-URS between 1st of October 2018 and 30th of April 2019 and the second group who underwent f-URS between 1st of May

2019 and 25th of August 2019. According to the assessed characteristics, the two study groups were quite superposable, with comparable age, sex, BMI, stone location, stone density, and stone sizes, with a p-value that showed no significance from a statistical point of view. The compared parameters of the two study groups are presented below in Table 1.

	Group 1 (n=30)	Group 2 (n=30)	p value
Age (years)	49.9 ± 14.1	48.8 ± 13.8	0.351
Gender			0.986
Male	18 (60%)	19 (63,33%)	
Female	12 (40%)	11 (36,66%)	
BMI	28.3 ± 5.2	27.9 ± 5.1	0.732
Stone density (HU)	1057.3 ± 110.5	1078.2 ± 104.3	0.797
Stone location			0.36
Superior Calyx	15 (50%)	13 (43.33%)	
Pelvis	7 (23.33%)	9 (30%)	
Inferior Calyx	4 (13.33%)	4 (13.33%)	
Multiple	4 (13.33%)	4 (13.33%)	
Stone size (mm)	10.5 ± 4.4	10.9 ± 4.2	0.689

Table 1 – Demographic data of the two study groups

Regarding the operative parameters and the surgical outcomes in terms of SFR and complications, the results (summed up in Table 2) showed the following: The time until the introduction of the flexible ureteroscope (calculated as the time passed from the induction of the general anaesthesia with Oro-tracheal intubation to extracting the previously placed JJ stent, insertion of the flexible device, including inspection ureteroscopy under the safety guide-wire, insertion of the UAS) was 18.5 minutes in group 1 and it decreased to 12.4 minutes in group 2 (p = 0.001). The fluoroscopy time was significantly longer in group 1 (83 seconds) compared to 40.8 seconds in group 2 (p = 0.001). The operative time (just the flexible ureteroscopy part with laser lithotripsy, fragment extracting, removing the UAS and placing the JJ stent) decreased significantly from 49.2 minutes in group 1 to 32 minutes in group 2 (p = 0.001).

The success rate of the procedure was defined as the stone free rate (SFR), which showed an important increase in group 2 compared to group 1 (86,66% versus 66%, respectively, p = 0.03).

Complications rate showed no major difference between the two patient groups, with two Grade 3-5 and three Grade 1-2 Clavien-Dindo classified complications out of 30 cases in group 1 versus one case of Grade 3-5 Clavien-Dindo and two cases Grade 1-2 respectively, in group 2 (p = 0.68). Furthermore, hospital stay assessment did not show an important difference in the study groups, with an average of approximately 4 days for each of the studied groups (p = 0.592).

	Group 1 (n=30)	Group 2 (n=30)	p value
Time till inserting the flexible ureteroscope (minutes)	18.5 ± 4.3	12.4 ± 2.2	0.001
Fluoroscopy time (seconds)	83 ± 14.6	40.8 ± 16.3	0.001
Operative time – only the flexible ureteroscopy part (minutes)	49.2 ± 6.1	32 ± 4.2	0.001
SFR	20 (66%)	26 (86.66%)	0.03
Complications (Clavien-Dindo)			0.68
Grade 1-2	3 (10%)	2 (6.66%)	
Grade 3-5	2 (6.66%)	1 (3.33%)	
Hospital stay (days)	4.08 ± 2.04	4.06 ± 2.06	0.592

Table 2 – Comparison of the surgical parameters and outcomes between the two study groups

DISCUSSIONS

As flexible ureteroscopy started to gain important field in the treatment of urolithiasis, maybe replacing some of the indications of PCNL in the latest years [9-13], few authors tried to study the learning curve in f-URS and its impact on gaining proficiency in terms of complications and favourable results in treating renal and/or ureteral lithiasis [5, 7, 14, 15]. This was also the goal of our study, and we consider we have reached interesting results in terms of operative time, fluoroscopy time and stone free rates.

The obtained results showed that the time until insertion of the flexible ureteroscope after the induction of the anaesthesia decreases after the first 30 cases in a statistically significant manner. This might be explained by the fact that ureteral access sheath (UAS) insertion might come handier to the surgeon once the number of completed cases increases, him being able to have more sensitivity and experience in choosing the UAS size from the beginning, after the semirigid inspection ureteroscopy. Furthermore, there's also a significant difference in fluoroscopy usage time between in favour of the second study group, a very important aspect, if we are to consider the carcinogenic impact of fluoroscopy vastly described in the literature [16-18]. The reasoning for the decrease is probably related to the increase in ease of handling of the device and orientation capacities of the surgeon while performing the „pyelocaliceal mapping" and identifying the location of the lithiasis, given the fact that the only experience before was with rigid ureteroscopes and nephroscopes.

Obviously, the goal of any urolithiasis surgery is mainly related to the stone free rate status, that of course with no or minor complications if possible. The stone-free rate following f-URS is reported with a wide range in the literature, from 50 to over 90% [19-22]. Our results show a SFR of 86% after 30 completed f-URS cases with an increase of over 20% in the second lot of patients, while the operating time also decreased considerably. These results are

although other authors specify a necessary of 60 cases to achieve competency in this type of procedure, specifically 60 cases to improve the operating time and 56 cases to achieve lithotripsy competency [5].

CONCLUSIONS

Defining the learning curves of various surgical urological procedures is a very complex aspect with several studies using different parameters to measure outcomes and to assess skill acquisition rates of surgeons with different prior experience. Our obtained results show that 30 cases may be enough for gaining proficiency in flexible ureteroscopy regarding a decrease in the operating and fluoroscopy times and a significantly increase in the stone free rate. The evidence produced by this article can serve as guidance for urologists in training to better evaluate the progress rate in f-URS procedures. Nonetheless, multi-operator, multicenter prospective trials using standard outcome measures should be conducted to better characterize and establish the exact learning curves.

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