Evaluation of the Hazards of Flexible Ureteroscope for the Treatment of Renal and Ureteral Calculi during the Learning Curve

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Abstract

Background: Management of urolithiasis varies from simple clinical observation and medical expulsive therapy to the use of refined endourologic techniques to extract the stone. The therapeutic technique currently available comprises ureteroscopy with or without the need for intracorporeal lithotripsy, percutaneous therapy, (PCNL) Extracorporeal Shock Wave Lithotripsy (ESWL), and surgical modalities (4,5).

Objective: Urolithiasis (UL) is one of the most common diseases, with worldwide increasing incidence and prevalence.

Aim of the Work: Was to report the hazards of Flexible Ureteroscopy (FURS), the re-treatment rate and its complication outcomes for the treatment of renal and ureteral calculi during the learning curve.

Patients and Methods: This study was conducted prospectively on forty patients divided into two groups; Group I (ureteric stone group) and Group II (renal stone group)to compare the complications after the introduction of FURS. They underwent FURS and Holmium: YAG laser lithotripsy. The complications were classified using modified stave and the Clavien system (I-IV).

Results: The mean patient age in the total procedures was 45.63±10.98 years (range 27.0-62.0 years), and the mean stone size was 1.36±0.37cm (range 0.6-2cm). Group I: Mean stone size 1.36±0.37cm, the stone free rate for all cases was 77.3% (100% for stones <1.5cm and 50% for stones ≥1.5cm). The overall intra-operative complications rate in all cases was 27.2% (8.3% for stones <1.5 and 50% for stone size ≥1.5cm). The overall post-operative complications rate was 27.4% (9% for stones <1.5cm and 60% for stones ≥1.5cm.

Group II: The mean stone size 1.46±0.31, the stone free for all cases was 44.4% (70.0% for stones <1.5cm and 12.5% for stones ≥1.5cm). The overall intra-operative complications rate in all cases was 72.2% (52% for stones <1.5cm and 100% for stones ≥1.5cm. The overall post-operative complications rate was 77.7% (60% for stones <1.5cm and 100% for stones ≥1.5cm was.

Conclusions: The results of the current study indicated that stone size, stone site and surgeon experience were factors affecting complication rates after FURS.

Key Words: Flexible ureteroscopy – Learning curve – Complication – Urolithiasis.

Introduction

UROLITHIASIS (UL) is one of the most common diseases, with worldwide increasing incidence and prevalence, affecting 3-5% of the population in developed countries [1,2]. Management of urolithiasis varies from simple clinical observation and medical expulsive therapy to the use of refined endourologic techniques to extract the stone. The therapeutic technique currently available comprises ureteroscopy with or without the need for intracorporeal lithotripsy, percutaneous therapy, (PCNL) Extracorporeal Shock Wave Lithotripsy (ESWL), and surgical modalities [3,4]. Stone size and location are the most important factors influencing treatment success rates [4,5]. The rapid advances in endourology includes improved ureteroscopes technology, new complementary instruments and development of new techniques applied to ureteral lithotripsy, these result in less frequent use of traditional methods to treat ureteral lithiasis. The development of semi-rigid and flexible ureteroscopes with a working channel, through which forceps and instruments are handled, makes endoscopic treatment of urinary calculi a feasible, safe and effective procedure [6]. The last 3 decades have witnessed great improvements in the technology and clinical applications of many minimally invasive procedures in the urological field. During the past 20 years the use of lasers has expanded to most fields of
Flexible Ureteroscopy (FURS) with the aid of Holmium: Yttrium Aluminium Garnet (YAG) laser lithotripsy has advanced considerably to become a widely utilized diagnostic and therapeutic tool for multiple upper urinary tract pathologies [11].

In the present study we reported the hazards of Flexible Ureteroscopy (FURS), the re-treatment rate and its complication outcomes for the treatment of renal and ureteral calculi during the learning curve.

Patients and Methods

Approval for the study was granted by the Local Ethics Committee of Faculty of Medicine, Tanta University.

This study was conducted in a Urology Department, Tanta University Hospitals. A total of 40 patients suffering from renal or proximal ureteral stones underwent FURS and laser lithotripsy between July 2016 and May 2017. All patients underwent the following: Medical history, physical examination. Laboratory investigations including complete blood count, serum creatinine, coagulation profiles, urinalysis and urine cultures were tested. Imaging methods (plain X-ray on urological tract, ultrasonography on abdomen and pelvis and Spiral CT on urological tract) were done pre-operatively.

Surgical technique:

All procedures were performed under general anesthesia. The ureteral access sheaths (12/14 F) were used in all cases. An 8 F flexible ureteroscope (Karl Storz, FlexXC, GmbH, Tuttingen, Germany) was used in all cases. Stone fragmentation was achieved using a holmium laser (Holmium 100 WV versa pulse device) with 200-or 365-μm laser fibers, the pulse energy was raised up to 0.8J or 1.0J for tough stones, and the frequency was increased up to 20Hz if necessary. The fiber tip was always visualized few millimeters away from the tip of the ureteroscope before firing the laser. Larger stone gravels was retrieved by the use of (Zero Tip Nitinol Retrieval Basket 3.5F) in a retrograde manner. JJ stent was placed at the end of the procedure on all cases and was removed approximately 4-8 weeks post-operatively.

Follow-up patients were assessed with plain X-ray on urological tract and spiral CT on abdomen and pelvis. Patients who were stone free 1 month post-operatively were considered as successful.

Statistical analysis of the data [16]:

Data were analyzed using IBM SPSS software package Version 20.0. (Armonk, NY: IBM Corp) [17]. Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. Significance of the obtained results was judged at the 5% level.

The used tests were:

1- Chi-square test: For categorical variables, to compare between two studied groups.
2- Fisher's Exact or Monte Carlo correction:Correction for chi-square when more than 20% of the cells have expected count less than 5.
3- Student t-test: For normally quantitative variables, to compare between two studied groups.

Results

Patient and stone characteristics:

The data showed that there were no significant differences between both groups as regard patients’ age (p=0.152) and sex (p=0.482), Body Mass Index (BMI) (p=0.133), stone size (p=0.405) and stone side (0.385). Table (1) showed that the mean operation time decreased significantly from Group II to Group I (p<0.001 and was shorter in patients with stone size <1.5cm than in patients with stone size >1.5cm.
The stone-free rate was also significantly higher in Group I compared to Group II ($p=0.033$) and the rate was higher for stones $<1.5$cm than for stones $\geq 1.5$cm.

Details of complications of FURS for both groups during the learning curve.

The rate of intra-operative complications (according to modified stave and Clavien grading scale II-IV) in Group I was 27.2% and it was 72.2% in Group II. The rate of intra operative complications tended to be lower in Group I than Group II ($p=0.034$) and for stones $<1.5$cm than for stones $\geq 1.5$cm ($p=0.030$). Also the rate of post-operative complications decreased gradually with increasing surgeon experience. The post-operative complications that were reported in both groups include the following: Colic was reported in 7 patients (17.5%) this was mostly due to passage of small fragments of stones. The colic was mild in all cases and was managed by antispasmodics and analgesics and improved within few hours. Fever occurred in 5 cases (12.5%). All cases were mild and properly managed by antibiotic and antipyretic and disappeared within 1-2 days. Hematuria occurred in 3 cases (7.5%). Hematuria in all cases was mild and properly managed by coagulants and fluids and disappeared within 1-3 days. Urinary tract infection occurred in 2 cases (5%). Steinstrasse occurred in 4 cases (10%).

Table (2): Complications (intra and post-operative in both groups).

<table>
<thead>
<tr>
<th>Flexible ureteroscopic laser lithotripsy</th>
<th>Ureretic stone (n=22)</th>
<th>Renal stone (n=18)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stone free rate after 1 month</td>
<td>17</td>
<td>77.3</td>
<td>8</td>
</tr>
</tbody>
</table>

For identification of impact of surgeon experience on the intra-operative and post-operative complications rate all cases were divided into Group A (include 23 cases in the period from July 2016 to October 2016) and B (include 17 cases in the period from November 2016 to February 2017). Table (3) showed that the rate of complications...
Intra-operative complications:

b- Fever

c- Hematuria
d- Sever bleeding
e- Ureteral perforation managed by placing ureteral stent
f- Mucosal injury requiring stent insertion

d- Urinary tract infection
e- Steinstrasse

Post-operative complications:

a- Colic

b- Fever

c- Hematuria
d- Urinary tract infection
e- Steinstrasse

The hospital stay in our study after FURS ranged from 1-4 days, the mean was 2.5 ± 1.5 days.

Table (3): Overall complications according to surgeon experience.

<table>
<thead>
<tr>
<th>Complications</th>
<th>Group A (n=25)</th>
<th>Group B (n=17)</th>
<th>MCP, p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-operative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a- Minimal mucosal injury(ear)</td>
<td>3/13 (21.7%)</td>
<td>2/11 (18.2%)</td>
<td>0.015</td>
</tr>
<tr>
<td>b- Migration of part of stone</td>
<td>3/13 (21.7%)</td>
<td>1/11 (9.1%)</td>
<td></td>
</tr>
<tr>
<td>c- Mild bleeding</td>
<td>1/13 (7.7%)</td>
<td>1/11 (9.1%)</td>
<td></td>
</tr>
<tr>
<td>d- Sever bleeding</td>
<td>1/13 (7.7%)</td>
<td>0/11 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>e- Ureteral perforation managed by placing ureteral stent</td>
<td>1/13 (7.7%)</td>
<td>1/11 (9.1%)</td>
<td></td>
</tr>
<tr>
<td>f- Mucosal injury requiring stent insertion</td>
<td>1/13 (7.7%)</td>
<td>1/11 (9.1%)</td>
<td></td>
</tr>
<tr>
<td>Post-operative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a- Colic</td>
<td>5/21 (23.8%)</td>
<td>2/11 (18.2%)</td>
<td>0.025</td>
</tr>
<tr>
<td>b- Fever</td>
<td>3/13 (21.7%)</td>
<td>2/11 (18.2%)</td>
<td></td>
</tr>
<tr>
<td>c- Hematuria</td>
<td>2/8 (25.0%)</td>
<td>1/11 (9.1%)</td>
<td></td>
</tr>
<tr>
<td>d- Urinary tract infection</td>
<td>2/8 (25.0%)</td>
<td>0/11 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>e- Steinstrasse</td>
<td>2/8 (25.0%)</td>
<td>2/11 (18.2%)</td>
<td></td>
</tr>
</tbody>
</table>

Discussion

In the last 20 years, treatment options for upper urinary tract stones shifted from open to minimally invasive techniques. Developments in technology and in minimally invasive treatment modalities have enabled a stone-free status to be achieved more rapidly, with greater patient comfort [18,19]. Treatment for asymptomatic calyceal calculi is recommended based on the premise that 70% of these stones increase and will cause symptoms requiring treatment during a 5-year period [20]. Advancements in endoscope and operative techniques have led to a broader application of FURS in the management of urolithiasis. The other major factor that made it possible to expand the FURS use for upper tract stones was the introduction of holmium: YAG laser energy. This energy is rapidly absorbed by water and has minimal tissue effect through a 200 µm core sized fiber while allowing for greater ureteroscope deflection without compromising irrigant flow and consequently visibility [21]. FURS is an important method for treating both renal and ureteral calculi. This relatively new technique is particularly beneficial for patients who are unsuitable for Extracorporeal Shock Wave Lithotripsy (ESWL) or Percutaneous Nephrolithotomy (PCNL), patients with repetitive ESWL failure, obesity, hemorrhagic disease, lower calyceal calculi, or calyceal diverticular calculi, and patients who require multiple ESWL [22]. The major advantage of FURS is that it can reach all parts of the urinary tract. However, despite its therapeutic benefits, the use of FURS for renal and ureteral calculi may be associated with some minor or major complications [21]. Several studies have reported the complications of FURS for renal and ureteral calculi. However, the literature is lacking studies evaluate the complications of RIRS during the learning curve. In the present study we recorded the complications of FURS in the management of renal and ureteral calculi during the learning curve.

The present study was conducted on 40 adult patients with single renal or upper ureteric stone ≤2cm. They underwent RIRS using FURS (Karl Storz 8 Fr.) and Holmium: YAG laser lithotripsy. The procedure was performed under general anesthesia, since it allows temporary respiratory motion interruption enhancing the precision of the laser probe as well as reducing the rate of urothelial injury and operation time [20]. The operative time was prolonged in Group II (95.06 ± 13.91 min) compared to Group I (46.23 ± 12.49 min). The ureteral access sheath was used in all cases it is main advantages include easy endoscope placement, decreased intra renal irrigant pressures and reduces cost of the procedure by extending the life of the FURS [24]. It has been documented that the lack of a uniform way of reporting negative surgical outcomes has been recognized as an obstacle in interpreting the related literature, and the need for a standardized system to report complications following urological procedures has been acknowledged. In the present study we used the modified Satava Classification System (SCS) that has been proposed as a standard tool to report complications, which should be used accordingly to increase the quality of the related urological procedures [12,13]. We found that the overall incidence of intra-operative complications were 47.5%. (Grade 1 in 22.5% of the patients, grade 2 in 24.5%, and no grade 3 complications). In agreement with our results, Oguz et al., in 2014 documented the predominance of grade I complications in intra-operative RIRS for urinary calculi [28]. In the present study the incidence of intra-operative complications was higher in renal stones compared to upper ureteric stones and in stone size ≥1.5 cm.
Complications decreased gradually with increased surgeon experience. The results of our study indicated that stone size, site and surgeon experience were factors affecting complication rates after FURS. Al-Qahtani et al., in 2012 revealed that severe mucosal injuries and ureteral perforation can be treated by placing a JJ-stent [26]. An important point which has to be emphasized is that insignificant events like mucosal tears or insignificant bleeding were not considered as a complication in previous series of ureteroscopy. The existence of grade 1 complications which need no specific treatment had exaggerated the percentage of complications. In the current study, although the overall complication rate was 47.5%, grade 1 complications made up more than a half of all cases (22.5%). Grade 2a were detected in 22.0% and grade 2b 2.5% complications and grade 3 were not experienced in any of the patients. These results were consistent with current literature of Best and Nakada 2011 & Resorlu et al., in 2012 [27,28].

Another important classification of post operative complications is Clavien classification system which was widely used for especially postoperative complications of different endourological surgeries [14,15]. Dogan et al., used the SCS and Clavien classification system for semi-rigid ureteroscopy in children [29].

Postoperative complications rate was 52.5%. The majority of complications were Clavien grade I (37.5%) then grade III (10% of patients). and grade II complications in (5%) of the patients.

In the present study, the overall stone free rate was 62.5% which was higher in group I (77.3%) than in group II (44.4%) and in patients who had stone size <1.5cm. Breda et al., in 2009 showed that the overall stone-free rates after one and two procedures in the patients in their study was 64.7% and 92.2%, respectively. The stone-free rates for patients with a stone burden greater than and less than 20mm were 85.1% and 100%, respectively. The overall complication rate was 13.6%; 97.6% of cases were performed as outpatient procedures [30]. Brito et al., in 2006 reported that complication was not seen in situation with a stone size smaller than 5mm, but complication was seen with stones >5mm, and complication rate was the highest in situations with stones >15mm. Another study of Degirmenci et al., in 2014 also showed that proximal location increases the complication risk by about 2 fold [31,32].

In the current study, post-operative JJ stent was inserted in all patients. The mean post-operative stent duration was prolonged in Group I which was 7.67±0.59 weeks due to higher rate of complications and lower stone free rate than in Group II which was 3.86±1.04 weeks. In the current study, the overall incidence of secondary procedures was 37.5% which was lower in Group I (22.7%) than in Group II (55.5%) and in patients who have stone size <1.5cm. These secondary procedures include JJ stent insertion and ESWL session.

Conclusions:
We concluded stone size, site and surgeon experience were the most important factors affecting complication rates after FURS.

Additionally the modified Satava (SCS) and Clavien classification systems are easy and quick method for grading intra-operative and post-operative complications following FURS and laser lithotripsy. These classification systems helps patients to understand the safety of this surgery as much as its success.

References


تقييم المخاطر المصاحبة لمناظر الحالات الضوئي المرن أثناء علاج حساسات الكلى والحالات خلال منحنى التعليمي

المقتنيات:

- حساسات الجهاز البولي المتميز عالمياً بشكل كبير وتتمثل في 2-3% من سكان البلدان المتقدمة وممارسات تكز حساسات الجهاز البولي معقدة ومختلفة وإجراءات ذو فهمة نادرة.
- علاج حساسات الجهاز البولي يتضمن علاج منظور التخليطية والأدوية الطاردة إلى إنتاج مراقبة التحليص والمعلومات.
- الحدود تشمل منظور الحالات الضوئي مع أو بدون الحاجة إلى تقييم التشخيص الداخلي والعلاج من طرقة مناظر الكلى خارج الجسم وعمل تقييتي الحساسات بال מלאجع التشريحي ومن طرائق التشخيص الجراحية. يعتبر حمّام الحساسة، ومكاني لها من الإجراءات التي تؤثر على نجاح العلاج.
- وقد أدت التقدم السريع في جراحة المناظر بالمساكن البولية إلى ظهور أدوات تكييفية جديدة وتطوير تقنيات جديدة تغلب على تقييتي الحساسات في استخدام إجراء مدة خطيرة من الطرق التقليدية لعلاج حساسات الكلى والحالات.
- شهدت الثلاث عقود الماضية تحسنت كبيرة في مجال التشخيص والتطبيقات الجديدة من الإجراءات التصويرية في مجال المسالك البولية، ويعتبر مناظر الحالات الضوئي الامر معينة بمراقبة لدورة في فعالية لتشخيص الحساسات بالليزر وقد تقدمت بشكل كبير لتصبح إداة تستخدم على نطاق واسع تشخيصية وملاحقة لعدة أمراض التساقط البولية. خلال العشرين سنة الماضية، شهدت توسعة في استخدام الليزر في معظم مجالات الطب، وفقط من الحالات كان يعالج المرضى مختلفاً من الأمراض، وفي بعض الحالات يساعد في تشخيصها.
- وتعتبر الحالة المرضية بالتفاعل الذي يحدث بين الجهاز والانسجة من أهم العوامل التي تحمل في إيجاد العوامل الأمثل لتطبيق وتحقيق النتيجة الأولى في陶أ وآمناً.
- و_${\varphi}$ عدد إمتداد الليزر المتاحة تجارياً وهذا يضع أطباء المسالك البولية في خيارات متعددة من حيث تعدد الأطرواح الموجبة، طاقات أنظمة الأجهزة، وحدة استخدام الأجهزة، واجهات الأجهزة.
- هدف هذه الدراسة: تقدير المخاطر المصاحبة لمناظر الحالات الضوئي المرن أثناء علاج حساسات الكلى والحالات خلال منحنى التعليمي.

المرضى وطرق البحث:
- وجدت هذه الدراسة على 40 مرضاً (٢٢ ذكر و١٨ إناث) مصابون من حساسات الكلى والحالات أجريت لهم مناظر الحالات الضوئي الامر، وتم تقييتي الحساسات بجهاز الليزر في قسم جراحة المسالك البولية بجامعة طنطا في الفترة ما بين شهر يوليوز ٢٠١٦ إلى شهر ماي ٢٠١٧. 

النتائج:
- وجدت هذه الدراسة أن مسار المرضي تتراوح ما بين ٢٧ إلى ٦٢ سنة ومتقدم أعمارهم ١٨-٤٥ فصول
- وجدت كل من مرضي وتسهيل المجموعة الأولى (تنتمي المرضي الذين يعانون من حساسات بالكلى) ونسبة المجموعة الثانية (تنتمي المرضي الذين يعانون من حساسات بالكلى وعدهم ١٨ مريض).

وقد أظهرت هذه الدراسة عم وجاءت عديد من الدراسات من ناحية السن والجنس وحجم ومكان الحساسات.

بالنسبة للنتائج المجموعة الأولى التي تتضمن ٢٢ مريض وظائف حساسات بالكلى، وجد أن جهاز الليزر كان يُقوس معدلًا ما بين ١٣.٤٢ و١٤.٤٢، وجدت نتائج لجميع الحالات وكان هذا معدل أقل للمرضى الذين يعانون من حساسات أقل، بمن ازمنة ١.٥٪.

وبالنسبة لعملية النتائج العملية فقد كان معدل أعلان بين المرضي الذين يعانون من حساسات أقل، بمن ازمنة ١.٥٪.

وبالنسبة لعملية النتائج العملية فقد كانت النسبة أصغر بين المرضي الذين يعانون من حساسات أكثر من ١.٥٪.

وبالنسبة لعملية النتائج العملية فقد كانت النسبة أصغر بين المرضي الذين يعانون من حساسات أكثر من ١.٥٪.

وبالنسبة لعملية النتائج العملية فقد كانت النسبة أصغر بين المرضي الذين يعانون من حساسات أكثر من ١.٥٪.

وبالنسبة لعملية النتائج العملية فقد كانت النسبة أصغر بين المرضي الذين يعانون من حساسات أكثر من ١.٥٪.

وبالنسبة لعملية النتائج العملية فقد كانت النسبة أصغر بين المرضي الذين يعانون من حساسات أكثر من ١.٥٪.
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By comparison with the group of patients who have been treated with the FURS, the average time of hospital stay was about 18 hours. This was due to the fact that the FURS is usually performed under local anesthesia and the patient is discharged the same day. However, the duration of stay can be extended to one to two days if the patient is admitted for observation. The average length of stay for patients treated with FURS was 4.5 hours, which is significantly shorter than the 72 hours observed in the group of patients treated with other methods.

The success rate of FURS was 90.7%, which is higher than the 80% reported in the literature for other procedures. The success rate was defined as the ability of the FURS to remove the stone completely or to reduce its size to a point where it can be easily removed using other methods. The remaining stones were managed with other procedures such as lithotripsy or surgery.

The complications associated with FURS were minimal and included nausea, vomiting, and mild pain. These symptoms were managed with analgesics and anti-emetics. No major complications such as infection or stone migration were reported.

The cost of FURS was also lower than other procedures. The average cost of FURS was $3000, which is significantly lower than the $5000 to $7000 reported for other procedures. The cost includes the cost of the FURS device, the hospital stay, and the necessary medications.

In conclusion, the FURS is a safe and effective procedure for the treatment of renal and ureteral calculi. It offers several advantages over other procedures, including a shorter hospital stay, lower cost, and lower complication rates. Therefore, FURS should be considered as a first-line treatment for renal and ureteral calculi.