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Do new generation flexible ureterorenoscopes offer a higher treatment success than their predecessors?

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Abstract New generation flexible ureterorenoscopes offer an improved deflection mechanism and a stiffer sheath compared to their predecessors. We aimed to determine if these improvements in design lead to a higher efficacy in the treatment of nephrolithiasis. Ninety patients with upper urinary tract calculi were included into a retrospective analysis. Twenty-nine cases were treated with the conventional flexible ureterorenoscope (11274 AA, Karl Storz Endoscopy, Germany) and 61 cases were treated with the new generation device (Flex-X, Karl Storz Endoscopy). Patients' and stone characteristics, intraoperative data, treatment success and complications were retrieved from the charts and compared between the two groups. Preoperative data were comparable in both groups. Whereas stone access was also comparable (97 vs. 100%; n.s.), immediate treatment success was significantly higher for the new flexible scope (70 vs. 38%; $p = 0.003$). For the subgroup of lower pole stones, stone access was possible in 94 versus 100% (n.s.) and treatment success was 31 versus 69% ($p = 0.0004$) for the conventional and the new generation device, respectively. No major complications were observed, minor complications were comparable in both groups. Our study suggests an advantage of the new generation flexible ureterorenoscopes compared to their predecessors. They offer an increased stone free rate especially in the treatment of lower pole stones. It seems therefore advisable to switch to the latest generation flexible devices.

Keywords Kidney stone · Flexible ureterorenoscopy · Lower pole calculi · Efficacy

Introduction

The introduction of flexible ureterorenoscopy (URS) has led to a new dimension in diagnosis and treatment of upper urinary tract diseases, especially for urinary tract calculi. Despite its first description in 1964 [1] and first successful clinical use of an actively deflectable scope in 1971 [2], the era of flexible URS began in the early 1990s. Constant progress in scope design has led to the development of flexible instruments with a tip diameter of less than 9F, active tip deflection in both directions and an incorporated working and irrigation channel. However, due to the miniaturization, the scopes, especially the deflection system, became more fragile causing high maintenance costs [3]. Another problem in clinical practice is the loss of maximal active tip deflection and irrigation flow after inserting stone fragmentation or extraction instruments into the working channel. This often prevents successful stone removal from the kidney despite possible stone access with the empty scope.

To overcome these problems, a new generation of flexible ureterorenoscopes has been introduced in recent years. They offer a stiffer sheath allowing a bare ureter

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passage in many cases and are more durable leading to reduced maintenance costs [4–7]. Furthermore, they offer an exaggerated maximal tip deflection of >270° in both directions which is maintained when working tools are inserted into the working channel [5, 8].

This higher maximal active tip deflection of the new generation scopes is postulated to offer an easier stone access and removal compared to the conventional flexible instruments, especially for lower pole stones. Several studies compare the devices in an in vitro setting to quantify technical characteristics [5, 8, 9]. However, so far it remains to be proven, if the advantages of the new generation scopes found in vitro lead to an improved treatment efficacy in a clinical setting. The aim of the present study is to compare the efficacy of a new generation flexible ureterorenoscope to a conventional device in the treatment of nephrolithiasis.

Patients and methods

Ninety patients with nephrolithiasis treated with flexible URS at the University Hospital Mannheim, Germany, were included into the retrospective analysis. Among these, 29 consecutive patients (Group 1) were treated with the conventional flexible instrument (11274 AA, Karl Storz Endoscopy, Tuttlingen, Germany) between January 2000 and July 2003. In 61 consecutive patients (Group 2) the new generation flexible scope (Flex-X, Karl Storz Endoscopy) was used between December 2005 and May 2007. Patients' demography, stone characteristics, intraoperative data, treatment success and associated complications were recorded from the patients' charts and compared between the two groups. Treatment success was defined as complete removal of all stones or remaining of insignificant residual fragments smaller than 4 mm requiring no further intervention.

Prior to the procedure, all patients underwent standard clinical and radiological workup; 23 (79%) and 30 (49%) patients in group 1 and group 2 were pretreated with ureteric stents due to ureteral obstruction.

All procedures were performed under general anesthesia and antibiotic prophylaxis. After a cystoscopy, two hydrophilic guidewires were passed up the ureter into the kidney. Afterwards, the flexible scope was passed over one guidewire to the renal pelvis (monorail technique), while the second was used as safety wire. In case of anticipated multiple ureter passages, an access sheath was placed in the proximal ureter. In the first group 10/12F 35 or 55 cm (Applied Medical, Rancho Santa Margarita, CA, USA), in the second group 10/12F 35 or 55 cm (Cook Medical, Ireland) ureter access sheaths were used. The length of the sheath was selected by the urologist dependent on patient size to place the sheath in the proximal ureter. In none of the patients an intramural dilation process was required. A thorough inspection of the complete collecting system followed before stone removal was initiated. Whenever necessary, the stones were fragmented before extraction using a holmium:yttrium–aluminum–garnet (Ho:YAG) laser and 230 μm fibers (Wavelight Lasertech, Erlangen, Germany). For the first group, in order to extract stones, tipless nitinol baskets 2.2F (Cook Medical) and nitinol graspers (2.6F Boston Scientific) were used. For the second group, 2.2F and 1.5F (Cook Medical), and 2.2F (Boston Scientific, MA, USA) nitinol baskets were used. In all the cases, the goal of the procedure was to extract all relevant fragments. A ureteric stent was placed at the end of the procedure in case of multiple ureter passages, bleeding, ureteral edema, perforation or residual calculi. Treatment success was evaluated with plain X-ray and sonography on the following day.

Statistical data are presented as mean ± standard deviation. Statistical significance was evaluated using the Mann–Whitney U test, Fisher's exact test and Chi-square test. A p value <0.05 was considered to be statistically significant.

Results

Patients' demography and stone characteristics are listed in Table 1. Patients' age, gender and treated side were comparable in both groups. In group 1, treated with the conventional scope, significantly more stones were located in the middle calyx, whereas in group 2, treated with the new

Table 1 Patients' demography and stone characteristics

	Group 1 ($n = 29$)	Group 2 ($n = 61$)	p value
Mean age (years)	58.6 ± 14.2	52.2 ± 14.7	n.s.
Gender: male/female (%)	52/48	59/41	n.s.
Side: left/right (%)	48/52	52/48	n.s.
Stone size (mm)	8.8 ± 3.0	8.5 ± 3.3	n.s.
Stone quantity			
Single/multiple (%)	62/38	39/61	0.036
Stone localization (%)			
Renal pelvis	10	13	n.s.
Upper calyx	14	11	n.s.
Middle calyx	38	16	0.025
Lower calyx	55	84	0.005
Pretreatment with Double-J (%)	79	49	0.00 6

The new generation flexible ureterorenoscope offered a significantly higher treatment success compared to its predecessor

Table 2 Intraoperative data, treatment success and complications

	Group 1 ($n = 29$)	Group 2 ($n = 61$)	p value
Operation time (min)	103 ± 40	99 ± 48	n.s.
Access sheath (%)	21	31	n.s.
Double-J at end of procedure (%)	66	51	n.s.
Overall stone access (%)	97	100	n.s.
Overall treatment success (%)	38	70	0.003
Lower pole stone access (%)	94	100	n.s.
Lower pole treatment success (%)	31	69	0.0004
Complications (%)			
Perforation	3	2	n.s.
Abortion for bleeding	7	7	n.s.
Fever	7	5	n.s.
Postoperative Double-J	3	2	n.s.

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generation instrument, more stones were located in the lower pole. With 8.8 ± 3.0 and 8.5 ± 3.3 mm, the overall stone volume was comparable in both groups, although in group 2 the portion of patients with multiple stones was higher.

Intraoperative data, treatment success, intra- and post-operative complication rates are displayed in Table 2. There was no statistical difference in mean operating time, the use of an access sheath or the rate of patients in whom a ureteric stent was placed postoperatively among both groups.

Overall, possible access to the stone was high in both groups (97 vs. 100%; n.s.). However, immediate treatment success was significantly improved in group 2 (70 vs. 38%; $p = 0.003$).

For the subgroup of lower pole stones, the mean stone size was 6.6 ± 2.1 mm in Group 1 ($n = 16$ patients) whereas it was found to be 6.3 ± 2.4 mm ($n = 51$ patients) in group 2 (n.s.). In this subgroup successful stone access was also comparable in both groups (94 vs. 100%). However, with a treatment success rate of 69 versus 31%, treatment efficacy was significantly higher in group 2 ($p = 0.0004$).

No major intra- or post-operative complications were observed in both groups. Minor intraoperative complications such as perforation (3 vs. 2%) and termination of the procedure due to bleeding or impaired visibility (7 vs. 7%) were not significantly different among both groups. Furthermore, postoperative minor complications including transient fever (7 vs. 5%) and symptomatic hydronephrosis requiring placement of a ureteric stent in one patient per group (3 vs. 2%) were comparable in both groups.

Discussion

Flexible ureterorenoscopes have been continuously improved since their introduction. Technical advancements include a continuous downsizing of the instrument diameter, improved optical quality and an enhanced deflection mechanism. The development of potent stone disintegration and extraction tools such as the Ho:YAG laser and nitinol baskets has further helped to increase the efficacy of flexible URS in the treatment of upper urinary tract stone disease.

The conventional flexible scopes, still widely used in clinical practice, offer a maximal active tip deflection of 170/120°. The insertion of working tools such as nitinol baskets or laser probes further reduce the available tip deflection. Furthermore, the high vulnerability of these instruments lead to a high repair frequency and significant associated maintenance costs [3].

In order to overcome these problems, a new generation of flexible ureterorenoscopes has been introduced in recent years. These new instruments feature a bilateral active tip deflection of more than 270° and a stiffer midsheath allowing easier intrarenal navigation [7]. Furthermore, the scopes are more durable than their predecessors leading to a reduction in maintenance costs [6]. The latest generation flexible ureterorenoscope introduced recently by Karl Storz recently, the Flex-X^2, provides a laser-resistant distal tip in addition to the 270° active tip deflection of the Flex-X.

The aim of our study was to determine whether the technical improvements of the new generation of flexible ureterorenoscopes lead to a higher treatment efficacy in comparison to their predecessors.

We could not find a significant difference in achieving a successful access to an intrarenal stone between the conventional and new flexible instrument (97 vs. 100%). Even in the subgroup of lower pole calculi, stone access was impossible only in one patient of the conventional URS group (6%). Our findings are in line with those of other large series. Johnson et al. [4] found an inability to access the lower pole of the kidney in 1.5% of patients treated with a new generation scope in comparison to 7% treated with a conventional flexible instrument. Even in pediatric patients with a small sized anatomy, a stone access rate of up to 100% has been described with the modern small diameter ureterorenoscopes [10].

We found an immediate treatment success rate of 70% in the group treated with the new flexible device. This is in line with other series reporting success rates between 45 and 95% depending on stone size, localization and definition of treatment success [4, 11–13]. However, in contrast to the similar stone access rates, the treatment success was significantly higher in the group treated with the new generation flexible device. With an immediate treatment success of 70% compared to 38%, the success rate was almost twice as high as that achieved with the conventional scope. This advantage in treatment efficacy was even more pronounced in the subgroup treated for lower pole stones.

A reason for the low treatment success despite the possible stone access in the conventional URS group may lay in the more relevant loss of maximal active deflection caused by the insertion of working instruments described in various in vitro studies [5, 8, 9, 14]. With an empty working channel, stone access was possible in almost all cases. However, after insertion of lithotripsy or stone removing tools, the loss of deflection often resulted either in failure to access the desired calyx completely or in failure to position the laser probe or stone removing tools adequately. In contrast to that, we found that even after the introduction of instruments in the working channel of the new generation scope, a high tip deflection was maintained allowing an easy and reproducible access to the desired calyx.

In a study published by Ankem et al. [15], a staged setting was used to compare a new generation to a conventional flexible instrument in a clinical setting. They started the procedure with a conventional device for diagnostic or therapeutic upper urinary tract endoscopy. In 28.9% of cases, the procedure could not be completed; hence the surgeon switched to the new instrument and successfully finished the procedure in 69.2% of cases proving the supremacy of the new scope.

Major complications were observed neither in the conventional nor in the new generation URS group confirming flexible URS being a safe procedure. Minor complications could be handled conservatively in most cases. Only one patient per group, who received no ureteric stent at the end of the procedure, required a stent on the following day due to symptomatic hydronephrosis.

We are aware of the limitations of the present study. As the data derive from a retrospective analysis, they lack the impact of a prospective randomized trial. Moreover, only immediate treatment success could be evaluated, as no standardized follow-up had been performed on the patients. Moreover, the growing experience with flexible URS in our department may have had an influence on the improved results of the later group. However, despite these shortcomings, we believe our study indicates, that the advantages of the new generation flexible ureterorenoscopes described in the in vitro studies do indeed offer a benefit for the patient.

Conclusions

The new generation flexible ureterorenoscopes offer an increased treatment success rate compared to their predecessors. For this reason, it seems advantageous to switch to a new generation flexible ureterorenoscope.

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Conflict of interest No competing financial interest exists.

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