Effect of the Polaris Loop ureteral stent on vesicoureteral reflux and relief of lumbago symptoms: a single-center study

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Abstract

Objective
To verify the effect of the Polaris Loop ureteral stent on vesicoureteral reflux and relief of lumbago symptoms in patients after ureteroscopic procedures.

Methods
This was a prospective single-center analysis of 20 patients who received indwelling bilateral ureteral stents after undergoing ureteroscopic lithotripsy. The Polaris Loop stent and Polaris Ultra stent (both F6 and 26 cm) were implanted randomly on the left and right sides of a patient. The results of the visual analogue scale (VAS) of the symptoms of lumbar discomfort that occurred within 2 weeks after surgery and whether or not vesicoureteral reflux occurred during postoperative cystography were recorded.

Results
The differences between the VAS scores and rates of vesicoureteral reflux for the 2 types of stents were significant (p<0.05). The patients receiving the Polaris Loop stent had lower VAS scores and lower rates of vesicoureteral reflux than the patients receiving the Polaris Ultra stent.

Conclusions
The Polaris Loop stent led to improved patient comfort after ureteroscopy and prevented vesicoureteral reflux of urine. However, careful selection of the appropriate length of stent and appropriate placement technique is required.

Background
Ureteral stents are widely used in the field of urology. Although some investigators believe that the routine placement of a stent after an uncomplicated ureteroscopy is unnecessary, a recent survey found that most urologists still routinely place ureteral
stents after ureteroscopy.\textsuperscript{1} A ureteral stent can be placed into a passively dilated ureter before surgery, maintain the patency of the renal pelvis and ureter, or treat a urinary tract infection. If perforation, obstruction, or edema of the ureter occur after ureteroscopy, a ureteral stent should be inserted for temporary drainage, facilitation of healing, or prevention of ureteral obstruction and stenosis. Although the widespread use of ureteral stents can benefit patients, approximately 80\% of patients will experience some urinary tract symptoms.\textsuperscript{2} Most of these symptoms occur during urination, or might be due to vesicoureteral reflux.\textsuperscript{3}

Many investigators have tried nonsteroidal anti-inflammatory analgesics, alpha blockers, M-receptor blockers, and other drugs to reduce the complication rate after ureteral stent placement, including the occurrence of postoperative ureteral fistula, and enhance patient comfort.\textsuperscript{4-7} In addition, investigators continue to develop new biological materials for creating degradable ureteral stents that might also carry less risk of infection and facilitate the healing of ureteral injury. At present, these investigations are being carried out in preclinical in vivo experiments.\textsuperscript{8}

Because of its fishtail design, the Polaris Loop stent can theoretically enhance patient comfort and reduce vesicoureteral reflux of urine, but its effects remain in need of verification by clinical trials. To the best of our knowledge, a self-controlled study of ureteral stents has not yet been published. The purpose of this study was to determine the effects of the Polaris Loop ureteral stent versus the Polaris Ultra ureteral stent implanted in the same patient with bilateral urinary calculi, with regard to reduction of lumbar pain and vesicoureteral reflux of urine by recording the VAS score for lumbar pain after surgery and occurrence of vesicoureteral reflux during postoperative cystography.

Materials And Methods
Study participants

20 patients with bilateral upper urinary tract stones who were hospitalized in our department from September 2017 to September 2018 were selected for the study. The inclusion criteria were as follows: preoperative diagnosis by computed tomography (CT) and abdominal kidney-ureter-bladder (KUB) radiography; bilateral uncomplicated stones in the upper urinary tract treated by similar procedures (bilateral ureteroscopic lithotripsy with simple catheterization or bilateral ureteroscopic lithotripsy with similar operative time for each of the 2 procedures and a total operative time of less than 1 hour); patients aged 18–60 years; patient height 155–180 cm; and ureteral stent position on each side generally “normal”. The exclusion criteria were as follows: preoperative urinary tract infection; urinary tract infection post stent implantation; vesicoureteral reflux of urine caused by neurogenic bladder, severe lower urinary tract obstruction, or congenital megaureter; history of kidney or ureter or bladder transplantation, especially vesicoureteral transplantation; open surgery or percutaneous nephroscopic stenting; history of depression, anxiety, or other psychiatric disorder; and complicated ureteral calculi.

The study was approved by the Ethics Committee of Beijing Tongren Hospital. All patients involved in the study were fully informed of the study and signed an informed consent.

Procedures

Bilateral ureteral stents were retrograde placed after the operation under general anesthesia. To minimize research errors due to different stent materials, the Polaris Loop stent was compared with the Polaris Ultra stent, since both are composed of the same material. The shape of each stent varies between the end of the renal pelvis to the end of the bladder. The bladder end of the Polaris Loop stent is constructed as a filamentous
fishtail, whereas the Polaris Ultra stent consists of a traditional annular design (Fig. 1). To minimize the influence of the procedures, we didn’t dilate the orifices in all of the cases. No access sheath was used. 8/9.8Fr Wolf uretero-renoscopes were used only in all procedures included.

Each patient underwent implantation of the Polaris Loop stent and the Polaris Ultra stent (both sized F6 and 26 cm), which were randomly implanted on either the left or right side the patient according to a random number table. We inserted Polaris Loop stent into the left ureter, and inserted Polaris Ultra stent into the right side in one group, and we exchanged the options of two stents accordingly in the other group. The Polaris Loop stent was placed to ensure that only the fishtail segment remained in the bladder, and the Polaris Ultra stent was placed on the opposite side to ensure that the distal end of the stent was coiled immediately at the ureteral orifice after the withdrawal of the guide wire. Perioperative application of antibiotics were ≤ 24hrs.

On the second day after surgery and before the catheter was removed, the patient was placed in the supine position, and 200 mL of 30% of meglumine diatrizoate was injected through the catheter. The bladder pressure was measured with the catheter connected to an empty infusion device, and the patient was instructed to urinate. After the level of infusate had reached the apex, the patients were observed by plain KUB radiography, and the vesicoureteral reflux volume of each patient was recorded.

For patients who underwent simple catheterization, the VAS score of lumbar discomfort was assessed before procedure in the second stage of operation, while for those undergoing bilateral ureteroscopy, the VAS score of lumbar discomfort was assessed before removal of the ureteral stent 2 weeks after the procedure. Observation indexes: 1. Vesicoureteral reflux after procedure; 2.2. VAS score for postoperative lumbar discomfort.

Statistical analysis
Statistical analysis was performed by SPSS ver. 19.0 software. Quantitative data are reported as means ± SD and percentages. The χ² test was used to compare the results. Statistical significance was considered to be P < 0.05.

Results

A total of 20 patients were included in the study, including 8 patients who underwent simple bilateral simultaneous catheterization and 12 patients who underwent simultaneous bilateral ureteroscopic lithotripsies. The length and diameter of the ureteral stones in each group were smaller than 1 cm, and the operative time was shorter than 1 hour. The basic patient characteristics are shown in Table 1–3.

Bilateral vesicoureteral reflux as observed by KUB radiography during cystography is shown in Fig. 2,3. On the right side, reflux is not seen in the Polaris Loop stent; on the left side, reflux is present in the Polaris Ultra stent. The tail segment of the Polaris Loop stent appears to be completely within the ureteral orifice without changing the orientation of the orifice and destroying the natural anti-reflux mechanism.

We also observed reflux in some of the Polaris Loop stents. As shown in Fig. 4, no reflux is seen in the left Polaris Ultra stent; however, on the right, the upper portion of the right Polaris Loop tail segment did not fully enter the ureteral orifice, and protrudes into the bladder. The protruding part is short and does not cross the midline; and interferes with the natural antireflux mechanism, leading to vesicoureteral reflux. As shown in Fig. 5, if the same portion of the stent body extends farther into the bladder and crosses the midline, it can maintain the normal course of the ureter without interfering with the natural antireflux mechanism of the ureter. It does not lead to vesicoureteral reflux within a specified range of pressures.

Discussion
The ureteral stent provides internal support, unobstructed drainage, treatment of infection, predilation of the ureter, and effective prevention of ureteral stricture after surgery; promotes discharge of calculi; and protects renal function. It is an indispensable consumable device in urology, especially endourology. At present, the indwelling ureteral stent is the choice of most urologists\(^1\). At the same time, complications of ureteral stents such as urinary symptoms and vesicoureteral reflux remain common\(^2\)−\(^3\). At present, most study reports conclude that bladder irritation is caused by double J-tube stimulation of the triangular region of the bladder and the posterior urethra\(^9\)−\(^10\). The Polaris Loop stent has improved biocompatibility because of its fishtail design, and its unique bladder coil design theoretically reduces bladder irritation and leads to increased comfort of the patient. However, to the best of our knowledge, whether or not this design can alleviate urinary vesicoureteral reflux has not been reported until now.

This controlled clinical study of 20 patients with bilateral urinary calculi found that the VAS score of postoperative urinary symptoms for the Polaris Loop stent was lower than the VAS score for the Polaris Ultra stent (\(P < 0.05\)). It was verified that two ureteral stent tubes made of the same material and fishtail design could reduce stimulation of the trigonium of the bladder and the posterior urethra, increase the patient’s comfort level and improve the symptoms of postoperative bladder stimulation.

During the same study, we assessed vesicoureteral reflux during postoperative cystography and verified that the the Polaris Loop stent was superior to the Polaris Ultra stent for reducing vesicoureteral reflux (\(P < 0.05\)).

Ureteroscopy can lead to injury of the ureteral orifice, with destruction of the antireflux mechanism, which results in vesicoureteral reflux. Therefore, all the patients in our study underwent the same operation on both sides, including 8 cases who underwent bilateral
ureteral stent implantation, and 12 cases who underwent bilateral ureteroscopic lithotripsy and ureteral stent implantation. The type of catheter placement was determined by the random number table, which minimizes errors and leads to more reliable results. Similarly, in order to minimize surgical errors, the length and diameter of the calculi were shorter than 1 cm, and the operative times were shorter than 1 hour. These conditions should reduce the impacts of excessive residual stone and long operative time on the ureteral wall. We also to reduce the risks that excessive residual stones and long operative time would lead to ischemia due to ureteral wall entrapment. In addition, patients with ureteral intramural calculi were excluded to avoid the effect of ureteral orifice edema, which can result in insufficient drainage of the fishtail segment of the Polaris Loop stent.

This study found that if the excessive parts of the tubular and fishtail structures of the Polaris Loop stents protruded outside the ureteral orifice to be directly opposite the triangular region of the bladder, even because of the change of natural resistance mechanism to bladder ureter reflux. The normal shape of the ureteral orifice is changed, which interferes with the natural antireflux mechanism of the ureter and leads to reflux. This accounts for the urinary reflux seen in the Polaris Loop stents of 4 of our study patients. However, the Polaris Ultra stent has a soft end which can smooth excessively and therefore exerts an antireflux effect for a specific range of bladder pressures. In all 20 study patients, we confirmed under direct vision that the ureteral stents were in good positions, but postoperative angiography revealed that the ends of the ureteral stents were in various positions. At present, the maintenance of a fixed stent position during ureteral peristalsis and urine flow remains a clinical problem.

The limitation of this study is that all the patients in our study underwent bilateral ureteral stent implantation. We could only observe differences between the symptoms of
lumbar discomfort on each side of a single patient, and could not perform a statistical analysis or compare symptoms of bladder irritation between different stents.

In summary, the clinical application of the Polaris Loop stent during ureteroscopy is valuable and shows promise for improving the postoperative quality of life and reducing the incidence of vesicoureteral reflux.

Declarations

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Contributors: Ludong Qiao designed the study and defined the research theme; Wei Yan, Lu-Dong Qiao, Zhen Du, Di Guan, Hao Ping, and Shan Chen performed the research. Wei Yan carried out statistical analysis, and Wei Yan and Lu-Dong Qiao interpreted the results. All authors participated in the writing of the article and have read and approved the manuscript.

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Tables

Tab. 1. Patient data

| N   | Gender (M/F) | Age (years) | Height (cm) | Calculus diameter (cm) | Operative time (min) |
|-----|--------------|-------------|-------------|------------------------|----------------------|
| 20  | 14/6         | 42.1±10.2   | 165.3±7.8   | 0.6±0.3                | 25±21                |

Tab. 2. VAS scores of postoperative lumbar discomfort

| Polaris Loop stent side | Polaris Ultra stent side | P value |
|--------------------------|--------------------------|---------|
| VAS                      | 2.12±1.52                | 4.26±1.71 | 0.05 |

Tab. 3. Vesicoureteral reflux (N = 20)

| Polaris Loop stent side | Polaris Ultra stent side | P value |
|--------------------------|--------------------------|---------|
| Reflux present           | 4 (20%)                  | 1260.0% | 0.05 |

Figures
Figure 1

Polaris Loop stent and Polaris Ultra stent
KUB radiograph: Reflux of urine can be seen in the Polaris Ultra stent (as shown by→); reflux is not seen in the contralateral Polaris Loop stent.
KUB radiograph: Polaris Ultra stent with visible reflux (as shown by →), reflux is not seen in the contralateral Polaris Loop stent. The opening of the stent is seen in the ureter (black▲).
KUB radiograph: The Polaris Ultra stent does not contain reflux, whereas the contralateral Polaris Loop stent is seen with visible reflux. A portion of the Polaris Loop stent is located in the bladder and has not crossed the midline (black ▲).
KUB radiograph: Reflux is neither seen in the Polaris Ultra stent nor in the contralateral Polaris Loop stent. The opening of the tail of the Polaris Loop stent is located in the bladder and is close to the midline (black ▲).