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Standard versus modified ureteral stenting: Clinical outcome and patient tolerance

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Abstract
This study was performed to evaluate the lower urinary tract symptoms in patients undergoing pigtail suture stent (PSS) fixation and compare it with LUTS due to traditional (JJ) stent. PSS stent has been used since December 2010 in 295 patients. In this innovative PSS, the lower part of the stent is replaced by a 0.3F thread of suture. Only the renal and ureteral parts of the stent are retained and are extended by a thin tail ending in a suture. Whether the obstruction is due to a stone, an ureteropelvic junction syndrome, or ureteral stenosis, the upper, unmodified part of the stent facilitates the passage of urine around the obstacle. The study included 40 patients had ureteric obstruction (stone or stricture) divided randomly in to two groups, each group containing 20 patients, 1st group subjected to PSS fixation, other group subjected to JJ stent fixation. Lower urinary tract Symptoms were evaluated with a validated symptom specific questionnaire (International Prostate Symptom Score) (IPSS) in both groups. It is concluded from the previous observations that the PSS significantly decreases urinary symptoms and pain scores and constitutes a medical advance in the domain of ureteral stent tolerance.

Keywords: JJ stent, ureter, PSS stent, URS, LUTS

Introduction
Double-pigtail stents are frequently implanted in the ureter in urological practice. However, they are poorly tolerated, severely impairing the quality of life of patients [1]. Several studies have clearly described symptoms associated with their use: urinary frequency, urgency, dysuria, incontinence, hematuria, incomplete emptying, a feeling of pelvic heaviness, and lumbar pain. These symptoms are due largely to the bladder irritation caused by the stent [2]. It has been suggested that changes to the size, form, and composition of stents could decrease discomfort. Indeed, by decreasing the amount of material in the bladder, it may be possible to attenuate the symptoms [2].
A pigtail suture stent (PSS), which has been used since December 2010 in 295 patients. In this innovative PSS, the lower part of the stent is replaced by a 0.3F thread of suture. Only the renal and ureteral parts of the stent are retained and are extended by a thin tail ending in a suture. Whether the obstruction is due to a stone, an ureteropelvic junction syndrome, or ureteral stenosis, the upper, unmodified part of the stent facilitates the passage of urine around the obstacle [3].
In a previous retrospective study with 56 patients fitted with a non-profiled PSS, we found that tolerance was improved, with surprisingly good levels of bladder tolerance, but frequent anterior flank discomfort. This discomfort seemed to be due to irritation caused by the lower part of the stent, which was sectioned manually and was unmodified. The answer rate to the questionnaires was 75 % [4]. In December 2012, the lower end of the stent was sculpted and thinned, like a radical or rootlet, to prevent irritation of the ureter. This clearly increased PSS tolerance. Furthermore, we discovered fortuitously that PSS had other surprising properties. We observed clear dilation of the ureter intubated with the sutures. In this study, we evaluate the effect of the PSS with the innovative profiled tail on urinary symptoms and pain by using a dedicated [2].

Patients and methods
Patients and study design
In this study, we compare the use of pigtail suture stent (PSS) and traditional (JJ) stent in relation to lower urinary tract symptoms in 40 patients who were admitted to Urology department AL-Azhar Assiut University Hospital during 2017. The cases were classified as Group 1 (20 patients) which was subjected to double (JJ) stent fixation and other (20 patients) were subjected to (PSS) fixation which classified as Group 2. The patient with associated bladder outlet obstruction, history of severe lower urinary tract symptoms prior to JJ stenting Gross hematuria, history of tuberculosis/Diabetes mellitus/ medications for chronic ailment, cystoscopy revealing Urinary bladder abnormality, lower coil of DJ stent crossing the midline and benign Prostatic Enlargement were excluded to avoid selection bias. The cases groups were selected according to criteria who undergoing JJ or PSS stenting after intracorporeal lithotripsy for ureteric calculi or post stricture ureter, Patients undergoing ureteric stenting for the first time, patients with age between 20 to 50 years.
Routine preoperative clinical evaluation in the form of history taking, general and local examination and complete Urine analysis, Urine culture and sensitivity, Blood urea and serum Creatinine, Routine laboratory investigation were performed for all patients.

Technique

For stent placement, the first step is to cystoscopically insert a guide wire up to the kidney under fluoroscopic guidance. A retrograde pyelogram to outline the collecting system was obtained by exchanging the wire for a 5 Fr ureteral catheter. The stent was inserted directly over the wire through the cystoscope as it is visualized directly and a stent pusher is used to deploy the stent. Alternatively, the cystoscope was removed and the stent was inserted using fluoroscopy and a stent pusher with a radiopaque tip. The pigtail is placed in the kidney, as for a normal double-pigtail stent under direct vision through the cystoscope and fluoroscopic guidance, but a sufficiently long ureteral stent is used to make up for the shortness of the pushing device. A stent (Open-End Flexi-Tip Ureteral Catheter, 5F, 70 cm, Cook Medical) was placed upside down on the wire guide to look like the end of the usual pusher. Approximately 50 cm is needed to push the PSS. The sutures were left in the bladder. PSS was withdrawn under local or general anesthesia, with the aid of flexible cystoscopy and forceps (Karl Storz-Endoskope, Biopsy Forceps, double action jaws, 7F, length 40 cm), by simply pulling on the sutures. The knot at the lower end of the sutures could facilitate stent removal.

All patients were kept under observation in the hospital after the procedure. Postoperative antibiotics were given routinely for 48 hours. Most of patients were discharged after 2 days while some patients in whom the procedure was complicated (false passage and small perforation) discharged accordingly. Ureteral stent symptoms questionnaire (USSQ) was used to evaluate stent tolerance. We have extracted exactly questions relating to urinary symptoms. We used questions relating to pain and question relating to impact on work postoperative at 1 week, 3 weeks and 6th week during stent removal.

Statistical analysis

The collected data were revised, organized, tabulated and statistically analyzed using statistical package for social sciences (SPSS) version 23.0 for windows. Data are presented as the Mean ± standard deviation (SD), frequency, and percentage. Categorical variables were compared using the chi-square ($\chi 2$) and Fisher's exact tests (if required). The level of significance was accepted if the P value < 0.05.

Results

This study included 40 patients diagnosed as having ureteric obstruction and underwent ureteroscopy with ureteric stenting (JJ or PSS). PSS group included 20 patients 12 males (60%) and 8 females (40%), 7 (35%) had urgency and frequency and 13 (65%) were free from urgency and frequency, 8 (40%) had dysuria and 12(60%) with free from dysuria, 12(60%) had hematuria and 8(40%) were free from hematuria, 2(10%) had fever and 18(90%) were free from fever, 6(30%) had flank pain and14(70%) free from pain. Regarding JJ group, it included 20 patients 12 males(60%) and 8 females(40%), 14 (70%) had urgency and frequency and 6 (30%) were free from urgency and frequency, 16(80%) had dysuria and 4(20%) were free from dysuria, 18(90%) had hematuria and 2(10%) free from hematuria, 8(40%) had fever and 12(60%) were free from fever, 6(30%) had flank pain and14(70%) free from pain

Table 1: Demographic data

Parameters	**N=20**	
Gestational Age (weeks): Mean +SD	33.15±5.8	
Range (Min-Max)	24(21-45)	
Gender:	N	%
Male	24	60.0
Female	16	40.0
Duration of stent (weeks): Mean +SD	1.85±1.16	
Range (Min-Max)	5(1-6)	

Table 2: Comparison between PSS and JJ stent patients regarding demographic data

Parameters	**JJ N=20**		**PSS N=20**		**P- value**
Age (years): Mean +SD	**33.7±5.6**		**32.6±6.29**		**0.68 NS**
Range (Min-Max)	18(27-45)		21(21-42)		
Gender:	N	%	N	%	
Male	12	60.0	12	60.0	0.67 NS
Female	8	40.0	8	40.0	
Duration of stent (weeks): Mean +SD	1.6±0.66		2.1±1.5		0.68 NS
Range (Min-Max)	2(1-3)		2.1(1-6)		

Table 3: Comparison between PSS and JJ stent patients regarding post-operative complications

	JJ N=20		**PSS N=20**		**P- value**
	N	**%**	**N**	**%**	
Urgency & Frequency	14	70.0	7	35.0	0.045 S
dysurea	16	80.0	8	40.0	0.011 S
Hematuria	18	90.0	12	60.0	0.032 S
Fever	8	40.0	2	10.0	0.032 S
Pain	6	30.0	6	30.0	0.63 NS
Complications:	11	55.0	4	20.0	0.024 S

Discussion

Ureteral stents are commonly used while management of stone or stricture diseases. Ureteroscopy is a common procedure done for ureteric obstruction. This procedure is usually followed by the insertion of JJ or PSS stent. In our hospital, patients are coming for follow up with lower urinary tract symptoms appearing for the first time after undergoing aforementioned procedure. Evaluation of these patients revealed absence of any obstruction and most of them can be attributed to the JJ or PSS stents [5]. So our study was aimed to evaluate the lower urinary tract symptoms in patients undergoing pigtail suture stent (PSS) fixation and compare it with LUTS due to traditional (JJ) stent. The replacement of the bladder loop with a fine suture results in the presence of only tiny amounts of material in the bladder. Only the suture should cross the junction between the ureter and the bladder and float in the bladder itself. The replacement of the lower part of the stent with a suture, resulting in the absence of an internal channel, probably also limits renal reflux fig 1 [2].

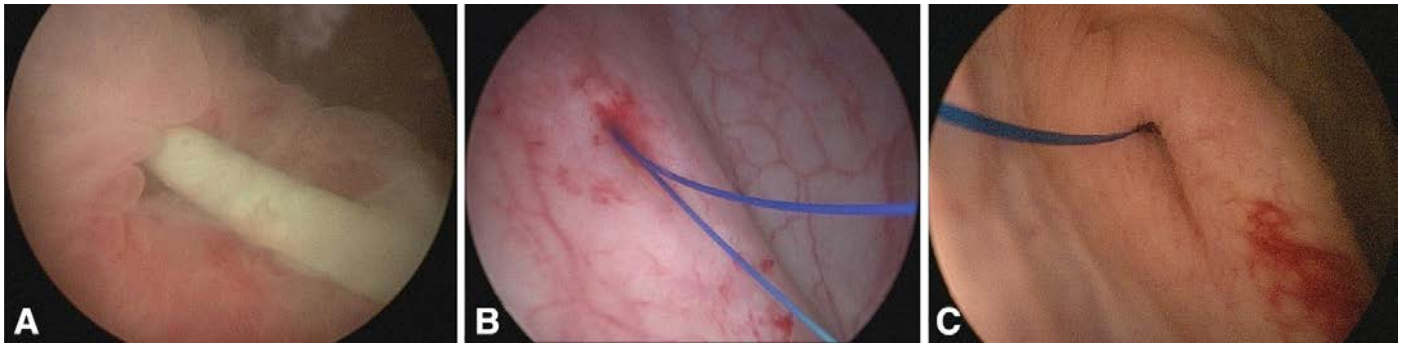

Fig 1: Appearance of the ureteral meatus. a Inflamed meatus around the double-pigtail stent. b Punctiform meatus immediately after PSS implantation. c Dilated meatus 1 month after PSS implantation. (Lingeman JE., *et al*; 2009) [2].

Innumerable symptoms occur after JJ or PSS stenting vary from flank pain, lower abdominal pain, and debris in urine, increased frequency of micturition, Nocturia, urgency, incontinence, and dysuria. Also there are other indirect and non-urological projections of these symptoms which include work performance, sexual matters, psychological distress and sense of general ill-health. In patient's words they describe themselves as "helpless", when they have stent related symptoms. Most of them have to restrict themselves from work due to pain. [6] found stent related bothersome symptoms present in 80% of patients.

Stents of several sizes, forms, and compositions have been studied, with the aim of reducing these symptoms. A short bladder loop seems to be preferable to a long loop extending throughout the bladder [7, 8].

Joshi *et al*. obtained a score of 14.9 for the control group without stent. We obtained a score of 15.3 for such patients. Patients with a JJ stent had urinary symptom scores of about 28. [9]. This score was about 30 in a subsequent study of 116 patients [10]. Damiano, Gianarini, and Davenport reported scores of about 27, 30, and 32, respectively [11-13].

Results indicated that a score of 35.2 for such patients. The score of our control group is 33.3 and was not significantly different than group 1 at baseline. The PSS decreased the total score from 35.2 to about 21. This results was in agreement with Voget *et al*. [14].

Despite the clear improvement observed with PSS, the patients still had symptoms statistically different from their normal state. It seems that some symptoms decrease with time (dysuria, hematuria), but the general tolerance remains unchanged. However, about 9 months are required to observe a significant decrease in urinary symptoms Even with PSS, duration of stenting must be as short as possible [15].

The stent is implanted to ensure the correct drainage of urine. In normal ureters, the urine passes between the stent and the ureter wall, rarely through the holes. In ureters that are compromised or have a reduced diameter, the urine passes through the holes and the internal channel. The bladder loop seems to play no role in urine flow [16]. The diameter of the stent (7or 3F) has no effect on the efficacy of urine flow. In cases in which the lower ureter is healthy, we can confirm the normal flow of urine around the PSS [17].

We developed the PSS as a means of decreasing urinary symptoms, but we discovered fortuitously that it had other surprising properties, probably due to the simple presence of the sutures in the ureter.

Firstly, after about 1 month of PSS implantation, we observed in all cases of ureteroscopy clear dilation of the ureter intubate.

It has been showed that preoperative stenting is effective for dilation of the ureter in preparation for ureteroscopy [18] and insertion of a ureteral access sheath. Three weeks seemed sufficient for dilation [18]. With the PSS, no patient required active dilation of the ureteral meatus at ureteroscopy. The prior implantation of a PSS could be used to prepare the ureter for the insertion of a sheath for flexible ureteroscopy without excessive discomfort. This could facilitate the introduction of a large ureteral access sheath (14/16F) for ureteroscopy treatment of large stone [19].

Secondly, after extracorporeal shockwave lithotripsy, the stone fragments gradually slid down the PSS sutures, without renal colic. Sutures behaves like a "stone's toboggan". Ureteral dilation might accelerate the removal of stone fragments. We believe that the use of a double-pigtail stent should no longer be considered the only way to drain the ureter. Instead, the form of the stent should depend on the patient's disease.

In our study three of the PSS had to be withdrawn under ureteroscopy, because the sutures were cut too short and had migrated into the ureter. In these three cases, the PSS gave effective renal drainage. Stent removal through the ureter was easy without the further enlargement of meatus. Following these observations, in male patients, we keep a long suture so that the PSS length is 30 cm. In women, we cut the sutures at the urethral meatus. However, we believe that the obstruction must be bypassed by a segment of rigid stent and not by the suture. At the beginning of our experience, we have observed one migration of the suture into the ureter when the obstruction was bypassed by the suture only. If the ureter is healthy, sutures have not been observed to migrate up the ureter. PSS without the profiled tail has been used since December 2010 and has greatly reduced bladder symptoms. But frequent anterior flank discomfort seemed to be due to irritation caused by the lower part of the stent, which was sectioned manually and was unmodified. Because of flank pain, we rarely used this stent for 2 years.

IPSS is a validated questionnaire for LUTS assessment. We utilized IPSS in all our patients and their response was documented. IPSS has 7 items and one separate for Quality of Life. IPSS has a possible score between 0-35. Among them

patients with score from 0-7 are taken to have mild symptoms. Patients with score 9-18 are taken to have moderate symptoms. Score from 20-35 are considered severe. In our study the mean IPSS score was 20.25for JJ stent and 6.25 for PSS. This value is categorized under severe symptoms for JJ and mild for PSS, indicating that most of the patients are suffering due to stent related symptoms. An analysis of this further revealed that female patients tend to have more severe stent related symptoms. Symptom severity tends to occur in certain group, with moderate symptoms more common in 26-30 years and severe symptoms more common in 31-35 years. This appears as though supporting the previous theory that Lower urinary tract symptoms are sever as the age increases.

Conclusion

It is concluded from the previous observations that the PSS significantly decreases urinary symptoms and pain scores and constitute a medical advance in the domain of ureteral stent tolerance. We observed unexpected dilation of the ureter by the sutures. We encourage and are convinced that multicenter studies with possibly a randomized controlled trial would confirm the improvement in patients quality of life reported here. These studies would make it possible to enlarge the indications for the PSS and would also make it possible to investigate the other properties of the ureteral suture.

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