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ORIGINAL PAPER

Initial experience with a newly developed antirefluxive ureter stent

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Abstract The objective of this study was to assess the functional efficacy of newly developed antirefluxive ureter stents (DJ), by performing immediate post-stenting cystograms on patients with acute ureteral obstruction requiring a DJ stent, and assessing stent-related symptoms by means of ureteral stent symptoms questionnaire (USSQ). Patients with acute hydronephrosis requiring internal drainage were randomized to receive either an antirefluxive DJ or a conventional DJ (7 Fr., 26 cm, polyurethane, Urovision®, Germany). Mean stone size was 6.64 ± 3.33 and 6.5 ± 3.54 mm. Immediately after correct placement of the DJ, 200 ml of diluted contrast media was introduced into the bladder under fluoroscopic control to detect vesicoureteral reflux (VUR). Patients completed German versions of the USSQ on days 2 and 7 following stent placement, and 1 week after stent removal. The results were analyzed. 13 conventional and 16 antirefluxive stents were placed in 29 patients. Reflux was documented in eight conventionally stented patients (62.5%). Two of the 16 patients with antirefluxive stents (22%) presented reflux. 1 week after stent implantation, the mean pain value was 1.1 in the antirefluxive group and 3 in the standard group ($p < 0.062$). Flank pain during micturition occurred after 2 days in seven patients (58%) with standard stents and in three patients (33%) with antirefluxive stents ($p < 0.23$). 1 week after stent insertion, flank pain had dropped to 40% in the standard group and 11% in the antirefluxive group ($p < 0.3$). Our initial experience showed that the antirefluxive system might be effective in terms of reflux prevention and reduction of stent related symptoms especially during sexual intercourse.

Keywords Urolithiasis · Ureter stent · USSQ

Abbreviations

cm	Centimeter
DJ	Ureter stent
Fr.	French
ml	Milliliter
mm	Millimeter
No.	Number
USSQ	Ureteral stent symptoms questionnaire
VUR	Vesicoureteral reflux
y	Years

Introduction

Since the first description of the first cystoscopically placed ureteral stent, more than 4 decades have passed [1]. Nowadays, the ureteral stent is regarded as a routine tool in urology, and placement of the stent is one of the most frequent urologic interventions [2]. There are many indications for stent placement today, but one of the most urgent is intolerable pain from acute renal colic. Although stents ensure drainage of the upper urinary tract, they are a significant cause of morbidity [3]. After stent implantation, up to 80% of patients suffer from irritative voiding symptoms [4], and 32% of patients experience sexual dysfunction [5]. In addition, flank pain diminishes the quality of life of patients. Stents with a longer intravesical segment are a considerable risk factor for

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irritative symptoms [6, 7]. The need to reduce the morbidity associated with indwelling ureteral stents has given rise to a great many innovations, including different biomaterials and ureteral stents with an antireflux-membrane valve. This valve allows urine to pass into the bladder only. When bladder pressure increases during micturition, the antireflux-membrane valve collapses, which prevents vesicoureteral reflux (VUR). As reflux is held responsible for inducing flank pain by generating pressure during micturition [8], these antirefluxive stents should reduce any stent-related irritative symptoms and flank pain. When assessing newly developed stents, it is important to review patient symptoms objectively. Joshi et al. [4, 5, 9] have developed a validated symptom questionnaire to analyze those stent-related symptoms that are irritative and affect sexual life, along with their impact on the patient's quality of life. The aim of our prospective, randomized study was to assess the functional efficacy of newly developed antirefluxive ureter stents (DJ) and their impact on stent-related symptoms (Table 1).

Materials and methods

Patients with acute hydronephrosis due to ureteral calculi requiring internal drainage were eligible to receive either an antirefluxive DJ (7 Fr., 26 cm, UF-110726 polyurethane, Urovision®, Bad Aibling, Germany) or a conventional DJ (7 Fr., 26 cm, ST-197726, polyurethane, Urovision®, Bad Aibling, Germany) until spontaneous passage of the stone or intervention to remove it. Exclusion criteria were urinary tract infection, known VUR, and patients under 18 years of age as well as anyone with a history of ureteral manipulation, including stent placement or URS. After the patients gave their informed consent, they were randomized into an antirefluxive and a standard group. Randomization was blinded for the patient. The antirefluxive mechanism consists of a synthetic, cone-shaped valve around the distal tip of the stent, which collapses during the increase in intravesical pressure induced by micturition and occludes the stent channel (Fig. 1). Moreover, the distal tip of the stent has no lateral orifices (Fig. 2). The study was approved by the local ethics committee (No. 2007-049 M-MA).

29 patients (19 male, 10 female) were enrolled in our study. 13 patients were randomly selected for the standard group and 16 patients for the antirefluxive group. The mean age in both groups was 46 ± 14.22 and 46 ± 13.85 years, respectively. Mean time until the stent removal was 33.5 ± 38.19 and 26.3 ± 17.86 days, respectively. Mean stone size was 6.64 ± 3.33 and 6.5 ± 3.54 mm respectively. The most common instrument currently used to evaluate stent-related symptoms is the ureteral stent symptom questionnaire (USSQ) [5]. This comprises 6 sections

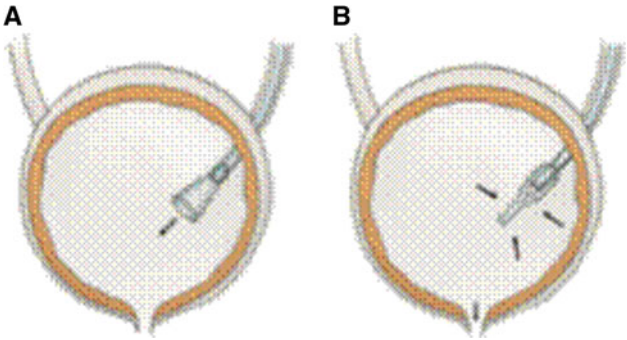

Fig. 1 Antirefluxive stent mechanism. **a** Empty bladder. **b** Full bladder with collapsed valve

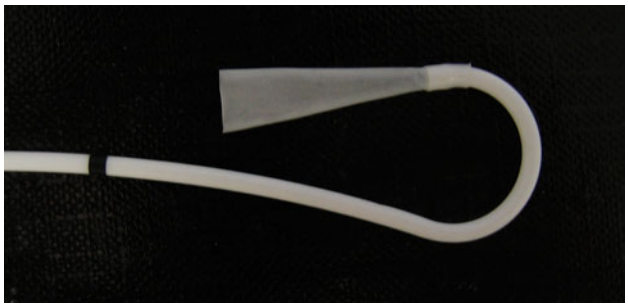

Fig. 2 Distal tip of the antirefluxive stent without lateral orifices and the cone shaped valve

Table 1 Statistical analysis of USSQ questionnaire

USSQ	Standard		Antirefluxive		*p*
	(*N* = 13)	%	(*N* = 16)	%	
USSQ sent back					
Day 2	12	92	10	62	
Day 7	10	77	9	56	
Flank pain during micturition					
Day 2	7	58	3	33	<0.23[b]
Day 7	4	40	1	11	<0.30[b]
Mean pain score (VAS)					
Day 2	12	92	11	69	<0.67[a]
Day 7	10	77	10	62	<0.97[a]
Impairment at work (score)					
Day 2	4.5		3		<0.63[c]
Day 7	3.05		1.5		<0.13[c]
Sexual intercourse (mean pain score)					
Day 2	1.5		0		<0.052[a]
Day 7	3		1.1		<0.062[a]
General satisfaction (mean score)					
Day 2	10		12		<0.61[a]
Day 7	8		12		<0.20[a]

[a] Wilcoxon two-sample test

[b] Fisher's exact test

[c] Mann–Whitney *U* test

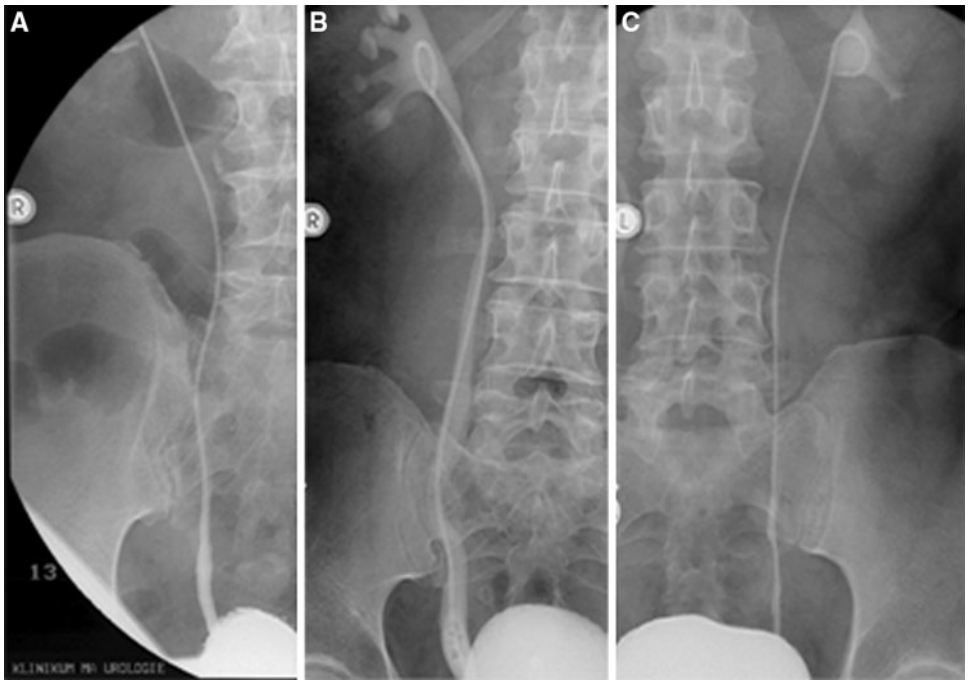

Fig. 3 Cystograms after stent implantation. **a** Patient after implantation of an antirefluxive stent. **b** Patient with standard stent presenting extraluminal reflux. **c** Patient with standard stent presenting intraluminal reflux

with a total of 48 items, covering voiding symptoms, pain, overall general health, work performance, sexual health, and additional problems. German versions of the validated USSQ were handed out to patients, together with prepared envelopes, and were sent back on days 2 and 7 after stent placement, and 1 week after stent removal. To eliminate the influence of the procedure itself, the questionnaire needs to be filled out at days 2 and 7 with the stent in place.

Immediately after the correct placement of the DJ, the bladder was filled with 200 ml of diluted contrast media, introduced through the cystoscope under fluoroscopic control. The VUR through the DJ (intraluminal) or along the stent (extraluminal) was documented during the process of carefully filling the bladder. If no VUR occurred after 5 min, the procedure was terminated (Fig. 3). The Wilcoxon Two-sample test, Fisher's exact test, and the Mann–Whitney *U*-test were used for statistical analysis.

Results

We placed 13 standard stents and 16 stents with the antirefluxive valve. No intra- or post-interventional complications were observed in any of the patients. Stent removal or stent replacement due to intolerance or obstruction was not necessary in either group. After stent placement, cystograms were performed on 12 of the 13 patients (92%) from the standard group and on 12 of the 16 patients (75%) from the antirefluxive group. Reflux was documented in seven of the patients (58%) with standard stents and in two of those (17%) with an antirefluxive stent ($p < 0.09$). 92% of the patients with standard stent and 62% of those with the antirefluxive stent sent back the first questionnaire, 2 days after stent placement. 77 and 63%, respectively, returned the second questionnaire 1 week after stent placement. Eleven patients answered the questions about their sexual life after stent implantation. Seven patients with the antirefluxive stents experienced no pain from the stent during sexual intercourse, 2 days after stent implantation. Four patients with a standard stent had a mean value of 1.5 on the mean pain score in the USSQ ($p < 0.052$). 1 week after stent implantation, the mean values were 1.1 and 3, respectively, in the antirefluxive group and the standard group ($p < 0.062$). Flank pain during micturition occurred after 2 days in seven (58%) of the patients with standard stents and in three (33%) of those with antirefluxive stents ($p < 0.23$). 1 week after stent insertion, flank pain occurred in 40% of the standard group and 11% of the antirefluxive group ($p < 0.3$).

We found no statistical significance in either group with respect to age, incidence of urinary infections, gender, time until stent removal, side, number of hospital visits or stone size.

Discussion

Nowadays, indwelling ureteral stents are one of the most important weapons in a urologist's everyday arsenal. Nevertheless, they are associated with irritative symptoms, flank pain, hematuria, infection, and encrustation [2]. To diminish stent-associated irritation and complications, risk

factors should be minimized by ensuring that patients have a high fluid intake and a timely clinical evaluation of their complaints as well as by aggressive treatment of any proven infection [10]. However, up to 80% of patients suffer from irritative voiding symptoms after stent implantation [4], while 32% experience sexual dysfunction [5]. 78% of the 85 patients surveyed by Joshi et al. reported bothersome urinary symptoms that included storage symptoms, incontinence, and hematuria. More than 80% of patients experienced stent-related pain that affected their daily activities, 32% reported sexual dysfunction, and 58% reported reduced work capacity and negative economic effects [9]. In our study, none of the patients with an antirefluxive stent complained of sexual dysfunction, but four patients in the standard stent group experienced pain during sexual intercourse after stent placement. Less pain from an implanted stent may well mean a better quality of sexual life [5, 11]. The superiority of the antirefluxive stent in our study should, nevertheless, be confronted to the small study sample size. Because of the regular use of ureteral stents nowadays, achieving a decrease in patient symptoms and an improved quality of life present us with a challenge. Obviously, there are different approaches to meeting this challenge. Maan et al. describe significant less pain by the use of thermo expandable segmental metallic stent for the treatment of ureteral strictures in comparison to conventional stents [12]. These findings support the belief that stent-related pain and increased urinary frequency might be related to lower ureteral spasm or local trigone irritation. Because they relax the ureteral smooth muscles, alpha 1-blockers seem to reduce urinary frequency, urgency, and nocturia. The intake of alpha 1-blockers has no significant influence on dysuria or quality of life [11]. Although ureteral reflux seems to increase in proportion to the indwelling time of the stent [13], our study showed that flank pain decreased during micturition after 1 week, or between the time of handing in the first and second questionnaires. This was accompanied by an increase in the USSQ pain score for both groups. These observations, however, would lead one to assume that pain caused by the inserted stent is not dependent on VUR, but on localized, irritative reactions to the stent. It is not clear as to whether the stent diameter has any effect on VUR. In a porcine model, increased intraluminal stent diameters showed increased flows, with a maximum flow occurring at 7 Fr [14]. However, no difference in VUR was observed in other groups using different stent diameters or lengths [15]. Only the consistency of the implanted stent would appear to have any effect on the flow characteristics. The flow resistance in ureters with existing kinking or external compression is higher in softer stents than in harder ones [16]. In turn, stent consistency does not influence stent-related symptoms. Even soft stents, if they are too long, and especially if they cross the midline of the bladder, seem to significantly increase the frequency of stent-related symptoms [6, 7]. In our prospective randomized study, we assessed the functional efficacy of antirefluxive DJ stents. The antirefluxive mechanism prevented VUR in most patients, as demonstrated by immediate post-interventional cystogram. Pain during sexual intercourse was only shown as statistically significant whenever the new stent seemed to be more comfortable. We noted a slight advantage in the case of the antirefluxive stent, but no statistical difference. This might only be observed in larger sample groups. This reflects the clear limitation of this study, being the small sample size. Another limitation of the study is that extraluminal reflux (alongside the stent) cannot truly be assessed.

Conclusion

In our study, the antirefluxive ureteral stent seemed to be effective in preventing reflux, immediately after stent placement. At the same time, antirefluxive ureteral stents might reduce stent-related symptoms and allow a better sexual life than non-refluxive ureteral stents.

Conflict of interest No competing financial interests exist.

References

1. Zimskind PD, Fetter TR, Wilkerson JL (1967) Clinical use of long-term indwelling silicone rubber ureteral splints inserted cystoscopically. J Urol 97(5):840–844
2. Chew BH, Knudsen BE, Denstedt JD (2004) The use of stents in contemporary urology. Curr Opin Urol 14(2):111–115. doi:10.1097/00042307-200403000-00011
3. Chew BH, Knudsen BE, Nott L, Pautler SE, Razvi H, Amann J, Denstedt JD (2007) Pilot study of ureteral movement in stented patients: first step in understanding dynamic ureteral anatomy to improve stent comfort. J Endourol 21(9):1069–1075. doi:10.1089/end.2006.0252
4. Joshi HB, Okeke A, Newns N, Keeley FX Jr, Timoney AG (2002) Characterization of urinary symptoms in patients with ureteral stents. Urology 59(4):511–516. doi:S0090429501016442
5. Joshi HB, Stainthorpe A, MacDonagh RP, Keeley FX Jr, Timoney AG, Barry MJ (2003) Indwelling ureteral stents: evaluation of symptoms, quality of life and utility. J Urol 169(3):1065–1069. doi:10.1097/01.ju.0000048980.33855.90
6. Chew BH, Lange D (2009) Ureteral stent symptoms and associated infections: a biomaterials perspective. Nat Rev Urol 6(8):440–448. doi:10.1038/nrurol.2009.124
7. Ho CH, Chen SC, Chung SD, Lee YJ, Chen J, Yu HJ, Huang KH (2008) Determining the appropriate length of a double-pigtail ureteral stent by both stent configurations and related symptoms. J Endourol 22(7):1427–1431. doi:10.1089/end.2008.0037
8. Ahmadzadeh M (1992) Flap valve ureteral stent with an antireflux function: a review of 46 cases. Urol Int 48(4):466–468
9. Joshi HB, Newns N, Stainthorpe A, MacDonagh RP, Keeley FX Jr, Timoney AG (2003) Ureteral stent symptom questionnaire: development and validation of a multidimensional quality of life

measure. J Urol 169(3):1060–1064. doi:10.1097/01.ju.0000049198.53424

10. Dyer RB, Chen MY, Zagoria RJ, Regan JD, Hood CG, Kavanagh PV (2002) Complications of ureteral stent placement. Radiographics 22(5):1005–1022
11. Deliveliotis C, Chrisofos M, Gougousis E, Papatsoris A, Dellis A, Varkarakis IM (2006) Is there a role for alpha1-blockers in treating double-J stent-related symptoms? Urology 67(1):35–39. doi:S0090-4295(05)01142-8
12. Maan Z, Patel D, Moraitis K, El-Husseiny T, Papatsoris AG, Buchholz NP, Masood J (2010) Comparison of stent-related symptoms between conventional Double-J stents and a new-generation thermoexpandable segmental metallic stent: a validated-questionnaire-based study. J Endourol 24(4):589–593. doi:10.1089/end.2009.0318
13. Yossepowitch O, Lifshitz DA, Dekel Y, Ehrlich Y, Gur U, Margel D, Livne PM, Baniel J (2005) Assessment of vesicoureteral reflux in patients with self-retaining ureteral stents: implications for upper urinary tract instillation. J Urol 173(3):890–893. doi:10.1097/01.ju.0000147747.89028.64
14. Brewer AV, Elbahnasy AM, Bercowsky E, Maxwell KL, Shalhav AL, Kahn SA, McDougall EM, Clayman RV (1999) Mechanism of ureteral stent flow: a comparative in vivo study. J Endourol 13(4):269–271
15. Olweny EO, Landman J, Andreoni C, Collyer W, Kerbl K, Onciu M, Valimaa T, Clayman RV (2002) Evaluation of the use of a biodegradable ureteral stent after retrograde endopyelotomy in a porcine model. J Urol 167(5):2198–2202. doi:S0022-5347(05)65128-2
16. Hubner WA, Plas EG, Stoller ML (1992) The double-J ureteral stent: in vivo and in vitro flow studies. J Urol 148(2 Pt 1):278–280