A New Customized Ureteral Stent with Nonrefluxing Silicone End-piece to Alleviate Stent-related Symptoms in Malignant Diseases

Benoît VOGT

OBJECTIVE To evaluate the stent-related symptoms using a new customized ureteral stent with a nonrefluxing silicone end-piece.

METHODS By decreasing the amount of material within the bladder, it should be possible to attenuate the stent-related symptoms. To minimize the amount of material, 17 consecutive patients already fitted with a double-pigtail stent for malignant ureteral obstruction agreed to be fitted with a customized stent where the bladder loop was replaced by a nonrefluxing silicone end-piece. The ureteral stent symptom questionnaire was prospectively administered to patients at baseline with double-pigtail stent and Day 15 after customized stent placement.

RESULTS No difficulty in the placement of the customized stent was encountered. No stent failure, no dislodgment and no calcification were observed 6 months after stenting. The scores for the main domain "Urinary symptoms" (34.4 ± 3.6 vs 23.0 ± 7.0; $P = .0004$) and the question "Global quality of life" (4.4 ± 2.0 vs 2.4 ± 2.1; $P = .01$) were significantly decreased by the replacement of the double-pigtail stent by the customized stent.

CONCLUSION The customized ureteral stent may constitute an improvement in the field of stent-related symptoms and seems fit for use in its current shape. Studies exploring and exploiting new concepts are greatly required to reduce stent-related symptoms in all patients including those with cancer. UROLOGY 137: 45–49, 2020. © 2019 Elsevier Inc.

Double-pigtail stents are frequently implanted in the ureter in urologic practice and ureteral obstruction caused by malignant diseases may require indwelling stent.[1,2] But, this stent is poorly tolerated, severely impairing the patients' quality of life.[3] Moreover, indwelling stent-related symptoms (SRS) induce additional suffering to the pre-existing bladder disease. Finally, obstruction may induce renal failure, and chronic renal insufficiency is a barrier to several therapies.[4]

SRS could be largely due to bladder irritation caused by the bladder loop.[5] Double-pigtail stent has been widely used in urology for half a century now, but the shape of the stent has not been substantially modified since its first introduction by Zimskind in 1967.[6] Current stent designs and materials are limited and novel concepts to prevent SRS are greatly required.[3]

It has been suggested that changes in the shape, stent positioning and stent diameter could ease discomfort.[7-9] By decreasing the amount of material within the bladder by using a 4.7F stent, it should be possible to attenuate the symptoms linked to the stent.[3,9,10] Moreover, using a thin 0.3F suture thread instead of a bladder loop may clearly improve urinary symptoms but, a thin thread cannot be used for malignant obstruction of the ureteral orifice.[8]

To keep an effective ureteral drainage and minimize the amount of material left in the bladder, a customized stent has been developed and the first results in 4 patients were encouraging.[11] The major characteristic of this stent was the replacement of the bladder part of the double-pigtail stent by a nonrefluxing silicone end-piece (Figs. 1A, 2).

The Ureteral Stent Symptom Questionnaire (USSQ) is the gold standard in the assessment of ureteral SRS.[12] Therefore, USSQ had to be used for a first evaluation of the customized stent.

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Author's Contributions: *BV designed the study, collected data, drafted the manuscript, and performed statistical analyses of data. BV had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.*

From the Department of Urology, Polyclinique de Blois, La Chaussée Saint-Victor, France

Address correspondence to: Benoît Vogt, M.D. Department of Urology, Polyclinique de Blois, 1 rue Robert Debré, 41260 La Chaussée Saint-Victor, France.
E-mail: message@benoitvogt.fr

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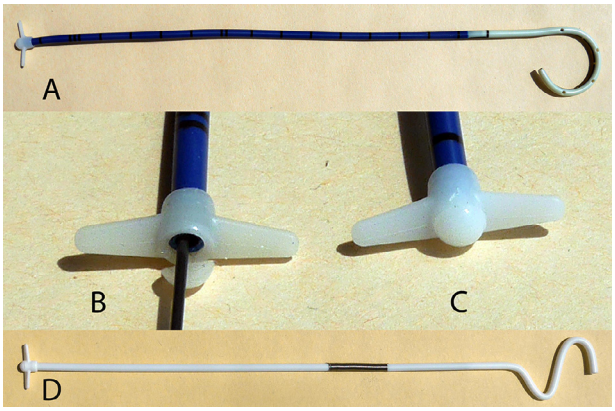

Figure 1. The customized stent. (**A**) The major characteristic of the current customized stent was the replacement of the bladder part of the double-pigtail stent by a nonrefluxing silicone end-piece. (**B**) Opening of the movable nonrefluxing valve allowing the introduction of the wire guide. (**C**) Closure of the movable nonrefluxing valve. (**D**) Theoretical embodiment of the customized stent with a spring producing a dynamic action on the end-piece during breathing movements. (Color version available online.)

The aim of the study consists in evaluating the feasibility and the tolerance of the customized stent in a consecutive series of 17 patients.

METHODS

From December 2017 to October 2018 in a single institution, 17 consecutive patients already fitted with a double-pigtail stent for ureteral obstruction agreed to be fitted with the customized stent and signed an informed consent form. The patients were assessed every 3 months with X-ray and flexible cystoscopy under local anesthesia.

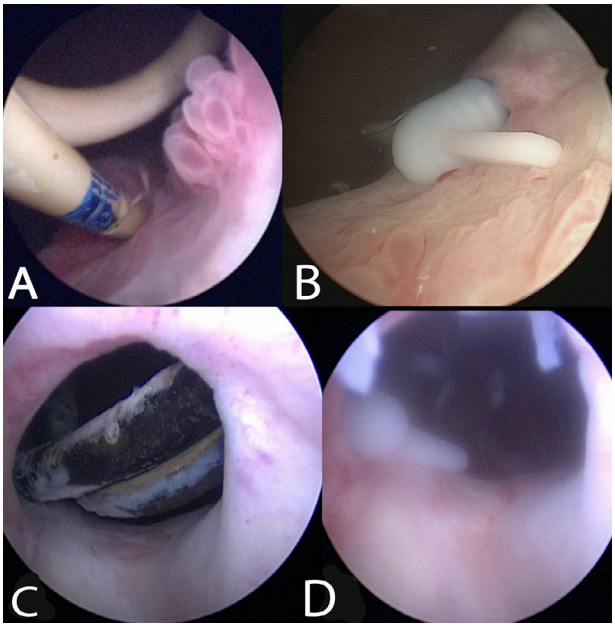

Figure 2. Endoscopic appearance of the stents. (**A**) Double-pigtail stent with bladder inflammation. (**B**) Silicone end-piece in ureteral orifice. (**C**) Double-pigtail stent overlapping the bladder. (**D**) Customized stent bound firmly in place to the ureteral orifice avoiding any conflict with the bladder neck in the same patient as in C. (Color version available online.)

Technique: Construction, Implantation, and Ablation of the Customized Stent

The intervention was carried out under general or regional anesthesia and was performed by the same surgeons (BV). The ureteral length was measured in each patient using the marks on the ureteral catheter that was introduced from the ureteral orifice up to the renal pelvis.

A double-pigtail stent (8F, Tumor DD Ureter Stent, Teleflex Medical, Ireland) was sectioned perpendicularly with the help of the mark of the ureteral catheter, ensuring that the renal loop was in the pelvis and the stent remained long enough to descend to the ureteral orifice. A silicone end-piece (Cisteo MEDICAL, France) was embedded at the bottom of the stent to prevent the stent from slipping off. The bottom of the silicone end-piece was terminated by a movable nonrefluxing valve allowing the introduction of the wire guide (Fig. 1B, C).

The stent was placed in the kidney, as for a normal double-pigtail stent under direct vision through the ureteroscope and fluoroscopic guidance. A plain abdomen X-ray was performed postoperatively to evaluate the end-piece position (Supplementary Fig. 1).

Questionnaires

A French translation of the USSQ was used to evaluate stent tolerance.[12,13] The USSQ was prospectively administered to patients at baseline with double-pigtail stent and Day 15 after customized stent placement.

Statistical Analysis

The data are presented as mean ± SD. Data were analyzed using the Wilcoxon-Mann-Whitney test. Values of $P < .05$ were considered significant.

RESULTS

Seventeen patients had retrograde ureteral stenting with the customized stent (6 women and 11 men, mean age 70.8 ± 11.8 years). Table 1 shows the distribution of the type of obstruction and malignancy. All patients were alive 6 months after the customized stent insertion.

No difficulty in the placement of the customized stent was encountered. In 3 patients, stents were placed bilaterally. One

Table 1. Distribution of the type of obstruction and malignancy

Type of Obstruction in 17 Patients	No. of Patients (%)
Previous radiation therapy for cancer	8 (47.0)
Previous surgery for cancer	6 (35.2)
Fibrosis postsurgery	3 (17.8)
Type of malignancy in 14 patients	
Prostate cancer	4 (28.6)
Cervical cancer	4 (28.6)
Colonic cancer	2 (14.3)
Bladder cancer	2 (14.3)
Rectal cancer	1 (7.1)
Ewing sarcoma	1 (7.1)

Table 2. Results of USSQ subscores for "Urinary symptoms"

Urinary Symptoms	Mean ± SD		*P* Value
	Baseline Double-pigtail stent	Day 15 Customized Stent	
Daytime frequency	2.9 ± 0.6	2.8 ± 1.2	.8
Nocturia	3.8 ± 1.0	2.8 ± 1.4	.07
Urgency	3.3 ± 1.3	2.2 ± 1.1	.03
Urge incontinence	3.2 ± 1.3	2.0 ± 1.1	.02
Nonurge incontinence	2.7 ± 1.3	1.5 ± 0.8	.01
Incomplete emptying	2.4 ± 1.0	1.6 ± 0.6	.03
Urethral pain	2.7 ± 1.4	1.7 ± 1.0	.04
Hematuria	2.4 ± 1.5	1.1 ± 0.3	.006
Hematuria amount	1.9 ± 1.0	1.2 ± 0.5	.01
Bothersome in life	3.8 ± 0.8	2.3 ± 1.2	.005
Feeling about lifelong enduring symptoms	5.7 ± 0.9	3.8 ± 2.0	.02
Total score	34.4 ± 3.6	23.0 ± 7.0	.0004

patient was fitted with customized tandem ureteral stents for recurrent stent obstruction. In all cases, the customized stent gave effective renal drainage. No stent failure, no dislodgment and no calcification were observed 6 months after stenting.

All questionnaires were analyzed. The scores in the main domain of USSQ and subscores for urinary symptoms are summarized respectively in Table 2 and Supplementary Table 1.

The scores for the main domain "Urinary symptoms" (34.4 ± 3.6 vs 23.0 ± 7.0; $P = .0004$) and the question "Global quality of life" (GQ) of "Additional Problems" (4.4 ± 2.0 vs 2.4 ± 2.1; $P = .01$) were significantly decreased by the replacement of the double-pigtail stent by the customized stent.

Subanalysis showed that the replacement of the double-pigtail stent by the customized stent seems to decrease each domain of "urinary symptoms" except frequency and nocturia.

Regarding urinary symptoms, patient satisfaction was constant over time but 2 patients complained of a reappearance of SRS 3 months after stenting with the customized stent.

One patient had metastatic hormone-sensitive prostate cancer with an initial prostate-specific antigen level at 270 and was treated with hormonal therapy. Three months after stenting with customized stent, the prostate-specific antigen dropped to 1, and the patient complained slightly of discomfort in the bladder area in sitting position.

The second patient was treated for colonic cancer with surgery and radiation therapy and 3 months after stenting with tandem customized stents, for no reason and without any infection, the patient complained bladder symptoms.[14]

For these 2 patients, the end-pieces of the customized stents were crossing the perpendicular line that goes through the middle of the symphysis pubis on the X-ray. Accordingly, the customized stents were replaced by new ones after truncating and adjusting their lengths to the exact ureteral length and, SRS were then improved again.

Comment

The silicone end-piece is a new medical device still unused in urologic practice. In the present study, the end-piece seems fit to be used in its current shape. Its flexible winglets allow easy movements through the urethra during insertion and removal, and seem strong enough to prevent the upward dislodgment of the stent. The silicone material could limit end-piece calcification. For Beysens et al silicone appears to be the most biocompatible material currently available and seems resistant to encrustations.[15] Renal drainage and ureteral flow through the nonrefluxing valve were effective 6 months after stenting.

For the main domain "Urinary symptoms," Joshi et al obtained a score of 14.9 for a control group without stent.[12] Patients with a double-pigtail stent usually had urinary symptom scores of about 25-35.[8,9,12,16-21] The customized stent significantly decreased the total score from 34.4 to about 23.0. Although the score may still seem high, bladder symptoms may not only be related to the stent itself but also to the pre-existing bladder disease.

For the main domain "Pain," patients with a double-pigtail stent usually had pain scores of about 15-35.[7,9,12,16-20] With values around 4, the pain scores of the study were dramatically lower than usual scores even for the patients with a double-pigtail stent. The difference can be explained by the difficulty to answer the questionnaire. The distinction between pain and discomfort is variously interpreted by the patient, and may explain the variations of scores between studies. Some difficulty in understanding the questions thoroughly have been described in the previous studies.[7,9] The USSQ is a lengthy and complicated instrument. Sometimes, the questions were not understood completely and had to be explained by an urologist staff member. Nevertheless, the USSQ in the mother tongue, is a feasible method to evaluate the SRS.[9]

There was no difference in "General health" and "Work performance." But, the score of the single question GQ was significantly decreased with the customized stent. Bosio et al highlighted question GQ to characterize the feeling about the stent, and 51.6% of patients who experienced double-pigtail stent answered they would feel "unhappy" or "terrible" to have another 1 in the future.[22]

The concept of material reduction within the bladder seems necessary in order to decrease bladder mucosal irritation.[7-9]

The influence of the shape of the bladder loop showed controversial results. The Polaris Loop attempts to reduce the bladder material by using 2 soft 2.1F loops intravesically. Kawahara et al reported that the stent significantly reduced almost all of SRS but the questionnaire used was not the USSQ.[23] With USSQ, neither Lingeman nor Davenport nor Park and his collaborators found significant reduction in bladder irritation using the Polaris Loop with a score around 30 for the main domain "Urinary symptoms."[7,16,17] Maybe those 4 tubes of 2.1F each still constitute a significant amount of material in the bladder.

The effects of intravesical stent position remain a matter of debate. Giannarini et al concluded that patients with stent distal loop crossing the midline experienced worse symptoms with urinary symptom scores of around 32 and 24 respectively on Day 7 and 28.[18] But stent position did not significantly influence

associated morbidity in the studies of Calvert or Abt et al with urinary symptom score of around 29 on Day 7 and 28.[19,20] However, Betschart et al pointed out a high flexibility of the stent location during the indwelling time but came to the conclusion that most of the trials showed that the use of shorter stent-ends in the bladder proved more beneficial.[3] Recently, Yoshida et al internalized the ureteral stent so that only a string stent floats in the bladder. The drainage was effective and the urinary symptoms were improved, but the USSQ was not used for evaluation.[24]

The influence of the stent diameter showed once again controversial results. Dunn et al showed that a thinned tail (3F) decreased lower tract symptoms compared with a 7F double-pigtail stent.[10] Nestler et al compared various stent sizes and concluded that scores of USSQ were significantly lower with small stent size (4.7F) than with a 6F or 7F double-pigtail stent. The urinary symptom score for the small size was 19 while the scores of 6F and 7F were respectively at 25 and 28.[9] Finally, the diameter of the stent can be decreased more drastically with the replacement of the bladder part of the double-pigtail stent by a thin 0.3F suture thread. The thread of the pigtail suture stent (ie, JFil) significantly decreased SRS with urinary symptom scores of USSQ around 22.[8]

The movable nonrefluxing valve of the lower part of the silicone end-piece, closing the internal channel, probably limits renal reflux and pain or discomfort in the kidney area while passing urine. But the analysis of the "Pain" domain was not feasible and no conclusion can be highlighted regarding the nonrefluxing valve. Moreover, no cystograms were performed for reflux assessment in the present study.

The replacement of the bladder loop by small end-piece results in the presence of only tiny amounts of material in the bladder. Although the decrease in the score may not seem substantial, it turned out that the patients preferred to have the customized stents than the double-pigtail stent and Dunn et al have already pointed out that any decrease in irritative urinary symptoms is likely to be appreciated by the patient.[10]

Patient satisfaction was constant over time but 2 patients complained of a reappearance of symptoms with the customized stent. The improvement of the SRS by the truncating of the stents suggests that mobility of the customized stent could be the origin of the reappearance of the SRS. Interestingly, in 13 patients, Zimskind et al described the first use of an indwelling straight-ended silicone stent in a ureter for malignant obstruction or fistula. The authors anticipated a downward dislodgment of the stent but this problem has been surprisingly rare. Moreover, by cystoscopic observation, the bladder mucosa remained intact, suggesting minimal irritation of the bladder by the stent. The authors explained that the obstructed segment of the ureter bound the stent firmly in place and allowed it to withstand downward migration during peristalsis.[6]

With the customized stent, by retaining the end-piece on the ureteral orifice, it should be possible to permanently alleviate the bladder symptoms. But, the disappearance of the ureteral compression can release the stent and allow its mobility with reappearance of bladder symptoms. In the field of SRS, maybe stent mobility should focus attention more than its intravesical position.

The customized stent still needs improvement to get closer to the targeted ideal stent. A permanent retention of the silicone end-piece seems crucial to maintain comfort improvement. To maintain the end-piece to the ureteral orifice, a permanent and immediate action is mandatory and requires an action from the rest of the stent. For this purpose, the use of a spring allowing an immediate and dynamic adaptation during breathing movements is 1 possible embodiment (Fig. 1D). The renal loop has been modified to "S" to facilitate the unfolding of the renal part. A recent publication with a video illustrates the necessary shaping of the stent and the possible research avenues for an innovative ureteral stent.[14] Thereby, many ideas, many designs and many available materials and methods exist[25] and studies exploring and exploiting these new concepts are greatly required.

There were several limitations to the present study. First, though prospective, the study was not randomized. Second, the present series included a cohort of patients with malignant ureteral obstruction near the ureteral orifice responding to the USSQ that is not specifically dedicated to this pathology. Third, the heterogeneity of the bladder diseases and the low number of patients require a more targeted study.

CONCLUSION

The silicone end-piece is a new medical device still unused in urological practice and seems fit for use in its current shape. The customized stent may constitute an improvement in the field of SRS. Studies exploring and exploiting new concepts are greatly required to reduce SRS in all patients including those with cancer.

ETHICAL APPROVAL

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (French Ethical Committee: CPP 17-VOGT-01 and National Medicine Safety Agency: 2017-A00205-48) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

INFORMED CONSENT

Written informed consent for the case details and accompanying images published was obtained from all individual participants included in the study.

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SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2019.12.022.

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