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Assessing The Impact Of Ureteral Stent Design On Patient Comfort

James E. Lingeman, M.D.,
Indianapolis, IN

Glenn M. Preminger, M.D.,
Durham, NC

Evan R. Goldfischer, M.D.,
Poughkeepsie, NY

Amy E. Krambeck, M.D., and
Indianapolis, IN

The Comfort Study Team

Abstract

Purpose—This study assessed near-term comfort of newly designed ureteral study stents or marketed control stents (Polaris™, Percuflex Plus®). Study stents substituted distal 6Fr pigtail ends with ≤3Fr loops. Reduced material in situ was hypothesized to enhance comfort. Utility of the patient self-administered Ureteric Stent Symptoms Questionnaire (USSQ) was assessed.

Materials and Methods—This 4-arm, multicenter study enrolled adults requiring retrograde unilateral ureteral stent placement for 4–28 days. USSQ administration occurred prior to placement (Baseline), at Day 4 post-placement, and Day 30 post-removal. 236 patients were randomized (1:1:1:1 ratio): Short Loop Tail (n=60), Long Loop Tail (n=59), Percuflex Plus (n=64); and Polaris (n=53).

Results—Overall, pain worsened from Baseline-Day 4 and improved from Day 4-Day 30. Mean pain medication usage peaked for all stents at Day 1 post-placement. Common device-related symptoms were mild or moderate in severity including flank pain (n=47 patients), hematuria (n=39), dysuria (n=34), frequent urination (n=30), and urinary urgency (n=27). Six patients experienced 9 device-related adverse events requiring hospitalization. All adverse events resolved, most within 3 days of in-patient treatment.

Conclusions—Although not statistically significant, patients stented with the Short Loop Tail had lower USSQ pain scores at Day 4 post-placement and lower pain medication usage at Day 1 post-placement, when pain peaked for all stent groups, suggesting that ureteral stent comfort, especially pain, may be improved with less material in situ. The USSQ may be better suited for longer-term comparisons among stented and non-stented patients rather than in this short term ureteral stent trial.

INTRODUCTION

The precise etiology of pain during ureteral stent indwell remains elusive. Previous studies have assessed the impact of ureteral stent composition, caliber, length, and configuration on

patient discomfort.^{1–5} With the introduction of the Ureteric Stent Symptoms Questionnaire (USSQ) (© Stone Management Unit, Southmead Hospital, UK) USSQ in 2003, a standardized instrument became available for use in clinical trials evaluating patient comfort after stent placement.^{6,7} Validation of the USSQ in the United Kingdom was conducted in a clinical trial setting comparing symptoms of stented and non-stented patients who were evaluated at 1 and 4 weeks after stent placement and 4 weeks after stent removal, timing that was consistent with standard practices in the UK. Near-term (< 1 week) comfort was not assessed in the USSQ validation study. Until recently, near-term comfort had not been assessed in a large clinical population involving comparison of multiple stent types.

Herein, we examine the hypothesis that substituting the distal pigtail end of a ureteral stent with Short or Long Loop Tail designs would enhance patient comfort by reduced mass and material in situ. The USSQ was utilized in this study and we secondarily evaluated it as a tool for assessing stent discomfort.

MATERIALS AND METHODS

This was a prospective, 4-arm, multicenter study comparing stent-related comfort among patients ≥ 18 years of age who had undergone an uncomplicated ureteroscopy requiring retrograde unilateral placement of a ureteral stent for 4 – 28 days (inclusive). Exclusion criteria for the study included: active urinary tract infection, urinary malignancy, non-stone related pain or stricture, spinal cord injury, bilateral stent placement, or patients chronically taking anti-inflammatory medications. Patients provided signed informed consent prior to study entry at study centers approved by local institutional review boards.

The study was designed to compare differences in patients' ureteral stent-related comfort assessed via the patient self-administered USSQ. The USSQ is the only standardized instrument available to assess patient comfort (pain and quality of life) after placement of a ureteral stent.^{6–8} Appropriate to anatomical differences, male and female versions of the USSQ were administered. Timing of administration of the USSQ instrument involved the following time points: Baseline (immediately prior to stent placement), 4 days after stent placement, and 30 days (± 5 days) after stent removal. Components of the USSQ are summarized in Table 1. Changes in pain scores were assessed between Day 4, when peak pain was expected, and Day 30, when patients' comfort levels were expected to return to near-normal levels.⁹

Patients were randomized in a 1:1:1:1 ratio to receive 1 of 4 stents. All patients were blinded as to which stent they received. The 2 study stents were the Short Loop Tail (SLT) and Long Loop Tail (LLT); the 2 control stents were the Polaris™ (PC) and Percuflex Plus® (PPC) stents. The proximal portions of all stents were configured in identical 6 Fr pigtail designs of the same basic composition but differed in the distal one-third portion. The control stents (PC and PPC) were standard double-pigtail designs and the study stents (SLT and LLT) substituted the distal pigtail ends (Figure 1) with either two 5 cm $\leq$ 3 Fr loops (SLT design) or two 8 cm $\leq$ 3 Fr loops (LLT design). The distal ends of the SLT and the LLT stents each had 70% less mass by volume than a standard pigtail end. The length of stent placed was determined by the patient's height.

During the post-operative period, patients had unrestricted access to pain medications such as oxycodone or hydrocodone, under the guidance of the principal investigator. At time of discharge, the pain management regimen included oxycodone 325 mg/5 mg or hydrocodone 500 mg/5 mg, 1 or 2 tablets every 4 to 6 hours, as needed for pain.

In comparing patients' comfort during stent placement, pair-wise comparisons were made among stent groups. Comparisons were performed using multiple comparison tests at an

overall 5% significance level. The F-test (2-sided) was used to declare significant differences in USSQ scores or pain medication usage between the four stent groups, followed by the Tukey HSD pair-wise tests when the p-value for the F-test was less than 0.05. Additionally, a comparison was made of the pooled pair of study stents with the pooled pair of control stents. Statistical analyses were performed using SAS® software.

Results

From April 2003 to February 2004, a total of 236 patients were eligible for ureteral stent placement and were assigned randomly to 1 of the 4 stent groups as follows: SLT (60 patients), LLT (59 patients), PPC (64 patients); and PC (53 patients). Since the study was stopped short after interim analysis an unequal number of patients appear in each group. The 4 treatment groups were comparable demographically (Table 2). A 17.7 year old patient was enrolled in the study as an inadvertent protocol deviation. Details of the surgical procedures are listed in Table 3. Operative times and type of anesthesia were not collected as part of the protocol.

For 231/236 patients (97.9%), the mean time (SD) of device indwell was 4.1 (1.99) days; subdivided by group indwell time was: 64 PPC patients 4.0 (0.13) days; 53 PC patients 4.0 (0.44) days; 57 LLT patients 4.5 (3.98) days; and 57 SLT patients 4.0 (0.26) days. For the remaining 5/236 patients (2.1%), a protocol deviation occurred due to adverse events and the stents were removed prior to Day 4: 1 patient each in the PC and SLT groups and 3 patients in the LLT group.

Many of the device-related adverse events (AEs) were expected side effects of ureteral stents. Procedure- and device-related adverse events are listed in Tables 4 and 5. The majority of device-related AEs (86.5%) were judged by the investigators as mild or moderate in severity. Comparison of overall adverse events between the 4 stent types (PPC 43.8%, PC 64.2%, LLT 52.5%, and SLT 40.0%) was not statistically significant ($p=0.051$). Comparison of device-related adverse events between the 4 stent types (PPC 37.5%, PC 49.1%, LLT 37.3%, and SLT 36.7%) was also not significant ($p=0.495$).

Six (2.5%) patients (1 SLT, 4 LLT, and 1 PC) experienced a total of 9 device-related AEs that led to hospitalization. These events were flank pain (3 patients, 3 events), stent migration (1 patient, 1 event), urinary tract infection (2 patients, 2 events), urosepsis and concurrent fever (1 patient, both events), and suicidal thoughts (1 patient, 1 event). All events resolved after hospitalization, most within 3 days of in-patient treatment.

A total of 10 patients (4 LLT, 4 SLT, 1 PC and 1 PPC) had their stents removed due to AEs. The stents for 5 patients were removed within 4 days of placement, while for 4 patients, stents were in place for 9 – 28 days. The duration of stenting for 1 patient was not recorded. AEs leading to stent removal typically included pain (flank, suprapubic) and urinary urgency or frequency.

The patterns of changes in overall USSQ comfort scores (combined Body Pain Questions P3-P9) were similar between all stent cohorts (Table 6). Comparison of the individual USSQ components, Body Pain Question P3 (VAS) and Body Pain Questions P4-P9 (kidney pain related to daily activities), again demonstrated no change from day 4 to day 30 between the different stent types ($p=0.667$ and $0=0.898$, respectively). Overall, patients experienced worsening of pain from Baseline to Day 4 (increasing USSQ score), and then improvement in pain from Day 4 to Day 30 (decreasing USSQ score). Patients who received the SLT stent had lower USSQ pain scores at Day 4 post-placement. However, differences in pain scores among stent types and between stent groups (study and control stents) at each time point were not statistically significant. For all stent groups, more patients reported pain localized

to the groin, bladder, or flank areas, although no statistically significant differences between the stents were observed.

Pain medication usage was measured daily from Baseline to Day 4 (Table 7). Mean usage peaked for all stent groups at Day 1 post-placement; patients who received the SLT stent had the lowest mean usage at this time point. Mean pain tablet counts at Day 2 and Day 3 were significantly higher for LLT patients than for other stents ($p < 0.05$, Tukey HSD Test), although mean usage at Day 4 was clinically and statistically the same as the other stents. Patients in the SLT and LLT groups experienced the largest percentage declines from peak usage to Day 4, falling 53% and 57%, respectively.

DISCUSSION

Multiple ureteral stent shapes, sizes, compositions (durometers), and designs have been studied to reduce patients' discomfort during ureteral stent placement and indwell. However, the precise etiology of pain during ureteral stent indwell remains elusive. Clinical evaluation of 2 investigational stents (SLT and LLT) and currently available double pigtail PC and PPC stents showed similar comfort and safety profiles. The absence of statistically significant differences between USSQ pain scores of patients with different stents may have been the result of several factors related to stent design, study design, and the choice of the USSQ as the instrument to measure near-term comfort.

The ureteral stent designs may have been too similar to generate statistically significant differences in the USSQ pain scores and thus each stent was equally comfortable. However, other data potentially support the hypothesis that less material in the bladder was associated with enhanced comfort. Patients who received the SLT stent had lower USSQ pain scores at Day 4 post-placement and lower pain medication usage at Day 1 post-placement, when pain peaked for all stent groups.

Compared to all other stent recipients, patients who received the LLT stent appeared to experience more pain: mean pain medication usage was higher at Day 1, and at Day 2 ($p < 0.05$) and Day 3 ($p < 0.05$). Further, greater proportions of patients who received the LLT reported flank pain and suprapubic pain compared to the other patients. Finally, all AEs of flank pain that led to hospitalization were experienced by patients who received the LLT stent. These observations seem contradictory to the study's central hypothesis of less stent material in the bladder or intramural ureter results in less patient discomfort, especially since the SLT and LLT stents maintain identical mass in the bladder. However, the additional loop length of the LLT stent resides in the ureter. Therefore, the etiology of pain caused by loop tailed ureteral stents may involve a combination of the stents' distal end profile, length, mass, and movement within the bladder, ureter, or at the ureteral orifice.

The study design validating the USSQ was based on the comparison of USSQ scores of stented and non-stented patients.⁶ In contrast to this "all-or-none" study design, the present study assessed patient comfort among 4 stents with only subtle design differences. Therefore, the USSQ, by design, may not have been sufficiently sensitive to detect differences in comfort between patients receiving the similarly designed stents. Furthermore, post-hoc statistical modeling in the present investigation indicated that a study population of approximately 1000 patients was needed to show statistical separation between the 4 study and control ureteral stents. Therefore, only one-fourth of the necessary patients were analyzed, and no statistically or clinically significant differences in patient comfort could have been observed between the stents at any time point. Recently, Lee reported no statistically significant differences in USSQ pain scores among 44 patients who completed the questionnaire 1, 3, and 5 days after ureteral stent placement.¹⁰

The USSQ is a lengthy and complicated instrument. A patient's psychological and physical status in the days immediately following ureteral stent placement can create a motivational challenge for completing the USSQ. Some studies of comfort have acknowledged the issue of patient discomfort vis-à-vis the complexity of the USSQ and have employed ad hoc questionnaires, while others have adapted existing instruments validated for other symptoms (e.g., following prostate biopsy) even though the USSQ is available.^{11,12} Modifying the USSQ by abridging the instrument or by validating its modules for discrete or improvisational use may enhance its utility in more diverse clinical study settings.

The timing of USSQ administration may play a role in obtaining robust data. In its validation study, USSQ administration time points reflected patient management regimes in the United Kingdom, where ureteral stents are typically placed for extended durations between physician visits. The present study was conducted primarily in the United States, where stents are typically placed for shorter durations. In the present study, pain was assessed by the USSQ at Baseline, Day 4 post-placement, and Day 30 post-removal. However, data collected on pain medication usage indicated that patients reached peak pain 1 day after stent placement. Therefore, the USSQ was administered when patients' pain was subsiding. Had maximum potential pain scores been obtained, differences between the stents at Day 30 may have shown greater separation. In a study comparing comfort among multiple similarly designed stents, optimal timing for USSQ administration appears to be 1 – 2 days after the stent is placed.

Certain limitations of the study must be recognized. Each study arm contains an unequal number of patients as the study was terminated early after interim statistical analysis demonstrated no significant differences between the study arms. Duration of stenting was not fixed between the study arms to allow for variations in clinical practices and treatment scenarios. Finally, two different control stents were used; however, both the Percuflex and Polaris stents are of similar design and material. By using 2 different control groups we could expand the study by further comparing different standard double pigtail stents. Despite these limitations the present study is the first to compare near-term comfort of in-dwelling ureteral stents using the USSQ in a large clinical study population involving comparison of multiple stent types.

In future investigations comparing stent comfort, study design considerations must include appropriate statistical powering and clinical assessments. The required population size will create challenges from the perspectives of multiple investigational centers, patient enrollment, the effect on study duration, and total cost. Survey instruments designed to measure patients' subjective assessments of comfort and pain must be appropriately timed and administered to coincide with expected maximum and minimum periods of comfort. Objective study assessments such as events of early stent removal, new or increased pain medication usage or pill counts, or the need for unscheduled physician visits should be measured. Clearly, there are many considerations for future clinical investigations of patient comfort after placement of a ureteral stent.

CONCLUSIONS

The present study examined the hypothesis that substituting the distal pigtail end of a ureteral stent with SLT or LLT designs would enhance patient comfort vis-à-vis reduced mass and material in situ. Patients who received the SLT stent had lower USSQ pain scores at Day 4 post-placement and lower pain medication usage at Day 1 post-placement, when pain peaked for all stent groups. The absence of statistically significant differences between USSQ pain scores of patients with different stents suggests that the USSQ may be better suited for longer-term comparisons among stented and non-stented patients rather than in

this short term study design. Future studies of ureteral stent comfort will require balancing of subjective and objective endpoints. Opportunities exist for further studies and survey instrument development.

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Figure 1. Loop Tail Design Features of Study Stents

Study stents substituted the control stent distal pigtail ends with either two 5 cm $\leq$ 3 Fr loops (Short Loop Tail design) or two 8 cm $\leq$ 3 Fr loops (Long Loop Tail design).

Table 1

Components of the Ureteric Stent Symptoms Questionnaire (USSQ)

Ureteric Stent Symptoms Questionnaire (USSQ) Component	Parameters
Extent of Body Pain *	7 Questions: <ul style="list-style-type: none"> • P3 a VAS (0 – 10, no pain/discomfort – worst possible pain) * • P4 – P9 multiple choice questions
Location of Body Pain **	VAS rating (P3) at 4 locations (females) and 5 locations(males) <ul style="list-style-type: none"> • kidney front/side area • groin area • bladder area • kidney back (flank) area • penis (males only)
Urinary Tract Symptoms	11 multiple choice questions (U1 – U11)
Other USSQ Information	General Health, Work Performance, Sexual Matters, and Additional Problems

* The VAS was read by 2 readers. If the respective readings were not within 0.5, the VAS readings were adjudicated by a third reader.

** The pictorial question P3 (Extent of Body Pain) asked the patient to rate his/her pain on the VAS at 4 locations (females) and 5 locations (males). Therefore, the maximum score for females was 40 and for males was 50. The scale for women was normalized to 50 to have the same scale for all patients including both sexes.

Table 2

Comparison of patient characteristics for each treatment cohort

Description	Percufflex Plus (N=64)	Polaris (N=53)	Long Loop Tail (N=59)	Short Loop Tail (N=60)	Total (N=236)
Age (yrs)					
N	64	53	59	60	236
Mean	50.48	50.33	46.57	53.65	50.27
Minimum	21.6	23.8	17.7	18.0	17.7
Maximum	81.6	81.7	85.0	78.9	85.0
Gender					
Male	38 (59.4 %)	34 (64.2 %)	34 (57.6 %)	37 (61.7 %)	143 (60.6 %)
Female	26 (40.6 %)	19 (35.8 %)	25 (42.4 %)	23 (38.3 %)	93 (39.4 %)
Weight (lbs)					
N	64	53	59	60	236
Mean	196.32	183.50	202.37	190.90	193.58
Minimum	127.9	95.0	101.0	117.0	95.0
Maximum	353.0	341.0	389.0	328.5	389.0
Height (inches)					
N	64	52	59	60	235
Mean	67.32	67.34	67.21	68.03	67.48
Minimum	59.0	60.0	59.0	61.0	59.0
Maximum	82.0	74.0	79.0	74.0	82.0

Table 3

Details of surgical procedures for each patient cohort

	Percutaneous Plus (N=64)	Polaris (N=53)	Long Loop Tail (N=59)	Short Loop Tail (N=60)	Total (N=236)
Antibiotic regimen pre-procedure					
120 mg Gentamycin w/ Ampicillin	20 (31.3 %)	17 (32.1 %)	20 (33.9 %)	19 (31.7 %)	76 (32.2 %)
120 mg Gentamycin w/o Ampicillin	8 (12.5 %)	6 (11.3 %)	5 (8.5 %)	4 (6.7 %)	23 (9.7 %)
Ciprofloxacin 400 mg	3 (4.7 %)	2 (3.8 %)	5 (8.5 %)	3 (5.0 %)	13 (5.5 %)
Ancef 1g	26 (40.6 %)	22 (41.5 %)	22 (37.3 %)	31 (51.7 %)	101 (42.8 %)
Other	6 (9.4 %)	6 (11.3 %)	5 (8.5 %)	3 (5.0 %)	20 (8.5 %)
Missing	1 (1.6 %)	0 (0.0 %)	2 (3.4 %)	0 (0.0 %)	3 (1.3 %)
Purpose for Ureteroscopy					
Stone	60 (93.8 %)	49 (92.5 %)	58 (98.3 %)	55 (91.7 %)	222 (94.1 %)
Diagnostic	4 (6.3 %)	3 (5.7 %)	1 (1.7 %)	5 (8.3 %)	13 (5.5 %)
Other	0 (0.0 %)	1 (1.9 %)	0 (0.0 %)	0 (0.0 %)	1 (0.4 %)
Ureteroscopy used					
Flexible	24 (37.5 %)	23 (43.4 %)	25 (42.4 %)	28 (46.7 %)	100 (42.4 %)
Rigid	27 (42.2 %)	21 (39.6 %)	27 (45.8 %)	26 (43.3 %)	101 (42.8 %)
Both Flexible and Rigid	13 (20.3 %)	9 (17.0 %)	7 (11.9 %)	6 (10.0 %)	35 (14.8 %)
Type of Dilatation					
None	45 (70.3 %)	41 (77.4 %)	48 (81.4 %)	42 (70.0 %)	176 (74.6 %)
Balloon	9 (14.1 %)	4 (7.5 %)	0 (0.0 %)	5 (8.3 %)	18 (7.6 %)
Rigid	4 (6.3 %)	6 (11.3 %)	7 (11.9 %)	8 (13.3 %)	25 (10.6 %)
Other	6 (9.4 %)	2 (3.8 %)	4 (6.8 %)	5 (8.3 %)	17 (7.2 %)
Dilator size					
12 Fr or smaller	9 (14.1 %)	6 (11.3 %)	7 (11.9 %)	10 (16.7 %)	32 (13.6 %)
Over 12 Fr but less than 18 Fr	4 (6.3 %)	3 (5.7 %)	4 (6.8 %)	7 (11.7 %)	18 (7.6 %)
18 Fr and above	6 (9.4 %)	3 (5.7 %)	0 (0.0 %)	1 (1.7 %)	10 (4.2 %)
Was procedure sheath used?					
Yes	32 (50.0 %)	23 (43.4 %)	24 (40.7 %)	25 (41.7 %)	104 (44.1 %)
No	32 (50.0 %)	29 (54.7 %)	35 (59.3 %)	35 (58.3 %)	131 (55.5 %)
Type of intracorporeal lithotripsy					

	Percutaneous Plus (N=64)	Polaris (N=53)	Long Loop Tail (N=59)	Short Loop Tail (N=60)	Total (N=236)
N/A	21 (32.8 %)	21 (39.6 %)	21 (35.6 %)	26 (43.3 %)	89 (37.7 %)
EHL	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
Holmium Laser	43 (67.2 %)	31 (58.5 %)	38 (64.4 %)	33 (55.0 %)	145 (61.4 %)
Pneumatic	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
Pulsed-dye Laser	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
Other	0 (0.0 %)	1 (1.9 %)	0 (0.0 %)	1 (1.7 %)	2 (0.8 %)
Type of stone removal device					
N/A	27 (42.2 %)	26 (49.1 %)	20 (33.9 %)	21 (35.0 %)	94 (39.8 %)
Alligator Graspers	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
Stone Basket	33 (51.6 %)	24 (45.3 %)	34 (57.6 %)	35 (58.3 %)	126 (53.4 %)
Stone Cone	2 (3.1 %)	1 (1.9 %)	2 (3.4 %)	2 (3.3 %)	7 (3.0 %)
3-Prong Graspers	1 (1.6 %)	2 (3.8 %)	2 (3.4 %)	0 (0.0 %)	5 (2.1 %)
Other	1 (1.6 %)	0 (0.0 %)	1 (1.7 %)	2 (3.3 %)	4 (1.7 %)
Were any fragments left					
No Visible Fragments	34 (53.1 %)	28 (52.8 %)	34 (57.6 %)	33 (55.0 %)	129 (54.7 %)
Residual Fragment(s) <=2mm	30 (46.9 %)	23 (43.4 %)	24 (40.7 %)	25 (41.7 %)	102 (43.2 %)
Residual Fragment(s) >2mm	0 (0.0 %)	2 (3.8 %)	1 (1.7 %)	0 (0.0 %)	3 (1.3 %)
Was a Foley catheter placed?					
Yes	11 (17.2 %)	6 (11.3 %)	3 (5.1 %)	3 (5.0 %)	23 (9.7 %)
No	53 (82.8 %)	47 (88.7 %)	56 (94.9 %)	57 (95.0 %)	213 (90.3 %)
Side of Stent Placement					
Left	20 (31.3 %)	19 (35.8 %)	21 (35.6 %)	18 (30.0 %)	78 (33.1 %)
Right	21 (32.8 %)	13 (24.5 %)	13 (22.0 %)	19 (31.7 %)	66 (28.0 %)

Table 4

Procedure Related Adverse Events. A total of 103 procedure related adverse events were reported

Condition	Percutaneous Plus		Polaris		Long Loop Tail		Short Loop Tail	
N=103	N=24	%	N=29	%	N=27	%	N=23	%
Abdominal Pain	1	4.2	0		1	3.7	4	17.3
Nausea	2	8.3	4	13.8	0		1	4.3
Vomiting	0		2	6.9	0		1	4.3
Rigors	0		1	3.4	0		0	
Fever	0		2	6.9	0		1	4.3
Catheter Migration	0		0		0		1	4.3
Fungal Infection	0		0		1	3.7	0	
Urosepsis	0		1	3.4	0		0	
UTI	3	12.5	0		2	7.4	1	4.3
Bladder/suprapubic pain/spasm	6	25.0	6	20.6	4	14.8	5	21.7
Back Pain	0		1	3.4	0		1	4.3
Flank Pain/Colic	16	66.7	15	51.7	20	74.1	10	43.5
Groin/Testicular Pain	0		2	6.9	0		1	4.3
Headache/Dizziness	0		2	6.9	1	3.7	0	
Suicidal Ideation	0		0		1	3.7	0	
Dysuria	11	45.8	10	34.5	7	25.9	7	30.4
Incontinence NOS	3	12.5	0		0		0	
Urgency	7	29.2	2	6.9	6	22.2	8	34.8
Frequency	9	37.5	3	10.3	6	22.2	5	21.7
Urethral Pain	0		0		0		2	8.7
Urinary Retention	1	4.2	0		1	3.7	1	4.3
Vesico-ureteral reflux	0		0		1	3.7	0	
Acute renal failure	0		0		1	3.7	0	
Ureteral perforation	0		0		1	3.7	0	
Hematuria	15	62.5	13	44.8	12	44.4	12	52.2
Nocturia	1	4.2	0		1	3.7	0	
Respiratory	0		0		0		1	4.3

Table 5

Device Related Adverse Events. A total of 94 procedure related adverse events were reported

Condition	Percutaneous Plus		Polaris		Long Loop Tail		Short Loop Tail	
N=94	N=24	%	N=26	%	N=22	%	N=22	%
Abdominal Pain	1	4.2	1	3.8	1	4.5	4	18.1
Nausea	2	8.3	3	11.5	0		1	4.5
Vomiting	0		0		0		1	4.5
Rigors	0		1	3.8	0		0	
Fever	0		2	7.7	0		1	4.5
Catheter Migration	0		0		1	4.5	1	4.5
Urosepsis	0		1	3.8	0		0	
UTI	3	12.5	0		1	4.5	1	4.5
Bladder/suprapubic pain/spasm	6	25.0	5	19.2	6	27.2	5	22.7
Back Pain	0		1	3.8	0		1	4.5
Flank Pain/Colic	15	62.5	14	53.8	18	81.8	9	40.9
Groin/Testicular Pain	0		1	3.8	0		1	4.5
Headache/Dizziness	0		2	6.9	0		0	
Suicidal Ideation	0		0		1	4.5	0	
Dysuria	11	45.8	10	38.5	7	25.9	7	31.8
Incontinence NOS	4	16.7	1	3.8	2	9.1	0	
Urgency	10	41.7	3	11.5	9	40.9	8	36.4
Frequency	12	50.0	4	15.4	9	40.9	6	27.3
Urethral Pain	0		1	3.8	0		2	9.1
Urinary Retention	0		2		0		1	4.5
Vesico-ureteral reflux	0		1	3.8	1	4.5	0	
Hematuria	14	58.3	10	38.5	10	45.5	10	45.5
Nocturia	1	4.2	1	3.8	2	9.1	0	

Table 6

USSQ combined body pain scores P3–P9 for each stent type from day 4 to day 30

Description	Percutaneous Plus	Polaris	Long Loop Tail	Short Loop Tail	Total	P-value
Day 4						
N	54	49	49	55	207	0.344
Mean	28.72	27.86	29.37	25.99	27.95	
Minimum	0.0	0.0	0.0	0.0	0.0	
Maximum	64.1	76.0	63.5	73.5	76.0	
Day 30						
N	54	49	49	55	207	
Mean	5.79	7.75	7.74	6.81	6.98	
Minimum	0.0	0.0	0.0	0.0	0.0	
Maximum	34.9	41.0	39.4	49.3	49.3	
Change at Day 30 from Day 4						
N	54	49	49	55	207	0.715
Mean	-22.93	-20.11	-21.63	-19.19	-20.96	
Minimum	-64.1	-76.0	-55.0	-73.5	-76.0	
Maximum	14.0	25.4	17.9	21.2	25.4	

Table 7

Summary of Analgesic, Acetaminophen with Oxycodone (325 mg/5 mg) or Hydrocodone (500mg/5mg) Use (Mean Tablet Count)

	Percuflex Plus (N=59)	Polaris (N=49)	Long Loop Tail (N=49)	Short Loop Tail (N=52)	Total (N=209)	P-Value
Day 0						
N	46	36	40	40	162	0.379
Mean	2.07	1.78	2.61	1.98	2.11	
Range	0.0–10.0	0.0–12.0	0.0–8.0	0.0–5.0	0.0–12.0	
Day 1						
N	47	41	41	42	171	0.137
Mean	3.87	4.00	5.05	3.60	4.12	
Range	0.0–15.0	0.0–12.0	0.0–10.0	0.0–12.0	0.0–15.0	
Day 2						
N	47	40	41	42	170	0.045
Mean	3.70	3.40	4.93	3.15	3.79	
Range	0.0–12.0	0.0–12.0	0.0–11.0	0.0–12.0	0.0–12.0	
Day 3						
N	48	39	41	41	169	0.036
Mean	3.17	2.56	4.44	2.83	3.25	
Range	0.0–10.0	0.0–12.0	0.0–16.0	0.0–12.0	0.0–16.0	
Day 4						
N	47	36	40	41	164	0.688
Mean	2.28	2.06	2.18	1.68	2.05	
Range	0.0–9.0	0.0–10.0	0.0–10.0	0.0–12.0	0.0–12.0	
Total of Pills						
N	49	43	41	42	175	0.035
Mean	14.37	12.51	19.09	13.04	14.70	
Range	1.0–54.0	0.0–58.0	4.0–46.0	0.0–47.0	0.0–58.0	