Association between material and design used in a ureteral stent with complication in ureteral catheterisation: A systematic review

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ABSTRACT

The double-J stent is one of the ureteral catheters with curved ends for fixation. Since its introduction in 1978, catheterisation using a double-J stent has become one of the most frequently performed procedures in urology. However, double-J stents may lead to various complications, causing patient discomfort, pain, and bladder symptoms. Technological advancements in stent design aim to minimise these complications and enhance comfort. This review aimed to determine the association between the material and design used in ureteral stents and complications in ureteral catheterisation. We conducted a systematic review following the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) checklist. Screening based on specific inclusion criteria was employed to select potential studies. A database search yielded a total of 124 studies. Nine full texts were evaluated for eligibility, resulting in the exclusion of one paper. Our findings indicate that ureteral stent insertion significantly increases the frequency of pain and urinary symptoms while decreasing overall health. The choice of materials and design plays a crucial role in minimising pain and improving the quality of life for patients. Physical properties such as firmness and tensile strength also affect the quality of life, with higher firmness and tensile strength causing lower quality of life. Stent material and design choice were context-dependent. Using soft stents and specialised soft distal pigtails has been shown to reduce patient stent-related symptoms. Silicone stents showed the least bladder symptoms than polymeric stents. Polymeric stents also showed no difference in utility from metallic stents for long-term usage.

INTRODUCTION

The double-J stent is one of the ureteral catheters with curved ends for fixation. Since its introduction in 1978, catheterisation using the Double-J stent has become one of the most performed procedures in urology. It is used to relieve benign or malignant obstructions, improve ureteral healing, manage ureteral leakage, or is placed before surgery to assist in intraoperative ureter identification. Double-J stent can lead to several complications, including stent migration, hardening, encrustation, and fragmentation. Additionally, stent placement causes patient discomfort, pain, and bladder symptoms such as dysuria, frequency, urgency, and haematuria. New stent materials and designs are continuously being developed to reduce the occurrence of these complications. In recent years, substantial progress has been achieved in both the design and material composition of the double J-stent. The constitutive materials for ureteric stents have undergone development to attain optimal mechanical strength, flexibility, biocompatibility, surface roughness, and cost-effectiveness. Frequently employed materials in this context comprise polyurethane, nitinol, and various biodegradable substances. Nitinol, a mixture of nickel and titanium, is one of the...
newest materials used for double-J stents. This is due to its resistance to external compression compared to polymeric materials, as well as its thermo-expandable properties, allowing them to be used for longer periods than double-J stents made from polymeric materials. Currently, many biodegradable materials are under development. Biodegradable stents were initially expected to increase patient comfort and prevent adhesion and bacterial interactions, thereby reducing morbidity. However, it has been observed that biodegradable stents may be unsuitable for situations requiring stenting for different durations, such as ureteral stricture conditions or after shockwave lithotripsy procedures.\(^5\)\(^-\)\(^7\) This review aims to determine the association between the material and design used in a ureteral stent and complications in ureteral catheterisation.

**METHODS**

This systematic review adhered to the PRISMA checklist. The inclusion criteria comprised observational studies, including cohort and cross-sectional studies, clinical trials, systematic reviews, and meta-analyses involving patients who underwent ureteral catheterisation with ureteral stents. The selected studies were required to analyse complications in patients using two or more different types of ureteral stents, with complications defined as unwanted symptoms or diseases resulting from stent placement. Inclusion was limited to papers with full text available and written in English, with no specific date criteria set. Editorials, case reports, and review studies were excluded from this investigation. The chosen studies were then subjected to critical appraisal for eligibility using Oxford's Centre for Evidence-Based Medicine (CEBM) Appraisal Tools.

**Information sources and search strategy**

Searching strategy was performed on various online databases such as PubMed, Scopus, ProQuest, Cochrane, Google Scholar, and additional sources. The exploration extended to screening the references of included studies. The database search was executed on 1\(^{st}\) June 2021. The terms utilised for the search encompassed "Double J", "Ureter", "Stent", "Catheter", "Metal", "Polymer", "Complication", "Ureteral Stent Symptoms Questionnaire (USSQ)", "Overactive Bladder Symptom Score (OABSS)", and "International Prostate Symptom Score (IPSS)". Additionally, review articles were scrutinised to identify potential studies cited in their references.

**Selection process**

One reviewer independently screened the titles and abstracts of all records identified during the search. Subsequently, studies were selected based on predetermined inclusion and exclusion criteria. Full-text articles were retrieved and reviewed if their relevance was not evident from the title and abstract alone.

**Data collection and analysis**

Data extraction was carried out independently, and the search results were consolidated using Microsoft Excel for database compilation. Studies incorporated into the systematic review underwent assessment using the Cochrane Risk of Bias tool for Randomized Control Studies (RoB 2) in the case of randomised controlled trials (RCTs) or the Cochrane Risk of Bias Tool for Non-Randomised Control Studies (ROBINS-I) for cohort studies.\(^8\)\(^,\)\(^9\) The extracted data from the studies encompassed details such as the first author, study design, year of publication, sample size, demographic characteristics of the sample, clinical conditions necessitating the use of double-J stents, the material of double-J stents employed in the study, and complications recorded through validated tools like the International Prostate Symptoms Score (IPSS),\(^10\) Ureteral Stent Symptoms Questionnaire (USSQ),\(^11\) and Overactive Bladder Symptoms Score (OABSS),\(^12\) or any other complications. Subsequently, this data was organised into a comprehensive table.

**RESULTS**

The flow chart illustrating the database searching process is depicted in Figure 1. The initial database search yielded a total of 124 studies involving 2446 patients. Among these studies, nine records met the predefined inclusion criteria, with noinstances of duplicate entries. Subsequently, a scrutiny of nine full-text studies was carried out to determine eligibility. One paper was excluded as it did not meet the validity criteria. Consequently, a total of eight studies were incorporated into the qualitative synthesis. The evaluation of the risk of bias adhered to the Cochrane guidelines, utilising the RoB 2 and the ROBINS-I for cohort
studies (Figure 2 and Figure 3). The remaining eight studies were included in this systematic review and are succinctly summarised in Table 1.

Assessing the risk of bias is crucial to conducting a systematic review or meta-analysis as it safeguards the validity and reliability of the findings from included studies. In this context, we evaluated the risk of bias for the study conducted by Ohtaka et al.13 using the ROBINS-1 tool, and our assessment indicates it to be a study with low risk. Furthermore, although we identified certain potential sources of bias in the RCTs included in our analysis, we concluded that they do not significantly undermine the suitability of these studies for inclusion in our review. Our assessment of the study by Ohtaka et al.13 revealed a low risk of bias, suggesting that the study design, conduct, and reporting were of high quality and minimised the potential for systematic errors, as illustrated in
Table 1. Studies included in the systematic review

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| Ohtaka et al. (2021)<sup>13</sup> | Prospective Cohort | 106 ureter units in patients with malignancy-related obstruction | Resonance™ was used for 59 ureter units in the treatment group, and Polaris™ was used for 47 ureter units in the control group. | - Median Overall survival  
  - Resonance™: 183 days  
  - Polaris™: 183.5 days  
  - p-value: 0.673  
- Median days to failure  
  - Resonance™: 105 days  
  - Polaris™: 169.5 days  
  - p-value: 0.498  
- No significance in complication rate between the two group |
| Joshi et al. (2005)<sup>14</sup>     | RCT     | 130 patients with urinary calculi                           | Patients were randomised to receive a firm stent (Percuflex™) and soft (Contour™) polymer, and then USSQ scores were taken during weeks 1 and 4 stent in situ and four weeks after its removal. | - No significant difference in USSQ score on 1 and 4 weeks in situ.  
- Compared with the USSQ score during in situ, there is a significant decrease in score in all domains for both groups (p < 0.0001) |
| Lingeman et al. (2008)<sup>15</sup> | RCT     | 236 patients who need retrograde unilateral ureteral stent placement for 4-28 days | Patients were randomised into four groups: 60 short loop tail stent, 59 long loop tail, 64 Percuflex™ plus, 53 Polaris™ | - No significant difference was found in device-related adverse effect rates for all groups.  
- No significant difference in USSQ score on days 4 and 30 for all groups.  
- No significant difference in USSQ score change from day 4 to 30 for all groups.  
- Mean pain tablet counts on the day.  
- Day 2 and Day 3 were significantly higher in long loop tail groups than in other (p < 0.05) |
| Davenport et al. (2011)<sup>16</sup> | RCT     | 170 patients requiring stent insertion for stone disease     | The patient was randomised into two groups: receiving Inlay™ stent and Polaris™ stent. USSQ was taken two weeks after stent insertion and one week after stent removal. A total of 98 patients (45 Inlay™, 53 Polaris™) completed the study | - No significant difference was found in USSQ from both groups.  
- More patients in the Polaris™ group had pain (94% vs 91%; p = not significant)  
- More patients in the Inlay group had hematuria (73% vs 62%; p = not significant)  
- Although statistically insignificant, more patients in the Polaris group had the sensation of UTI (77% vs 70%) and received antibiotics (39% vs 29%)  
- More patients in the Polaris™ group reported pain decrease after stent removal than in the Inlay™ group (p < 0.05) |
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| Park et al. (2014)\(^{17}\) | RCT    | 144 patients undergoing Ureterorenoscopy (URS)                                          | Patients were randomised into the PolarisTM (test) group (n=64) and Percuflex (control) group (n=80). The USSQ was then conducted one week after the stent insertion. | • No significance was found in all USSQ domain scores.  
• Patients in the test group  
  o Reported less pain (p < 0.001)  
  o Requires less painkiller (p < 0.005)  
  o Experienced less difficulty in normal and hard physical activities (p < 0.02)  
  o Fewer work-associated issues (p < 0.015)  
  o Less antibiotic use (p < 0.015)  
  o Visit the outpatient department more often (p < 0.036)  
• No significance was found in the early stent removal rate |
| Lee and Kim (2014)\(^{18}\)              | RCT    | 90 patients who underwent ureteral stent insertion after ureteroscopic stone removal    | Patients were randomised in a double-blind fashion into three groups receiving different stents: patient into Endo-sofTM (group 1; n = 30), BioteqTM enhanced durometer loop stent (group 2; n = 30), Polaris UltraTM (group 3; n = 30). The patient was then assessed for IPSS, OABSS, VAPS, QoL, and gross hematuria questionnaire two weeks after stent insertion and four weeks after stent removal | • Group 3 showed significantly less increase in total IPSS score after stent insertion than the other group (p = 0.016)  
• Group 3 showed significantly less increase in IPSS irritative group 1 (p = 0.037)  
• No significant differences in the obstructive IPSS, QoL, and OABSS in all three groups after stent insertion  
• No significant difference in any variable after stent removal  
• Mean VAPS on the flank pain after ureteral stent was significantly lower in groups 2 and 3 than in group 1 (p < 0.001)  
• Mean VAPS on the urethral pain after the ureteral stent was significantly different between group 3 and 1 (p = 0.001)  
• The presence of gross hematuria after ureteral stent occurred more in group 1 than in group 3 (p = 0.013)  
• The second author is the consultant in Boston Scientific, manufacturer of stents used in group 3 |
| Scarneciu et al. (2015)\(^{19}\)        | RCT    | 1520 patients in 10 years with many indications for stent insertion, with the majority of cases include | Patients were randomised into four groups: Aliphatic polyurethane (40.98%), hydrophilic polyurethane (20.72%), carborane (17.82%), silicon (20.46%) | • All four groups significantly increased urinary frequency, dysuria, urgency, and persistent haematuria after seven days and decreased after 14 days of stent removal.  
• Suprapubic pain and lumbar pain also increased after seven days. |
Gadzniev et al. (2020)\textsuperscript{20} & RCT & 50 patients admitted with ureteral stone disease indicated stent placement for pain relief & Patients were stratified (non-randomised) into two groups: Group A received a polyurethane stent (n=20), and Group B received a silicone stent (n=30). The patient was assessed by VAPS and OABSS 1 hour after insertion and two weeks before stent removal. Secondary outcomes were also measured, including difficulty with stent placement, unplanned visits, encrustation, and gross hematuria. & • No demographic difference between the two groups, except the stone size was significantly larger in group A  
• In group B, the VAPS score is significantly lower two weeks after stent insertion.  
• VAPS score significantly decreased between 1 hour and two weeks after stent insertion in group B.  
• Mean VAPS and mean OABSS were significantly lower in silicone groups.  
• No significant difference between the two groups for secondary outcomes

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RCT: Randomized Controlled Trials; USSQ: Ureteral Stent Symptoms Questionnaire; OABSS: Overactive Bladder Symptom Score; IPSS: International Prostate Symptom Score; UTI: Urinary Tract Infection; VAPS: visual analogue pain scale; QoL: Quality of Life.
Figure 2. This assessment was crucial as it ensures that the results of this study can be relied upon as robust evidence in our overall analysis. We considered factors such as participant selection, confounding, measurement of exposure and outcomes, and missing data, all contributing to our overall judgment of bias. The low risk of bias observed in this study implies that its findings are credible and can be confidently integrated into our meta-analysis.

As shown in Figure 3, we identified some potential sources of bias for the RCT studies included in our analysis. It is important to recognise that despite their rigorous design, RCTs can still be susceptible to various biases. It might arise from issues related to randomisation, allocation concealment, blinding, incomplete outcome data, and selective reporting. Our careful examination of these factors allowed us to make an informed assessment of the overall risk of bias in these trials. While we acknowledge the presence of these potential biases, it is crucial to emphasise that they did not reach a level that would render these RCTs unsuitable for inclusion in our systematic review. In other words, the identified sources of bias were not deemed disruptive or substantial enough to undermine the validity of the studies’ findings. We considered the overall quality of the trials, the magnitude of potential bias, and the impact on the research question. Our conclusion, therefore, was that these RCTs can still contribute valuable insights to our analysis, and their inclusion was justified.

**DISCUSSION**

The majority of studies identified during the literature search utilised RCTs to compare two or more different types of stents. However, most studies employing cohort designs did not compare different stents; instead, they solely observed complications in patients with one type of stent. These types of studies did not meet the inclusion criteria and were excluded during abstract screening. Only one cohort study was identified that compared two different types of stents. Most of the included studies used the USSQ because it has already been validated and adopted in various languages.\(^1\)\(^{11,21,22}\) Some other studies use different assessment tools to assess the complications and symptoms after stent insertion, such as IPSS and OABSS, and the Flanagan Quality of Life (QoL) Scale.\(^1\)\(^{10,12,23}\)

The variations in comfort related to stent material and hardness were inconsistent. Three studies assessed comfort using the USSQ score. Davenport et al. and Joshi et al. reported no difference in comfort after stent insertion for stents with the same material but differing
in hardness. On the contrary, Park et al. contradicted this, asserting that while the overall USSQ score remained consistent, differences were evident when examining individual questions within each USSQ subdomain. Specifically, distinctions were noted when comparing a firm stent to a softer distal pigtail. Meanwhile, Lee and Kim compared the outcomes between stents with different hardness levels using IPSS and QoL scales and revealed that having a soft stent can increase patient comfort by decreasing the change in IPSS irritative score and reducing flank and lower abdominal pain. This comparison highlights the insensitivity of using the USSQ score to address patient comfort when comparing stents with different hardness levels and suggests that using the IPSS score may be more suitable in this particular context.

According to Davenport et al., the lengthy and intricate elements of the USSQ were the cause of the poor completion rate. Additionally, they suggest that a condensed version of the USSQ could be used to increase the completion rate. Furthermore, it is challenging to assess suitable stent-related symptoms in patients who have had prior voiding dysfunction because the USSQ does not consider the condition of the patient's underlying lower urinary tract symptoms. Due to this, the straightforward IPSS, OABSS, and VAPS questionnaires most likely had an impact on the significant outcomes with a high completion rate.

The USSQ is a lengthy and complex instrument. Completing the USSQ may become more difficult due to the psychological and physical state of the patient in the days immediately following ureteral stent implantation. While the USSQ was available, some researchers realised the problem of patient discomfort in relation to the USSQ's complexity and employed ad hoc surveys, while others modified previously developed tools that were validated for different symptoms, such as those following a prostate biopsy. The utility of USSQ in a wider range of clinical research contexts may be increased by abridging it or verifying its modules for discrete or improvisational use.

The study by Scarneciu et al. constitutes a significant contribution to urology, delving into potential discrepancies in complications and patient discomfort associated with commonly used stent materials in clinical practice. The study comprises four groups employing different stent materials, namely aliphatic polyurethane, hydrophilic polyurethane, carbothane, and silicone. This comprehensive comparison illuminates the practical implications of stent selection for healthcare providers and patients alike. Over a ten-year prospective research period, patients with double-J stents (DJS) exhibited various discomforts. While the four stent types showed disparities in the data, none reached statistical significance. Concerning secondary symptoms related to foreign materials in the urinary tract, no single substance
demonstrated superiority over others. Urination symptoms directly attributed to mechanical factors included increased frequency and urgency. Most patients reported a worsening of these symptoms during the day, hinting at a potential link with physical activity. The presence of DJS correlated with heightened bladder muscle activation, with a statistically significant increase in frequency and urgency of urination within seven days of stent placement. Prolonged stent use appeared to elevate the incidence of dysuria, with a statistically significant proportion experiencing dysuria seven days after stent implantation, persisting after removal.

Suprapubic pain is brought on by direct irritation of the bladder mucosa, which is identified by the implantation of a stent. However, subsequent infections or stones in the distal volute may make the condition worse. Although it was not statistically significant in this group, the study showed that this was more common after stent insertion. The percentage of baseline values 14 days following stent removal was also very similar. Hematuria is a frequently occurring symptom of mucosal microtrauma that is mostly reliant on physical activity. A statistically substantial proportion of DJS patients experienced single episodes or intermittent hematuria, which continued for up to 14 days following stent removal (albeit not significantly). After internal drainage concentration, the percentage of patients with persistent hematuria was nearly back to the baseline value, indicating a statistically significant rise in DJS patients. Before the stent was utilised, the average QoLs score was almost the same, hovering around 90. The exception to this was in cases with carbothane stents, most of which had cancer, where the condition had a significant negative impact on quality of life. The patient's quality of life was clearly reduced seven days after stent placement, as indicated by the mean score. However, by 14 days following stent compression, the mean score was slightly closer to the baseline value. One important aspect to consider when interpreting the results of this study is the baseline QoLs among the different groups. Groups aliphatic polyurethane, hydrophilic polyurethane and silicone exhibited relatively similar QoLs scores before stent insertion, with scores around 90, suggesting that the underlying diseases and conditions in these groups were comparable in terms of their impact on patient's quality of life. However, Group C, receiving carbothane stents, had notably lower baseline QoL scores, hovering around 60. This divergence in baseline QoL scores raises an intriguing point for discussion.

Carbothane stents are primarily used for malignancy-related obstructions. It is well-established that malignancies, particularly those involving the urinary tract, can exert a more profound and debilitating effect on a patient's overall quality of life compared to non-malignant conditions. This discrepancy in baseline QoLs might be attributed to the underlying malignancy in carbothane group, which could significantly impact the patient's quality of life even before stent insertion. Therefore, it is crucial to acknowledge this baseline disparity when interpreting results concerning patient discomfort and complications. The observed differences may be influenced not only by the stent material itself but also by the underlying disease state. According to the results of the previous study, ureteral stent softness directly affected patient acceptability; softer stents were associated with lower rates of discomfort and dysuria.

Furthermore, silicone ureteral stents were linked to less patient discomfort on day 20 post-operatively, according to a recent study. Therefore, changing the composition of the stent may help to minimise stent-related symptoms (SRS) further. The intensity of SRS in contemporary silicone ureteral stents and conventional polyurethane ureteral stents was examined in a study by Gadzhiev et al.

According to the results, using the OAB awareness instrument to evaluate patient quality of life was not appropriate. On the contrary, patients who received silicone ureteral stents had a significantly better quality of life (QoL) than those who received polyurethane ureteral stents at the midpoint of the stent indwelling period and right before stent removal, according to data from the visual analogues scale of pain (VASP). Some research, however, has not discovered a connection between patient quality of life and the nature of the stent material. Further long-term research studies should be carried out to reach a definitive conclusion on stent material and its impact on quality of life because of these inconsistent findings. However, none of these trials particularly contrasted polyurethane and silicone...
ureteral stents. This might be primarily because silicone ureteral stents can now be produced with the same external diameter, internal diameter, and side hole size as polyurethane ureteral stents, thanks to recent technological breakthroughs. As a result of these developments, our research showed that silicone ureteral stents were superior in terms of body pain both two weeks and one week prior to stent removal. There was no significant difference in the stent-related problems between the groups receiving silicone and polyurethane ureteral stents. These findings support the general safety of silicone ureteral stents. Polyurethane ureteral stents first took the place of silicone ureteral stents because of the latter’s poor tensile strength, which restricted the stent’s internal diameter and side-hole aperture. Polyurethane ureteral stents were substituted for silicone ureteral stents because silicone ureteral stents were more costly to create and proved more difficult to install because of excessive friction. Silicone ureteral stents are starting to resemble conventional polyurethane ureteral stents in terms of size and safety due to recent technological developments. The stent encrustation rate did not significantly differ in our investigation. Consequently, patients who have had a bad experience with polyurethane ureteral stents in the past or who now have indwelling polyurethane ureteral stents and are having SRS may find that silicone ureteral stents are a good choice. However, depending on the nation, silicone ureteral stents may cost more than polyurethane ureteral stents. This could be a barrier to getting such stents.20

The study’s findings regarding the performance of different stent materials in preventing specific complications are noteworthy. Hydrophilic stents, as revealed by the study, appeared to be superior in preventing urinary frequency, dysuria, urgency, and macroscopic hematuria compared to aliphatic coating within the seven days following insertion. Similarly, silicone stents seemed to outperform both coated polymer groups in preventing urinary frequency and macroscopic hematuria. However, when comparing carbothane stents (a metallic stent) with a hydrophilic coating, the urinary frequency rate was found to be similar but worse than silicone stents. These findings provide valuable insights into the potential benefits of choosing specific stent materials based on the desired clinical outcomes, which can inform clinical decision-making.19,30

Nevertheless, it is crucial to acknowledge the study’s limitations. The small sample size, as mentioned, is a notable constraint. A larger sample size would enhance the statistical power of the study and allow for more robust conclusions. Additionally, as this study demonstrates an association between stent design and material with complications and patient comfort, it serves as a catalyst for future research. Larger studies with diverse patient populations are warranted to validate further and extend these findings, potentially leading to more precise guidelines for stent selection in clinical practice.

Moreover, the study highlights an intriguing aspect regarding the assessment of patient discomfort. It emphasises differences in sensitivity when using different assessment tools, such as the IPSS and the USSQ. These differences underscore the importance of choosing appropriate assessment tools that align with the specific research objectives and patient populations. Future studies should delve deeper into these variations to refine the measurement of patient discomfort and provide a more comprehensive understanding of its impact on stent-related outcomes.

CONCLUSION

In summary, our review highlights the significance of assessing patient comfort during stent insertion and the choice of stent materials. While polymeric stents show promise for long-term use in malignancy-related obstructions, further research is required. Stent material selection should consider factors like silicone’s comfort advantages, friction, and cost. Our review suggests that polymeric stents may be a viable alternative to metallic ones for prolonged use, emphasising the importance of patient-centred care in urological practice and the potential for future advancements in stent interventions.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHOR CONTRIBUTION
KAP, PB contributed to planning of research and data collecting; KAP, WD contributed to data collecting, writing the manuscript, and English editing; KAP, NR contributed to data analysis and proofread. All authors have read and approved the final manuscript.

LIST OF ABBREVIATION
AE: Adverse effect; IPSS: International Prostate Symptoms Score; OABSS: Overactive Bladder Symptoms Score; PC: Polaris stent; PPC: Percuflex plus stent; PRISMA: Preferred Reporting Items for Systematic Review and Meta-analysis; RoB 2: Cochrane Risk of Bias tool for Randomized Control Studies; ROBINS-I: Cochrane Risk of Bias Tool for non-randomised Control Studies; USSQ: Ureteral Stent Symptoms Questionnaire; RCT: Randomized Controlled Trials; USSQ: Ureteral Stent Symptoms Questionnaire; OABSS: Overactive Bladder Symptom Score; IPSS: International Prostate Symptom Score; SLT: Short Loop Tail Stent; LLT: Long Loop Tail; PPC: PercuflexTM plus; PC: PolarisTM; UTI: Urinary Tract Infection; VAPS: visual analogue pain scale; QoL: Quality of Life; DJS: double J stent.

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