International Journal of Urology and Nephrology, ISSN 2756-3855, Vol. 13 (1), pp. 001-006, February, 2025. Available Online at www.internationalscholarsjournals.com © International Scholars Journals

Research Article

Trends and incidence of reported events associated with ureteral stents: An analysis of the food and drug administration's Manufacturer and User Facility Device Experience (MAUDE) database

Riccardo Lombardo*, Alessio Guidotti, Antonio Nacchia, Daniele Fiasconaro, Giuseppe Santoro, Matteo Romagnoli, Yazan al Salhi, Giorgio Franco, Antonio Franco, Giorgia Tema, Giorgio Guarnotta, Antonio Cicione, Andrea Tubaro, Cosimo de Nunzio

Department of Urology, Ospedale Sant'Andrea, University of Rome, Sapienza, Rome, Italy

Received: 23-Dec-2023, Manuscript No. IJUN-23-123409; Editor assigned: 26-Dec-2023, Pre QC No. IJUN-23-123409 (PQ); Reviewed: 10-Jan-2024, QC No. IJUN-23-123409; Revised: 14-Feb-2025 Manuscript No IJUN-23-123409 (R); Published: 23-Feb-2025

ABSTRACT

Background: To summarize medical device reports (MDRs) between 2012 and 2022 relating to ureteral stents within the Manufacturer and User Facility Device Experience (MAUDE) database maintained by The Food and Drug Administration (FDA).
Methods: The MAUDE database was analyzed for all MDRs relating to each FDA-approved ureteral stent for the last ten years. Event descriptions were reviewed and characterized into specific event types. Outcome measures include specific ureteral stent and reported events as detailed by the MDRs. All data is de-identified and in compliance with the Health Insurance Portability and Accountability Act (HIPAA). No further data was available in the database. Data is presented as number of specific event/total events. Pooled Relative risk was used to compare data.
Results: Overall, 2652 reports were retrieved in 10 years and a progressive rise in reported events was recorded. Overall, 831/2652 (31%) were reported as injury while 1810/2652 (68%) as malfunction of the ureteral stent and 4 events of death. The most frequently reported AEs were stent break (627/2652: 23%); material problems (384/2652: 14%); calcification (222/2652: 8%); difficult to insert, advance or remove the device (155/2652: 6%). Bard stents were associated with most material problems reports (19%), Resonance stents were associated with most difficulty to insert advance or remove the device (9%) and calcification (15%) while filiform double pigtail ureteral stent set were associated with most break reports (56%) when compare to the other stents (PRR>1, p<0,05).
Conclusions: Standing to MAUDE database the most frequent complications related to ureteral stents are break, material problems, calcification and difficulty to insert, advance or remove the device. As well Resonance ureteral stents seem to be associated with a higher risk of device problems.

Keywords: MAUDE database, Ureteral stents, Urolithiasis, Ureteral stent complications

INTRODUCTION

First ureteral stent usage was described more than one century ago by Shoemaker who implanted the first ureteral tube in a woman (Shoemaker, 1895). In 1974 Gibbons, et al. designed a new stent with a distal flange to prevent proximal migration (Gibbons, Mason, and Correa 1974). Shortly thereafter, Finney and Hepperlen, et al., almost simultaneously, reported on a new stent design with a J-shaped curl on each side, which is still used nowadays. The indications to place stents are very broad and include the drainage of the upper urinary tract when obstruction of the ureter is present or anticipated. Most cases of ureteral stents

*Corresponding author. Riccardo Lombardo, E-mail: rlombardo@me.com

placements are described in the management of urolithiasis, in particular in cases of obstructed ureter by stone fragment(s) or following Ureterorenoscopy (URS) and Percutaneous Nephrolithotripsy (PCNL) and prophylactic insertion before Extracorporeal Shock Wave Lithotripsy (ESWL) or URS (Beysens and Tailly 2018). In addition, stents can also be placed after iatrogenic injuries of the ureter or to protect and reveal the ureter in complex abdominal or pelvic surgery (Kuno et al. 1998). Ureteral stent placement is also one of the most common urological procedures performed in an emergency setting. In fact, decompression is often necessary to prevent further complications in infected hydronephrosis secondary to internal or external issues, which could lead to urosepsis, acute renal failure or even death.

Different types of ureteral stents and biomaterials have been developed in recent years to reduce the risk of negative effects. Although ureteral stenting is considered a minimally invasive operation, with a very low risk of major complications, it may also induce adverse events.

In 2021, Gaevlete, et al. analyzed 50,000 procedures of ureteral stent placement performed between 1996 and 2021 on 36,688 patients retrospectively (Geavlete et al. 2021). They found 153 cases of double J stent malposition (0.3%); 779 cases of stent migration (427 proximal migrations and 352 distal double J migrations) (1.6%); stent obstruction was observed in 925 cases (1.85%). Encrustation and calcification were retrieved after 832 procedures (1.6%), while stent fragmentation occurred only in 52 cases (0.1%). The results obtained in this study, evaluating 25 years of procedures, clearly show how low the number of adverse events is in relation to the number of procedures performed.

Manufacturer and User Facility Device Experience (MAUDE) database was released in 1991 by the Food and Drug Administration (FDA) and it represents the most widely utilized reporting system. Each year, the FDA receives medical device reports regarding associated adverse events including deaths, injuries, or malfunctions. These reports are logged within the MAUDE database and are submitted by manufacturers, importers, device user facilities as well as voluntary reports from healthcare providers, patients and consumers.

The objective of our study was to evaluate and summarize all the Medical Device Reports (MDRs) relating to ureteral stents within the Manufacturer and User Facility Device Experience (MAUDE).

MATERIALS AND METHODS

The MAUDE database was queried for cases involving ureteral stents from January 1, 2012 to August 31, 2022 using the product class "Stent, Ureteral". The database was last accessed on October 9th, 2022, by two independent reviewers. Information about event type, date received, report source, source type, and manufacturer were collected and analyzed. The MAUDE database reports MDRs in three main groups: device malfunctions, injuries, and deaths. These are submitted mainly by mandatory reporters (manufacturers, importers, and device user facilities) and to a lesser extent by voluntary reporters (healthcare professionals, patients and consumers).

Duplicate entries were carefully checked and removed accordingly as were entries that did not pertain to ureteroscopes. As well, MDRs with limited or missing information were excluded [9]. All data is de-identified and in compliance with the Health Insurance Portability and Accountability Act (HIPAA), then ethical approval was not deemed to be required.

Event descriptions

These data were further classified by reviewing the event description text for each MDR and classified as: "Break", "Material problems", "Calcification", "Difficulty to insert, advance or remove the device" and "Other problems". Other problems included several categories which amounted less than 1% of overall reports.
Manufacturers reported in each event were recorded and individually searched in the database. The frequency of each event was analyzed in relation to each manufacturer.

Manufacturers

Manufacturers were also registered in association with their events. Four different brands were present in the database: Bard; Resonance; Cook and filiform double pigtail set.
No further data was available in the database.

Statistical analysis

The statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS v.24, IBM Corp., Armonk, NY, USA); Pooled relative risk was used as a statistical measure to compare the data. This is a method used in meta-analysis to combine the results of multiple studies and obtain an overall estimate of the risk ratio. In this context, it might have been used to assess the risk of specific events associated with different ureteral stents.

RESULTS

The analysis of the MAUDE database for FDA-approved ureteral stents over the course of last ten years (2012-2022) includes the number of reported events, the types of Adverse Events (AEs) reported, and a comparison of manufacturers based on the proportion of reported events.

In the period of time taken into account, the number of reports identified was 2652 with the number of reports considerably increasing every year between 2019 and 2021 (Figure 1).

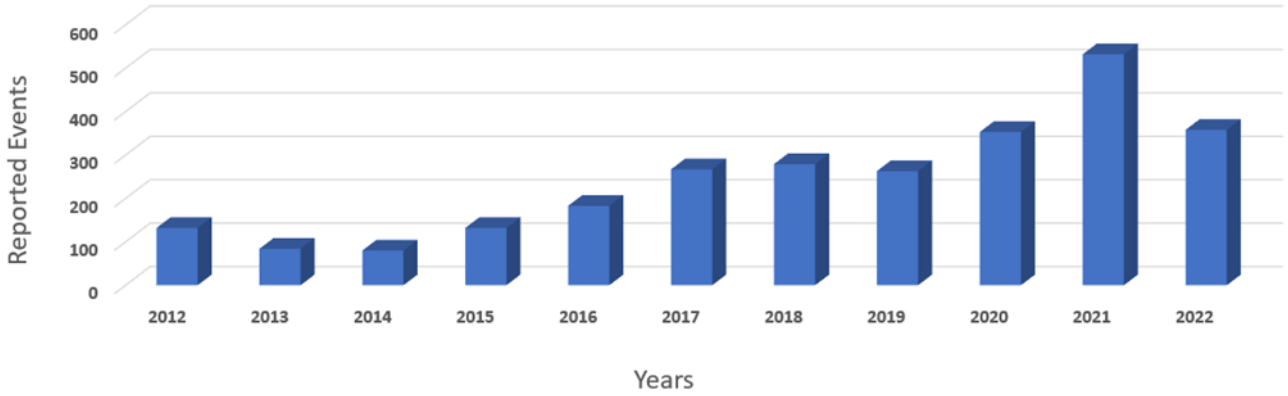

Figure 1. The analysis of the MAUDE database.

Among these reports, 831 were related to injury (31%), 1810 as malfunction of the device (68%); and 4 events of death (0,1%). The most frequently reported specific Adverse Events (AEs) were stent break in 627 cases (23%); 384 reports related to material problems (14%), 222 calcification reports (8%) and difficulty to insert, advance or remove the device was retrieved in 155 reports (6%).

In terms of manufacturer: 875 reports were associated with Resonance stents (33%), 871 were Cook (33%), 690 were Bard (26%) and 130 (5%) were Filiform Double Pigtail ureteral stent set. Bard stents were associated with some higher-rate material problems reports (19%) when compared to Resonance (PRR=0.64; p<0.01). Resonance stents were associated with most difficulty to insert advance or remove the device (9%) and calcification (15%) when compared to the other brands. Lastly, filiform double pigtail ureteral stent set were associated with most break reports (56%) when compared to the other stents (Tables 1-3).

Table 1. Stents compared with brands.

	Overall	**Bard**	**Resonance**	**Cook**	**Filiform double pigtailset**
Device problem					
Break	627 (23%)	132/690 (19%)	261/875 (30%	146/871 (17%)	73/130 (56%)
Material problems	384 (14%)	175/690 (24%)	41/875 (4%	165/871 (18%)	1/130 (<1%)
Calcification	222 (8%)	71/690 (10%)	126/875 (15%	9/871 (1%)	16/130 (12%)
Difficulty to insert, advance or remove the device	155 (6%)	5/690(<1%)	76/875 (9%	69/871 (8%)	2/130 (1%)
Other problems	1264 (47%)	307/690 (44%)	353/875 (40%)	482/817 (55%)	38/130 (29%)
TOTAL	2652	690	875	871	130

Table 2. Bard stents were associated with a higher-rate material problem reports when compared with resonance.

Patient problem	**PRR Bard *vs.* Resonance**	**PRR Bard *vs.* Cook**	**PRR Cook *vs.* Resonance**
Break	0.64* (0.53-0.77)	1.14 (p=0.22) (0.92-1.41)	0.56* (0.47 to 0.67)
Material problems	5.41* (3.91-7.49)	1.34* (1.11-1.629	4.04* (2.91-5.62)
Calcification	0.71* (0.54-0.94)	9.96* (5.01-19.78)	0.07* (0.04-0.14)
Difficult to insert	0.08* (0.03-0.20)	0.09* (0.04-0.23)	0.91 (p=0.56) (0.67-1.24)

Table 3. Filiform double pigtail ureteral stent set were associated with most break reports when compared with other stents.

Patient problem	**PRR Filiform double pigtail set *vs.* Bard**	**PRR Filiform double pigtail set *vs.* Resonance**	**PRR Filiform double pigtail set *vs.* Cook**
Break	2.93* (2.36-3.64)	1.88* (1.57-2.26)	3.35* (2.71-4.14)

Material problems	0.03* (0.004-0.21)	0.164 (p=0.07) (0.02-1.18)	0.4* (0.006-0.29)
Calcification	1.196 (p=0.49) (0.72-1.99)	0.85 (p=0.5) (0.52-1.39)	11.91* (5.37-26.39)
Difficult to insert	2.09 (p=0.37) (0.41-10.66)	0.17* (0.04-0.70)	0.19* (0.047-0.77)

DISCUSSION

Ureteral stents are widely used in urological practice and nowadays represent an irreplaceable tool for urologists to treat patients with ureteral obstructions.

The present study is the first to systematically analyze reports from the MAUDE database. According to our results the most common problems are break (23%), material problems (14%) and calcification (8%). Moreover, AEs were analyzed per manufacturer highlighting different safety profiles between them. The perfect stent should meet several criteria including easy insertion and removal, easy manipulation, resistance to encrustation and migration, biocompatibility, radio-opacity, biodurability, cost-effectiveness and tolerability (Bernasconi et al. 2023).

Urolithiasis represents the main field of application of ureteral stents, in fact these devices are considered both as a treatment and as an act of prevention of renal colic, therefore it is routinely used both in the pre-operative as in the post-operative setting of a lithotripsy (Sali and Joshi 2020). Nevertheless, the indications for the placement of a stent are extremely wide and include also chronic conditions which require periodical replacement of the device every 3-6 months. Ureteral stents accidentally left in situ indefinitely, commonly dubbed ‘‘forgotten’’ stents, can have severe consequences. The forgotten stent has proven to be a recurring source of morbidity in urology patients. These stents may serve as a nidus for urinary stone formation in a period of weeks to months and may result in the formation of large renal calculi and bladder stones (Veltman et al. 2010). Singh, et al. noted that the most of encrustations appear to be associated with the upper curl of the stent, requiring in some cases a percutaneous approach to release it (Singh et al. 2001).

The most frequently reported specific AEs were stent break (23%) and material problems (14%). In 2023, Bernasconi, et al. analyzed the difference of AEs rate per material, demonstrating a higher risk of encrustation, especially by calcium oxalate, for Polyurethane (PU) ureteral stents, while silicon has the lowest encrustation rate) (Venkatesan et al. 2010) and seems to be the best choice for stenting for stone disease after ureteroscopy (Wiseman et al. 2020). Stent encrustation is an uncommon event with a significant impact in patients’ management (Lombardo, Tubaro, and de Nunzio 2022). Several scores are available to predict a complex surgery due to stent encrustation, *i.e.*, the Forgotten Encrusted Calcificated (FECal) Score (Cicione et al. 2022).

Metallic stents can resist high compression forces and are useful in long-term drainage. Metals make stents ductile, malleable, easy-to-mold and resistant to compression. Scientific evidence suggests that these stents when compared to other double J stents provide less morbidity, a longer indwelling time, a greater patency rate and a better management of the strictures. However, they cause epithelial hyperplasia and ingrowth of this hyperplastic tissue, and stent exchange may be challenging.

Ureteral stent break is an extremely uncommon AE and it has been described only in a handful of case reports in literature. Analyzing these reports, we can see a higher risk of breakage when the indwelling period is extended, or when performing procedures like ESWL. In such situations ureteral stents fragments can cause the obstruction of the kidney leading in some cases to the necessity to perform nephroureterectomy.

Differences in manufacturers are difficult to interpret since it is not possible to assess the real number of stents per manufacturer produced and placed. However, when reading the results, it is important to consider that MAUDE database is supplied by voluntary reports from healthcare providers, patients and consumers. In our analysis, most of the reports were associated with Resonance and Cook ureteral stents. This is not thought to be related to materials or shape of these manufacturers’ devices, but the most plausible hypothesis is that these stents represent the most used in urological practice, making them more likely to be subject to reporting.

Polymeric stents remain the leading choice in the ureteric stent market. Their relatively inert nature provides a reliable short-term option. Progress has been made through enhancements in polymer compositions and stent coatings. Developments in biodegradable/bioresorbable stents and various stent coatings aim to tackle issues associated with stents, such as infection, pain, and encrustation. Yet, many of these new technologies are still in the preclinical stage and have shown limited effectiveness in clinical trials. Research and development in stent design are ongoing. The advancement of metallic stents has proven beneficial for patients with chronic ureteral constriction, especially in instances of malignant blockage. Future directions in ureteric stent research could involve the creation of smart stents equipped with monitoring and communication features. It is anticipated that ongoing design improvements and innovations will lead to reduced complications for all patients using ureteral stents.

There are several key limitations of the MAUDE database. Submissions may be incomplete, inaccurate, untimely, unverified, or biased. Since reporting is voluntary, there is a very high risk of underreporting; the incidence or prevalence of an event cannot be determined from these data alone. There is also restricted patient demographic and follow-up data and no information on surgeon experience and case volume. Despite these limitations, the present study is the first to analyze a real-life scenario of stent related adverse events (Din-Lovinescu et al. 2021).

CONCLUSION

Double J stents are a valuable tool for urologists to prevent and alleviate hydronephrosis. Unfortunately, there is no such thing as a "perfect urinary stent", and these are not without risks. Complications of the Double J stent should be assessed and addressed as soon as possible. Standing to MAUDE database the most frequent complications related to ureteral stents are break, material problems, calcification, and difficulty to insert, advance or remove the device. Different brands may have different safety profiles.

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