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RESEARCH

# 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

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## Abstract

**Purpose** Aim of this study is 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** MAUDE was analyzed for all MDRs relating to each FDA-approved ureteral stent. Event descriptions were reviewed and characterized into specific event types. Outcome measures include specific ureteral stent and reported events as detailed by the MDRs. Data is presented as number of specific event/total events. Pooled Relative risk was used to compare data.

**Results** 2652 reports were retrieved in 10 years and a progressive rise in reported events was recorded. 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 adverse events (AEs) were stent break (627/2652: 23%); material problems (384/2652: 14%); calcification (222/2652: 8%); difficulty to insert, advance or remove the device (155/2652: 6%). Bard stents were associated with most material problems (19%), Resonance stents were associated with most difficulty to insert, advance or remove the device (9%) and calcification (15%) while filiform double pigtail stent set were associated with most breakage reports (56%) when compared to the other stents (PRR > 1, $p < 0{,}05$).

**Conclusions** According to MAUDE database the most frequent complications related to ureteral stents are breakage, material problems, calcification and difficulty to insert/advance/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 · Adverse events

## Introduction

The first use of a ureteral stent was described over a century ago by Shoemake [1], who implanted the first ureteral tube in a woman. In 1974, Gibbons et al. designed a new stent with a distal flange to prevent proximal migration [2]. Shortly thereafter, Finney [3] and Hepperlen et al. [4] almost simultaneously reported on a new stent design with a J-shaped curl on each end, which is still in use today.

The indications for placing stents are broad, including the drainage of the upper urinary tract when ureteral obstruction is present or anticipated. Most cases of ureteral stent placement are related to the management of urolithiasis [5], particularly in cases of ureteral obstruction by stone fragments or following ureterorenoscopy (URS) and percutaneous nephrolithotripsy (PCNL). Stents are also prophylactically inserted before extracorporeal shock wave lithotripsy (ESWL) or URS [6]. Additionally, stents can be placed after

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iatrogenic injuries to the ureter or to protect and identify the ureter during complex abdominal or pelvic surgery [7].

Ureteral stent placement is also one of the most common urological procedures performed in emergency settings. Decompression is often necessary to prevent further complications in cases of infected hydronephrosis caused by internal or external issues, which could lead to urosepsis, acute renal failure, or even death.

In recent years, various types of ureteral stents and biomaterials have been developed to reduce the risk of negative effects. Although ureteral stenting is considered a minimally invasive procedure with a very low risk of major complications, it can still induce adverse events.

In 2021, Gaevlete et al. analyzed 50,000 ureteral stent placement procedures performed between 1996 and 2021 on 36,688 patients retrospectively [8]. 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%); and stent obstruction in 925 cases (1.85%). Encrustation and calcification occurred after 832 procedures (1.6%), while stent fragmentation was observed in only 52 cases (0.1%). The results of this 25-year study clearly demonstrate the low incidence of adverse events relative to the number of procedures performed.

The Manufacturer and User Facility Device Experience (MAUDE) database was released in 1991 by the Food and Drug Administration (FDA) and represents the most widely utilized reporting system for medical device-related adverse events. Each year, the FDA receives medical device reports detailing associated adverse events, including deaths, injuries, and malfunctions. These reports are logged within the MAUDE database and are submitted by manufacturers, importers, device user facilities, and 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 [9] 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.

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. Break is intended as any partial or complete rupture of the stent pre, peri or postoperatively. Material problems are mainly related to biocompatibility.

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 past 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. This comprehensive review highlights trends in adverse events, identifies

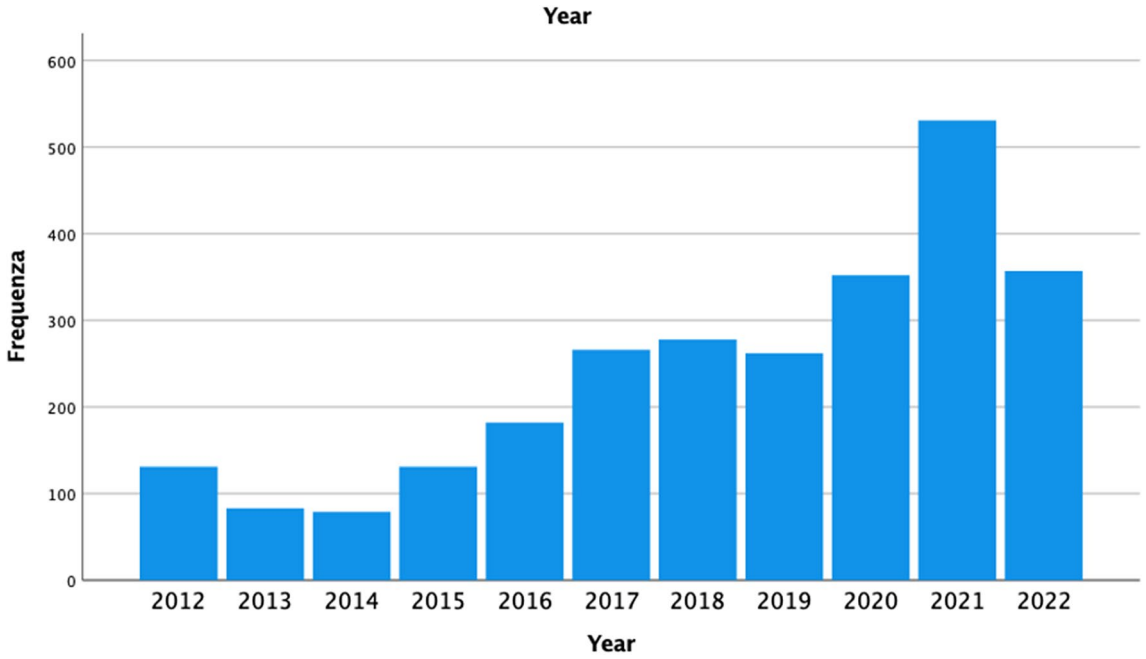


**Fig. 1** Number of reported events from 2012 to 2022

**Table 1** Device reported problems: overall and according to each stent type

| Device Problem | Overall | Bard | Resonance | Cook | Filiform double pigtail set |
|---|---|---|---|---|---|
| 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 | 155 (6%) | 5/690 (< 1%) | 76/875 (9%) | 69/871 (8%) | 2/130 (1%) |
| Other problems | 1264 (47%) | 307/690 (44%) | 353/875 (40%) | 482/871 (55%) | 38/130 (29%) |
| Total | 2652 | 690 | 875 | 871 | 130 |

common issues associated with ureteral stents, and provides insights into the performance and reliability of different manufacturers.

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 (Fig. 1).

Among these reports, 831 were related to injury (31%), 1,810 to device malfunctions (68%), and there were 4 events of death (0.1%). The most frequently reported specific adverse events (AEs) included stent breakage in 627 cases (23%), material problems in 384 reports (14%), calcification in 222 reports (8%), and difficulty in inserting, advancing, or removing the device in 155 reports (6%).

In terms of manufacturers, 875 reports were associated with Resonance stents (33%), 871 with Cook stents (33%), 690 with Bard stents (26%), and 130 with Filiform Double Pigtail ureteral stent sets (5%).

Bard stents had a higher rate of material problems reports (19%) compared to Resonance stents (PRR = 0.64; $p < 0.01$) (Table 1). Resonance stents were most frequently associated with difficulties in inserting, advancing, or removing the device (9%) and with calcification (15%) compared to other brands. Lastly, Filiform Double Pigtail ureteral stent sets had the highest rate of breakage reports (56%) compared to other stents (Tables 2, 1 and 3).

**Table 2** Pooled relative risk (PRR) of device reported problems among different stent types

| 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) |

*= *p value* < 0.05

**Table 3** Pooled relative risk (PRR) of device reported problems among different stent types

| 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) |

*= *p value* < 0.05

## Discussion

The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers. MAUDE works mainly in the United States considering it is an FDA managed database. Overall, reports may include intra or postoperative data however reports do not include this information which may be considered a limitation of the MAUDE database.

Ureteral stents are widely used in urological practice and are now 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 stent breakage (23%), material issues (14%), and calcification (8%). Additionally, adverse events (AEs) were analyzed by manufacturer, highlighting different safety profiles among them.

The perfect stent should meet several criteria, including easy insertion and removal, ease of manipulation, resistance to encrustation and migration, biocompatibility, radio-opacity, biodurability, cost-effectiveness, and tolerability [10]. Urolithiasis represents the primary field of application for ureteral stents. These devices are considered both a treatment and a preventative measure for renal colic, and are routinely used in both the pre-operative and post-operative settings of lithotripsy [11]. However, the indications for stent placement are broad, including chronic conditions that require periodic replacement of the device every 3–6 months. Ureteral stents accidentally left in situ indefinitely, commonly dubbed "forgotten" stents, can have severe consequences. Forgotten stents have proven to be a recurring source of morbidity in urology patients. These stents may serve as a nidus for urinary stone formation within weeks to months, potentially resulting in the formation of large renal calculi and bladder stones [12]. Singh et al. [13] noted that most encrustations appear to be associated with the upper curl of the stent, sometimes necessitating a percutaneous approach for removal.

The most frequently reported specific adverse events (AEs) were stent breakage (23%) and material problems (14%). In 2023, Bernasconi et al. [10] analyzed the difference in AE rates per material, demonstrating a higher risk of encrustation, especially by calcium oxalate, for polyurethane (PU) ureteral stents. In contrast, silicone has the lowest encrustation rate [14] and appears to be the best choice for stenting in stone disease after ureteroscopy [15].

Stent encrustation is an uncommon event with a significant impact on patient management [16]. Several scoring systems are available to predict the complexity of surgery due to stent encrustation, such as the Forgotten Encrusted Calcified (FECal) Score [17].

Metallic stents can resist high compression forces and are useful for long-term drainage [11]. Metals make stents ductile, malleable, easy to mold, and resistant to compression. Scientific evidence suggests that these stents, compared to other double J stents, provide less morbidity, a longer indwelling time, a greater patency rate, and better management of strictures. However, they can cause epithelial hyperplasia and ingrowth of this hyperplastic tissue, making stent exchange challenging [18].

Ureteral stent breakage is an extremely uncommon adverse event and has been described in only a handful of case reports in the literature. Analysis of these reports indicates a higher risk of breakage when the indwelling period is extended or when performing procedures like ESWL [19–22]. In such situations, ureteral stent fragments can obstruct the kidney, occasionally necessitating nephroureterectomy [22].

Differences in manufacturers are difficult to interpret since it is not possible to assess the actual number of stents produced and placed per manufacturer. However, it is important to consider that the MAUDE database is

supplied by voluntary reports from healthcare providers, patients, and consumers. In our analysis, most reports were associated with Resonance and Cook ureteral stents. This is likely not related to the materials or shape of these manufacturers' devices but rather because these stents are among 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 due to their relatively inert nature, providing a reliable short-term option. Enhancements in polymer compositions and stent coatings have been made [23]. Developments in biodegradable/bioresorbable stents and various stent coatings aim to tackle issues such as infection, pain, and encrustation, but 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 may 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.

In the present study, Resonance stents presented a different safety profile when compared to other stents. Authors should interpret these results with caution considering that Resonance stents present different materials and a different configuration when compared to classic stents. The present study confirms the high frequency of break problems related to resonance stents which is poorly reported in the actual literature. The studies available on the subject are often case series and concentrate on success of positioning and patency times while complications are poorly reported [24].

There are several key limitations of the MAUDE database including the lack of data on indications for stent placement or material of stents used. Given the wide number of stents available, even within the same brand, the purpose of this manuscript was to highlight the main adverse events and the different safety profiles of the most used brands. Moreover, the available reports often lack data on the exact model of the stent therefore analysis per material was not performed to avoid other possible biases. Data was pooled by brand type to simplify the analysis and give an overview of the real-life scenario of ureteral stents. Moreover, often reports are incomplete and do not include indications or the precise model of the stent. So far, to minimize sources of bias, the present study was conducted following the same methodology described in other MAUDE articles [25–29].

There is also limited patient demographic and follow-up data, and no information on surgeon experience and case volume [30]. Despite these limitations, the present study is the first to analyze a real-life scenario of stent-related adverse events [31].

## Conclusions

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 devices are not without risks. Complications of Double J stents should be assessed and addressed as soon as possible. According to the MAUDE database, the most frequent complications related to ureteral stents are breakage, material problems, calcification, and difficulty in inserting, advancing, or removing the device. Different brands may have different safety profiles.

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**Data availability** All data supporting the finding of this study are available within the paper and at MAUDE – Manufacturer and User Facility Device Experience from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

## Declarations

**Competing interests** The authors declare no competing interests.

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