Complications of Stone Baskets: 14-Year Review of the Manufacturer and User Facility Device Experience Database

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Purpose: We categorized trends in failure of the stone baskets as reported in the United States Food and Drug Administration Manufacturer and User Facility Device Experience database.

Materials and Methods: We queried the online database using the code for stone baskets (FFL) from January 1996 to December 2009. Variables extracted were the type of basket, malfunction and treatment, and patient outcome.

Results: We identified 556 adverse events related to stone baskets. The device configuration was tipped in 48% of cases, tipless in 36%, forceps in 8% and the Stone Cone™ in 8%. Malfunction type included detachment of a portion of the basket in 49% of cases, breakage without detachment in 39% and inability to withdraw the basket in 12%. Compared to the early period studied (1996 to 2004) there was a 3-fold increase in adverse events from 2005 to 2007 and a 6-fold increase from 2008 to 2009. Of adverse events 79% and 11% were managed by endoscopy and open surgery, respectively. Of the patients 42 experienced serious complications requiring major surgery, including ureteral reconstruction in 7, reimplantation in 4 and nephrectomy in 7.

Conclusions: With the increased use of stone baskets in the upper collecting system the number of adverse events has increased. Urologists should remain vigilant to prevent, recognize and manage these events.

Key Words: ureter, kidney, urinary calculi, equipment failure, complications

Abbreviations and Acronyms

MAUDE = Manufacturer and User Facility Device Experience

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TECHNICAL advances in ureteroscopes and stone retrieval devices have led to widespread acceptance of endoscopic management for upper urinary tract calculi. Many different basket designs and makes exist. The type of basket suitable for stone removal depends on the situation and operator preference. Despite the evolution of instruments and techniques the overall ureteroscopy complication rate is 7%.[1] Studies specifically evaluating the complications attributable to the basket are limited.

We evaluated the complications of stone baskets used during endourological procedures, as reported to MAUDE, the United States Food and Drug Administration medical device complication database. We categorized trends in stone basket failure during endourological procedures and management for these complications.

MATERIALS AND METHODS

We queried MAUDE, the online United States Food and Drug Administration Manufacturer and User Facility Device Experience database, which contains reports of adverse events involving medical devices.[2] Data consist of user reports since 1991, voluntary and distributor reports since June 1993, and manufacturer reports since August 1996. MAUDE is up-

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dated monthly. The online search engine consists of information on medical devices that have malfunctioned and may have caused death or serious injury.

We searched the database using FFL, which is the code for stone baskets. We reviewed all data from January 1996 to December 2009. Only information on stone baskets, forceps and stone migration devices used in an endourological procedure were included. The results of these queries were reviewed and each incident was categorized by the type of basket, malfunction and treatment, and patient outcome. Detachment was defined as any part of the basket or wire that separated from the whole device. Breakage was defined as any portion of the basket that broke but did not separate from the whole basket, including when it could not be closed or opened. Inability to withdraw was defined as the basket with or without stone that could not be pulled from the urinary tract.

RESULTS

A total of 556 adverse events related to stone baskets used in endourological procedures were reported to the MAUDE database from January 1996 to December 2009. We summarized basket failure type vs year (fig. 1). Basket type was categorized according to its primary physical configuration as tipped (48%), tipless (36%), forceps (8%), Stone Cone (8%) or unknown (0.2%) if insufficient information was provided in the report. We noted an initial increase in adverse events in 2003 with an exponential increase in 2008 to 2009.

Figure 2 shows the malfunction of each device using the broad categories of detachment (49% of cases), breakage (39%) and inability to withdraw (12%). Detachment was a more common failure pattern earlier in the series but device breakage increased dramatically in the last 2 years. Figure 3 shows the type of retrieval device vs the type of device malfunction summarized for the more recent years (2005 to 2009) of contemporary accessory instrumentation. Tipped and tipless baskets were similar in the mode of failure, although the proportion of devices that could not be withdrawn was highest for tipped baskets and rare for forceps or a Stone Cone.

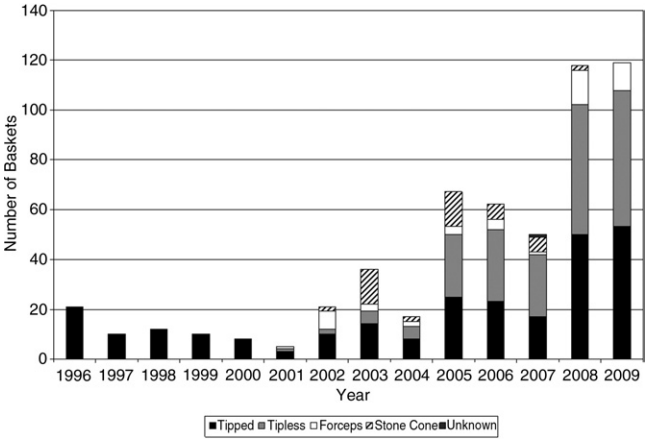

Figure 1. Stone basket complications by basket type

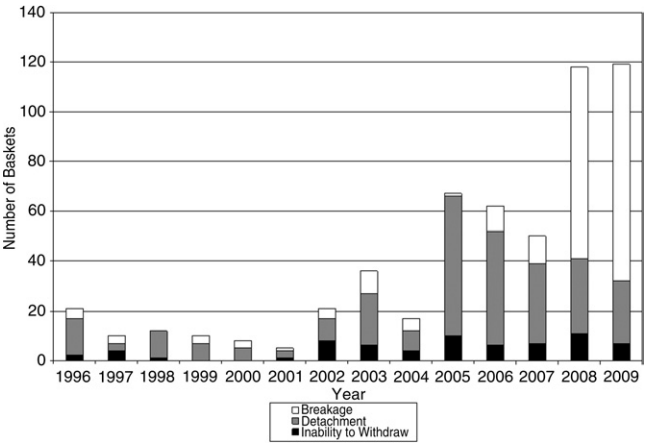

Figure 2. Stone basket complications by malfunction type

We categorized management for device related adverse events as endoscopic treatment in 79% of patients, open surgery in 11%, a portion of the basket left in the patient in 2% and unknown in 8% due to insufficient data in the record (fig. 4). There was increasing dependence on endoscopic procedures to manage these events in the last decade. The MAUDE database also includes some information on the serious sequelae of device malfunctions. Part of the device was left in 229 patients, of whom 176, 42 and 1 underwent endoscopic and surgical removal, and nephrectomy for removal, respectively. Three patients with ureteral stricture underwent surgical repair. Ureteral perforation or tear in 17 patients required stenting in 10 and open surgical repair in 7. Ureteral avulsion in 5 patients required ureteral reimplantation in 4 and nephrectomy in 1. All 5 patients with ureteral necrosis required nephrectomy. Overall 7 patients required nephrectomy.

DISCUSSION

Using a catheter to remove a ureteral stone was first reported in 1947 by Ellik.[3] Blind stone extraction was replaced by stone basketing under direct endoscopic guidance with up to 90% reported success.[4,5] Various stone retrieval devices for endourological procedures are available that differ in important properties such as size, configuration, visibility during stone manipulation, sufficient radial force to open in the ureter and ability to capture, retain or if needed disengage a stone.[6] Complications related to stone baskets carry the potential for serious patient morbidity and can lead to increased operating room time and costs.