## Balloon Dilation of the Ureter: A Contemporary Review of Outcomes and Complications

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Purpose: During ureteroscopy ureteral balloon dilation may be necessary to allow for passage of endoscopic instruments or access sheaths. We assessed the efficacy and complications associated with ureteral balloon dilation.

Materials and Methods: We retrospectively reviewed the records at 2 institutions from 2000 to 2012 to identify patients who underwent ureteral balloon dilation during ureteroscopic treatment of upper tract stones. An 18Fr balloon dilator was used in all cases. Patients with documented ureteral stricture, radiation therapy or urothelial cancer were excluded from analysis. Primary outcomes were the stone-free rate, operative complications, balloon dilation failure and the postoperative ureteral stricture rate. Complications were divided into intraoperative and postoperative groups according to the Satava and Clavien-Dindo classifications, respectively.

Results: A total of 151 patients fulfilled study criteria. Median followup was 12 months. The stone-free rate was 72% and median time to first postoperative imaging was 2.8 months. Balloon dilation failed in only 8 patients (5%). Eight intraoperative ureteral perforations (5%) were identified, which were managed by a ureteral stent in 7 patients and a percutaneous tube in 1. Endoscopic retreatment was required in 4 patients with Satava 2b postoperative complications. The postoperative complication rate was 8% (11 cases). A single ureteral stricture was attributable to balloon dilation.

Conclusions: In this contemporary review balloon dilation of the ureter before endoscopic treatment of stone disease was associated with a high success rate and few complications. Ureteral balloon dilation may decrease the need for a secondary procedure in patients undergoing ureteroscopy to manage proximal ureteral and intrarenal stones.

Key Words: ureter, urolithiasis, dilatation, ureteroscopy, complications

UROLITHIASIS is a common disease affecting approximately 1 of 11 Americans. Treatment trends appear to be shifting toward higher use of ureteroscopy for symptomatic renal and ureteral stones.<sup>2</sup> An unpredictable but common hindrance to retrograde access in many patients is the anatomical caliber of the ureteral orifice or ureter. Balloon dilation of the ureter is a wellknown technique to facilitate passage of instruments to access upper tract stones. However, many practicing urologists in the elective setting may avoid this technique based on the potential risk of ureteral injury.

#### **Abbreviations** and Acronyms

CT = computerized tomography

IVP = excretory urogram

UAS = ureteral access sheath

URS = ureteroscopy

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Few groups have evaluated the safety and efficacy of balloon dilation of the ureter to allow for the passage of instruments or ureteroscopes. Thus, we assessed outcomes and complications in a contemporary cohort from high volume centers.

#### **MATERIALS AND METHODS**

After receiving institutional review board approval and a data sharing agreement we performed a multicenter retrospective review. Patients who underwent balloon dilation of the ureter between 2000 and 2012 were included in analysis. The patient cohort was identified by operative supply billing records for a UroMax ureteral balloon dilator (Boston Scientific®), the only ureteral balloon dilator used at the 2 participating institutions. Operative dictations were manually reviewed to confirm the indication and the use of the device. Patients with ureteral stricture disease, upper tract malignancy, or prior abdominal or pelvic radiation were excluded from study.

Demographic and clinical information was abstracted. Descriptive analysis was performed for the entire cohort, including patient age, race, gender, stone size, stone location, number of stones and prior endoscopic procedures. Operative information included balloon dilation indication, location and extent, UAS use and ureteral stent placement. In general retrograde pyelogram was performed at the start of each case. One or 2 wires were placed depending on stone size and location followed by an endoscopic instrument. At each participating institution a UAS is routinely used for proximal ureteral and renal stones. If the UAS does not pass, the inner tapered sheath of the UAS is used. If placement is still unsuccessful, an 18Fr balloon is used to dilate the mid and distal ureter to 18 cm  $H_2O$ . After treating the stone the ureteroscope is removed under direct vision to identify signs of ureteral injury. The flexible ureteroscopes used during the study duration ranged in size from 8.5Fr to 10Fr. A 10 cm 18Fr UroMax balloon dilator was used in all cases.

Due to the nonparametric distribution the data are summarized as the median and IQR for age, time to postoperative imaging and postoperative followup duration. The remaining variables are shown as the frequency.

The primary study outcome was twofold. We determined 1) the proportion of successful ureteroscopic treatments after balloon dilation, defined as the ability to access upper tract stones after balloon dilation, and 2) the complication rate, defined as a composite of intraoperative and postoperative complications. Intraoperative and postoperative complications were classified according to the modified Satava classification<sup>3</sup> and the Clavien-Dindo classification, respectively. Stricture disease was defined as postoperative hydronephrosis in the absence of an obstructing stone. This required another study (ureteroscopy or functional imaging) to confirm and document ureteral stricture. The secondary outcome was the stone-free rate, defined as zero residual stones on followup imaging by digital tomogram, renal ultrasound or CT. Data were analyzed with R, version 2.13 (http:// www.r-project.org/).

#### **RESULTS**

A total of 151 patients met study inclusion criteria and were evaluated. The table lists patient demographic and stone characteristics. Notably a UAS was used in almost 80% of cases and internal ureteral stents were placed in 96%. Median followup was 12 months. Figure 1 shows indications for balloon dilation, which was performed in the distal ureter in 54% of cases. UAS size was not documented in a third of the cases but when reported, the most common size was 12Fr to 14Fr (73 of 100 cases or 73%). Approximately 50% of cases in which balloon dilation was done were cited in the operative note as secondary to inability to pass a UAS while in 25% inability to pass the ureteroscope was cited.

The primary outcome (successful balloon dilation) was noted in 95% of cases (143 of 151) and the intraoperative complication rate was 5% (8 of 151). Figure 2 further categorizes these complications. Half of the complications were Satava grade 1 and by definition were without further clinical consequence. The remaining complications were Satava grade 2, which resulted in a subsequent endoscopic procedure. These complications included significant perforation in 3 patients and lost access in 1. The overall postoperative complication rate was 8% (11 of 140 cases). Figure 3 shows postoperative complications by Clavien grade. Notably only 4 of these 11 complications were a direct result from the balloon dilation.

A single postoperative stricture (0.9%) was identified as a result of balloon dilation. Because this patient was asymptomatic with normal renal function, he refused further corrective intervention. The overall stone-free rate was 72% with IVP and CT predominantly done as postoperative imaging (see table).

#### DISCUSSION

Ureteroscopy to manage ureteral and renal stones is becoming more common, particularly in the younger

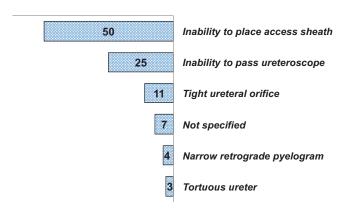


Figure 1. Indications for ureteral balloon dilation. Values represent percents.

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