Use of a polymeric gel to prevent retropulsion during intracorporeal lithotripsy


Division of Urology, Department of Surgery, Denver Health Medical Center, University of Colorado, School of Medicine, Denver, CO, USA

Abstract
Introduction: Stone retropulsion during ureteroscopic lithotripsy may lead to additional procedures needed for residual calculi. Several devices have been introduced in an attempt to reduce retropulsion. We set out to report our initial experience utilizing the new polymeric gel, BackStop®.

Materials and methods: We prospectively collected data on 7 ureteroscopy procedures with distal ureteral calculi treated with BackStop®. Perioperative data including stone size, location, operative time, stone free rate, the presence or absence of retropulsion were collected. Success was defined as no residual fragments, no retropulsion, and no additional procedures required.

Results: All of the patients were rendered stone free after URS and no retropulsion occurred. There were no intraoperative complications nor gel migration or problems with dissolving the gel.

Conclusions: BackStop® is a new promising therapy to prevent retropulsion during ureteral intracorporeal lithotripsy. It is safe, easy to apply and very effective in preventing stone fragment migration. BackStop® has the potential to reduce operative time.

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Keywords
Ureteroscopy; Retropulsion; Intracorporeal lithotripsy

PALABRAS CLAVE
Ureteroscopia; Retropulsión; Litotricia intracorpórea

Uso de un gel polimérico para evitar retropulsión durante la litotricia intracorpórea

Resumen
Introducción: La retropulsión de los cálculos durante la litotricia ureteroscópica puede conducir a procedimientos adicionales necesarios para los cálculos residuales. Se han introducido varios dispositivos en un intento de reducir la retropulsión. Nos pusimos en marcha para informar de nuestra experiencia inicial al utilizar el nuevo gel polimérico BackStop®.

Material y métodos: Hemos recogido de forma prospectiva los datos sobre 7 procedimientos de ureteroscopia con cálculos ureterales distales tratados con BackStop®. Se recogieron los datos perioperatorios, tales como tamaño del cálculo, ubicación, tiempo quirúrgico, tasa libre de cálculo, presencia o ausencia de retropulsión. El éxito se definió como la ausencia de fragmentos residuales, de retropulsión y de procedimientos adicionales que se requieren.

* Corresponding author.
E-mail address: wilson.molina@dhha.org (W.R. Molina).
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Introduction

Both the American Urological Association and the European Association of Urology recommend ureteroscopy (URS) as one of the first-line treatment modalities for ureteral calculi. Advances in technique and instrument technology have encouraged urologists to choose URS rather than extracorporeal shockwave lithotripsy (SWL) for ureteral stones. Despite these advances, urologists continue to seek effective means of addressing the problem of retrograde stone migration (retropulsion) during URS and intracorporeal laser lithotripsy.¹

Retropulsion occurs in 5–40% of all URS cases.² The location, source of energy, and stone size influence these rates. Retropulsion has been reported in 3–15% of distal ureteral stones³ and 28–48% of proximal stones.⁴,⁵ Pneumatic and electrohydraulic lithotriptors cause more retropulsion than holmium laser lithotripsy; and smaller stones are more likely to undergo retropulsion.⁶ Retropulsion may increase the need for additional procedures such as flexible URS, shock wave lithotripsy, or even percutaneous nephrolithotomy.⁷ Additional fractionation can lead to increased hospital visits and surgical cost. If left untreated, these fragments can cause persistent infection and renal colic.⁷

Several devices have been developed to address retropulsion such as the stone cone (Boston Scientific, Boston, MA), Cook N-Trap (Cook Urological, Spencer, IN), and the Perc-Sys Accordion (Percutaneous System, Palo Alto, CA). While these devices achieve some level of effectiveness, they all have mechanical elements with the potential to cause direct injury to the ureter. Moreover, they may interfere with the energy delivered by the laser source.²,⁹ BackStop is a new generation tool to prevent retropulsion and it is a polymeric thermo reversible gel that is dispensed proximally to the stone using a catheter.

From the best of our knowledge, we present the first single-center experience using BackStop to prevent retropulsion during URS.

Materials and methods

Product description

BackStop is a water soluble viscous liquid at room temperature that forms a plug when introduced into the ureter to prevent stone migration. It is injected using a 3 Fr radiopaque tipped catheter and it is dissolved using cold saline following stone extraction.

Procedure description

Beginning November 2011, a prospective data analysis of our initial experience was performed using BackStop collected from 7 procedures. Three patients had bilateral ureteral stones while 1 patient had unilateral ureterolithiasis. Preoperative imaging included non-contrast computed tomography.

URS and stone fragmentation were performed with the patient in the lithotomy position under general anesthesia. An 8.5 Fr digital flexible or 7.5 Fr semirigid ureteroscope (Olympus Corp, Tokyo, Japan) was used depending on stone location. Irrigation with saline was performed using a single action pump (Boston Scientific, Boston, MA). Cystoscopy was routinely performed and a wire was passed to the renal pelvis under fluoroscopy. The stone was accessed and BackStop was dispensed approximately 2 cm proximal to the stone under fluoroscopy. Lithotripsy was performed using a Holmium laser with a power of 10 W. Larger fragments were removed using a basket while smaller fragments were flushed out by the saline backflow developed secondary to the BackStop plug. Following complete stone removal, BackStop was dissolved using cold saline and URS was performed to the level of the renal pelvis to evaluate any residual stones (Fig. 1).

Patient demographics, stone size, location, operative time, stone free rate, the presence of retropulsion, and the need for additional procedures were collected. Stone
m..., migration was defined as retropulsion of fragments above BackStop after complete fragmentation of the stone.

Ureteral occlusion was accessed to determine the abil..., or distal after the procedure which was removed two weeks postoperatively.

Results

BackStop was successful in all 7 URS cases; mean age was 42.8 yrs and body mass index was 30.0 kg/m². Mean treated stone size with BackStop was 8.3 mm. Table 1 shows patients demographics. Fig. 2 illustrates a preoperative CT scan of a patient selected to undergo URS using BackStop. The radio-opaque BackStop catheter injects gel approximately 2 cm proximal to the stone under fluoroscopy. Three patients were treated for bilateral stones. Two were managed with separate procedures while another one was treated concomitantly. Five procedures involved multiple ipsilateral stones which increased operative time. Each procedure started distally and worked proximally. In procedure 4, the 4-mm distal stone was removed prior to the application of BackStop because of its small size and location. BackStop was then applied and the 7-mm mid-ureteral stone was treated. The gel was then dissolved and a renal lower pole stone was then successfully removed.

Mean operative time was 47.9 min, with all procedures involving exclusively ureteral stones being under one hour (Fig. 3). There were no intraoperative complications observed such as ureteral injury or migration of the gel. The gel was dispensed without complications. All of the cases except for one utilized laser lithotripsy for stone fragmentation. Retropulsion did not occur in any procedure. Incidentally observed, irrigation with backstop flushes smaller fragments out of the ureter. Only larger fragments required the use of the basket which considerably decreases operative time. In procedure 7, after positioning the gel and initiating flushing, it was observed that no fragmentation was required and the stone was removed intact. Table 2 shows the intra and postoperative outcomes.

After complete removal of fragments from the ureter (Fig. 4), a saline solution was used to dissolve the gel and complete URS of the ureter was performed to evaluate success. One complication (UTI) occurred postoperatively that was treated conservatively with an antibiotic. None of the patients required additional procedures after postoperatively for the treated stones. All of the patients were considered stone free after complete URS.

Discussion

The management of ureteral calculi has changed considerably over the past decade. The improvements in technology and techniques have resulted in higher

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**Table 1**  Patient demographics.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Gender</th>
<th>Age (years)</th>
<th>BMI (kg/m²)</th>
<th>ASA</th>
<th>Side</th>
<th>Size</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>46.9</td>
<td>26.4</td>
<td>1</td>
<td>Right</td>
<td>8 mm, 10 mm</td>
<td>Distal</td>
</tr>
<tr>
<td>2</td>
<td>Male</td>
<td>37.1</td>
<td>26.9</td>
<td>2</td>
<td>Right</td>
<td>9 mm, 12 mm</td>
<td>Distal</td>
</tr>
<tr>
<td>3</td>
<td>Female</td>
<td>37.4</td>
<td>26.9</td>
<td>2</td>
<td>Right</td>
<td>8 mm</td>
<td>Mid</td>
</tr>
<tr>
<td>4</td>
<td>Male</td>
<td>37.1</td>
<td>26.9</td>
<td>2</td>
<td>Left</td>
<td>4 mm², 10 mm, 7 mm</td>
<td>Distal, mid, lower pole</td>
</tr>
<tr>
<td>5</td>
<td>Male</td>
<td>46.9</td>
<td>26.4</td>
<td>1</td>
<td>Left</td>
<td>8 mm</td>
<td>Distal</td>
</tr>
<tr>
<td>6</td>
<td>Female</td>
<td>47.0</td>
<td>38.1</td>
<td>2</td>
<td>Right</td>
<td>7 mm, 8 mm</td>
<td>Distal</td>
</tr>
<tr>
<td>7</td>
<td>Female</td>
<td>47.0</td>
<td>38.1</td>
<td>2</td>
<td>Left</td>
<td>5 mm, 6 mm</td>
<td>Distal</td>
</tr>
</tbody>
</table>

* Stones not treated with the use of BackStop.

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**Figure 2**  (A) Guidewire was passed through the stone; (B) BackStop gel was dispensed above the stone (2 cm); (C) fragmentation of the stone was performed using holmium laser; (D) removal of the fragments with basket; (E) the gel was dissolved with warm saline; and (F) complete URS was performed.
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Figure 3 Preoperative CT demonstrating an 8-mm distal ureteral left stone. BackStop dispensed under fluoroscopy. Observe the tip of the catheter that was radiopaque which facilitate its positioning.

Figure 4 Complete removal of the fragments and dissolving of the gel with saline.

Stone retropulsion during URS remains a problem as it increases cost, operative time, and potential need for additional procedures. Retropulsion rates for various lithotriptors are as high as 5–48%. In order to minimize the risk of retropulsion, several devices have been released such as the stone cone (Boston Scientific, Boston, MA), Cook N-Trap (Cook Urological, Spencer, IN), and PercSys Accordion (Percutaneous System, Palo Alto, CA). The N-Trap is composed of a tightly woven mesh of nitinol wires that essentially consists of the inner wire and the outer radiopaque carrying catheter. The Stone Cone is a collapsing conical coil that is delivered cystoscopically or ureteroscopically and expanded when above the stone. The Accordion Percutaneous Systems is a hydrophilic microcatheter-based tool with a film occlusion that expands to prevent migration of stones. While these instruments demonstrated effectiveness in retropulsion prevention, they are all mechanical elements with reports of injury to the ureter. The two devices (Stone Cone and N-Trap) had been previously tested and compared for pull-through strength, which is the force required for each device to deploy and release the beads in a structured ureter model. Quwenga et al. reported statistically significant but clinically insignificant differences as these forces were too low to result in ureteral avulsion. Evidence exists that the wire of these devices can interfere with the delivery of the laser as well.

Although mechanical elements have shown potential, developments with viscous gels have been thought to be a valuable alternative. The use of lubricating jelly was studied.

Table 2 Intra and postoperative outcomes.

<table>
<thead>
<tr>
<th>Patient</th>
<th>ORT (min)</th>
<th>Laser time (min)</th>
<th>Retropulsion</th>
<th>Stone free</th>
<th>Complications</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>53</td>
<td>5:17</td>
<td>No</td>
<td>Yes</td>
<td>None</td>
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<tr>
<td>2</td>
<td>45</td>
<td>5:46</td>
<td>No</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>3</td>
<td>35</td>
<td>0:40</td>
<td>No</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>4</td>
<td>120</td>
<td>2:04</td>
<td>No</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>5</td>
<td>40</td>
<td>2:25</td>
<td>No</td>
<td>Yes</td>
<td>UTI</td>
</tr>
<tr>
<td>6</td>
<td>28</td>
<td>3:58</td>
<td>No</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>7</td>
<td>14</td>
<td>0:00</td>
<td>No</td>
<td>Yes</td>
<td>None</td>
</tr>
</tbody>
</table>
and indicated that the rate of retropulsion in the study group (4%) represented a reduction compared to the control group (28%). The authors noted that the use of the lidocaine jelly has the potential to impair visibility during URS.\(^1\) Another viscous gel, BackStop, was evaluated in a randomized controlled multi-center study by Rane et al.,\(^1\) on 68 patients with ureteral stone either with or without BackStop. The subjects randomized to the BACKSTOP group experienced a statistically significant (p < 0.0002) lower rate of retropulsion (8.8%, 3/34) vs. the control group (52.9%, 18/34). There were no adverse events in the BackStop group and it was successfully dissolved in every subject.

Conclusion

From the best of our knowledge, this is the first single-institution evaluation of retropulsion rates using BackStop. Although our series is limited due to the small caseload, several conclusions can still be made: BackStop is safe with minimal risk to the patient; BackStop is simple and easy to apply; BackStop is effective in avoiding retropulsion as we demonstrated in 100% of our cases; the application of BackStop appears to decrease the OR time as fewer fragments need to be retrieved by the basket. Small fragments tend to be flushed out by the saline irrigation back flow secondary to the obstruction that the BackStop causes, reducing the surgical time. BackStop is a new promising tool to prevent retropulsion during ureteral intracorporeal lithotripsy.

Conflict of interest

The authors declare that they have no conflict of interest.

References