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In Vivo Evaluation of a Reverse Thermosensitive Polymer for Ureteroscopy with Laser Lithotripsy: Porcine Model

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Abstract

Purpose: To evaluate the effects of a reverse thermosensitive polymer during ureteroscopy with laser lithotripsy in an *in vivo* porcine model.

Materials and Methods: Six pigs underwent general anesthesia followed by bilateral ureteroscopy with laser lithotripsy of stone phantoms while measuring intrapelvic renal pressures through bilateral nephrostomy tubes. The procedures were performed in one ureter with the reverse thermosensitive polymer and in the contralateral, control ureter without the reverse thermosensitive polymer. Stone migration lengths, operative times, laser times, laser energy usage, intrapelvic pressures, and postnecropsy histologic examinations of the ureters were compared between the two groups.

Results: Bilateral ureteroscopy with lithotripsy was successfully performed in five of six pigs. In one pig, only the unilateral control was performed, because the ureter was too narrow to complete the contralateral side. The mean laser time was 12.8 minutes shorter with the use of the reverse thermosensitive polymer group than in the controls ($P = 0.021$). The procedure time, laser energy usage, and retropulsion length was shorter in the reverse thermosensitive polymer group, but did not reach significance. Between the two groups, there was no difference in mean renal pelvic pressures, peak renal pelvic pressures, or postprocedure histologic examinations of the ureters.

Conclusions: The use of a reverse thermosensitive polymer during ureteroscopy with lithotripsy may have greater advantages beyond preventing stone retropulsion. Here, the use of a reverse thermosensitive polymer during ureteroscopy with lithotripsy resulted in a significant decrease in laser times. Further clinical investigations could further delineate the advantages of using a reverse thermosensitive polymer during intracorporeal lithotripsy.

Introduction

Ureteroscopy is well-established as a primary intervention for patients with ureteral calculi. The technique offers higher stone-free rates than extracorporeal shockwave lithotripsy for distal ureteral stones of all sizes and proximal ureteral stones more than 1 cm in diameter.[1] Stone retropulsion, the proximal migration of stones within the ureter in response to insertion of the ureteroscope, flow of irrigation fluid, or forces exerted by lithotripters, continues to occur in management of up to 15% of distal ureteral stones and 60% of proximal ureteral stones, however.[2,3] Such retropulsion can lead to increased operative times, decreased stone-free rates, and increased requirements for further interventions.[2–5] A number of mechanical devices have been introduced to prevent stone retropulsion with varying efficacy, advantages, and disadvantages.[3]

BackStop™ (Boston Scientific, Natick, MA) is a reverse thermosensitive polymer (RTP) that has been proposed as an alternative to mechanical antiretropulsion devices such as the Stone Cone® (Boston Scientific, Natick, MA), Accordian® (Percutaneous System, Palo Alto, CA), and the NTrap® (Cook Urological, Spencer, IN).[3] It exists as a viscous liquid at room temperature that forms a firm gel plug when heated by the body after it is injected into the ureter proximal to the stone. After lithotripsy, the RTP easily washes away as a soluble liquid with injection of cooled saline.[6] The use of RTPs is unique among antiretropulsion techniques in that it completely occludes the ureter and does not occupy space distal to the ureteral calculi.[3] Rane and associates[2] randomized 68 patients with proximal ureteral stones to ureteroscopic lithotripsy with or without the RTP. The use of the RTP resulted in a decreased rate of retropulsion, while maintaining equivocal stone-free rates, need for secondary

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procedures, and adverse events when compared with controls.[2] Although the qualitative prevention of stone retropulsion has been shown with the use of RTP, the quantitative measurement of retropulsion along with the effects on operative time and intrarenal pressure with RTP use have not been described.

We used an *in vivo* porcine model to evaluate the effects of the RTP on lithotripsy time, total operative time, stone retropulsion length, intrarenal pressures, and histologic tissue effects during ureteroscopy with laser lithotripsy of mid to distal ureteral stones. Bilateral ureteroscopy with lithotripsy was performed with the use of the RTP in one ureter and the contralateral, control ureter without the RTP. We also hypothesized that RTP use would have the secondary benefit of decreasing intraoperative intrarenal pressures by completely occluding the ureter proximal to the stone and preventing the irrigant from reaching the renal pelvis. If RTP use prevents the rise of intrarenal pressures above 40 cm H_2O, then less pyelovenous, pyelosinus, and pyelolymphatic backflow would occur with the potential benefit of decreased bacteremia, fever, and sepsis.[7]

We report the results of continuous intraoperative monitoring of renal pelvic pressure and microscopic examination of ureters obtained from necropsy 2 days postoperatively.

Materials and Methods

The experimental protocol was approved by the Animal Studies Committee of Washington University. From April 2013 to July 2013, six adult female farm pigs weighing 70 to 90 lb were entered into the study. The pigs were acclimated for 72 hours before surgery. After fasting overnight, the pig was induced by an intramuscular (IM) injection of 4 mg/kg of telazol, 2 mg/kg of ketamine, and 2 mg/kg of xylazine. The pig was then intubated and maintained under general anesthesia with 1% to 5% isoflurane. Cefazolin, 15 to 25 mg/kg IM, was given preoperatively for antibiotic prophylaxis. Buprenorphine, 0.02 to 0.05 mg/kg IM was given preoperatively for analgesia. Postoperative analgesia was given with buprenorphine, 0.02 to 0.05 mg/kg IM, and carprofen, 4.4 mg/kg IM, every 8 hours as needed.

Flexible cystoscopy was performed, and a 0.038 Sensor® wire (Boston Scientific, Natick, MA) was advanced into each ureter to the level of the renal pelvis under fluoroscopic guidance. A second Sensor wire was placed into each ureter with the use of an 8/10 dilator/sheath (Boston Scientific, Natick, MA). A 6F open end ureteral catheter was advanced over one of the wires and retrograde pyelography was performed to outline the collecting system. Under fluoroscopy, percutaneous access to a renal calix was gained with a 20-cm 18-gauge introducer needle), and a Sensor wire was then passed into the collecting system. Next, an 8/10 coaxial dilator was advanced into the renal pelvis over the wire, and the 10F sheath was used as a nephrostomy tube. The 10F sheath was connected to a Transpac® IV disposable pressure transducer (ICU Medical, Inc., San Clemente, CA) at kidney level that was then connected to a Propac® Encore vital signs monitor (Welch Allyn Inc., Skaneateles Falls, NY). Baseline renal pelvic pressures were recorded, and pressures were then monitored at minute intervals throughout the ureteroscopy.

Three millimeter spherical, stone phantoms of uniform size and shape were created by the precision injection molding technique previously described by Carey and colleagues.[8] Stone phantoms were prepared from BegoStone (BEGO USA, Lincoln, RI) at a 15:3 powder-to-water ratio to approximate the properties of calcium oxalate monohydrate.[9] Two 3-mm stone phantoms were placed retrograde into each ureter through a 13/15F, 28-cm access sheath. The 13/15F access sheath was advanced to the level of the mid to distal ureter over one of the Sensor wires under fluoroscopic guidance. The obturator and Sensor wire were removed, and each 3-mm stone phantom was grasped with a three-prong grasping forceps and advanced retrograde through the 15F access sheath until properly positioned into the ureter. Two stone phantoms were placed into each ureter with both sides equidistant from the bladder. The initial position of these phantoms was marked on the body wall under fluoroscopic guidance.

Before each unilateral ureteroscopy, the bladder was emptied. Bilateral ureteroscopy was performed using a 9F, Wolf 7330.072, flexible ureteroscope (Richard Wolf Medical Instruments Corporation, Vernon Hills, IL) without an access sheath, but with a safety wire in place at all times. The flexible ureteroscope was advanced into the ureter over a Sensor wire under fluoroscopic guidance. After positioning the ureteroscope just distal to the stone, the Sensor wire was removed, and the procedure time began. Ureteroscopy was performed in the control ureter without the use of the RTP. In the contralateral ureter, a 3F catheter was passed proximal to the two stones through the ureteroscope's working channel, the RTP was injected through the 3F catheter, and then the catheter was removed. Physiologic saline was continuously infused through the ureteroscope at a constant pressure of 60 mm Hg.

The stone phantoms were fragmented with a holmium:yttrium-aluminum-garnet (YAG) laser using a 200 micron fiber at 0.5 to 0.8 J at 10 Hz until all fragments were approximately twice the width of the 200 fiber. The same laser settings were used for bilateral lithotripsy. After complete fragmentation of the phantom in the RTP ureter, the RTP was evacuated from the ureter by instilling cold physiologic saline through the ureteroscope until the RTP was completely dissipated. Complete dissolution of the RTP was confirmed by performing retrograde pyelography through the ureteroscope and visualizing contrast extending into the proximal ureter and renal collecting system. Postoperatively, the pig was left with bilateral 6F × 28-cm Percuflex® ureteral stents (Boston Scientific, Natick, MA).

The procedure time in the control ureter ended when all stones were fragmented to the appropriate size, while in the RTP, ureter time ended with completion of retrograde pyelography. The final location of the most proximal stone fragment was compared with the initial position of the phantoms to calculate stone retropulsion length. The stone retropulsion length, laser energy usage, total procedure time, laser time, and time needed for the RTP was recorded for each ureter. We also recorded whether the control or RTP ureteroscopy appeared subjectively easier to perform.

Two days after the procedure, the pigs were euthanized, and the kidney, ureters, and bladders were harvested *en bloc.* Hematoxylin and eosin histopathologic analysis was performed on 17 to 21 cross-sections per ureter, depending on the ureteral length. We modified a histologic grading scale previously described by McDougall and coworkers.[10] Each section was scored on a scale of 0 to 3 for four criteria: Integrity of urothelium, degree of urothelial inflammation, inflammation in the lamina propria, and the integrity of the musculature. Scores were defined as follows: 0 = normal, 1 = mild, 2 = moderate, and 3 = severe. Scores per cross section were summed and means were reported.

Analysis was performed using R statistical software (R Development Core Team, 2010). Comparisons of continuous variables for the two groups were performed using the *t*-test assuming nonequal variance. Categorical variables were compared with the chi-square test. Tests were performed two-sided with statistical significance set at the 0.05 level.

Results

Table 1 displays the raw data for all procedures performed. Stone placement, ureteroscopy, and lithotripsy were successfully performed bilaterally in five pigs. In the sixth animal, the protocol was successfully performed in the control ureter, but no data could be collected from the contralateral RTP ureter because it was found to be too narrow to admit passage of the 15F ureteral access sheath, which precluded stone placement. In the five ureteroscopic procedures in which RTP was used, the RTP was successfully instilled proximal to the ureteral stones and then successfully dissolved with irrigation of cold saline through the ureteroscope. In 4/5 (80%) cases where bilateral ureteroscopy was performed, the lithotripsy of the stone phantoms was deemed easier with the use of the RTP when compared with the control ($P = 0.180$).

Procedure times and laser use

Table 2 provides comparisons of procedure times and laser use in the control and RTP procedures. Use of the RTP significantly shortened the time from initiation to completion of laser lithotripsy ($P = 0.021$). Lithotripsy in ureters with the RTP on average also used less laser energy, although this was not statistically significant ($P = 0.134$).

The mean time to procedure completion was 24.8 minutes and 29.0 minutes with and without use of the RTP, respectively ($P = 0.421$). When RTP was used, an average of 9.6 minutes was needed to instill and dissolve the gel. Notably, none of the investigators had previous experience using the RTP before the first pig, and there was a sharp decline in the amount of time needed to apply and remove the RTP as the series progressed. For example, in the first pig, the time associated with the RTP instillation and removal was 17 minutes, but by the fifth pig, the time was decreased to 7 minutes.

Retropulsion

Table 2 shows that the distance of stone retropulsion during lithotripsy was on average less with the use of the RTP, but this difference was not found to be statistically significant ($P = 0.136$). There was also an apparent qualitative trend for antegrade propulsion of smaller stone fragments in ureters when the RTP gel was present. During the first ureteroscopy with RTP, all stone fragments were flushed out of the ureter into the bladder with the continuous saline irrigation. Movement of these smaller stone fragments antegrade was not captured by our method of measuring retropulsion by the position of the most proximally migrated fragment.

Renal pelvic pressures

There was no significant difference in the baseline, peak, or average pressures in the renal pelvis between the control and the RTP (Table 2).

Histologic examination

There was no difference between groups for the total histologic score or four subcategories: Urothelial integrity, urothelial inflammation, lamina propria inflammation, and musculature integrity (Table 3).

Discussion

One common argument against the use of an antiretropulsion devise is that, in the hands of most experienced surgeons, there is no need to prevent stone retropulsion, because a flexible ureteroscope can still reach migrated

Table 1. Results of Lithotripsy Procedures by Animal

	Ureter	Procedure easier than contralateral side?	Procedure time (min)	Laser time (min)	RTP instillation/ removal (min)	Laser energy (KJ)	Retropulsion length (cm)	Avg. RP pressure (mm Hg)	Peak RP pressure (mm Hg)
Control									
1	Left	No	25	22	—	2.08	5.0	19.7	39
2	Right	No	43	42	—	4.03	4.0	14.7	49
3	Right	No	30	29	—	2.95	5.0	14.7	22
4	Left	Yes	14	14	—	1.86	9.0	24.1	50
5	Right	No	31	30	—	3.71	0.0	28.9	39
6	Left	—	31	31	—	3.04	2.0	24.0	48
RTP									
1	Right	Yes	28	11	17	1.97	0.0	24.1	37
2	Left	Yes	33	21	12	2.83	3.5	22.5	45
3	Left	Yes	16	12	4	1.22	2.5	10.3	20
4	Right	No	28	20	8	2.63	2.5	19.1	50
5	Left	Yes	19	12	7	2.35	0.5	14.1	23
6[a]	—	—	—	—	—		—	—	—

[a]Data for RTP procedure 6 is missing from inability to perform procedure because of a narrow ureter.
RTP = reverse thermosensitive polymer; KJ = kilojoule; RP = renal pelvic.

Table 2. Effects of Reverse Thermosensitive Polymer on Laser Lithotripsy Procedures

	Control	*RTP*	P
Procedure time (min)	29.0 ± 3.86	24.8 ± 3.15	0.421
Laser time (min)	28.0 ± 3.84	15.2 ± 2.18	0.021
RTP time (min)	—	9.6 ± 2.25	—
Laser energy (KJ)	2.95 ± 0.35	2.20 ± 0.28	0.134
Retropulsion length (cm)	4.17 ± 1.25	1.80 ± 0.66	0.136
Baseline RP pressure (mm Hg)	15.4 ± 2.45	13.2 ± 1.58	0.474
Average RP pressure (mm Hg)	21.0 ± 2.33	18.0 ± 2.58	0.410
Peak RP pressure (mm Hg)	41.2 ± 4.33	35.0 ± 5.91	0.425

Data are presented in mean ± standard error of the mean.
RTP = reverse thermosensitive polymer; KJ = kilojoule; RP = renal pelvic.

fragments. Furthermore, some argue that retrograde placement of stones in the kidney may allow for more aggressive and safer lithotripsy.[11] This study demonstrates there may be more advantages to using a RTP than just the prevention of stone retropulsion. In this series, the use of the RTP during laser lithotripsy resulted in a subjectively less challenging and shorter ureteroscopy in 80% and 60% of the cases, respectively, when compared with the contralateral control. Next, the mean laser time needed to properly fragment the stones was 12.8 minutes less with the RTP than without ($P = 0.021$). There was also a trend toward decreased laser energy requirements and a decrease in mean procedure time by 4.2 minutes with RTP use, but unfortunately neither parameter reached significance. The lack of statistical significance in mean procedure time may be partially explained by our lack of previous experience with the RTP, or by the relatively small study population.

Overall, we found the RTP simple to use, and after only two procedures, we were able to consistently decrease our time needed to instill and evacuate the RTP to less than 9 minutes. These findings raise the question, ‘‘Can the use of the RTP in experienced hands result in decreased procedure times and anesthesia costs sufficient to account for the additional expense of the RTP, while maintaining the same efficacy and safety profile?’’

Three previous publications illustrate the use of the RTP in preventing stone retropulsion during ureteroscopy with intracorporeal lithotripsy.[2,6,12] Sacco and colleagues[6] first performed *in vivo* ureteroscopy with lithotripsy of stone phantoms (via an electrohydrolic lithotripter) through open ureterotomies in five pigs. Similar to this experiment, bilateral ureteroscopies were performed with the RTP on one side and the contralateral ureter without the RTP. The first two pigs were immediately sacrificed, and histologic examination of both ureters was performed, while the final three pigs survived 1 week and then underwent harvest of the kidneys and ureters as well as collection of serum and ureteral urine creatinine, urea, and sodium. Retropulsion of stone fragments was prevented in all pigs with RTP use, and there was no difference in histologic or metabolic parameters in either the RTP or control ureters.

Rane and coworkers[2] evaluated ‘‘clinically significant retropulsion’’ in a prospective, randomized, case-control study of 68 subjects undergoing ureteroscopy with lithotripsy of proximal ureteral stones. In the study, retropulsion was defined as either having to convert from a rigid to flexible ureteroscope because of stone migration, having to use a different treatment modality to manage the migrating stone, migration of the stone into the kidney, or the use of interventions such as baskets, wires, or graspers to prevent stone migration. Using this definition, the RTP group experienced a significantly lower rate of retropulsion (8.8%) compared with the control group (52.9%). Also, the two groups were similar in stone-free rates, need for additional procedures, episodes of ureteral occlusion, and adverse events. Unfortunately, this study did not address the differences in operative times with and without the use of the RTP.

Finally, Molina and associates[12] reported the results of seven patients with mid and distal ureteral stones undergoing ureteroscopy with lithotripsy while using the RTP. No episodes of retropulsion occurred as defined as migration of fragments above the RTP.

This *in vivo* porcine investigation is the first to quantitatively evaluate the retropulsion of ureteral fragments with and without the RTP. In 4/5 (80%) procedures in which bilateral ureteroscopy was successfully performed, the RTP lithotripsy experienced shorter retropulsion distances than the control. The mean retropulsion length was less in the RTP group (1.8 ± 0.66 cm) compared with the control group (4.17 ± 1.25 cm), but did not reach significance ($P = 0.136$). Of note, if we used the definition of of retropulsion either Rane and associates[2] or Molina and coworkers,[12] then all episodes of retropulsion were prevented with the RTP.

Several study design factors were implemented to maintain consistency and resemble common practice patterns but may have decreased the potential for retropulsion. First, in humans, the rate of stone retropulsion is higher for proximal ureteral stones when compared with distal ureteral stones, but we placed the stones in the distal to mid ureter to maximize the potential length that a stone could migrate before reaching the kidney.[3] Next, the 200 micron fiber was selected to maximize the maneuverability of the flexible ureteroscope, but the extent of retropulsion is known to increase with larger laser fiber diameters.[5] Also, the holmium:YAG laser was the lithotripsy modality chosen because of availability, safety profile, and familiarity, but other lithotripsy modalities such as electrohydraulic and pneumatic lithotriptors are known to cause greater retropulsion.[13,14] Finally, the fluid irrigation was maintained at 60 mmHg, while other urologists may

Table 3. Effects of Reverse Thermosensitive Polymer on Ureteral and Pelvic Injury as Evaluated by Histologic Scoring

	Control	*RTP*	P
Urothelial integrity	2.7 ± 0.1	2.5 ± 0.2	0.470
Urothelial inflammation	0.1 ± 0.4	0.1 ± 0.0	0.543
Lamina propria inflammation	1.4 ± 0.1	1.2 ± 0.2	0.576
Muscular integrity	1.0 ± 0.1	0.7 ± 0.1	0.147
Total score	5.2 ± 0.2	4.5 ± 0.5	0.275

Histologic scores: 0 = normal, 1 = mild, 2 = moderate, 3 = severe.
RTP = reverse thermosensitive polymer.

perform ureteroscopy at higher or variable irrigation pressures. Although several procedural modalities are known to increase the chance of retropulsion, it is unknown whether changing these factors would have resulted in statistically significant differences in retropulsion lengths between the two groups.

We hypothesized that the RTP would decrease intrarenal pressures by preventing the retrograde irrigation of fluid to the kidney. Suh and colleagues[7] evaluated the the ability of the Accordian®, a multifold mechanical device that completely occludes the ureter, to decrease intrarenal pressures in an *ex vivo* porcine model. Intrarenal pressures were decreased with the use of the device when irrigation was instilled through an 8F flexible ureteroscope at 300 mm Hg but not when irrigation was instilled at 150 mm Hg.[7] In this investigation, there was no significant difference in renal pelvic pressures in either group when saline was instilled at a constant 60 mm Hg, but the study was limited in that intrarenal pressures were not evaluated at higher irrigation pressures.

Sacco and coworkers[6] found no difference in pathologic examinations of porcine ureters after ureteroscopy with lithotripsy with and without the use of the RTP.[6] Likewise, we found no difference in urothelial integrity, muscular integrity, urothelial inflammation, lamina propria inflammation, or total histologic scores between the control and RTP ureters. We do caution the interpretation of these data, because there were limits to our methods. In both groups, examination of the ureters showed severe defects in the urothelium, which reflected in high urothelial integrity scores. It is unknown whether these high urothelial integrity scores were caused during ureteroscopy with lithotripsy or other portions of the procedure such as placement of the 8/10 dilator/sheaths, 13/15 access sheaths, or effects of the postoperative stents.

Although some advantages of RTP use during ureteroscopy with lithotripsy have been demonstrated above, the few potential drawbacks to RTP use were not addressed in this study. First, this model did not evaluated RTP use in the scenario of impacted stones. Placement of the 3F ureteral catheter above an impacted stone may not be feasible or may necessitate a limited lithotripsy to provide passage of the catheter. Next, the additional fluoroscopy time associated with ureteral catheter placement or the retrograde pyelography needed to ensure complete dissolution was not recorded.

Complete dissolution of the RTP was determined by the presence of contrast extending to the upper tract collecting system. Although this method confirms an unobstructed ureter at the time of the procedure, there is admittedly a possibility of retained polymer. We experienced no outcomes, however, that would suggest continued functional obstruction from incomplete dissolution of the RTP. Indeed, Rane and associates[2] found no short-term effects in 34 patients with the use of the RTP. Complete dissolution of the RTP was assumed because of the lack of ureteral obstruction or adverse events.[6] To the best of our knowledge, no study to date has reported instances of incomplete polymer dissolution.

This *in vivo* porcine model has several limitations, some have been described above. The procedure time, retropulsion length, and laser energy usage favored ureteroscopy with RTP use but did not reach significance. Because no previous investigation evaluated these parameters in a porcine model, prospective power calculations could not determine the number needed to reach significance for these variables. Also, because the phenomenon of antegrade propulsion of stones with RTP use is lacking in the literature and none of the investigators had previous experience with the novel RTP, a quantitative method to measure antegrade propulsion was not devised for this study. Future clinical investigations could elaborate on the potential benefits of antegrade propulsion of fragments with RTP use. Finally, it is unknown how these findings will translate to human clinical trials.

Conclusion

The use of a RTP during ureteroscopy with lithotripsy may have clinical advantages beyond the prevention of stone retropulsion. Here, RTP use resulted in decreased laser times by 12 minutes. Total procedure time, laser energy use, and retropulsion length were decreased with RTP use but did not reach significance. Intraoperative intrarenal pressures and postmortem histologic examination were similar between the RTP and control groups. In light of the information given, further investigations are warranted to fully understand the advantages of RTP use during ureteroscopy with lithotripsy.

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Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

IM = intramuscular
RTP = reverse thermosensitive polymer
YAG = yttrium-aluminum-garnet