

# **Putting Post-Procedure Catheterization into Perspective**

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The sentiments expressed within this article are representative of the opinions and experiences of the respective physicians. Drs. Cantrill, Chughtai and Pearlman are Boston Scientific consultants and were compensated. Physician experience and patient responses can and do vary.

Benign prostatic hyperplasia (BPH) is a long-term disease, so patients are looking for a long-term solution. One effective and enduring procedure for treating BPH is Rezūm™ Water Vapor Therapy.¹

"Every patient who comes to see me wants to empty their bladder better and get off of their medications," Dr. Christopher Cantrill said. "Rezūm Therapy does a great job of meeting that goal," he said.

For men suffering from BPH, this minimally invasive water vapor thermal therapy leads to significant, sustained improvement of lower urinary tract syndrome (LUTS) and quality of life through five years after the procedure.¹ Rezūm Therapy is the only minimally invasive surgical therapy recommended by the American Urological Association for the treatment of obstructive middle lobes.² In a small, retrospective, head-to-head study with the UroLift™ system, which uses clips to lift the enlarged prostate out of the way to relieve the symptoms of BPH, Rezūm Therapy delivered greater IPSS improvements and a lower reintervention rate at 12 months (25% for UroLift vs. 8.3% for Rezūm Therapy).³ These results align with the pivotal studies for both procedures; in fact, five years post-procedure, only 4.4% of Rezūm Therapy patients required surgical retreatment¹ compared to 13.6% for UroLift (with no reports of de novo device related erectile dysfunction with either device).\*⁴

For many patients, the main drawback to Rezūm Therapy is that it typically requires the patient to be catheterized for a few days after the procedure. However, catheter use is expected for many transurethral procedures.<sup>5</sup>

We talked to several leading urologists about how they talk about catheterization with patients and how they manage patient expectations.

#### Catheterization as a Part of Rezūm Therapy

"For Rezūm Therapy patients, a catheter is usually left in post-procedure because patients will likely have an inflammatory response to the procedure and swelling may make it difficult or impossible for them to urinate," said Dr. Bilal Chughtai.

"If the tube swells shut, there are going to be a lot of problems," said Dr. Cantrill.

Putting a catheter in is better than having the patient "feel uncomfortable, like they're not emptying their bladder, not sure if they're in retention, need to go to the ER, or just feel terrible urinary symptoms," said Dr. Amy Pearlman.

# Discussing the Pros and Cons of Catheterization

When discussing the drawbacks of the Rezūm Therapy procedure, one patient said that, for him, having a catheter was "the only downside" to the Rezūm Therapy procedure.

Dr. Pearlman said that patients tend to fall into one of three categories when it comes to catheterization:

- They don't mind the catheter
- It's bothersome, but they'll get through it
- They are significantly bothered by the catheter

"For patients in the last category, Rezūm Therapy may not be the right option," she said.

Aside from the discomfort, some patients worry about the inconvenience and embarrassment of wearing a catheter. <sup>6</sup> But typically, physicians can find an option that suits the patient. For example, during the day, some patients choose to wear a bag strapped to their leg inside their pants that collects the urine because it is less obtrusive than other types of bags, while they have a different bag at night. Or others may choose a flip-flop valve that allows patients to forgo the bag all together (see sidebar).

"Among the benefits of catheterization, aside from keeping the patient's urinary tract open, is that it supports the body's natural healing process, allowing the tissue to repair itself, the swelling to go down, and the symptoms to improve," Dr. Chughtai said. "Leaving a catheter for a short period allows patients to recover after the procedure, leading to greater patient satisfaction," Dr. Cantrill said.

"Having a catheter following a transurethral procedure doesn't necessarily mean something went wrong," he said. "In fact, patients may actually be more comfortable with a catheter."

"They will sleep all night, and there is little risk they will have to go to the emergency room due to blockage," Dr. Cantrill said. "Their body just needs time for the inflammatory response to subside."

In fact, Dr. Cantrill recalls that a few years back after having done several Rezūm Therapy procedures, he started treating patients and not leaving a foley if they were able to do a clean intermittent catheterization (CIC). Overall, the patients did not do well. He said, "They had significant urgency and incidences of catheterization trauma in that three-day period. This generated a great deal of calls of patients frustrated or confused by their symptoms. I stopped doing that and overwhelmingly patients have a much better recovery as a result."

However, it should be noted that urinary catheter placement may cause urethral trauma and poses a risk of infection.<sup>7</sup>

# **Preparing Patients for Catheterization**

It's best if physicians cover catheterization as part of their care instructions both before and after a Rezūm Therapy procedure. For example, Dr. Cantrill explains to them why he uses a catheter, why they need it, and what the benefits are. "Patients who have no idea what will happen during the process will be very stressed out," he said.

"Be up front and honest with patients," Dr. Cantrill said. "Build a partnership with them – invest in your patient relationship. Five minutes of your time will save you 50 minutes later of an angry patient yelling at your staff and yelling at you."

Often physicians have video scripts that the patient can watch and learn about Rezūm Therapy and about what it means to have a catheter for a few days after the procedure.

Many patients are "scared" at first when they see a long list of catheter care instructions, but they usually relax once they realize that the care is "pretty straightforward," Dr. Chughtai said. "The key is to explain to the patient what is happening and why."

"As long as patients understand what a catheter is, how long it's going to be there, and the fact that it's going to be temporary, I think most patients are willing to accept a catheter for a short period of time," Dr. Chughtai said.

#### Managing Patient Expectations for BPH Therapy

As part of the discussion about their condition and what therapies are available to treat it, Dr. Cantrill discusses the pros and cons of each option. For example, Dr. Pearlman recorded a webinar that goes through all of the BPH treatment options covering lifestyle modification, medications, and the different therapeutic options, which she posts on her website.

"Rezūm Therapy isn't right for every patient, UroLift isn't right for every patient, TURP isn't right for every patient," Dr. Cantrill said. "Our job is to help them find what that right thing is for them."

Dr. Pearlman tries to get a sense for which procedure they would be the best candidate for, even if it means referring them to another physician.

"I tell my patients that my goal is to guide them on what I think the best option is, and that may or may not be something that I personally offer," she said.

In discussing BPH, she shows them models of the bladder and prostate and shows them pictures of Rezūm Therapy. She scopes them while they are awake to show them what the procedure will do and to discuss the health of their bladder.

The patient discussion should set expectations. "For example, a patient might have many causes for their urinary symptoms only one of which is an enlarged prostate," Dr. Pearlman said. That could include anything from sleep apnea or drinking a lot of coffee or soda."

"Rezūm Therapy is not going to fix someone drinking a pot of coffee in the morning," Dr. Pearlman said. "I can address the big prostate part, but only the patient can reduce their coffee intake."

At the conclusion of the visit, Dr. Pearlman sends them home with instructions to watch a video and read about the procedure.

"I tell them, 'Hey, you don't have to make any decisions today, so why don't you go home and think about it?'" Dr. Pearlman said. "I would never put pressure on someone to make a decision at that point."

# Putting Catheterization in the Context of the Overall Procedure

"The discussion about which therapy is best for any given BPH patient often includes a whole host of issues associated with each alternative, such as catheters, sexual function, infection, recovery time and durability," Dr. Cantrill said. Here are the key questions about Rezūm Therapy and how to put them in context:

- Ejaculatory dysfunction: Dr. Chughtai tells patients concerned about ejaculatory dysfunction that the research shows that this is rare in Rezūm Therapy and in other minimally invasive therapies. But, Dr. Pearlman adds, "The only way to completely avoid ejaculatory dysfunction is not to do a procedure involving the urinary tract."
- Infection: Any procedure involving a catheter (or any invasive procedure) increases the risk for infection,<sup>5</sup> and that's why Dr. Pearlman prescribes her patients antibiotics while they have the catheter in place and even for a few days after it comes out. If her patients' symptoms, such as urgency, frequency and night-time urination, get better then worse again, she tells them that they need to get tested for infection.
- Recovery time: "The biggest overall concern patients have about Rezūm Therapy is the recovery time," Dr. Chughtai said. Research indicates that patients who have UroLift generally have a relatively quick recovery, while those who get Rezūm Therapy may take a few months to fully recover, due to the body's natural healing process. But it's important to note that recovery doesn't equal discomfort. Many Rezūm Therapy patients are

- perfectly comfortable while still healing and most men return to regular activities within a few days.\*\* "Once the catheter is removed, patients no longer have any activity restrictions," Dr. Pearlman said.
- *Durability*: One of the most significant benefits of Rezūm Therapy compared to other minimally invasive procedures, such as UroLift, is its durability. Through five years, the surgical retreatment rate with Rezūm Therapy was 4.4%, compared to 13.6% for UroLift, in the pivotal studies.\*4

"When I explain to them that long-term durability may require enduring a catheter for a couple of days, a lot of my patients are willing to accept that," Dr. Chughtai said.

# Patient Understanding and Preparation Contribute to a Better Outcome

Patients need to understand their condition, the pros and cons of the alternative therapies to treat it, and how best to prepare for the therapy. When it comes to Rezūm Therapy, this includes understanding that the procedure provides significant symptom improvement and has demonstrated long-term durability;<sup>1</sup> but it also includes understanding the need for a catheter and putting that need into context. A well-prepared patient who goes into Rezūm Therapy with confidence and reasonable expectations will enhance his chances of having the best possible outcome.

#### SIDEBAR 1

# What Kind of Equipment to Provide Catheterized Rezūm Therapy Patients

We have already seen that the education and understanding provided to patients can determine their attitude toward and experience with post-procedure catheterization. We asked our urologists what type of equipment they use in catheterized patients and why.

- **Type of catheter:** A 16 French catheter is preferred by many. Dr. Cantrill likes a council-tip catheter because they're a little bit stiffer and easy to place when using the channel of the scope. On rare occasions, Dr. Pearlman will go up a size to an 18 French catheter, particularly in those patients who stay on their anti-platelet or anticoagulation medications through their procedure. If the patient has a high bladder neck, then she will put in a coudé catheter.
- **Urine collection devices:** For day-time use, a leg bag is often used. Dr. Chughtai prefers taking an extra few minutes to review leg bag placement and guidelines for avoiding catheter pulling to focus on comfort care. He says a few minutes here can make the whole experience with the catheter more tolerable. "A flip-flop valve allows patients who do not want a bag, the convenience of a one-way valve attached to the end of the catheter," Dr. Cantrill said. When the patient needs to urinate, the catheter will wind up, signaling them to go to the bathroom, open the valve and drain the catheter into the toilet. This allows patients to discretely keep their catheter hidden and when they need to void they can use the valve to drain their bladder. This is a good option for patients who need to return to an office setting after the procedure, as they can easily conceal the catheter from those around them. For *night-time use*, most patients get an evening bag, which doesn't have to be hidden or secured to the body.

#### SIDEBAR 2

#### The Four Pillars for Addressing the Patient

In meeting with a patient to discuss their condition and how to treat it, Dr. Pearlman finds that the art of medicine, when it really works well, consists of answering four questions:

- What does the research tell us? For Rezūm Therapy, we have five-year follow-up data. We know that the benefits can remain strong at five years, but we do not know yet how strong the benefits of the procedure will be after seven or 10 years.
- What do guidelines summarize for us? Regarding Rezūm Therapy, the American Urological Association recommends this type of therapy as an option for patients with a prostate volume of 30-80cc, including patients with a median lobe and to eligible patients who desire preservation of erectile and ejaculatory function.<sup>2</sup>

- What are the goals of our patients? Rezūm Therapy poses risk of some uncomfortable short-term side-effects post-procedure, such as urgency, frequency, catheterization, painful urination, blood in the urine or semen, retention, and UTI. Many patients still choose Rezūm Therapy because it is effective and durable; however, some patients prefer to avoid the potential post-procedure discomfort and choose an alternative therapy.
- What is my own experience with patients? I have found that few of my Rezūm Therapy patients complain about short-term discomfort from the procedure; overall, I have been happy with my patients' outcomes and experience.

#### SIDEBAR 3

# How Long to Leave the Catheter in Post Rezūm Therapy

How long the catheter is left in after a Rezūm Therapy procedure varies by such factors as the physician, the technique, the size of the prostate gland, and the patient. In the Rezūm Therapy pivotal trial, patients received a catheter for an average of 3.4 days.<sup>1</sup>

Dr. Pearlman leaves the catheter in for "a little bit longer" than others because she wants to avoid patient issues, such as "urgency, frequency and night-time urination." She acknowledges that there are "no perfect options." Dr. Pearlman will also take out the catheter earlier if the patient is willing to self-catheterize if they begin to have trouble urinating. "My goal is to minimize any trips to the emergency room in urinary retention. As a result, I steer towards slightly longer catheterization compared to those used in clinical trials and have all of my patients who are willing to learn how to perform clean intermittent catheterization do so at time of catheter removal, just in case."

Dr. Chughtai bases how long he leaves the catheter in on how many treatments the patient has received. "For example, if only one lobe is treated, the patient may need a catheter for only one to three days," he said. The more treatments the lobe gets or the weaker the bladder functions, the longer the catheter should be left in.

"If we did a total of four treatments, it's usually three to four days. But the bladder function plays a huge role in how long the catheter is in for," Dr. Chughtai said. Dr. Pearlman agrees that how well their bladder functions also ties into how long the catheter should stay in.

Dr. Cantrill typically leaves the catheter in for up to three days because he estimates only 5% of patients require catheterization for longer than three days. For those who are unable, he says a short-term CIC or a foley for a few additional days is indicated but "the vast majority of patients are able to void," which helps to decrease post catheter UTI rates and increase overall patient satisfaction. For large glands or patients who have larger pre-procedure post void residuals, however, Dr. Cantrill will leave the catheter in for up to five to seven days. He adds, "another reason to leave a catheter in a little longer is for patients with very large median lobes that require more than two treatments."

"I tell patients: you're going to forget about these three days of having a catheter, three months down the line when you're doing better," Dr. Cantrill said.

"As physicians have refined their techniques in using Rezūm Therapy, they have gotten better at understanding how long their patient will need a catheter – and ways to limit how long a catheter will be necessary," Dr. Cantrill said.

"Deeper application of vapor in a Rezūm Therapy procedure leads to less irritative symptoms and, as a result, shorter catheter times," Dr. Chughtai said. In addition, if during the procedure he sees the tissue blanching, or if there is a vapor leak, Dr. Chughtai will reposition the device and redo the treatment. "By precise positioning of the vapor, there is less opportunity for the vapor to leak back into the urethra and cause urethral irritation," he said.

#### References and Disclaimers

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