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Treatment of Post, High-Intensity-Focused Ultrasound Urethral Stricture with Novel Long-term Stent

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ABSTRACT

Urethral strictures (US) can be recurrent chronic illnesses leading to severe side effects and poor quality of life. Several options to treat US exist, including repeated dilatations, stents, and open surgery. A urethral stent is a good, minimally invasive option but has major limitations, such as stent migration, mucosal growth, and incontinence, especially for bladder-neck strictures. Herein, we describe a new stent that, due to its design, may solve some of the above-mentioned problems, enabling long-term use and safe removal.

CASE REPORT

A 66-year-old presented to us who, three years earlier, had undergone high-intensity-focused ultrasound (HIFU) treatment for organ-confined (Gleason score 3+4) prostate cancer. Approximately 3 months after the procedure, he presented to his local urologist with progressive-obstructive voiding symptoms that were managed endoscopically via visual internal urethrotomy, followed by a transurethral resection of stenotic scar tissue. Afterwards, he underwent repeated endoscopic treatment for restenosis every 10 to 12 weeks. A typical pre- and post-treatment endoscopic view is shown in Figure 1. Upon arrival at our medical center, the patient underwent a rinary ultrasound that revealed a normal upper urinary tract, small prostate, and 240 ml of post-void residual urinary volume. Uroflowmetry demonstrated an obstructive pattern with maximal urinary flow of 5.6 ml/sec. A cystoscopy demonstrated a tiny opening of the urethra at the level of the prostatic urethra/bladder-neck area. The patient was referred for an Allium round posterior urethral stent (RPS) placement.

Description of the Allium RPS Stent

The Allium RPS system is indicated for the management of bladder outlet obstruction in adult males. The stent, presented in Figure 2 and Figure 3, is a large-caliber, long-term, fully covered stent made of a self-expandable Nitinol skeleton covered with a thin membrane of biocompatible and biostable copolymer. The entire skeleton of the RPS is made of a single Nitinol wire. The copolymer covers the entire stent body and its anchor to prevent intraluminal tissue ingrowth. It has a single length of 40 mm, a 45 Fr round cross-section, and is composed of 3 segments: body (40 mm), anchor (14 mm), and trans-sphincteric wire, which connects the body to the anchor.

KEYWORDS: High-intensity-focused ultrasound; Urethral stricture; Long-term urethral stent

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case report
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Figure 1. Typical endoscopic view of the bladder neck area of the case presented before and after transurethral resection.
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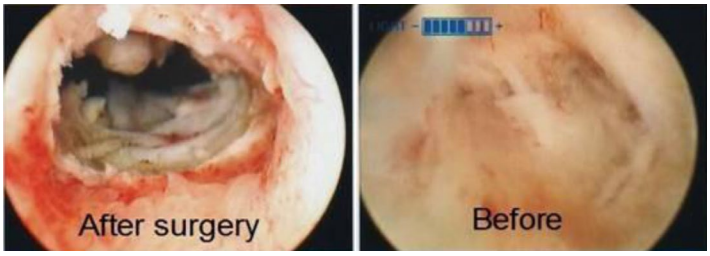

Figure 2. Allium round posterior stent (RPS) with its insertion device, demonstrating body, trans-sphincter wire, and anchor.
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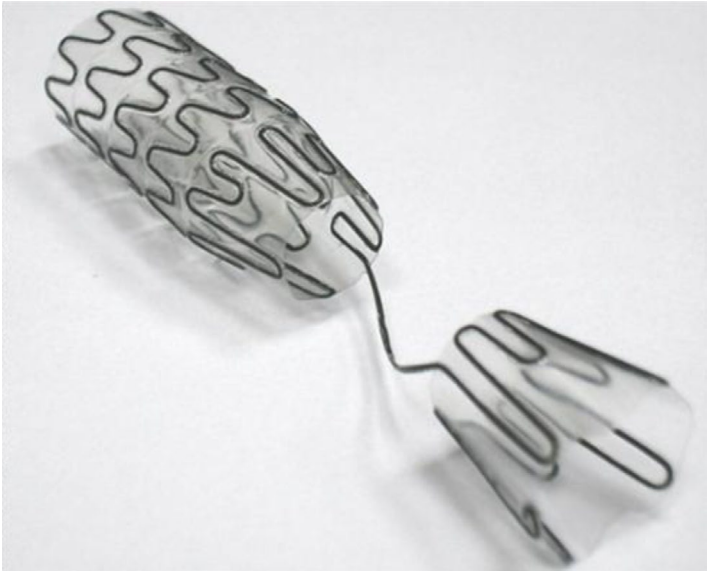

Stent Insertion

The procedure was done under spinal anesthesia with the patient in the dorsal lithotomy position. Initially, a retrograde urethrography was performed to evaluate the length of the structure and to mark the urethral sphincter's exact location. This was followed by a cold-knife visual internal urethrotomy at the 5, 7, and 12 o'clock positions. After dilating the occluded prostatic urethra and bladder neck, the RPS was inserted using a special delivery system (Figure 4), which was done under fluoroscopy. Once located in the target area, the delivery system was gradually removed from the urethra and, simultaneously, the stent was released, leaving the body in the prostatic area and the anchor in the bulbar segment. To verify the stent's patency, a second urethrography was performed (Figure 5), and at the end of the procedure, no catheter was left.

Follow-up

Postoperatively, the patient reported mild perineal discomfort with few episodes of urge incontinence, but no bleeding. After 2 weeks, the patient was fully continent for the next 12 months. One episode of urinary tract infection occurred 4 months after the stent insertion, which was controlled by a short course of oral antibiotics. At 1 year under local anesthesia, the RPS stent was removed endoscopically by simply pulling its anchor end, situated in the bulbar urethra, using standard biopsy forceps. Now, 8 months after stent removal, the patient voids spontaneously, emptying his bladder adequately with complete urinary control.

Figure 3. Allium round posterior stent (RPS) with its insertion device, demonstrating body, trans-sphincter wire, and anchor.
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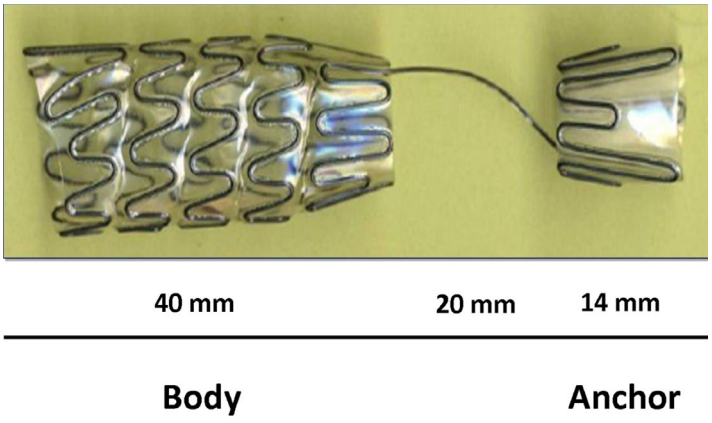

DISCUSSION

In recent years, a number of ablative therapies have been introduced for the management of localized prostate cancer, including cryosurgery, high-intensity-focused ultrasound (HIFU), radio frequency ablations, and photodynamic therapy, which are in various stages of evolution, evaluation, and clinical implication. HIFU treatment relies on the physical properties of ultrasound, which allows it to be brought into small focus at the target tissue. When the energy density at the focus is sufficiently high, thermal tissue damage occurs through coagulative necrosis [1]. Despite being a minimally invasive procedure, HIFU treatment is associated with morbidity. The most common complications after HIFU treatment are stress urinary incontinence, urinary tract infection, urethral/bladder neck stenosis or strictures, and erectile dysfunction. In a recent literature review performed by the French association of urology, the rate of urethral stricture reaches up to 31% [2]. With similar results (30.2%), the intervention rate for stricture or retained necrotic-tissue removal were described by Ahmed HU et al. who summarized the first 172 men treated in the UK. About half of the strictures are managed by urethral dilation on local anesthesia while the other half require anesthesia and bladder-neck incision and/or resection [3]. The HIFU device enables transformation of the energy delivered into heat reaching between 56°C up to 90°C. Such temperatures can cause urethral strictures due to protein denaturation. Some of them may involve the periurethral tissue, resulting in extensive fibrosis giving rise to resistant urethral stricture [4]. Most often, such strictures are initially managed either by balloon dilation or visual internal urethrotomy. Unfortunately, for some of the patients, early treatment failure is observed, and after the third endoscopic treatment, the success rate is extremely low [5]. Alternative endoscopic options for the management of stenotic bladder neck areas include endoscopic resection using either cold-knife or laser energy, combined with steroid or mitomycine C injection to inhibit scar regrowth [6,7]. The transurethral resection of scar tissue at the bladder neck provides a modest chance of successl in treating recurrent stenosis. After endoscopic technique failure, a patient may be offered an open surgical reconstruction of the scar tissue. This treatment option is technically demanding and would typically leave the patient incontinent. A completely different approach is the use

Figure 4. Showing the expanded stent located at the prostatic urethra.
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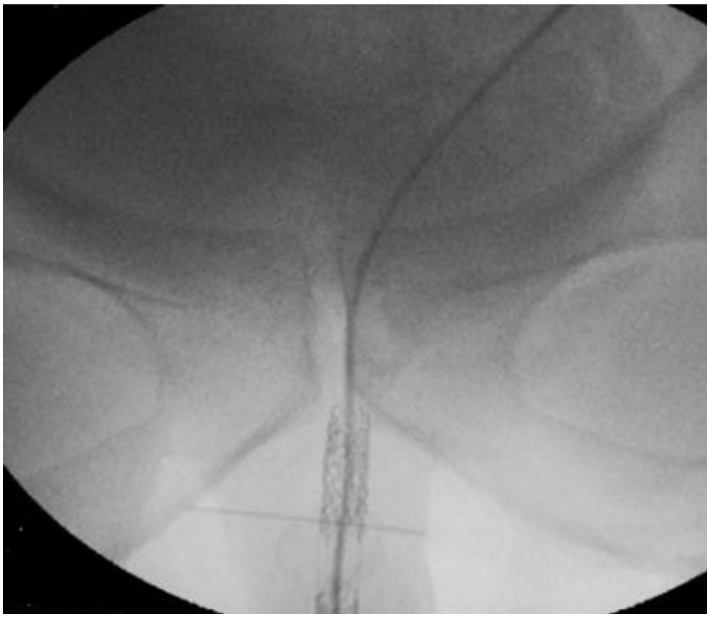

Figure 5. Showing the expanded stent located at the prostatic urethra.
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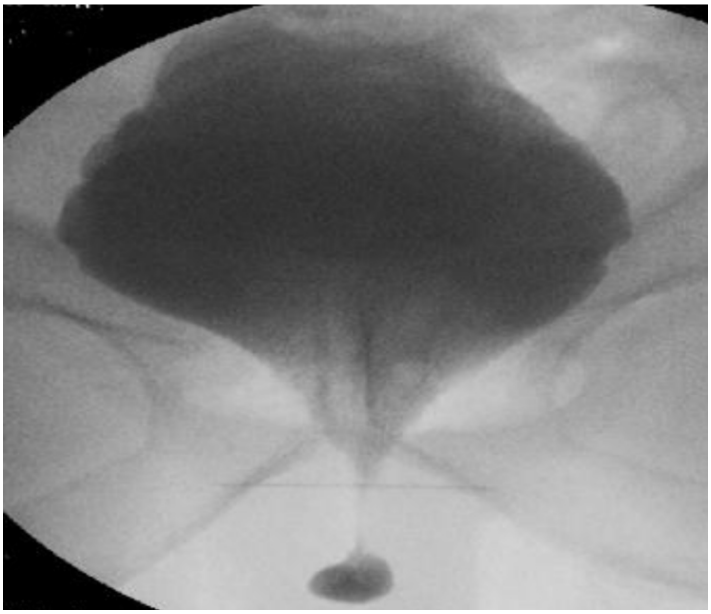

of an intraurethral stent, which may be either permanent or temporary. Elliot SP et al. reported their experience with 10 cases, using the UroLume permanent stent. Unfortunately, this stent, if placed near the trigon, might cause urinary irritative symptoms, can be occluded by calcification or by scar tissue, and, once inserted, the endoprosthesis is extremely difficult to remove, requiring an open surgical approach [8]. Henderson et al. described their experience with the Spanner temporary urethral stent to relieve bladder outflow obstruction after prostate brachytherapy [9]. Although they were not treating resistant strictures, and no prior endoscopic treatment was performed, they reported early (after 7 days) stent removal due to severe discomfort, while the remaining 60% were able to hold the stent for the planned 30 days.

In the case presented, we describe successful management of post-HIFU, severe bladder-neck and prostatic urethral strictures using a new temporary urethral stent called the Allium RPS. It is a temporary long-term and temporary self-retaining intraurethral stent. Insertion of the stent is simple, and its positioning is under fluoroscopy while the removal can be done as an outpatient procedure under local anesthesia. Being covered by a thin copolymer, intraluminal ingrowth was prevented, allowing the stenotic area to remain open for the duration of 1 year in which no bladder discomfort or incontinence were reported. During 7 months of post-stent removal follow-up, no outflow obstruction developed and the patient is able to completely empty the bladder. This favorable outcome may be related to an extended duration (1 year) of the stent that enabled bladder neck remodeling and stabilization of the periurethral scar tissue. Finally, this minimally invasive treatment alternative is more efficient than current endoscopic treatments, is safe, tolerable by the patient, and more cost-effective.

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