Optilume® drug-coated balloon dilation in complex female urethral stricture

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ABSTRACT

The treatment of female urethral stricture disease is in flux in terms of developing guidelines for surgical treatment. Urethral strictures in women are rare, but frequently result because of urethral instrumentation or surgery. Stricture sites vary from proximal, intrasphincteric, distal or at the meatus. Stricture formation after previous urethral surgery may pose a special challenge. We describe the first Optilume® urethral drug-coated balloon dilation for female urethral stricture disease involving the sphincter. After six months follow-up the patient remains stricture free with full continence and complete bladder emptying.

1. Introduction

Female stricture disease is rare. Contemporary treatment includes dilation (usually only once) and after failure a graft augmentation urethroplasty. Direct vision internal urethrotomy (DVIU) is questionable because of potential damage to the female urethral sphincter. Furthermore, a large prospective randomized comparison showed no significant difference between urethral dilation and DVIU in the treatment of male urethral stricture disease. Europe granted CE Mark approval for Optilume®, the paclitaxel-coated balloon dilation technology in September 2020. Published studies were limited to bulbar strictures ≤2cm in male patients, excluding the sphincter. We describe the first case of drug-coated balloon (DCB) dilation in a female patient with urethral stricture disease involving the sphincter. This patient suffered from urethral stricture disease due to multiple previous urethral surgeries.

2. Case presentation

A 50-year-old woman presented with bladder outlet obstruction and residual urine after micturition. It was maximally possible to pass a 10Fr transurethral catheter. Her previous history included urethral surgery involving the removal of a large semicircular urethral diverticulum (Fig. 1) four years prior to present symptoms. The patient also underwent a vaginal hysterectomy. She then developed vaginal vault prolapse, corrected by anterior colporrhaphy. Careful rigid paediatric endoscopy confirmed a 1.8 cm tight fibrotic stricture involving the sphincteric urethra (Fig. 2). Treatment options after previous urethral surgery are limited. Various treatment possibilities include simple urethral dilation, open graft augmentation urethroplasty or off-label use of DCB dilation. The patient opted for DCB dilation and full consent was obtained. The procedure followed in general anaesthesia after confirming sterile urine by culture. After placing a transurethral guidewire, the 3cm Optilume® DCB was positioned to overlap the stricture on both ends (Fig. 3). Balloon dilation followed to 30Fr for 10 minutes after which a 14Fr transurethral catheter was placed for two days. The operation and follow-up were without complications. Six months after the procedure the patient has a good urinary stream (Qmax 26ml/s) without residual urine. It was possible to pass a 16Fr transurethral catheter without signs of obstruction, which is one of the contemporary follow-up parameters after stricture treatment. The patient was very satisfied with the outcome. She would also recommend it to other patients with similar symptoms and signs, especially as an alternative to surgery.

3. Discussion

This is a single patient, who may have done equally well with a balloon dilation of the area. Previous studies report quick short-term recurrence of stricture disease after second or third dilations. Unclear are the outcomes after treatment with dilation of stricture disease...
post-surgery. Drug-eluting coronary and peripheral artery dilatation and stents are widely used in cardiology and angiology. Paclitaxel or similar drugs aim to inhibit vascular smooth muscle cell proliferation and migration, but may also impair reendothelialization. The accepted mechanism of action is to stop cell cycle progression by inhibiting DNA synthesis. Large studies still have to confirm the advantage of this expensive technology over uncoated balloons or bare stents. Recurrent urethral stricture disease is annoying for the patient and difficult to treat. The development of new technology may open new ways to treat primary strictures. In this patient with a complex urethral stricture after previous vaginal and urethral surgery, although short term, the outcome is promising. It also demonstrates that the 30Fr balloon dilation within the urethral sphincter did not interfere with the continence mechanism over a period of six months. A prospective randomized controlled trial shows higher patency rates at one year of follow-up in the Optilume® group compared with the DVIU/dilation group for anterior urethral strictures in male patients.3

4. Conclusion

The treatment of a complex urethral stricture in a female patient with drug-coated balloon technology seems promising and successful in the short term with a follow-up of 6 months. No damage seems to occur when used within the urethral sphincter. As with drug-eluting devices in angiology proper studies in urology will steer the way towards better design, drug alternatives, application, repeatability, and long-term follow-up. One case report does not warrant any therapy conclusions.

Consent

Patient data anonymized and consent obtained for publication of data.

Declaration of competing interest

None.

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Fig. 1. T2-weighted MRI sagittal images a) large periurethral diverticulum before excision, b) multiple periurethral glands four years after surgical removal of diverticulum.

Fig. 2. Endoscopic image of female urethral stricture after careful dilation.

Fig. 3. Inflated Optilume® drug-coated balloon 30Fr within female urethra.
agencies in the public, commercial, or not-for-profit sectors.

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