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Is Urethrotomy as Good as Urethroplasty in Men with Recurrent Bulbar Urethral Strictures?

Nadir I. Osman, Christopher R. Chapple *

Department of Urology, The Royal Hallamshire Hospital, Sheffield, UK

Direct-vision internal urethrotomy (DVIU) and urethral dilatation (UD) have traditionally been considered as first-line treatments for primary bulbar urethral strictures in men. A randomised clinical study demonstrated no significant difference in recurrence between the two as treatments for anterior urethral strictures, with one-third of men having had prior treatment. The recurrence rate at 12 mo was approximately 40% for strictures <2 cm, 50% for strictures of 2–4 cm, and 80% for strictures >4 cm. The recurrence rate for strictures of 2–4 cm increased to 75% at 48 mo. For each 1-cm increase in length of the stricture, the risk of recurrence increased by 1.22 [1].

In recurrent urethral strictures, repeat DVIU and UD are considered to have poor outcomes unless combined with intermittent self-dilatation (ISD). Supportive evidence for this (not considering stricture length or site) is that the recurrence rate after a second DVIU/UD for a stricture recurring by 3 mo was 50–70% at 24 mo and 60–100% at 48 mo [2]. After a third DVIU/UD, the recurrence rate at 24 mo was 100% [2]. Thus, conventional wisdom has been that after a second DVIU/UD, further minimally invasive interventions are palliative. This is reflected in the International Consultation on Urological Disease guidelines, which recommend that men with bulbar strictures that recur within 6 mo or have failed to respond to a second DVIU/UD should be offered urethroplasty [3].

In this issue of European Urology, Goulao et al [4] report results from the OPEN trial. This is the first multicentre randomised controlled trial comparing DVIU directly with urethroplasty in men with a recurrent bulbar stricture. The primary as-randomised analysis included 69 (63%) and 90 (81%) of those allocated to urethroplasty and DVIU, respectively. While at 24-mo follow-up, both groups had a similar improvement in the primary outcome of voiding symptom score, men undergoing DVIU were twice as likely to undergo reintervention as men undergoing urethroplasty (29 vs 15; hazard ratio 0.52, 95% confidence interval 0.31–0.89). Other secondary outcomes of time to reintervention and change in maximal flow rate favoured urethroplasty on average, with similar results homogeneous across different subgroups [4]. This pragmatic study is an excellent attempt to establish the relative efficacy of DVIU and urethroplasty in real clinical practice.

Several aspects of the study design are worthy of discussion. Recruitment was problematic, with only 222 out of 853 eligible patients randomised. Of those not randomised, 306 declined, attributable to a preference for urethroplasty in 60% (Supplementary Table 1 [4]). This is understandable given that many patients who have had a failed prior intervention would be reluctant to be included in a study that has a 50% chance of randomisation to the same intervention. Indeed, the majority of patients had undergone more than one prior DVIU, with a median number (standard deviation) of 1.8 (1.7) and 1.9 (2.0) for the DVIU and urethroplasty groups, respectively. It is not clear whether those declining to take part had more difficult strictures. Retaining patients was also challenging, such that overall only 72% could be included in the primary analysis, with 81% and 63% in the urethrotomy and urethroplasty groups, respectively. The authors have attempted to address this issue in the statistical analysis.

DVIU is a routine and commonly performed procedure, in contrast to urethroplasty. Although a volume-outcome relationship is yet to be described for urethroplasty, surgeon experience and cases performed per centre are likely to be important factors. These data are not presented. The type of

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* Corresponding author: Department of Urology, The Royal Hallamshire Hospital, Glossop Road, Sheffield S10 2JF, UK.
E-mail address: c.r.chapple@shef.ac.uk (C.R. Chapple).
procedure performed is also relevant, as it is recognised that recurrence is higher for augmentation compared to anastomotic urethroplasty. In the urethroplasty arm, 16.6% and 48.5% of procedures were anastomotic and augmentation, respectively (Supplementary Table 2 [4]). A further factor that may influence outcome is stricture length, which was relatively short in both groups (DVIU 1.7 cm, urethroplasty 2.0 cm) but not significantly different. Bulbar stricture lengths reported in the literature are in general longer [5], so shorter stricture length may have biased DVIU in comparisons of efficacy.

Most postoperative complications of urethroplasty are infection-related. A low postoperative infection rate of 8.6% was reported for the urethroplasty group (wound infection 4.9%, urinary infection 3.7%). This is similar to contemporary real-world data from the British Association of Urological Surgeons audit of 957 bulbar urethroplasties (40 surgeons, 35 centres), for which the 30-d complication rate was 5.9% [6]. At face value this suggests that the case mix in the study is representative of real clinical practice and that surgeon experience and volume were not skewed towards highly specialised surgeons operating in high-volume centres.

How best to assess outcomes has been a point of much discussion in urethral surgery. Most clinical series have focused on the “need for further intervention” to define success or failure and have ignored symptoms. The authors should be commended for focusing on patients’ symptoms in the primary outcome and using a validated patient-reported outcome measure [7]. Nevertheless, it is inevitable that surgeons will be drawn to “harder” measures such as re-intervention rates or anatomic recurrence as the metrics most helpful to informing their clinical practice.

Although the study did not report anatomic recurrence, it did report reintervention. In the per-protocol analysis, 15/71 (21.1%) men had a reintervention after urethroplasty compared to 29/93 (31.2%) after DVIU. In the as-randomised analysis, 15/93 (16.1%) men post urethroplasty had a reintervention compared to 29/104 (27.9%) after DVIU. At face value, this challenges some of the long-standing assumptions held about how much better urethroplasty is than DVIU/UD for recurrent bulbar stricture.

It is important to discuss what constitutes a reintervention as there is some inconsistency in the literature. Some consider it as a further urethroplasty, while others set the bar lower at a further DVIU/UD. Still others, including us, are stricter considering the need to perform ISD as reintervention. We hold this view, as for many of our patients avoiding the need to perform lifelong ISD is one of the main reasons they choose urethroplasty over repeat DVIU/UD. Thus, we consider it to be an outcome important to patients. The study definition of further intervention did not include ISD and it is not clear what proportion of patients needed to perform long-term ISD in each group. We can see that no patients randomised to and receiving urethroplasty commenced a regimen of ISD; the data for those randomised to and receiving DVIU are not provided (Supplementary Table 2 [4]).

It is well recognised that the most accurate means of follow-up for patients after stricture surgery is direct visualisation using endoscopy or urethrography [8]. Both symptomatic improvement and flow rate can be misleading in terms of whether a stricture has recurred, as the flow rate with a normally functioning bladder does not diminish until the calibre of the urethra falls below 11Fr [9]. The absence of an anatomic outcome is a potential criticism of the study but is reflective of the pragmatism in the design and the emphasis on patient-reported measures.

The OPEN trial is the first study to provide high-quality evidence to support the recommendation that urethroplasty is the most effective treatment for recurrent bulbar strictures in contemporary practice. Despite the limitations, the authors should be congratulated on constructing and executing such an ambitious study. In particular, we would like to pay tribute to the late Professor Robert Pickard for his major contributions to this study and the advancement of evidence-based reconstructive urology.

**Conflicts of interest:** Neither of the authors has any relevant conflicts of interest to disclose apart from the fact that they agreed to participate in the OPEN study, but all patients declined participation as they had all had a prior intervention and were not prepared to undergo a further DVIU.

**References**


