



Clinical Commissioning Policy Proposition:

Urethroplasty for benign urethral strictures in adult men

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Clinical Commissioning Policy Proposition: Urethroplasty for benign urethral strictures in adult men

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Equality Statement

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Plain Language Summary

Urethroplasty is a surgical procedure to repair injury or defects in the walls of the water pipe (urethra), the duct by which urine leaves the body from the bladder. These injuries or defects may be caused by injury, infection, or inflammation and can cause reduced flow or blockage of urine, or other complications. It mostly affects men.

The first treatment typically includes widening of the urethra to allow better flow of urine; however, in a small number of patients this procedure is not effective in controlling their symptoms. Where this is the case, a reconstruction of the urethra (otherwise known as urethroplasty) is proposed to help alleviate the symptoms of disease. While European Association of Urology (EAU) guidelines exist for this procedure, there is currently unequal access to this treatment for men across England.

NHS England has concluded that there is sufficient evidence to support a proposal for the routine commissioning of urethroplasty for treatment of benign (non-cancerous) urethral strictures in adult men.

1. Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to routinely commission urethroplasty for treatment of benign urethral strictures in adult men.

This document also describes the proposed criteria for commissioning, governance arrangements and funding mechanisms.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final decision as to whether urethroplasty for treatment of benign urethral strictures will be routinely commissioned is planned to be made by NHS England by June 2016 following a recommendation from the Clinical Priorities Advisory Group.

2. The proposed intervention and clinical indication

A urethral stricture is a narrowing of the anterior urethra as a consequence of ischaemic spongiosclerosis caused by scarring, injury, infection, or non-infectious forms of urethritis, which can lead to reduced flow or blockage of urine (retention), and other complications such as penile swelling and pain, and pain in the pelvic or lower abdominal area. Strictures are the most common cause of difficulty passing urine in younger and middle aged men.

Urethral strictures can be divided into a) anterior urethral strictures, and b) the less common and complex posterior urethral strictures that are caused by the disruption of the urethra by injury.

Typically, patients experiencing a benign anterior urethral strictures are subject to either an urethrotomy or urethral dilation as first-line treatment options. Where patients show incomplete response and/or are contraindicated or have a stated preference, an urethral reconstruction via urethroplasty is potential second line treatment. This policy proposition considers the latter; urethral reconstruction for benign anterior urethral stricture disease.

Urethroplasty is the open repair of a stricture in the urethra; the most common site is the bulbar urethra, followed by the penile urethra. A one-stage repair is the most common form of repair. Depending on the length and location of the stricture, different options are available: 1) excision of the stricture and reconnection of healthy urethra; 2) augmentation of the urethra, with or without excision of the strictures segment.

The policy proposition is in line with European Association of Urology (EAU) and International Consultation on Urological Disease (ICUD) guidelines (both 2010).

Greater availability of trained urethroplasty surgeons, use of managed care pathways to reduce hospital stay, and adoption of oral mucosa as graft material has broadened its application.

3. Definitions

Urethral stricture is a narrowing of the urethra caused by ischaemic fibrosis of the corpus spongiosum leading to scarring. Strictures can either be congenital or acquired, most are of unknown etiology, but causes can include infection, sclerosis and trauma (accidental or iatrogenic). They are non-malignant, i.e. non-cancerous (benign).

The hallmarks of a urethral stricture are progressive voiding symptoms, lower urinary tract symptoms and reduced urinary flow rate. Symptomatic men with strictures need treatment to resolve their lower urinary tract symptoms. As noted above, this requires urethral reconstruction of the urethra either by direct anastomosis or implantation of tissue, the most common tissue being oral mucosa.

Urethrotomy is an operation which involves incision of the urethra, especially for relief of a stricture.

Urethral dilatation is a procedure to widen the urethra leading from the bladder, so that is easier to pass urine.

Urethroplasty is a surgical procedure of open repair of the urethra for a stricture close to the bladder, occasionally performed immediately after severe injury to the urethra. An incision is made over the stricture either on the penis or in the skin between the scrotum and the anus (the perineum). The scar is either cut away and the urethra re-joined over a catheter or widened with a piece of cheek lining (buccal mucosa) over a catheter.

4. Aim and objectives

This policy proposition aims to define NHS England's commissioning position on urethroplasty for the treatment of benign urethral strictures in adult men.

The objective is to ensure evidence based commissioning with the aim of improving outcomes for patients with urethral stricture.

5. Epidemiology and needs assessment

The prevalence of urethral stricture is approximately 200 per 100,000 men in their 20s, rising to 900 per 100,000 men in their 70s. An American study quotes a 0.6% incidence in the susceptible population (Alwaal, et al., 2014). At any one time, urethral strictures affect about 62,000 men in the UK (ONS, 2011).

A stricture does not become clinically apparent until the caliber of the urethra is narrowed significantly if the patient has a normally functioning bladder, which is usually the case. It has been reported that the urinary stream doesn't diminish until the caliber of the urethra has fallen below 11F (4 mm diameter). Strictures will become more apparent in patients with a poorly functioning bladder, or with associated bladder outlet obstruction due to bladder neck stenosis or benign prostatic hyperplasia.

In NHS England, this corresponds to 17,000 hospital admissions annually, 16,000 bed-days and 12,000 operations, at a cost in excess of £10M (Health & Social Care Information

Centre, 2013-14).

In 2010, 15,000 urethrotomies were conducted (Hospital Episode Statistics). Of these, approximately 3,075 were for a recurrent stricture (Dr Foster).

That year, 713 urethroplasties were conducted (or c. 4.8% of urethrotomies) (Hospital Episode Statistics).

6. Evidence base

NHS England has concluded that there is sufficient evidence to support a proposal for the routine commissioning of urethroplasty for the treatment of benign urethral strictures in adult men.

Summary

The body of evidence for this review comprised of two systematic reviews including one Cochrane review, one case control study and a few large and small case series. The overall evidence was limited in direct comparison of urethroplasty with other interventions. The Cochrane review was low quality with the entire body of evidence based on an abstract of a single non published study (Wong et al. 2010, updated 2012). Two studies comparing the current surgical practice and beliefs were included in the evidence review to provide background information but not summarised.

In summary, the current clinical evidence review provides low level but supportive evidence in favour of urethroplasty compared to urethrotomy with reduction in recurrence rates ranging from 11 to 24% over 1 to 4 years and significant improvement in peak urinary flow in up to 86% of patients. Success in terms of stricture recurrence may be impacted by stricture length, and anatomical location of the stricture segment. Some studies appear to identify patients with longer stricture lengths as an ideal subgroup for primary urethroplasty. Additionally, there appears to be a volume-outcome relationship with a continuous learning curve beyond 600 patients/ surgeon. The literature search did not find any studies on patient-reported outcomes or cost-effectiveness for urethroplasty.

Detailed Evidence

Part 1: Clinical effectiveness of urethroplasty versus endoscopic therapy for the treatment of urethral strictures

The clinical effectiveness of a urethral stricture treatment was defined in most studies in terms of rate of stricture recurrence and improvement in urinary peak flow.

Meeks et al. (2009) evaluated clinical outcomes of urethroplasty based on stricture recurrence in a systematic review of 86 studies published between 2000 and 2008. Recurrence was defined as the need for a repeat surgical procedure or dilation after urethroplasty. The time period for follow-up was not reported and is likely to be varied across studies, which should be noted given the tendency towards recurrence over time. Average stricture recurrence rate for urethroplasty was found to be 15.6%, with significantly

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higher rates for longer strictures (>5 cm) ($p=0.0006$). Additionally, the recurrence rate was lowest for bulbar urethral strictures (13.9%) compared with that for penile strictures (18.4%, $p=0.00001$) and posterior urethral strictures (17.5%, $p=0.0006$). The reconstructive technique did not appear to affect the recurrence rate (15.6% for graft vs 16.4% for anastomotic, $p=0.37$).

A recent large case series by Warner et al. (2015) updated these findings, reporting recurrence rate of 22.5% at average follow-up of 20 months (12-344 months) for urethroplasty on long-segment urethral strictures in 466 patients treated at 8 international centres. Lowest recurrence rate was reported for one-stage buccal mucosal graft at 17.5%. However, given the retrospective nature of the study and non-random allocation of treatment, there is significant risk of patient selection bias between different sub-types of urethroplasty.

In a much smaller retrospective case series of patients who underwent bulbar end-to-end anastomosis urethroplasty ($n=33$), stricture recurrence was observed in 12% of patients at average 42.6 months (8 – 96 months) follow-up. All recurrences were limited to patients with non-traumatic strictures (Suh et al., 2013). This could indicate the potential role of the underlying aetiology (e.g. if there is an ongoing disease process, recurrence is more likely). Similarly, Xu et al. (2014) reported a recurrence rate of 11% with mean postoperative urinary peak flow rate of 24.2mL/s over a long follow up (mean 38.7 months, range 12-110 months) in a case series of 36 patient with relatively long strictures (median length 12.5cm) secondary to genital lichen sclerosis.

The Cochrane systematic review comparing simple urethral dilatation, endoscopic urethrotomy, and urethroplasty for urethral stricture disease in adult men was limited to a review of one unpublished study comparing urethroplasty with urethrotomy (Wong et al. 2010, update on 2012). The review reported a study by Ravichandran et al. (2003) on 50 males who were randomised to initial treatment by urethroplasty (anastomotic technique) or urethrotomy. More men in the urethrotomy (64%) group were likely to require further surgery or dilation compared with the urethroplasty group (24%). These findings need to be treated with extreme caution given that the review was based on an abstract of this study which has not been published in any peer reviewed journal.

More definitive evidence for comparative effectiveness of urethroplasty comes from a retrospective case control study ($n=45$) in Spain which reported that urethroplasty was significantly successful ($p=0.01$) in 86.4% of the patients compared with 47.8% for urethrotomy, using urinary peak flow > 15mL/s after surgery as the definition for successful outcome. The urethroplasty ($n=31$) group included 9 patients (20%) in whom the previous urethrotomy had failed. This subgroup had longer strictures (3.4 ± 3.1) compared to primary urethroplasty (1.6 ± 1.6) and primary urethrotomy (1.1 ± 0.5) subgroups. Based on these findings the authors concluded that urethroplasty would be an ideal choice for patients with stricture length >1.5cm. The retrospective nature of the study, non-randomised assignment of procedures and small number of patients are likely to limit the representativeness of the study population and hence generalisability of the findings. (Tinaut-Ranera et al. 2014).

In conclusion, there is currently low level but supportive evidence for greater effectiveness of urethroplasty in treatment of urethral strictures compared to urethrotomy, with reduction

in recurrence rates ranging from 11% to 24% (mean follow up time period 20-42.6 months) and significant improvement in urinary peak flow in up to 86% of patients. Success in terms of stricture recurrence may be impacted by stricture length. The studies appear to identify patients with longer stricture lengths as an ideal subgroup for primary urethroplasty.

Part 2: Patient-reported outcome measures for urethroplasty

The literature search did not find any studies on patient-reported outcomes for urethroplasty.

Part 3: Safety issues or adverse events (complications)

Warner et al. (2015) indicate early complications including infection (UTI), local pain, inflammation, numbness, oedema, and penile skin ischemia in up to 15 out of 466 patients. More serious side effects were wound dehiscence in 8 cases and one case each of fistula and scrotal abscess. Late complications mainly included penile chordee (11), persistent hypoesthesia (7), fistula (6), and erectile dysfunction (3). Authors report that occurrence of a complication conferred no statistical impact on stricture recurrence ($p=0.29$). The complication rate was higher in the cases with fasciocutaneous flap urethroplasty compared with those without a flap (32% vs 14%, respectively; $p=0.02$).

Suh et al. (2013) reported that early complications with the open surgery were minor and limited to one case each of catheter-related infection and epididymitis (2/33 patients). Late complications included intermittent perineal or scrotal pain, which affected 8/33 patients and responded to analgesics.

Xu et al. (2014) report postoperative complications occurred in approximately 11% of patients with one patient developing urinary fistula secondary to infection and three patients developing meatal stenosis 3-11 months postoperatively which required correction with meatoplasty.

Part 4: Volume-outcome relationship of urethroplasty

The only evidence on the relationship between volume and outcomes was from the study by Fossati et al. (2015). This study evaluated the surgical learning curve for one-stage anterior urethroplasty in 641 patients performed by one surgeon over 20 years in Italy. The outcome measure was treatment failure, defined as any postoperative instrumentation needed after urethroplasty. Surgical experience was a significant predictor of failure-free survival after adjusting for case mix (hazard ratio per 20 procedures: 0.98; 95% CI, 0.97–0.99; $p=0.008$). The 5-year failure-free survival increased from 70% to 80% over the first 400 procedures and to 85% from procedure number 400 to 600. Probability between surgical success and surgical experience was nearly linear with improvement in outcomes by approximately 5% per 200 procedures. The learning curve did not reach plateau after 600 procedures.

In the absence of further validation from other multi-centre and multi-surgeon studies, this study indicates a volume-outcome relationship for urethroplasty and highlights the need for minimum volume per surgeon and good training.

Part 5: Cost-effectiveness of urethroplasty

The literature search did not identify any studies on cost-effectiveness analysis for urethroplasty.

7. Proposed criteria for commissioning

Inclusion criteria:

NHS England will routinely commission urethroplasty for the treatment of benign urethral strictures in patients following assessment by MDT, including a urologist specialising in urethral surgery (see Section 9: Proposed governance arrangements for more detail). Specifically:

- (i) Patients with urethral strictures longer than 3cm in length: OR
- (ii) Patients with lichen sclerosis and lengthy penile urethral strictures which are unlikely to respond to first-line treatment (urethrotomy); OR
- (iii) Patients with short bulbar urethral strictures following at least one urethrotomy, unless after counselling about treatment options the patient would prefer to undergo primary urethroplasty and is aware of the risks and benefits of surgery.

Repeat procedures for patients who have recurrent urethral strictures following urethral dilation, urethrotomy or urethroplasty will be funded.

Exclusions criteria:

- (i) Patients contraindicated for surgery (medical and/or psychological reasons); OR
- (ii) Patients who chose not to have surgery: OR
- (iii) Patients with a lengthy stricture who have significant comorbidities, for whom perineal urethrotomy should be considered as a primary approach.

8. Proposed patient pathway

Patients who see their local GP or present at A&E with urinary symptoms, infection or retention will be referred to a urologist. The urologist will investigate and most patients will have a flexible cystoscopy under local anaesthetic, while some patients would have a urethrogram based upon their poor flow rate and a typical stricture pattern on the flow rate.

If a stricture is discovered, there are a number of treatment options including urethrotomy, urethral dilation and clean intermittent self dilation, or urethral reconstruction via urethroplasty.

Having identified an anterior urethral stricture, a urethrogram should be carried out to identify the length of the stricture and its exact relationship to the rest of the urinary tract. The alternative to this would be the use of ultrasound or endoscopy of the corpus

spongiosum.

To determine the management of a stricture certain features need to be taken into account including the length of the stricture, the location of the stricture (e.g. penile or bulbar), the presumed cause of the stricture and patient preference. Treatment options are considered as part of an MDT, and all patients will undergo further investigation with an urethrogram or flexible cystoscopy to confirm the stricture before a decision is made about going onto surgery.

Urethroplasty should be considered for strictures longer than 3cm in length and for patients with lichen sclerosis and lengthy strictures and penile urethral strictures which are unlikely to respond to urethrotomy. Patients with a lengthy stricture who have significant comorbidities should consider perineal urethrostomy as a primary approach. Traumatic anterior urethral strictures require open surgical resolution.

Urethrotomies and/or urethral dilation should be considered for strictures shorter than 3cm in length as first-line treatment, unless patients are contraindicated and/or after counselling about treatment options the patient would prefer to undergo urethroplasty. Where patient shows incomplete response to first-line treatment, urethroplasty is proposed.

Patients will receive information from a urologist explaining the risks and benefits of the procedure as compared to endoscopic treatment, outlining the potential side effects of urethroplasty which include: a low incidence of impotence (no more than 2-6% at six months); erectile dysfunction; slowed ejaculation; a risk of failure which is highest with augmentation urethroplasty; and, risk of post-micturition dribbling following urethroplasty although this is often present previously with a stricture.

If patients do not want to have urethroplasty, alternative treatment includes intermittent self dilation for at least six months following a urethrotomy.

During the urethroplasty procedure, the scar is either cut away and the urethra re-joined over a catheter or widened with a graft (a piece of cheek lining (buccal mucosa)) over a catheter. In cases where there is either anastomosis or augmentation then a catheter is used routinely and is left in for at least two weeks. A drain may be used although this is usually unnecessary. The wound is closed with absorbable sutures. If a graft is taken from the cheek lining, this area heals quickly and does not necessarily require any stitches. A small dressing (pack) is usually inserted into the mouth overnight to prevent bruising or swelling.

9. Proposed governance arrangements

Urethroplasty must be performed in accordance with EAU and ICUD guidelines, and is only commissioned from highly specialist adult urological surgery centres.

Surgeons must participate in the national clinical audit administered by British Association of Urological Surgeons (BAUS).

All surgeons performing reconstructive urethral surgery should be members of the British

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Association of Urological Surgeons (BAUS) / British Association of Genito-Urinary Reconstructive Surgeons (BAGURS) for the purposes of case discussion and Continuing Professional Development.

10. Proposed mechanism for funding

Urethroplasty for the treatment of benign urethral strictures will be funded through the local service specialised commissioning team.

11. Proposed audit requirements

All patients should have their data entered on the BAUS Urethral Surgery Database.

12. Documents which have informed this policy proposition

EAU Guidelines on Urethral Trauma (2010).

ICUD International Consultation on Urethral Strictures (2010).

13. Date of review

This document will lapse upon publication by NHS England of a clinical commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned (expected by June 2016).