

Urethrotech UCD for difficult or failed catheterisation

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is the Urethrotech urethral catheterisation device (UCD). It is designed to be used for difficult or failed catheterisations in men.
- The **innovative aspect** is that it is the only currently available system which integrates a guidewire into a standard Foley catheter.
- The **intended place in therapy** would be instead of cystoscopy and supra-pubic catheterisation methods after standard catheterisation has failed, or when it is difficult (such as in men with an enlarged prostate). The device could potentially be used in any healthcare setting by appropriately trained staff.
- The **main points from the evidence** summarised in this briefing are from 2 conference abstracts reporting prospective non-comparative studies including a total of 157 patients in a UK setting. They show that the Urethrotech UCD can be a useful urethral catheterisation method in men, and reported no adverse events.
- **Key uncertainties** are that the evidence base is still developing. Although the available non-comparative studies reported technical success with the device, most men in the studies had the Urethrotech UCD as a first-line catheterisation method. The current studies are available only as abstracts and so they present limited detail.
- The **cost** of the Urethrotech UCD is £198.98 per unit (exclusive of VAT). Training costs are an additional £290.00 per person, which is waived if the clinician subsequently trains others. The

resource impact may be less than standard care if the Urethrotech UCD avoids the need for more complex and costly cystoscopy and suprapubic catheterisations as second-line procedures.

The technology

The Urethrotech UCD (Urethrotech) is a single-use device designed for second-line catheterisation in men after catheterisation has failed or is difficult, such as those with an enlarged prostate.

The device comprises a flexible hydrophilic Nitinol guidewire, which protrudes 50 cm from the tip of a standard 5.3 mm diameter 3-way Foley catheter. The user lubricates the soft tip of the guidewire with sterile water before inserting it through the urethra and into the bladder. The guidewire is designed to allow the catheter to be navigated around an enlarged prostate. The soft tip is designed to avoid urethral trauma, and will turn back if the wire is pushed against an obstruction or a non-negotiable false passage.

When the guidewire enters the bladder, it curls up on itself as the catheter is advanced. The catheter is passed over the guidewire when it reaches the tip of the penis. When the catheter reaches the bladder, urine should flow freely through the main catheter urine drainage channel. This indicates that the catheter is correctly positioned and that the balloon at the end may be safely inflated so that the catheter stays in place. The guidewire is then withdrawn and disposed of.

The catheter can remain in place for up to 30 days, after which it must be replaced (like any other urinary catheter). The Urethrotech UCD cannot be used for men with known urethral obstructions or injuries, or urorectal fistulae.

Innovations

The Urethrotech UCD is the only currently available system which incorporates a guidewire within a standard Foley catheter. This is designed to allow the correct positioning of the catheter while avoiding trauma to the urethra, which can be caused by repeated attempts to insert a Foley catheter. This may allow second-line catheterisations to be done by clinical staff other than consultants, and may avoid the need for cystoscopy which needs anaesthetic.

Current NHS pathway or current care pathway

The NICE guideline on [lower urinary tract symptoms in men](#) recommends immediate catheterization for men with acute urinary retention. Urinary catheters are also routinely used for some types of surgery. Inserting an ordinary Foley catheter may be difficult, because an enlarged

prostate can distort the prostatic urethra or the external urethral sphincter muscle may contract. In 1 study done in Ireland, 6% of urology referrals were because of failed first-line catheterisation attempts in men. Of these referrals, 68% of men had significant urethral trauma because of the failed catheterisation (the number of attempts is not reported; [Thomas et al. 2009](#)). Another study done in Ireland showed that the incidence of male traumatic urethral catheterisation was 6.7 per 1,000 catheters inserted, with an average of 3.2 used per patient before referral for second-line catheterisation ([Davis et al. 2016](#)).

Second-line catheterisation is done using either cystoscopic or suprapubic catheterisation.

- Cystoscopic catheterisation uses a flexible cystoscope, a thin tube with a light and camera on the end, to insert a guidewire and catheter into the bladder using anaesthetic. It is usually necessary to pierce a hole in the tip of the Foley catheter with a needle, to allow insertion of the guidewire.
- Suprapubic catheterisation uses ultrasound guidance to insert the catheter directly into the bladder, through a hole in the abdomen, using anaesthetic.

Which method is used depends on clinical preference and local specialist availability. There is commonly a delay between the first failed catheterisation and these second-line methods because of a need for interventional radiology, a theatre or endoscopy suite, or admission for general anaesthetic.

The Urethrotech UCD would be used as an optional intermediate step before cystoscopy and suprapubic catheterisation methods.

Population, setting and intended user

The Urethrotech UCD is designed for second-line urethral catheterisation in men. This will most likely be older men with prostatic enlargement. The device may be used in any hospital setting where catheterisation is part of the acute care pathway, such as emergency departments, inpatient wards or intensive care units. It may be used by specialist nurses, nurse practitioners and junior doctors. It could also be used in the community and home settings, within an appropriate training framework, by GPs, community nurses and emergency services.

Costs

Technology costs

Each single-use Urethrotech UCD costs £198.98 (excluding VAT). The manufacturer offers a 2-hour training course and a video for £290; this is provided at no cost to clinicians who agree to subsequently train others in using the device.

Assuming that the device takes 5 minutes to insert, the cost of staff time for a band 8a urology nurse practitioner would be £5.16; for a band 6 urology nurse specialist this would be £3.67, and for a specialist trainee registrar this would be £3.33 ([PSSRU costs 2016](#)).

Costs of standard care

A cystoscopic catheterisation procedure costs £694 (excluding VAT) per catheterisation. An outpatient suprapubic catheterisation procedure costs £454 (excluding VAT) per catheterisation ([NHS National Tariff 2017/2018](#)). [Khan and Abrams \(2009\)](#) conducted a study within the NHS and estimated costs for suprapubic catheterisation as £2,400 for an inpatient case and £462 for an outpatient case (based on salaries, disposables, anaesthetic and instruments).

Resource consequences

The cost per catheterisation with the Urethrotech UCD may be less than that for cystoscopic or suprapubic catheterisation. If it were shown to be as effective as these methods, cost savings may arise from a shorter procedure (about 5 minutes compared with 15 to 20 minutes), avoiding the need for a theatre or endoscopy suite, or even avoiding the need to cancel surgery because of failed pre-surgical catheterisations.

The Urethrotech UCD is currently being used in 1 NHS trust.

Regulatory information

The Urethrotech UCD was CE marked as a class IIa device in October 2016.

A search of the Medicines and Healthcare products Regulatory Agency website revealed that no manufacturer field safety notices or medical device alerts have been issued for this technology.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

This Urethrotech UCD is designed for catheterisation in men only, and cannot be used for women. The device can only be used in people who have a penis, so it may be unsuitable for some people who identify as men.

Acute urinary retention is more common in older men.

Age and sex are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing summarises 2 conference abstracts including a total of 157 patients. Both studies used non-comparative prospective designs. Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The available evidence is limited in both quantity and quality, and comprises only abstracts of non-comparative studies reporting technical success. Only 1 of the studies used the Urethrotech UCD for second-line catheterisation, and only 9 patients in this study were catheterised with it. Both studies were done in the UK in men having cardiac or urological surgery, so the results are generalisable to the current NHS pathway.

To determine the clinical effectiveness of the Urethrotech UCD, studies comparing it with standard care in men who need second-line catheterisation would be useful. Important outcome measures would include the rate of successful catheterisations, adverse events (such as rates of urethral trauma including false passages and infections), patient satisfaction and healthcare resource use.

Table 1 Published evidence

<u>Bugeja et al. (2016)</u>	
Study size, design and location	57 men having bulbar and posterior urethroplasty. Only 9 had catheterisation using the Urethrotech UCD. Prospective non-comparative design. UK-based.
Intervention and comparator(s)	Intervention was the Urethrotech UCD. No comparator.
Key outcomes	Of 57 patients, 9 needed second-line catheterisation. The Urethrotech UCD was used successfully without any adverse events in all 9.
Strengths and limitations	Only a small number of patients had the intervention. It was a non-comparative study and reported only limited outcomes.
<u>Mundy et al. (2015)</u>	
Study size, design and location	100 men having cardiac surgery. Prospective non-comparative design to test safety and efficacy. UK-based.
Intervention and comparator(s)	Intervention was the Urethrotech UCD. No comparator.
Key outcomes	All 100 patients had successful first-line catheterisations using the Urethrotech UCD, with no adverse events.
Strengths and limitations	The study had a large sample size but the device was used for first-line catheterisation, not second line as is intended for general NHS use.

Recent and ongoing studies

No ongoing or in-development trials were identified.

Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Two of the 3 specialist commentators were familiar with the concept of the device, but none had used it before.

Level of innovation

All specialist commentators agreed that the Urethrotech UCD has a moderate to high level of innovation. One commentator stated that this innovation came from the guidewire and catheter being integrated in 1 medical device.

Potential patient impact

All commentators agreed that the Urethrotech UCD could benefit patients. It may avoid the need for more invasive and complex second-line procedures, which in turn could lead to fewer in-patient stays and reduced morbidity from urethral trauma.

Potential system impact

Two commentators agreed that the device could have a positive effect on the NHS, because it is quick and simple to use and could lead to fewer referrals to secondary care. It may also reduce costs associated with radiology, second-line catheterisation methods, acute care and staff costs. Both commentators agreed that adopting the Urethrotech UCD would have minimal resource impact but there may be a shift in care to primary care settings, where staff may need further training and monitoring.

One commentator felt that the Urethrotech UCD would most likely be used for men whose initial catheterisation attempts had led to the creation of a posterior urethral false passage. Because the device uses a very malleable guidewire, it may not pass anterior to this false passage and so could fail to reach the bladder. This would mean that more invasive and complex approaches would subsequently be needed. Because of this, the specialist commentator was sceptical about the benefits that the Urethrotech UCD could offer.

General comments

One commentator stated that the device is a sensible development to address difficult or failed first-line catheterisations. Another noted that there is currently very little evidence available to support its use, so they felt that more evidence was needed.

Specialist commentators

The following clinicians contributed to this briefing:

- Ms Ann Yates, director of continence services, Cardiff and Vale University Health Board. Advisory member of the charity Shine.
- Dr Neil Barber, consultant urological surgeon, Frimley Health NHS Foundation Trust. No conflicts of interest declared.
- Professor John Kelly, professor of urology, UCL Hospitals NHS Foundation Trust. No conflicts of interest declared.

Development of this briefing

This briefing was developed for NICE by Cedar. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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