NICE advice

TUC Safety Valve to prevent balloon inflation in the urethra during transurethral catheterisation

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is TUC Safety Valve. It is suitable for anyone aged over 16 who needs transurethral catheterisation.
- The **innovative aspects** are that it is claimed to be the only device that eradicates the risk of urethral injury from accidentally inflating the catheter retention balloon in the urethra instead of the bladder.
- The intended **place in therapy** would be in addition to an indwelling urinary catheter in men with urinary dysfunction and other conditions that prevent them from emptying their bladder.

- The **main points from the evidence** summarised in this briefing are from 1 observational study including a total of 100 adult men in a tertiary referral teaching hospital. The valve activated 7 times in the study. The study shows that the TUC Safety Valve is effective at stopping accidental catheter inflation in the urethra.
- **Key uncertainties** around the evidence or technology are that there is limited evidence on using the device in a clinical setting, no comparative evidence, and no evidence from the UK. The company plans to address this by collecting prospective audit data on the technology's use in the NHS.
- **Safety** issues identified are that the TUC Safety Valve does not have a CE mark. However this is expected in May 2020.
- The **cost** of the TUC Safety Valve is £15 per unit (excluding VAT). The **resource impact** will be in addition to standard care. This could be offset by savings from complications avoided by preventing accidental inflation of catheter balloons in the urethra. There is limited published evidence to support this.

The technology

The TUC (transurethral catheter) Safety Valve (Class Medical) is a single-use device consisting of a proximal female luer lock, a flow restrictor, pressure value and a distal male luer slip.

It's designed to be used with a Foley catheter during transurethral catheterisation, to prevent the retaining balloon inflating if it is still in the urethra rather than the bladder.

Once the urinary catheter is inserted, the TUC Safety Valve's female luer lock is fitted to the syringe and the male luer slip to the balloon inflation port of the catheter. The catheter retaining balloon is then inflated as normal, allowing 10 to 15 seconds longer because the device causes it to take longer to inflate.

If the balloon is accidentally placed in the urethra, the pressure valve is activated. Any fluid pushed into the catheter at that point leaks out of the TUC Safety Valve and balloon inflation stops, indicating that the balloon is not inside the bladder. At this point the balloon should be deflated, fluid drawn back into the syringe, and the catheter repositioned in the bladder. When it is correctly positioned in the bladder, the TUC Safety Valve deactivates, allowing fluid to pass and the balloon to inflate.

If the valve is activated, it's important to make sure the syringe has the correct volume of saline or fluid to allow the recommended inflation of the catheter balloon as instructed by the manufacturer. Once the balloon is inflated in the bladder, the TUC Safety Valve and syringe should be immediately disconnected. Failure to do so may result in the catheter balloon deflating and the catheter migrating or getting lost.

Innovations

The device is claimed to be the only one on the market that prevents accidental inflation of the catheter in the urethra. It could improve standard care by avoiding urethra trauma and complications from it such as urethral bleeding, urethral stricture disease, and, in some cases, death.

Current care pathway

Transurethral catheterisation is commonly used for bladder drainage and urine collection in a range of conditions.

Men with acute urinary retention should be immediately catheterised. Urinary catheters are also routinely used for some types of surgery.

Bladder catheterisation (intermittent or indwelling urethral or suprapubic) should also be considered for women who have persistent urinary retention that is causing incontinence, symptomatic infections or renal dysfunction, if it cannot be corrected any other way. Intermittent urethral catheterisation in women with urinary retention who can be taught to self-catheterise or who have a carer who can perform the technique.

The following publications have been identified as relevant to this care pathway:

- NICE guideline on lower urinary tract symptoms in men: management
- NICE guideline on urinary incontinence and pelvic organ prolapse in women: management.

Population, setting and intended user

The technology would be used for anyone who needs transurethral catheterisation, usually

someone who has difficulty passing urine. Transurethral catheterisation is a common procedure done in hospitals and in the community by doctors and nurses. The company estimates the qualifying population for the technology would be more than 500,000 men a year.

Costs

Technology costs

The TUC Safety Valve costs £15 (excluding VAT) each; the company says that volume discounts are available on this price. One single-use TUC Safety Valve is needed for each transurethral catheterisation. This cost is addition to the cost of standard care with a Foley catheter.

Costs of standard care

The cost of a Foley catheter is around £5.

Resource consequences

A study by Davis et al. (2016) done at 2 tertiary referral hospitals in Dublin over 6 months in 2015 found 37 incidences of traumatic catheterisation, a rate of 6.7 per 1,000 catheters inserted. Thirty (81%) had complications as a result which they costed at 335,377 Euros, around 61 Euros per catheter inserted, or 122 Euros for those inserted into male patients (information provided by the company based on all complications occurring in men, who were half of the total population; this information is not in the published paper so could not be confirmed). This figure did not include costs from long-term complications, repeated urological interventions and follow-up appointments, and so was considered conservative.

A separate study, Davis et al. (2020), provided longer-term follow-up data on these patients (mean 37 months) and found that 29 (78%) developed urethral stricture disease in this period. One death was directly related to severe progressive urosepsis provoked by the inflation of the catheter balloon in the urethra. The cost of these complications is not provided, and it's possible that some patients could have had undiagnosed urethral stricture disease before their traumatic catheterisation. It is not clear if these rates, costs and findings would apply directly to the NHS.

The device is not currently in use in the NHS. It is a simple, easy to use device that requires no new, or changes to existing, infrastructure. Training requirements are minimal.

Regulatory information

The TUC Safety Valve does not currently have a CE mark, but a CE mark is expected in May 2020.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

No equality issues were identified.

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

One study is summarised in this briefing, involving 100 patients.

There is evidence on technology design and validation in peer-reviewed publications and unpublished abstracts, but this is not included in this briefing.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

There is not much clinical evidence on the TUC Safety Valve. Most of the published evidence are proof of concept, and design validation studies on porcine models showing that the TUC Safety Valve eliminates user variability and restricts balloon inflation pressure to below a safe level of under 150 kPa. Only 1 study was identified on using the device (a validated prototype) in a clinical patient setting. Another, Davis et al. (2018a), which is not summarised, used 9 urethras removed from patients undergoing male to female gender reassignment to look at the relationship between urethral diametric stretch, catheter balloon inflation pressures and urethral trauma. This reported urethra rupture in the thinnest urethras when external urethral diametric stretch was 1.26 and greater, and balloon inflation pressures of 120 kPa, and a mean across the 3 ruptures of 165.16 kPa.

Results from a health economics study by Davis et al. (2016) are summarised in the resource consequences section of this briefing. Davis et al. (2020), which looked at the longer-term outcomes of those patients from the same sample who sustained a urethral injury during transurethral catheterisation, is also summarised. Neither study involved the use of the TUC Safety Valve and so are not included in this section.

Davis et al. (2018b)

Study size, design and location

A prospective observational study of 100 adult men needing urethral catheterisation at the Beaumont Hospital, Dublin, Ireland, a tertiary referral teaching hospital.

Intervention and comparator(s)

A validated prototype version of the TUC Safety Valve; no comparator.

Key outcomes

All patients had a successful catheterisation with the TUC Safety Valve. This was defined as urine exiting the catheter's drainage port, witnessed by the user, with successful inflation of the catheter's anchoring balloon. No urethra injuries from traumatic catheterisation were recorded. The TUC Safety Valve activated in 7 patients, preventing accidental inflation in the urethra. On all 7 occasions the catheter was successfully

repositioned into the bladder and inflated.

In a survey of the 34 hospital interns who did the catheterisations with the TUC Safety Valve, of the 31 who responded: 10% reported that they had inflated the catheter balloon in the urethra on previous occasions; 87% were interested in the concept of the TUC Safety Valve; 84% said the device was user friendly; and all said they would use it again.

Strengths and limitations

This is a reasonably large study that also gathers feedback from users of the technology. However it is non-comparative, limited to a single centre, involves medical interns, and uses a prototype version of the device. It's therefore not clear if the outcomes and survey responses would translate into the NHS. Four of the 5 authors are cofounders of the company and stated as inventors on the US patent.

Sustainability

The company claims the technology prevents urethral injury and this will save resources associated with treating these injuries. There is no published evidence to support these claims.

Recent and ongoing studies

The company has told NICE that it intends to do a 2-stage before-and-after study in the NHS using prospective audit data to look at the impact of using the TUC Safety Valve on urethral catheter-related injuries. The intention is to publish any final results. No further details are currently available.

Expert 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.

Three experts were involved in the production of this briefing. One had used the technology before in an ex-vivo demonstration model. One was familiar with the technology.

Level of innovation

Two experts agreed that the technology is innovative; 1 said the technology has the potential to prevent significant complications from urethral catheterisation. One expert described the technology as entirely novel. This expert also noted that current standard care depends on the clinician's experience and use of guidewires or endoscopic methods. All experts noted that the TUC Safety Valve is not used in the NHS. Another expert felt there was not enough research data on the technology. No similar devices were mentioned.

Potential patient impact

Two experts believed the technology offers an opportunity to avoid complications resulting from accidental balloon inflation within the urethra. One expert felt men with chronic indwelling urethral catheters will benefit the most. Two experts said the technology is likely to most benefit men who need catheterisation. Another expert noted that recommending the technology for all patients will have a substantial cost impact, considering the low incidence of incorrect balloon inflation. One expert noted that the incidence and prevalence of the clinical problem is under reported.

Potential system impact

Two experts noted that using the technology could potentially avoid the costs associated with urethral injury. They agreed that the resource impact will be greater than standard care, with 1 noting that the cost of the device for all patients and the cost of training would be significant. One of them also said that it may be costly to use the technology for repeat or long-term catheterisation. Another expert noted that cost saving linked to reduced morbidity would likely outweigh the cost of the early version of the technology. This expert noted that the technology is intuitive to use and that it can be used in primary and secondary care by trained healthcare professionals.

General comments

One expert said that clinical trials are needed to show patient and system benefits. This expert also noted that using the technology may support best clinical practice.

Expert commentators

The following clinicians contributed to this briefing:

- Prof Ian Pearce, consultant urological surgeon and andrologist, Manchester Royal Infirmary. Recruiting to a multicentre audit of catheter-associated urethral trauma on behalf of the company.
- Ms Ann Yates, director of continence services, Cardiff and Vale University Health Board. No interest declared.
- Oliver Kayes, consultant urologist and honorary senior lecturer, Leeds Teaching Hospitals NHS Trust. No interest declared.

Development of this briefing

This briefing was developed by NICE. 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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