



Topic Exploration Report ¹

Urethral catheter safety valves

What is a Topic Exploration Report?

Topic Exploration Reports are not health technology assessments. These reports provide a high-level briefing on new topics submitted to Health Technology Wales and are not based on exhaustive or systematic literature searches. Instead, they rely on a focussed scan of key resources.

What evidence is used in a Topic Exploration Report?

Priority is given to summarising the most relevant or useful evidence, rather than covering all possible evidence. Information reported is typically based on abstracts and study authors' own conclusions, rather than detailed scrutiny of full texts.

What are the aims of a Topic Exploration Report?

Topic Exploration Reports offer an overview of the available evidence on a topic and aim to highlight any uncertainties or gaps in the evidence. These reports outline the quantity and type of evidence found, but no critical appraisal or formal evidence synthesis is conducted.

How should a Topic Exploration Report be used?

Topic Exploration Reports can be used to indicate what evidence may be available for a topic, and do not provide definitive guidance on how a technology should be used. The evidence presented within the reports should be interpreted with caution.

¹ [Cyfieithu dogfennau HTW wedi'u cyhoeddi o'r Saesneg i'r Gymraeg](#)
Translation of published technical HTW documents from English into Welsh

Topic exploration report number	TER645
Topic	Urethral catheter safety valves
Summary of findings	A urethral catheter is a tube inserted in the urethra to carry urine out of the bladder when people have difficulty urinating. A malpositioned urethral catheter, with subsequent inflation of its anchoring balloon in the patient's urethra instead of the bladder, may cause damage to the urethra. Current practice relies on a clinician's training and experience to avoid injury. The Trans Urethral Catheter Safety Valve is attached between the balloon inflation port and the inflation syringe. It ensures that if a balloon is malpositioned, inflation fluid is vented externally, providing visual feedback to the clinician to stop inflating the anchoring balloon before repositioning the catheter. Two observational studies conducted in the UK and Ireland reported that the Trans Urethral Catheter Safety Valve eliminated catheter balloon injuries. No studies reporting on short-term or long-term patient and system outcomes were identified, including the impact on mortality, need for further treatment, quality of life, and length of hospital stay. One economic analysis based on the UK perspective reported that the Trans Urethral Catheter Safety Valve is dominant, meaning it provides superior clinical outcomes while nearly halving systemic costs. Two studies reported the cost of iatrogenic injuries caused during the procedures, but these studies did not include the costs of long-term patient management or potential medicolegal claims.

Introduction and aims

A urinary catheter is a flexible tube used to empty the bladder and collect urine in a drainage bag (NHS 2023). One way in which they can be inserted is through the tube that carries urine out of the bladder (urethral catheter). Indwelling catheters are a type of urethral catheter that remain in place for many days or weeks and are held in position by an inflated balloon in the bladder. A urinary catheter is usually used when people have difficulty urinating or to empty the bladder before or after surgery and to help perform certain tests (NHS 2023).

Approximately 25% of hospitalised patients undergo urethral catheterisation during their inpatient stay (Davis et al. 2018). The topic proposer reports that more than three million indwelling catheters are inserted annually in the NHS, equating to approximately 138,000 catheterisations annually in Wales.

A malpositioned urethral catheter, with subsequent inflation of its anchoring balloon in the patient's urethra, is a frequently encountered complication that can lead to debilitating long-term comorbidities, including urethral stricture disease requiring subsequent reconstructive procedures (Davis et al. 2018; Davis et al. 2020). Short-term complications associated with traumatic urethral catheterisation are penile and perineal pain, urosepsis, acute urinary retention, urethral bleeding, or urinary tract infection (Davis et al. 2018). Two studies conducted in the UK and Ireland reported general catheter balloon injury rates of between 5.5 and 6.7 per 1,000 catheterisations (Davis et al. 2016, O'Connor et al. 2023), and a rate of 13 per 1,000 catheterisations in men (O'Connor et al. 2023).

Current practice does not address the risk for the anchoring balloon of the catheter to be accidentally inflated within the urethra rather than the bladder. Indwelling catheters rely entirely on a clinician's training and experience to avoid injury during "blind" insertion.

The Trans Urethral Catheter Safety Valve (TUC Safety Valve) (Class Medical, Ireland) is a Class I regulated, sterile, single-use safety device intended to be used during the insertion of a transurethral urinary catheter to prevent accidental inflation of the anchoring balloon within the urethra. The device is attached between the balloon inflation port and the inflation syringe. By acting as a calibrated pressure-relief valve, it ensures that if a balloon is malpositioned, inflation fluid is vented externally, thereby stopping intraurethral expansion before pressure reaches the threshold for tissue rupture. The venting action provides visual feedback to the clinician to stop inflating the anchoring balloon before repositioning the catheter (Davis et al. 2017).

The topic proposer suggests that urology departments would be the primary users of this device, which would enable safer day-case discharges (for example, post-Holmium Laser Enucleation of the Prostate [HoLEP]) and eliminate emergency readmissions for catheter trauma. The topic proposer also notes that 13% of residents in nursing homes require long-term catheter changes, and so the device could also be used in these settings.

A National Institute for Health and Care Excellence (NICE) Medtech Innovation Briefing (MIB) reported that experts said the technology is likely to most benefit men who need catheterisation (NICE 2020). The MIB noted that the TUC Safety Valve was not used in the NHS as of 2020 (NICE 2020).

Health Technology Wales researchers searched for evidence on urethral catheter safety valves, including, but not limited to, the TUC Safety Valve.

Overview

One non-comparative observational study (Davis *et al.* 2018) was included in the NICE MIB (NICE 2020). An additional observational study (O'Connor *et al.* 2023), published since the NICE MIB, was also identified. This more recent study included an embedded study of comparative data of people catheterised without safety-valve use in a sub-group of centres (O'Connor *et al.* 2023). Both studies reported that the TUC Safety Valve eliminated catheter balloon injuries. One economic analysis, published since the NICE MIB, reported that the TUC Safety Valve is dominant, meaning it provides superior clinical outcomes while nearly halving systemic costs, saving the NHS £93.19 per patient (Croghan *et al.* 2024). Two studies reported the cost of iatrogenic injuries caused during the procedure (Croghan *et al.* 2022; Davis *et al.* 2016).

HTA guidance and guidelines

The NICE MIB identified one non-comparative observational study including a total of 100 men undergoing urethral catheterisation for painless acute urinary retention in a hospital in Ireland (Davis *et al.* 2018). The TUC Safety Valve was utilised by 34 clinicians during urethral catheterisation, and in 7% of patients the valve showed the catheter to be in the incorrect position. In these seven cases, the catheter was successfully repositioned into the urinary bladder and inflated. Of the 31 clinicians who completed a questionnaire after performing the urethral catheterisation procedure, 100% felt that a safety mechanism for preventing balloon inflation in the urethra should be compulsory for all urethral catheterisations (Davis *et al.* 2018). The topic did not proceed to full appraisal due to insufficient evidence (NICE 2020).

Primary studies

In a 12-month observational study, 994 urethral catheterisations were performed across six hospital groups (four in Ireland, two in the UK) (O'Connor *et al.* 2023). Twenty-two (2.2%) episodes of TUC Safety Valve venting (signalling incorrect positioning) were recorded. No urethral injuries occurred in these patients. Data related to catheter balloon injuries during catheterisation without safety-valve use was recorded in an embedded study in three centres. In this embedded three-month study, 18 catheter balloon injuries were recorded in association with catheterisations performed without the safety valve. The injury rate for urethral catheterisation without safety-valve use was calculated to be 5.5 per 1,000 catheterisations (O'Connor *et al.* 2023).

Economic evidence

In an economic analysis conducted from the UK perspective on a cohort of adults requiring transurethral catheterisation, the safety valve was predicted to reduce catheter balloon injuries by 0.04 per person and catheter-balloon injury-related short-term complications by 0.03 per person, over a person's lifetime, and nearly halve costs (Croghan *et al.* 2024). The safety valve was dominant, resulting in 0.02 quality-adjusted life years (QALYs) gained and relative cost savings of £93.19 per person. A probabilistic sensitivity analysis indicated that the safety valve would be cost saving in 97% of simulations run versus standard of care (Croghan *et al.* 2024).

The cost of the TUC Safety Valve is listed as £10.49 on the NHS Supply Chain and £10.65 per unit on the Drug Tariff. The resource impact will be in addition to standard care. In the NICE MIB, some experts suggested that this could be offset by savings from complications avoided by preventing accidental inflation of catheter balloons in the urethra (NICE 2020).

The topic proposer states that managing iatrogenic trauma is costly; information from the topic proposer suggests that treating a single catheter-associated infection costs nearly £10,000. Two studies in the UK and Ireland reported the estimated cost of complications due to catheter balloon injuries. One of these studies reported a cost in excess of €122 per catheter

Evidence overview

placed to cover the costs of iatrogenic injuries caused during the procedures (Davis *et al.* 2016). The other study estimated a cumulative national cost of managing these injuries exceeding £69.35 million per annum across the UK (Croghan *et al.* 2022). It should be noted that the figures from both studies do not include costs of long-term patient management or potential medicolegal claims.

Areas of uncertainty

We identified two observational studies, one of which provided some comparative data in an embedded study in a sub-group of centres. No studies reporting on short-term or long-term patient and system outcomes were identified, including the impact on mortality, need for further treatment, quality of life, and length of hospital stay. One economic analysis was identified reporting the cost effectiveness of the TUC Safety Valve. Two studies reported the cost of iatrogenic injuries caused during the procedures, but these studies did not include the costs of long-term patient management or potential medicolegal claims.

Literature search results

Health technology assessments and guidance, and background information

[HTW](#)

No relevant evidence found

[NHS](#)

NHS (2023). Urinary catheter: <https://www.nhs.uk/tests-and-treatments/urinary-catheters/>

[NICE](#)

NICE MIB210 (2020). TUC Safety Valve to prevent balloon inflation in the urethra during transurethral catheterisation: <https://www.nice.org.uk/advice/mib210>

[Scottish Health Technologies Group](#)

No relevant evidence found

[SIGN Guidelines](#)

No relevant evidence found

[Health Information and Quality Authority](#)

No relevant evidence found

[International HTA Database](#)

No relevant evidence found

[International Guidelines Library](#)

No relevant evidence found

Evidence supplied by topic proposer or manufacturer's website

Bhatt NR, Davis NF, Addie D, et al. Evaluating the cost of iatrogenic urethral catheterisation injuries. *Ir J Med Sci*. Nov 2017;186(4):1051-1055. doi:10.1007/s11845-016-1451-5: <https://doi.org/10.1007/s11845-016-1451-5>

Croghan, S.M., Hayes, L., O'Connor, E.M., Rochester, M., Finch, W., Carrie, A., Considine, S.W., D'Arcy, F., Riogh, A.N.A., Mahmalji, W. and Elhadi, M., 2022. A prospective multi-institutional evaluation of iatrogenic urethral catheterization injuries. *Journal of Investigative surgery*, 35(10), pp.1761-1766: <https://doi.org/10.1080/08941939.2022.2109226>

Croghan, S.M., Malcolm, R., Flood, H.D., Mealing, S., Avey, B., Leonard, G., Wright, J., Davis, N.F. and Walsh, M.T., 2024. Cost-effectiveness of a novel urethral catheter safety device in preventing catheterization injuries in the UK. *Journal of Medical Economics*, 27(1), pp.154-164: <https://doi.org/10.1080/13696998.2023.2298121>

Davis, N.F., Quinlan, M.R., Bhatt, N.R., Browne, C., MacCraith, E., Manecksha, R., Walsh, M.T., Thornhill, J.A. and Mulvin, D., 2016. Incidence, cost, complications and clinical outcomes of iatrogenic urethral catheterization injuries: a prospective multi-institutional study. *The Journal of urology*, 196(5), pp.1473-1477: <https://doi.org/10.1016/j.juro.2016.05.114>

Davis, N.F., Cunnane, E.M., Mooney, R.C., Manecksha, R.P., Thornhill, J.A. and Walsh, M.T., 2017. Quantification of user and manufacturer variabilities in urinary catheter anchoring balloon inflation and mitigation of variability by flow resistance. *Urology*, 102, pp.258-263: <https://doi.org/10.1016/j.jurology.2016.11.037>

Davis, N.F., Cunnane, E.M., Mooney, R.O.C., Forde, J.C. and Walsh, M.T., 2018. Clinical evaluation of a safety-device to prevent urinary catheter inflation related injuries. *Urology*, 115, pp.179-183: <https://doi.org/10.1016/j.urology.2018.02.026>

Davis, N.F., Bhatt, N.R., MacCraith, E., Flood, H.D., Mooney, R., Leonard, G. and Walsh, M.T., 2020. Long-term outcomes of urethral catheterisation injuries: a prospective multi-institutional study. *World journal of urology*, 38(2), pp.473-480: <https://doi.org/10.1007/s00345-019-02775-x>

O'Connor, E.M., Croghan, S.M., Baird, O., Fallon, J., Loughman, P., Esoof, J., Keenan, R.A., Ryan, J., Manecksha, R., D'Arcy, F. and Purtill, H., 2023. A prospective multi-institutional study using a novel safety valve for the prevention of catheter balloon inflation injury of the urethra. *The Journal of Urology*, 210(1), pp.179-185: <https://doi.org/10.1097/JU.0000000000003449>

Date of search	6 March 2026
Concepts used	Transurethral catheter safety valve, trans urethral catheter safety valve, TUC Safety Valve, TUCSV, catheter valve, urethral catheter

Proposed research question and evidence selection criteria (if selected)

Proposed Research question	What is the clinical and cost effectiveness of urethral catheter safety valves?
-----------------------------------	---

	Inclusion criteria	Exclusion criteria
Population	People requiring indwelling urethral catheters (males and females)	People with other types of urinary catheter
Intervention	Urethral catheter balloon safety valves used during urethral catheter insertion, plus standard care (clinician training and experience)	
Comparison/ Comparators	Standard care (clinician training and experience)	
Outcome measures	Frequency of catheter-related balloon injuries Mortality Need for further treatment Safety Length of hospital stay Health-related quality of life Resource use Economic outcomes	

Proposed speciality	Genitourinary system
----------------------------	----------------------