

Use of a new Urethral Catheterisation Device (UCD[®]) to reduce the risks of urethral trauma due to urethral catheterisation



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INTRODUCTION

Up to 25% of hospitalised patients undergo routine urethral catheterisation (UC) during their inpatient stay and approximately 0.3% will sustain iatrogenic urethral trauma during the catheter insertion process [1] resulting in bleeding, false passage and stricture formation, associated with a considerable health care costs of managing these complications [2], but in practice this seems to be more common than this. Urethrotech[®] [3] has developed a 'ready-to-use' 2nd-line medical device (integrated hydrophilic nitinol guide wire into 16F Silicone 3-way Foley catheter) for failed or difficult urethral catheterisation, particularly in clinical environments where no specialist equipment or expertise is available, avoiding more dangerous alternatives such as suprapubic catheter (SPC) insertion.

AIM

- To determine the incidence of traumatic urethral catheterisation retrospectively and prospectively.
- To evaluate the safety and efficacy of this new Urethrotech[®] UCD[®] in men undergoing routine urethral catheterisation prior to cardiac surgery.

MATERIALS & METHODS

- 150 consecutive male patients undergoing Cardiac Surgery at the Heart Hospital evaluated retrospectively
- Complete search through the patients' Cardiac Surgery ICP documentation.
- 74 similar patients evaluated prospectively
- Incidence of traumatic urethral catheterisation and need for suprapubic catheter (SPC) insertion determined
- 100 similar patients then studied prospectively after UCLH Clinical Effectiveness Steering (CESG) to trial a UCD[®] to see if it reduced the incidence of trauma
- Mean patient age 64.4 years
- Standard of procedure documentation also reviewed

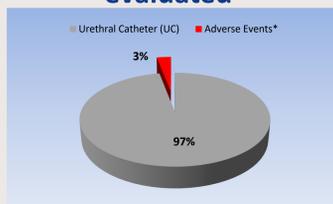
REFERENCE

- [1] Kashefi C, Messer K, Barden R et al. Incidence and prevention of iatrogenic urethral injuries. J Urol. 2008; 179: 2254
- [2] Davis NF et al. Incidence, cost and clinical outcomes of iatrogenic urethral catheterisation injuries: A prospective multi-institutional study. J Urol 2016; 196: 1473-77
- [3] www.urethrotech.com

RESULTS

- 127 of 150 patients reviewed retrospectively had complete documentation in their clinical notes and none had documented consent or been counselled about potential complications of urethral catheterisation.
- No adverse events were encountered using the UCD[®] in this high-risk group of patients and all 100 UCD's were inserted without technical difficulty by non-specialist clinical staff normally performing the pre-operative catheterisation.

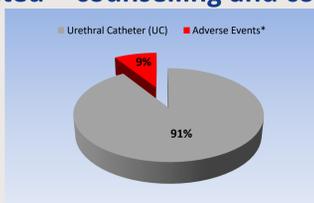
UC- Outcome in 150 high risk patients retrospectively evaluated



4 adverse events:

- all required SPC for traumatic and unsuccessful urethral catheterisation

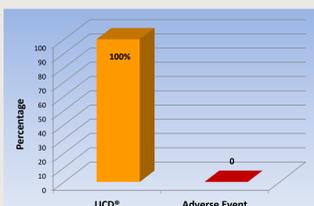
UC- Outcome in 74 high risk patients prospectively evaluated - counselling and consent



7 adverse events:

- Urethral pain/perineal pain/urethral bleeding (n=5; 6.8%)
- Suprapubic catheter (n=2; 2.7%)

UCD Outcome in 100 high risk patients prospectively trialed using Urethrotech[®] UCD[®]

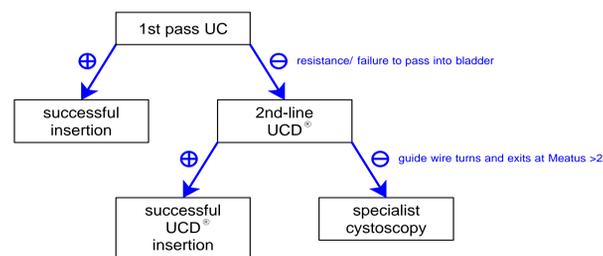


0 adverse events

Advantages of the Urethrotech[®] UCD[®]

UCD is a safe 2 nd -line urethral catheterisation device which can solve a medical emergency of failed urethral catheterisation	Integrated guide wire system avoids needle-stick injuries and risk of damage to the catheter balloon inflation channel when using a DIY-approach (.. trying to puncture the tip of a standard Foley catheter to introduce a non-integrated guide wire)
Integrated UCD guide wire allows for 'One-Man' management of a medical emergency	Minimal additional training required to enable non-specialist health care professionals to use UCD
UCD empowers advanced Nurse-led Services in a non-specialised clinical setting, suitable for 'out-of-hours' Service.	Guide wire in separate catheter wall channel prevents obstruction of the central catheter urine drainage channel by the wire itself allowing urine to drain freely once the catheter is correctly positioned in the bladder
Use in the community avoids unnecessary visits to A & E, hospital admission, catheterisation under cystoscopic vision and suprapubic catheter insertion	Once the guide wire is removed, the guide wire channel may be used for continuous bladder irrigation in haematuria patients

TREATMENT ALGORITHM

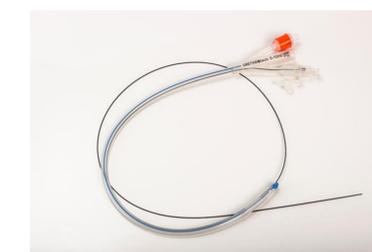


UC : urethral catheter
UCD : Urethral Catheterisation Device[®]

CONCLUSIONS

- Urethral catheterisation is associated with a significant risk of trauma – ten times the reported incidence.
- To reduce that risk, the catheter should be passed over a guide wire, should 1st pass standard catheter insertion be encountered with resistance, as offered with the Urethrotech[®] UCD[®], as is common practice for passing catheters into other anatomical structures of the body.
- This should particularly apply in high risk patients, such as those being catheterised prior to cardiac surgery who are about to be heparinised.
- The UCD allows for safe urethral catheterisation in situations where initial catheterisation has failed and can be performed by nursing staff in the community, preventing urethral trauma and avoiding unnecessary visits to the emergency department, hospital admission, catheterisation under cystoscopic vision or suprapubic catheter insertion.

URETHROtech[®] URETHRAL CATHETERISATION DEVICE[®] (UCD[®])

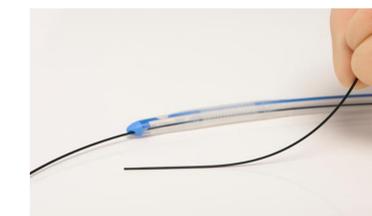


16F 3-way Silicone urethral catheter with integrated guide wire for safe 2nd-line urethral catheterisation



Guide wire is glued to luer lock 'guide wire stopper', which fits snugly into catheter guide wire side arm to form **ONE** secure Medical Device UNIT.

Syringe is attached to luer lock 'guide wire stopper' to prime and lubricate the guide wire with sterile water or saline.



Non-traumatic Nitinol guide wire exits the round Nelaton catheter tip



The guide wire is introduced into the urethral meatus with the penis on stretch and advanced with even movements into the bladder where it curls up, dragging the catheter behind.



The catheter is then passed over the guide wire into the bladder bypassing an enlarged prostate avoiding urethral trauma.