Safe access for bladder entry (SAFE) in transgender men following genital gender affirmation surgery: a randomised controlled trial

Objectives:
Genital gender affirmation surgery (gGAS) requires the formation of a skin tube urethra for urethral lengthening to allow for standing micturition. Over time, the urethral segment dilates and becomes tortuous making catheterisation challenging. The Urethrotech UCD® (UCD) is a catheter with an integrated hydrophilic guidewire developed for difficult male catheterisation. This study tested the hypothesis that the UCD would facilitate catheterisation in transgender men following gGAS.

Methods:
Transmen following phalloplasty with tube-in-tube urethra and urethral lengthening presenting for insertion or revision of erectile device were recruited. They were randomised for catheterisation using a Urethrotech UCD® or a Bardia Aquafil® (standard) Foley catheter. If unsuccessful, a guidewire was directed by flexible cystoscopy into the bladder to aid catheterisation. Results reported as mean $\pm$ SEM. Statistical significant defined as $p<0.05$. ClinicalTrials.gov NCT04454970; https://clinicaltrials.gov/study/NCT04454970.

Results
Twenty transmen were block randomised to either arm of the study. Most men were for insertion of an erectile device (70%) while 25% had revision of their erectile device. One case didn't proceed when a stricture was identified during catheterisation attempt. The UCD was successful in 60% of men while a standard catheter was successful in 30% ($p=0.19$). Time taken to catheterise was longer for the UCD (122 ± 21s vs 37 ± 7s, $p<0.0001$). Catheterisation was successful in all transmen once flexible cystoscopy was performed. Two transmen developed a postoperative scrotal haematoma following UCD insertion while another developed an infected erectile device within 30 days of standard catheterisation.

Conclusions:
The overall success rate of catheterisation was 45% without the aid of flexible cystoscopy with a trend suggesting better success with the UCD. Catheterisation is difficult following phalloplasty and urethral lengthening for gGAS even with the aid of an integrated guidewire. There should be a low threshold to utilise flexible cystoscopy when attempting catheterisation in transmen following gGAS.