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IMPROVED PERFORMANCE WITH THE INTERMITTENT URINARY MICRO-HOLE ZONE CATHETER: A COMBINED ANALYSIS OF THREE RANDOMIZED CONTROLLED STUDIES

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Background

Risk for UTIs in IC users centres around underlying conditions, IC compliance and technique, and factors related to the individual IC device and process. Conventional two-eyelet catheters (CEC) have been associated with premature flow-stops due to mucosal suctions during bladder emptying leaving residual urine unless the catheter is repositioned, and risk for microtrauma. The objective was therefore to evaluate the performance of a newly developed intermittent catheter with multiple micro-holes, designed to improve emptying and without premature flow-stops.

Methods

Three similar randomized controlled cross-over studies evaluated the Micro-hole Zone Catheter (MHZC) and CEC during three single test visits in a healthy volunteer (HV) study (15 males and 15 females), in a male IC-user study (15 males), and a female IC-user study (15 females) (ClinicalTrials.gov: NCT04445051, NCT04543136 and NCT04557787). Subjects were randomized to evaluate one of three catheters at each visit, including two different prototypes of the MHZC, differing by the length of the drainage zone and the number of drainage holes, and one CEC.

Results

Compared to catheterisations with MHZC, CEC resulted in a significantly higher mean residual urine at 1st flow-stop (mean difference: 49mL in males and 32mL in females, both $p<0.001$) and a higher average number of flow-stop incidents (8 and 21 times more frequent for males and females, respectively, both $p<0.001$). During normal micturition in HV, the likelihood for haematuria post-catheterisation was 5.84 higher with CEC compared to MHZC, $p=0.053$, whereas there was no difference in haematuria between catheter IC users.

Conclusion

The new MHZC shows the ability to reduce premature flow-stops and residual urine compared to a CEC and thus provides IC users with a simple catheterisation process without the need to reposition the catheter to escape potential UTI risk factors common in users dependent on IC.