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MICRO-HOLE ZONE TECHNOLOGY SHOWS SUPERIOR ABILITY TO EMPTY THE BLADDER: A CROSSOVER RANDOMISED CONTROLLED TRIAL IN USERS OF INTERMITTENT CATHETERS

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Background:

Residual urine is seen as a risk factor for acquiring UTIs and many clean intermittent catheter (CIC) users are uncertain about whether they have residual urine after performing IC. With conventional eyelet catheters (CEC), users can experience urine flow stops during catheterisation leading to possible residual urine. This study investigated the performance of an intermittent catheter with Micro-hole Zone Technology (MHZC) designed to avoid urinary flow-stops and residual urine.

Method:

The investigation was a single-centre, crossover, randomised, controlled study performed at Sanos Clinic, Denmark (ClinicalTrials.gov NCT05485922). The study consisted of one inclusion visit and two single test visits. Subjects were catheterized by a health-care professional with a MHZC and a CEC (Hollister Vapro®). Primary study endpoints were number of flow-stop episodes and residual urine volume at 1st flow-stop (RV1).

Results:

Forty-two male CIC users were enrolled, and the background characteristics were not significantly different in the two groups. Results showed that catheterisation with MHZC resulted in close to zero flow-stops (mean: 0.17; 95% CI: 0.06-0.45) compared to approximately 1 flow-stop with CEC (mean: 1.09; 95% CI: 0.75-1.6). Mean [SE] residual urine at 1st flow-stop was 5.10 mL [1.14] for MHZC vs. 39.40 mL [9.65] for CEC ($p<0.001$). In addition, 90% of the catheterisations with MHZC led to less than 10mL urine at 1st flow-stop. The results also showed 74% less likelihood for haematuria post-catheterisation with MHZC compared to CEC ($p<0.05$).

Conclusion:

Results from this study underlines the superiority of the MHZC with significantly reduced numbers of flow-stops and residual urine volume at 1st flow-stop compared to a CEC. With this new micro-hole zone technology, CIC users will experience a simpler catheterisation process without flow-stops and no need for repositioning the catheter to completely empty their bladder, potentially lowering the risk for future UTIs.