Improved performance with the intermittent urinary micro-hole zone catheter: a combined analysis of three randomised controlled studies

M. H. Landauro[1], R. Vaabengaard[1], L. Jacobsen [1], F. Tentor [1], J. Hannibalsen[2], R. Permild[2], and P. Bagi[2]

[1]Coloplast A/S, Humlebæk, Denmark, [2]Department of Urology, Righospitalet, 2100 Copenhagen, Denmark

Background: Risk for urinary tract infections (UTIs) in intermittent catheter (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, which increases the risk for residual urine and microtrauma. The objective was therefore to evaluate the performance of new intermittent catheter prototypes with a drainage zone featuring micro-holes, designed to reduce mucosal suction, flow stops, microtrauma, and to improve bladder emptying".

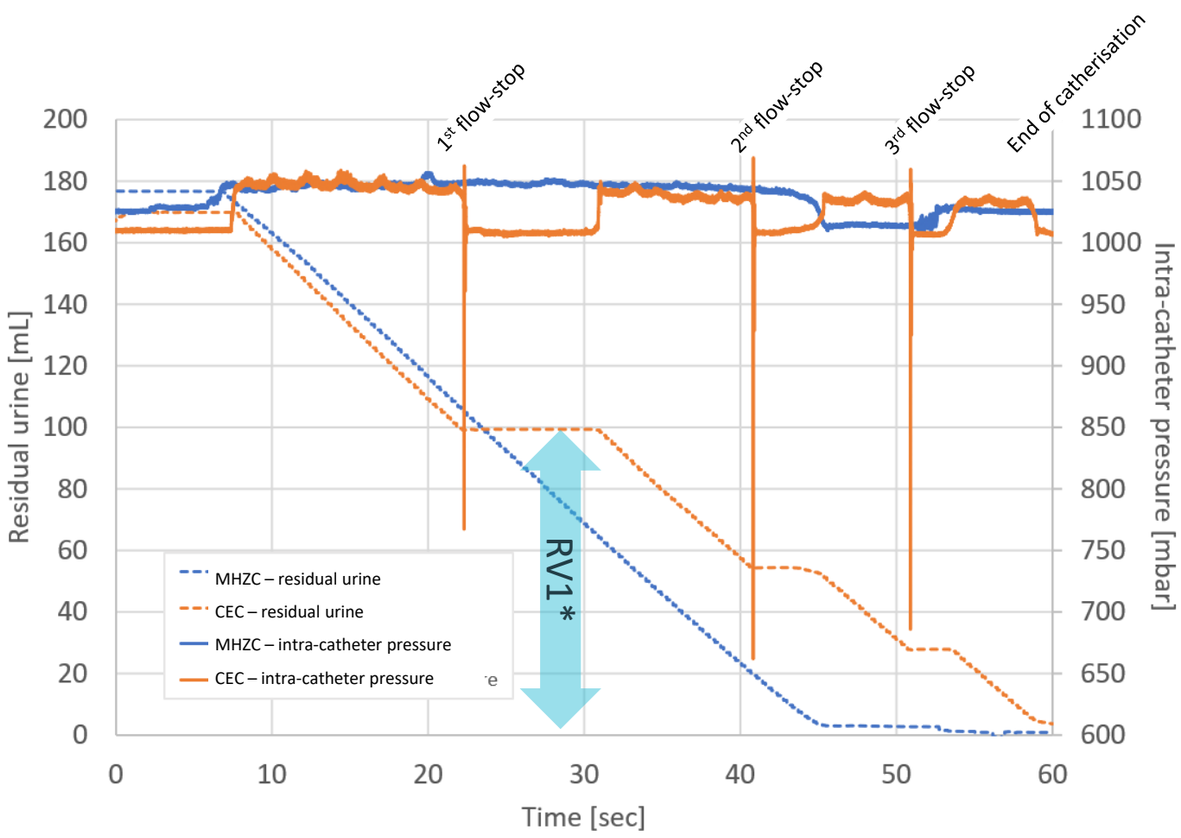

Figure 3. Illustrative example of pressure/ volume graph for one catheterisation with CEC and one with MHZC. *Residual volume at 1st flow stop (RV1) represented by the light blue arrow, calculated as total catheterised volume minus catheterized volume at first flow-stop. RV1 represent level of residual volume in worst case when CEC is withdrawn without proper repositioning. At flow stops, repositioning of the catheter is needed to reinitiate urinary flow.

Figure 1. Male prototype catheter. Hole size: 0.4mm, 4 rows of holes. Short variant 1: 21x4 holes. Long variant 2: 38x4 holes.

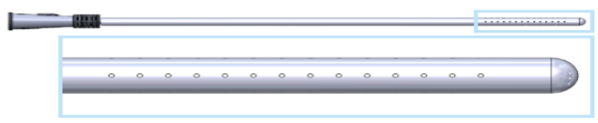

Figure 2. female prototype catheter. Hole size: 0.4mm, 4 rows of holes. Short variant 1: 14x4 holes. Long variant 2: 17x4 holes.

Method: Three similar randomized controlled cross-over studies evaluated the Micro-hole Zone Catheter (MHZC) and CEC during three single test visits in study 1) 15 males and 15 females healthy volunteers (HV); study 2) 15 male IC users; and study 3) 15 female IC users (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 (fig. 1+2), differing by the length of drainage zone and number of drainage holes, and one CEC.

Primary endpoints were residual urine volume at 1st flow-stop (total urine catheterised minus urine catheterised at 1st flow-stop), and number of flow-stop episodes (fig.3), combining results from the three studies, assuming same effects for HV and IC-users, but separated on sex. For incidents of haematuria, an effect of underlying condition was assumed, and results were separated for HV and IC-users but combined on sex.

Results: Compared to catheterisations with CEC, MHZC resulted in a significantly lower mean residual urine at 1st flow-stop (mean difference: 49mL in males and 32mL in females, both p<0.001) (fig.4) and lower average number of flow-stop incidents (8 and 21 times less frequent for males and females, respectively, both p<0.001) (fig.5)
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 secure complete bladder emptying, measured as residual urine at 1st flow-stop, compared to a CEC. The new MHZC thus provides IC-users with a simple catheterisation process without the need to reposition the catheter escaping potential UTI risk factors, common in users dependent on IC.

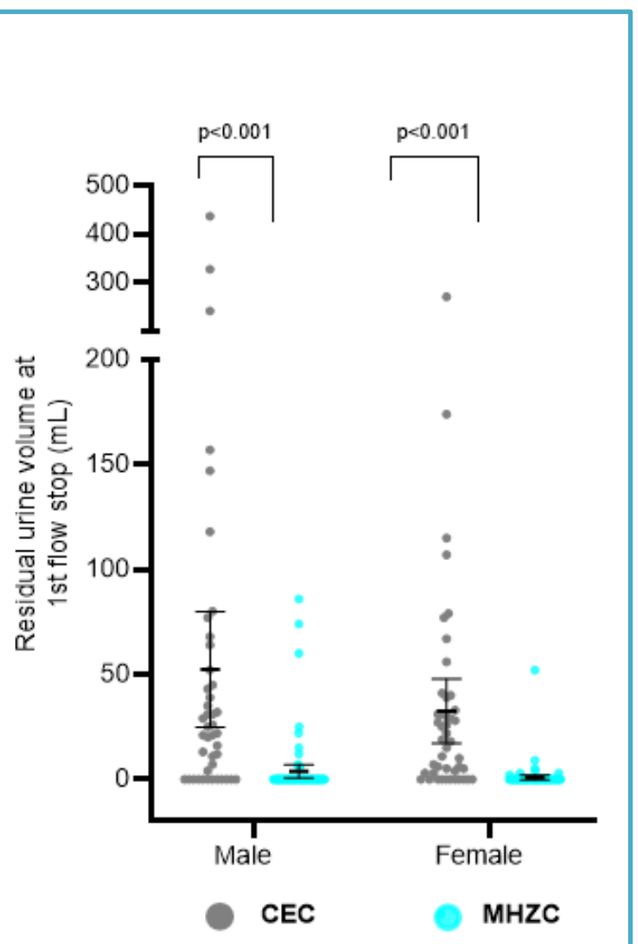

Figure 4. Residual urine at 1st flow-stop with CEC and MHZC, in male and female subjects

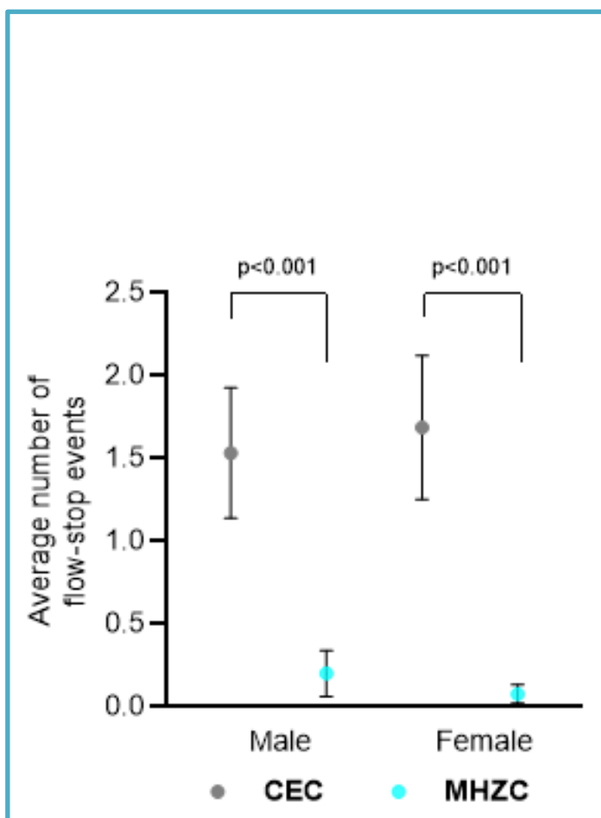

Figure 5. Average number of flow-stops with CEC and MHZC, in male and female subjects

* Kennelly, M., et al., Adv Urol. 2019;2019:2757862.