

USEFULNESS OF NEWLY DESIGNED REUSE SILICONE CATHETER FOR FEMALE INTERMITTENT SELF-CATHETERIZATION - RESULTS OF 2 YEAR FOLLOW UP -

Hypothesis / aims of study

We evaluated long term (2 years) safety and efficacy of new reuse silicone catheter to improve problems of conventional catheter for female clean intermittent self-catheterization (CIC), for comfortable use, easy maintenance, and decrease of urinary tract infection.

Study design, materials and methods

The subjects were 20 women with flaccid bladder who were skilled in the conventional CIC techniques for more than 3 years, and agreed to participate in this clinical study after fully informed consent. The newly designed device has two holes with an opening on the side with the distal end of the catheter, around the side and tip hole was polished enough to avoid mechanical mucosal injury. We were fitted original light cap for easy opening and closing to funnel (distal) section. The proximal tip hole and distal funnel end of the catheter is very useful for easy washing and advantageous to dry the catheter lumen. We compared and examined the following six items with other 20 female conventional CIC catheter users for 2 year follow up.

- 1) Degree of ladder mucosal injury at the time of catheterization (using cystoscopy after CIC, numerical VAS, 0: no injury, 4: severe injury)
- 2) Satisfaction during washing and drying of the catheter (satisfaction VAS, 0: terrible, 10: delighted)
- 3) Time required for completion of the washing up from the start of the catheterization in the toilet when going out
- 4) Frequency of occurrence of pyuria (/ year)
- 5) Frequency of occurrence of symptomatic urinary tract infections (afebrile, / year)
- 6) Frequency of occurrence of febrile urinary tract infections (/ year)

Results

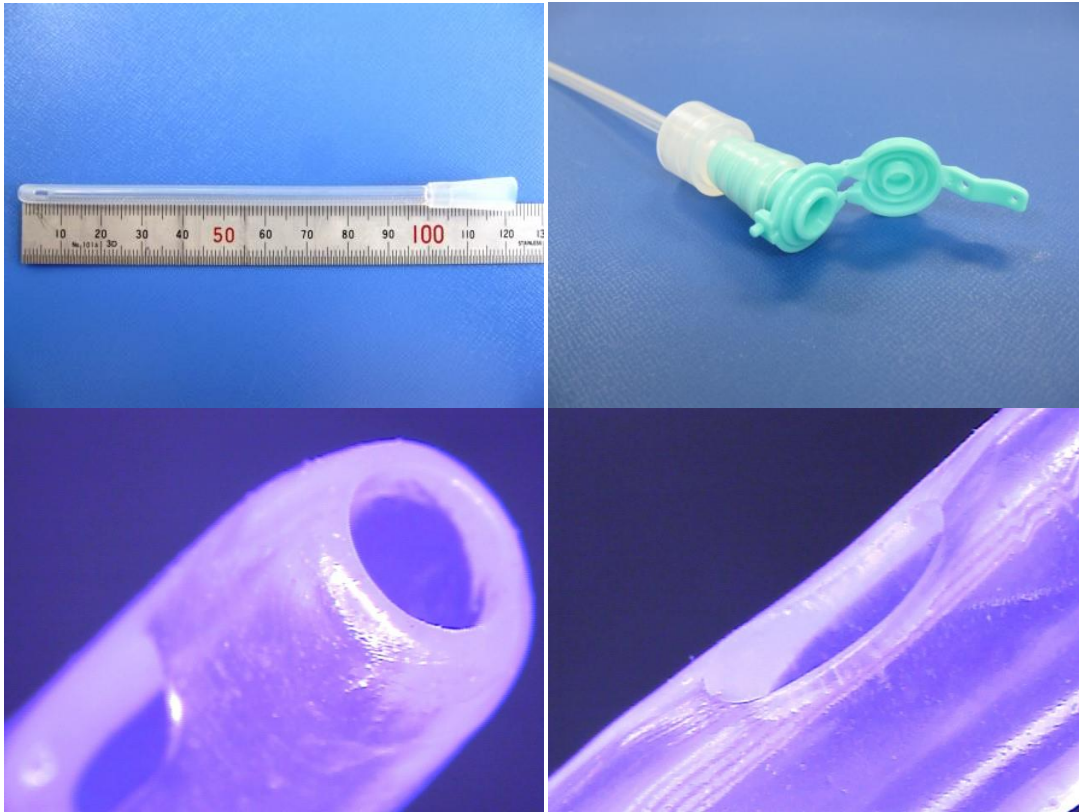
- 1) Minor trend was observed bladder injury at the time of catheter insertion (no significant differences)
- 2) Satisfaction was significantly higher in the cleaning and drying operation ($p=0.001$, unpaired t-test)
- 3) The time required to completion of washing is significantly reduced ($p=0.004$), new catheter: 535.3 ± 16.9 (average \pm standard error) vs. conventional catheter: 645.5 ± 31.6 sec.
- 4) There was no significant difference in frequency of occurrence pyuria (new catheter: 0.9 ± 0.2 vs. conventional catheter: 0.9 ± 0.2 times/year).
- 5) There was no significant difference in frequency of occurrence of afebrile symptomatic urinary tract infections (new catheter: 0.35 ± 0.11 vs. conventional catheter: 0.40 ± 0.11 times/year).
- 6) There was no significant difference in frequency of occurrence of febrile urinary tract infections (new catheter: 0.10 ± 0.07 vs. conventional catheter: 0.30 ± 0.11 times/year).

Interpretation of results

This newly designed reuse silicone catheter could improve QOL and ADL for female CIC patients, effective in cost savings, and also has the potential to become CIC possible for patients who are impossible using conventional device.

Concluding message

Evaluating opinions and advices from doctors and patients, We would like to modify a catheter more that is easy to use for CIC patients.



Disclosures

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