

#507: A female intermittent catheter improving well-being, independence, dignity and control.

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Hypothesis / aims of study

Intermittent self-catheterization (IC) is the gold standard for bladder management of patients suffering from **neurogenic lower urinary tract dysfunction**.

Improving the catheters design
Make IC easier: less time consuming, less complexity
Enhance independence for patients
Reduce the risk of damaging the urinary tract
More adherence to the treatment, and better managing their neurogenic bladder
Better handling for patients with reduced motor skills
More satisfaction and Quality of Life (QoL) for patients

LoFric® Elle

- A ready-to-use, hydrophilic intermittent female catheter.
- Urotonic® Surface Technology + angulated handle.
 - Smooth surface → safe insertion and withdrawal.
 - More compact and slimer than previous LoFric® catheters
- Ergonomic handle:**
 - Its container transforms into an L-shaped handle after connection to the catheter funnel's end.
 - Better control and acts as an extension for better visibility and greater reach to facilitate the procedure.
 - Multiple gripping possibilities to accommodate individual preferences and adapt to potential alterations in dexterity.
 - More upright position on the toilet while creating greater distance from the toilet bowl which improves hygiene.

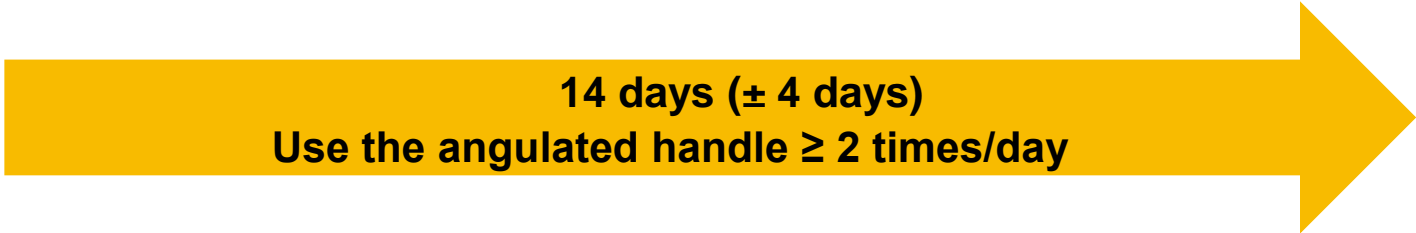


Aims of study:

- To investigate the **QoL** of subjects using LoFric® Elle: satisfaction, perception, and compliance of the subjects.
- To assess the **safety** of the catheter using the ISC-Q.

Study design, materials and methods

- A prospective, single-arm, interventional, multi-center study.
- Investigate QoL: **ISC-Q questionnaire**
- Evaluate compliance, satisfaction and perception of the subjects when using LoFric® Elle:
 - Specific domains of ISC-Q score**
 - Wellspect questionnaire**



Visit 1

- Explain the study
- Inclusion/exclusion criteria
- Sign an informed consent
- Initial questionnaires (**usual catheter**)
- Training in the use of LoFric® Elle
- Dispense study products for 2 weeks of use

Visit 2

- Return unused devices
- Questionnaires: adherence, safety and compliance **with LoFric® Elle**
- Discontinuation: register the cause

- Participant centres:** 2 sites in Sweden and 2 sites in Spain.
- Recruitment time:** between March 2020 and January 2023.

Inclusion criteria	Exclusion criteria
Females ≥ 18 years Maintained urethra sensibility IC ≥ 3 months and ≤ 5 years IC ≥ 2 times/day Provision of informed consent Ability to read, write and to understand the study information	Symptomatic UTI Urethral stricture Involvement in the study planning Simultaneous participation in another clinical study Non-compliance to protocol

Objective QoL: ISC-Q score > 60

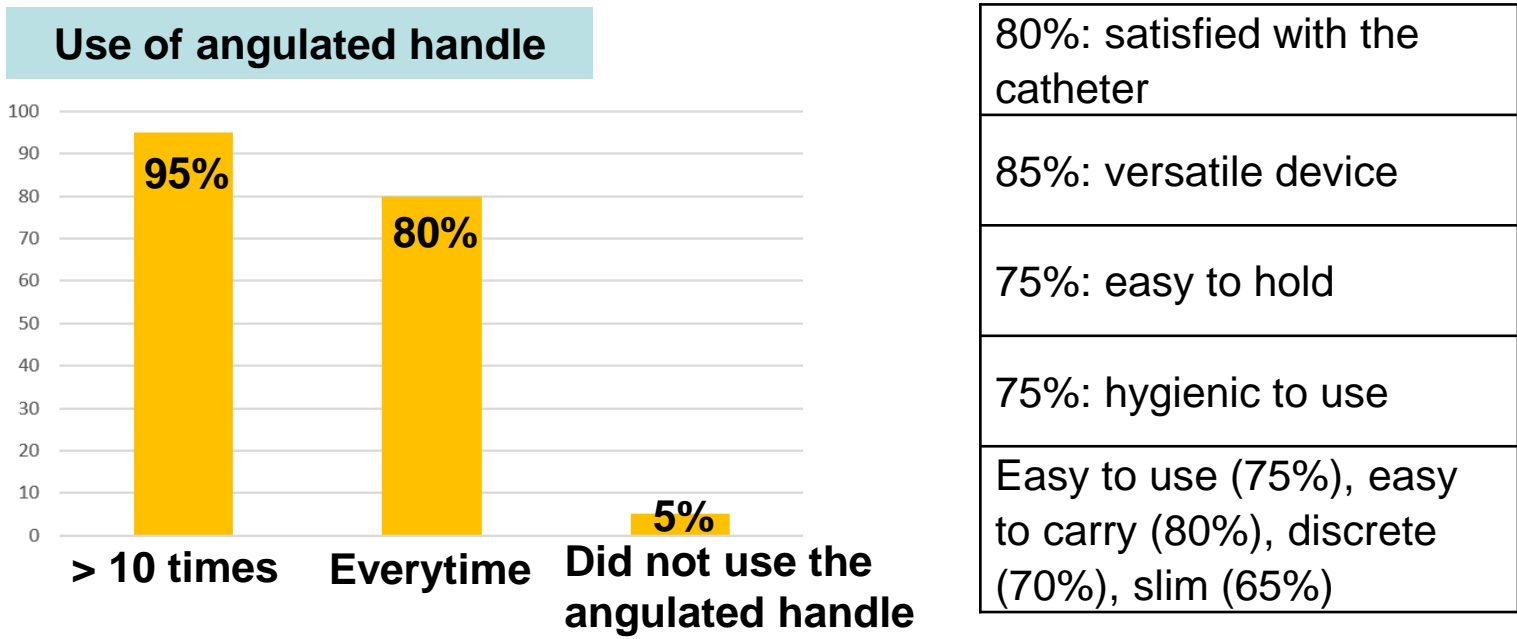
Results and interpretation

20 subjects enrolled
Mean age: 56.30 ± 13.31 years (23-72)
Reason for catheterization: <ul style="list-style-type: none">Urological (50%)Neurological (35%)Surgical or others (15%)
90%: self-catheterization while sitting on a toilet 90%: did not use urine bag 95%: did not use extension device 75%: did not use a mirror
100%: satisfied with their usual catheter 50%: were not familiar with LoFric® Elle catheters

Quality of Life (QoL)

ISC-Q score	V1	V2
Total ISC-Q (mean)	76.61	75.89
P-value	0.0007	0.0002
95% CI	[68.78,84.45]	[69.78,81.99]
”Ease of use” domain (mean)	88.75	78.13
”Convenience” domain (mean)	56.88	67.50
”Discreetness” domain (mean)	78.33	88.33
”Psychological well being” domain	71.88	66.04

Compliance, versatility and perception



Safety

30% subjects reported AEs (all mild and transient)
3 events possibly related to device use (UTI, itching in urethra)

Conclusions

- LoFric® Elle: safe treatment option for subjects in IC.
- Its ergonomic design makes it easy to use with or without the angulated handle.
- LoFric® Elle provides **high QoL for the subjects**: the ISC-Q total mean score and mean scores for most specific domains were > 60 after 2 weeks of using the catheter.
- ↑ compliance and satisfaction (80%).
- 60% were ready to continue using this catheter after the study.
- LoFric® Elle is a viable option for women requiring IC:
 - The angulated handle offers new possibilities to use the catheter.
 - The distance it creates provides more hygienic catheterization conditions.
- Longer studies with more patients are necessary.

References

- 1) Chartier-Kastler E, Denys P. Intermittent catheterization with hydrophilic catheters as a treatment of chronic neurogenic urinary retention. Neurourol Urodyn. 2011;30(1):21-31.
- 2) Looby A, Davies H, Mealing S, Smith AB, Avey B, Laezza A, et al. Time trade-off study to establish utility decrements in individuals with a spinal cord injury who perform intermittent catheterization. J Med Econ. 2023;26(1):430-40.
- 3) Kinnear N, Barnett D, O’Callaghan M, Horsell K, Gani J, Hennessey D. The impact of catheter-based bladder drainage method on urinary tract infection risk in spinal cord injury and neurogenic bladder: A systematic review. Neurourol Urodyn. 2020;39(2):854-62.
- 4) Herbert AS, Welk B, Elliott CS. Internal and External Barriers to Bladder Management in Persons with Neurologic Disease Performing Intermittent Catheterization. Int J Environ Res Public Health. 2023;20(12).
- 5) Håkansson MA, Neovius K, Norrbäck M, Svensson J, Lundqvist T. Health Care Utilization and Complications Rates among Users Of Hydrophilic-Coated Catheters. Urol Nurs. 2015;35(5):239-47.
- 6) Ginsberg DA, Boone TB, Cameron AP, Gousse A, Kaufman MR, Keays E, et al. The AUA/SUFU Guideline on Adult Neurogenic Lower Urinary Tract Dysfunction: Diagnosis and Evaluation. J Urol. 2021;206(5):1097-105.
- 7) Engberg S, Clapper J, McNichol L, Thompson D, Welch VW, Gray M. Current Evidence Related to Intermittent Catheterization: A Scoping Review. J Wound Ostomy Continence Nurs. 2020;47(2):140-65.