



Letters to the editor

Re: The importance of osmolality in hydrophilic urethral catheters: a crossover study, Waller *et al.* *Spinal Cord* (1997) 35: 229–233.

The above mentioned article is a comparative clinical study between two coated urethral catheters Conveen EasiCath[®] manufactured by Coloplast A/S, Denmark, and LoFric[®] manufactured by Astra Tech, Sweden. In the article, the authors bring up grave accusations against Coloplast A/S as follows:

- a) 'Although our request for information concerning the osmolality of the hydrophilic layer was not respected by the manufacturer of the EasiCath[®] we decided to carry on with the test on our own initiative' (page 230, section 2, lines 15–19).
- b) EasiCath[®] is a '...commercial hydrophilic catheter with unknown physical properties...' (page 230, section 2, lines 43–44).
- c) Missing product information, basic test results and documentation as referred to above, have been promised, but never provided, by the manufacturers of new hydrophilic catheters, including the catheter tested against LoFric[®] in this study' (page 232, section 2, lines 1–5).

In the light of the seriousness of this matter, Coloplast A/S feels that such accusations must be commented upon to reach the readers of *Spinal Cord*.

It should be emphasised that neither before, nor during or after the present study, did the authors contact or in any way inform Coloplast A/S about the study. On request, Coloplast A/S would have supplied the authors with technical data and documentation concerning EasiCath[®], needed in order to compare the two catheter types in a correct manner, and in order to soundly evaluate the experimental data with reference to the importance of osmolality in hydrophilic catheters.

Having read the article upon release in April 1997, Coloplast A/S wanted to reproduce the study. As several issues, especially regarding the methodology of the study, seemed unclear, on May 20th Coloplast contacted the first author Lena Waller in order for her to comment upon these issues. In her reply of June 10th, Lena Waller did not supply the requested information needed to reproduce the study.

Since the present study compares two competitive products, Coloplast A/S finds it mandatory that essential parts of the questions forwarded to Lena Waller, as well as general comments by Coloplast A/S regarding the article, should be published and commented upon.

1) In Material and methods it is stated that 'The maximum friction during standard removal of the catheter (10 cm/sec) was measured with an electronic dynamometer...'

Question: What is standardised removal in regard to assuring the same values of acceleration (at start) as well as the angle and velocity during all measurements of friction?

How is the velocity of the catheter removal of 10 cm/sec registered and what is the variation hereof?

Comment: Measurements of friction during catheter removal was made manually by the nurse with a dynamometer of the brand Mecmesin AFG-25. The supplier of this dynamometer, JKM Systems, Denmark, has informed Coloplast A/S that reproducible results using manual measurements as mentioned above are doubtful.

2) In Results it is stated that the number of catheter stickings to the urethra were registered.

Question: How was the registration of catheter sticking performed?

Why was the measurements of friction during catheter removal (using the dynamometer) not used for registration of catheter sticking?

Comment: Registration of catheter sticking in the present study seems to rely solely on a personal feel by the nurse performing the catheter removal. As the study was not blinded it must be assumed that the nurse was aware of the origin of each specific catheter.

3) In Background the authors mention that the osmolality of humane urine is approximately 800 mOsm/kg. They further state that 'The osmolality of a hydrophilic catheter should equalise the osmolality of humane urine. Soaked in water the polyvinyl pyrrolidone chains bind the lubrication liquid to approximately the same osmolality as exists in urethral epithelium'.

Question: On what basis do the authors state that the osmolality of hydrophilic catheters should equalise that of humane urine, and what documentation exists on the osmolality of humane urethral epithelium being approximately 800 mOsm/kg?

Comment: In a previous study, (ref. 1), use of LoFric[®] catheters with coatings of different osmolality (from 30 to 800 mOsm/kg), showed no correlation between coating osmolality and friction during removal. One could wonder why the results of this study, which clearly contradict the main conclusions of the present study, have not been included by the authors as subject for discussion.

4) In Discussion the authors indicate the existence of a correlation between the osmolality of catheter coating and microtrauma of the urethral epithelium.

Question: What is the scientific basis for this correlation?

Comment: The present study does not investigate the presence of possible microtrauma in the urethral epithelium. Former studies indicate that LoFric[®] causes less trauma to the epithelium when compared with older ordinary catheters with gel, but in the scientific literature no evidence establishes a correlation between osmolality of catheter coating and urethral trauma, and no evidence points to the EasiCath[®] catheter causing more urethral trauma than the LoFric[®] catheter.

5) In **Discussion** the authors state that 'As osmolality is a decisive factor for a hydrophilic catheter's water retention and, hence, level of friction...'

Question: Why do the authors not bring up the fact that the two catheters tested are different, and that differences other than the osmolality of the catheter coating may have influenced the results?

Comment: In scientific studies, it is standard practice that factors, which may influence the results, but are not for investigation, be held constant.

Final comment:: In trying to reproduce the study it is crucial for Coloplast A/S that the above mentioned information becomes available. The same information is essential for the scientific community, and for physicians and patients in making the right decision concerning their choice of products.

References

1. Carlsten J, Bowall S, Sullivan L, Nilsson A. Effect of catheterization and surface osmolality on urethral epithelium. Abstract from Annual Scientific Meeting in Stoke Mandeville, England, May 1987.

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Reply from Dr L Waller

Before replying to the questions, I would like once more to emphasise that our request for information before the study was neglected and that the clinical part of the study has been reproducible ever since the initial presentation at the regional meeting of IMSOP in Cyprus in April 1995.

- 1 It has proved suitable to use the dynamometer the way it was used in the study. Our nurse was informed about the importance of keeping strictly to the same technique in all measurements and trained for some time to standardise her methodology before the actual study started. The

velocity was not recorded due to practical reasons. Although there may have been small differences in angles, velocity and acceleration, these can be ignored in view of the large number of measurements ($n=526$). The statistical analysis also pointed to a significant difference between the two catheters ($p<0.001$).

- 2 In clinical trials adverse events (AE) must be reported. In the study two reporting methods were used. One of them consisted of the AE that occurred during the measurements and reported by the nurse performing them, while the other comprised AE reported by patients and the rest of the staff. It is important to inform about the AE frequency in a study so we present those reported by the nurse. The relationship between sticking and dynamometer value can be seen in the article. It should also be mentioned that the study was designed to use tap water as lubricator but due to severe stickings when using the EasiCath we had to change to saline solution.
- 3 Measurement of the osmolality of the urethral epithelium has proved to be difficult. The actual sampling of the cell layer destroys the cells, which makes measurement of osmolality impossible. However, this is not inconsistent with the logic of our theory, namely that the outer layer of a hydrophilic catheter should equalise what normally passes through the urethra. According to the original abstract (your ref. 1), the osmolality of human urine is 700–1100 mOsm/kg. The absence of a relationship between friction and osmolality was, in our view, due to the short catheterisation time (60 s). In the present study the catheterisation time was slightly more than 4 min.
- 4 The results of our first study (your ref. 1) show a clear relationship between friction and trauma of the urethral epithelium. In this study there was a clear relationship between *removal* friction and the osmolality of the outer layer of hydrophilic catheters. Therefore, we assume that there is also a relationship between trauma and osmolality, although it remains for this to be demonstrated scientifically. We have now experienced on two occasions severe stickings and stuck catheters when using lowosmolar catheters and so have a very good reason for assuming the existence of such a relationship.
- 5 The aim of this study was to ascertain the significance of the osmolality of the outer layer of hydrophilic catheters. According to the laboratory tests performed, both the catheters were PVC catheters with a hydrophilic coating, while LoFric[®] also had an outer layer of sodium chloride. No other significant differences was observed between the two catheters.

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