

Chartier-Kastler E¹, Ballanger P², Petit J³, Fourmarier M⁴, Bart S⁵, Ragni-Ghazarossian E⁶, Ruffion A⁷, Lenormand L⁸, Costa P⁹

1. *Hopital Pitie-Salpetriere, Assitance Publique Hopitaux de Paris, université Paris VI*, 2. *CHU Bordeaux*, 3. *CHU Amiens*, 4. *CH Aix en Provence*, 5. *Hopital Pitie-Salpetriere, Assitance Publique Hopitaux de Paris*, 6. *Hopital Nord, Marseille*, 7. *Hopital Lyon Sud*, 8. *CHU Nantes*, 9. *CHU caremeau, Nîmes*

RANDOMIZED CROSSOVER STUDY EVALUATING IMPACT ON QUALITY OF LIFE AND PATIENT PREFERENCE OF URINARY SHEATHS VERSUS DIAPERS IN INCONTINENT MEN

Hypothesis / aims of study

To evaluate the impact of urisheaths versus absorbent products (APs) on QoL in incontinent men.

Study design, materials and methods

randomised, controlled, crossover trial in 61 outpatient adult men with stable, moderate/heavy urinary incontinence was conducted from June 2007 to February 2009 in 14 urology centres. Participants tested Conveen Optima urisheaths and their usual AP for 2 wk each in random order. Impact on QoL was measured with the King's Health Questionnaire (KHQ) and the SF-12 Acute questionnaire. Patient's preference was recorded. A 10-item patient questionnaire was used to assess the product main advantages on an 11-point scale (0: worst; 10: best). A 72-h leakage diary was used to record the number and severity of leaks and daily product consumption. Safety was measured as the number of local adverse events.

Results

All dimensions of the KHQ were scored lower with urisheaths, indicating an improvement in QoL, especially for "limitations of daily activities" (-10.24 ± 3.99 , $p = 0.01$) and "impact of incontinence" (-7.05 ± 3.45 , $p < 0.05$). The majority (69%) of patients preferred urisheaths to their usual AP ($p = 0.002$). Urisheaths scored significantly higher for all parameters (efficacy, self-image, odour management, discretion, skin integrity) other than ease of use. Safety was considered to be good

Interpretation of results

Urisheaths showed a positive impact on QoL (according to the KHQ results) in moderate/heavily incontinent men, long-term users of APs. Participants largely preferred urisheaths. In view of these results, urisheaths may be recommended in preference to APs in incontinent men.

<i>Specify source of funding or grant</i>	Coloplast
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	Yes
<i>Specify Name of Public Registry, Registration Number</i>	Clinicaltrial.gov
<i>Is this a Randomised Controlled Trial (RCT)?</i>	Yes
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	CHU Nîmes
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes