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.

Specify source of funding or grant
Coloplast

Is this a clinical trial?
Yes

Is this study registered in a public clinical trials registry?
Yes

Specify Name of Public Registry, Registration Number
Clinicaltrial.gov

Is this a Randomised Controlled Trial (RCT)?
Yes

What were the subjects in the study?
HUMAN

Was this study approved by an ethics committee?
Yes

Specify Name of Ethics Committee
CHU Nîmes

Was the Declaration of Helsinki followed?
Yes

Was informed consent obtained from the patients?
Yes