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Randomized, crossover study evaluating patient preference and the impact on quality of life of urisheaths vs absorbent products in incontinent men

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Study Type – Therapy (RCT)
Level of Evidence 1b

OBJECTIVE

- To evaluate the impact of urisheaths vs absorbent products (APs) on quality of life (QoL) in men with moderate to severe urinary incontinence (UI).

PATIENTS AND METHODS

- A randomized, controlled, crossover trial in 61 outpatient adult men with stable, moderate to severe UI, with no concomitant faecal incontinence, was conducted from June 2007 to February 2009 in 14 urology centres.
- Participants tested Conveen Optima urisheaths (Coloplast, Humlebaek, Denmark) with collecting bags and their usual AP in random order for 2 weeks each.
- The impact of each on QoL was measured using the King's Health Questionnaire (KHQ) and the short form-12 acute questionnaire, and each patient's preference was recorded.
- A 10-item patient questionnaire was also 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. The greatest mean score reductions were in Limitations of Daily Activities (–10.24, $P = 0.01$) and Incontinence Impact (–7.05, $P = 0.045$).
- The majority (69%) of patients preferred Conveen Optima urisheaths to their usual AP ($P = 0.002$).
- Urisheaths scored significantly higher for all categories in the patient questionnaire (efficacy, self-image, odour management, discretion, skin integrity) except ease of use.
- Safety was considered to be good.

CONCLUSIONS

- Conveen Optima urisheaths showed a positive impact on QoL (according to the KHQ results) in moderate to severe incontinent men, who were long-term users of APs, and participants largely preferred urisheaths.
- Conveen Optima urisheaths should be recommended to incontinent men in preference to APs.

KEYWORDS

evaluation study, male, quality of life, urinary incontinence, urinary sheath

INTRODUCTION

Urinary incontinence (UI) is a common disorder which has a substantial impact on quality of life (QoL) [1–6]. Perceived as truly debilitating from a physical, psychological and social point of view, it may cause both isolation and loss of independence, and eventually result in some elderly patients being admitted to an institution [1,2]. UI affects up to 11% of men aged 60–64 years and 30% of men ≥85 years [4,7]. Most have urge UI. Despite the development of new therapies, a large proportion of patients do not respond to conventional treatments [8,9]. For incontinent men not cured completely, or whilst waiting for surgery, and for men who may not be candidates for treatment, or who may choose management over attempted cure, urisheaths (also called condom catheters, external catheters, penile or urinary sheaths) are one of the most appropriate palliative options for restoring normal social life [1,8]. Urisheaths were developed to meet

the specific needs of incontinent patients in terms of: comfort, particularly when used for a whole day; hygiene, in allowing patients to stay dry; and clothing protection, sparing patients from potentially embarrassing situations.

Despite the theoretical advantages of urisheaths, the use of pads or absorbent products (APs) is still widespread in the incontinent male population, and the use of urisheaths still limited. Several factors may be responsible for the restricted use of urisheaths: prescribers may have misconceptions about their uses, patients may refuse to use them, and urisheaths may be considered as not having any advantages over conventional APs. A literature review does not provide answers to these questions, as no published articles have compared urisheaths with APs. In its recommendations for the use of continence products, the International Consultation on Incontinence (ICI) committee in 2005 drew attention to the lack of such studies and strongly recommended that such studies be performed according to strict methodological principles [1].

In view of the lack of existing evidence this randomized, prospective controlled trial was initiated. Its aim was to determine whether urisheaths are comparable with or superior to APs. Two validated QoL questionnaires were used, the validated UI-specific King's Health Questionnaire (KHQ) [10] and the short form–12 (SF-12) acute questionnaire [11,12]. Patients' preference and product efficacy and safety were also evaluated.

PATIENTS AND METHODS

DESIGN

The present study was a randomized, controlled, crossover, multicentre study conducted from June 2007 to February 2009 in 14 urology centres in France. Participants were asked to use their usual AP and urisheaths, each for a 2-week period, in a random order defined by central randomization (interactive voice response services). Three visits were performed (Fig. 1). The 2-week study duration allowed patients to get accustomed to urisheath use before evaluating its impact on QoL using the KHQ and SF-12 questionnaire. The questionnaires evaluated the patients' last week in the study [10–12].

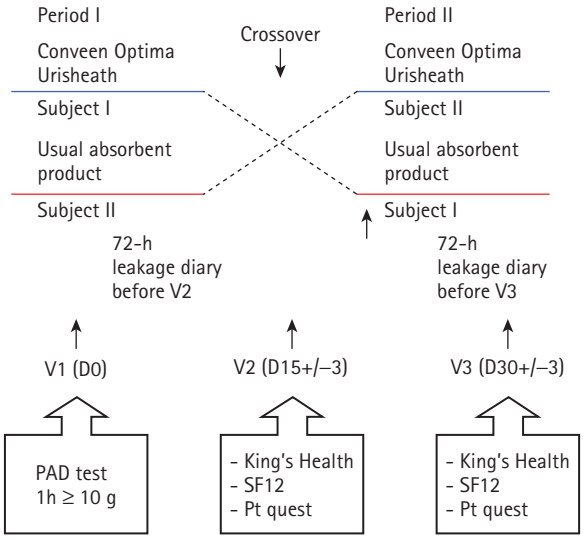


FIG. 1.
Study design. V, visit; D, day; Pt quest, 10-item patient questionnaire.

POPULATION

Participants were outpatient adult men with stable, moderate to severe UI (1-h pad test, performed before being included in the study, ≥10 g), who used APs to deal with their UI, and who were able to understand the questions posed on the questionnaires. Patients presenting a contraindication to urisheath use (e.g. retracted penis, penile skin lesions) and patients with concomitant faecal incontinence were excluded, as were patients unable to apply the urisheath (and empty the drainage bag) themselves, because the involvement of a third party would have interfered with the patient evaluation. The study protocol was approved by the Nîmes Ethics Committee in April 2007. The participants signed a written informed consent form before their inclusion.

STUDY PRODUCTS

The urisheath evaluated was the Conveen Optima urisheath (Coloplast, Humlebaek, Denmark), which comes in two lengths, standard and specific (penis <6 cm long), with four different diameters available for each length. It is fitted with an unrolling double-grip strip to allow easier application of the urisheath on the penis, and to avoid wrinkle formation, ensuring it stays securely in place. An anti-kink system channels the urine effectively into a urine drainage bag. The urisheath was used with Conveen 750 mL body worn urine leg bags held in place using leg straps and Conveen 1.5 L night drainage bags (Coloplast), all equipped with a tap for emptying.

The AP used varied greatly from patient to patient, both in terms of quality (e.g. thickness and consistency) and quantity. To avoid any bias in this study or any influence on the evaluation of preferences, patients were permitted to continue using the AP of their choice.

OUTCOME MEASURES

The impact on QoL was measured with two validated questionnaires, the UI-specific self-administered KHQ (primary endpoint) and the generic SF-12 acute questionnaire. The weighted scores for the nine dimensions of the KHQ ranged from 0 (best) to 100 (worst), with a low score indicating an improvement in QoL. In contrast, the weighted scores for the eight categories in the SF-12 ranged from 0 (worst) to 100 (best).

A 10-item patient questionnaire was used to assess the product main advantages (degree of satisfaction, efficacy, feeling of security, feeling of freedom, self-image, ease of use, discretion, odour management, skin integrity and comfort) rated on an 11-point scale (0: worst, 10: best). Each patient's preference was also recorded.

A 72-h leakage diary was used to record the frequency and severity of leaks, daily product consumption, number of bladder control exercises and fluid intake.

FIG. 2. Patient population included in the analysis.

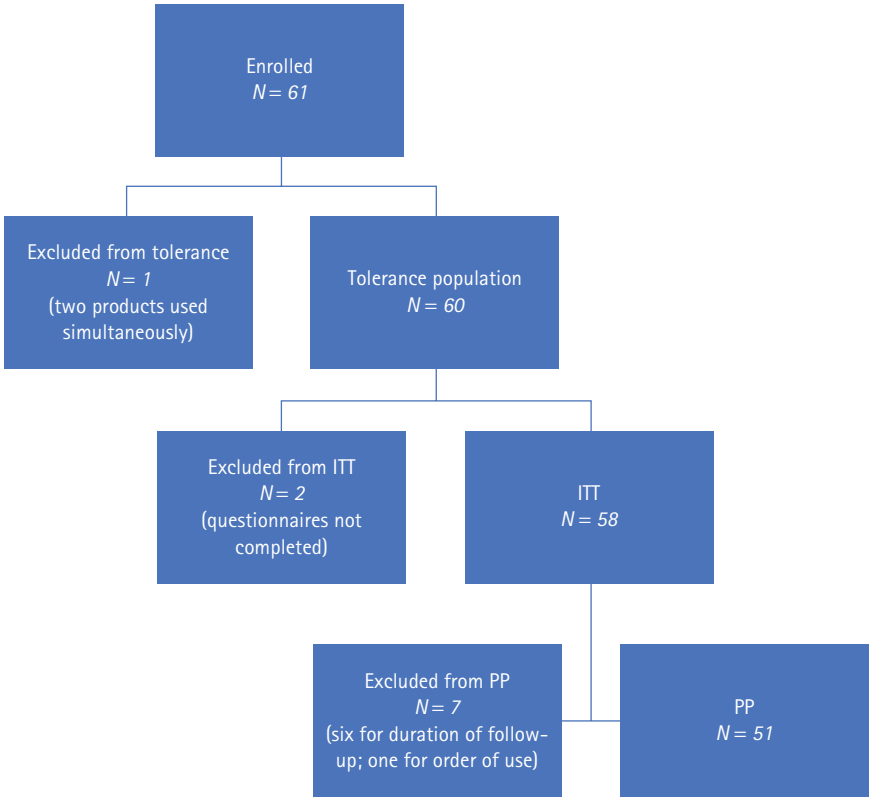
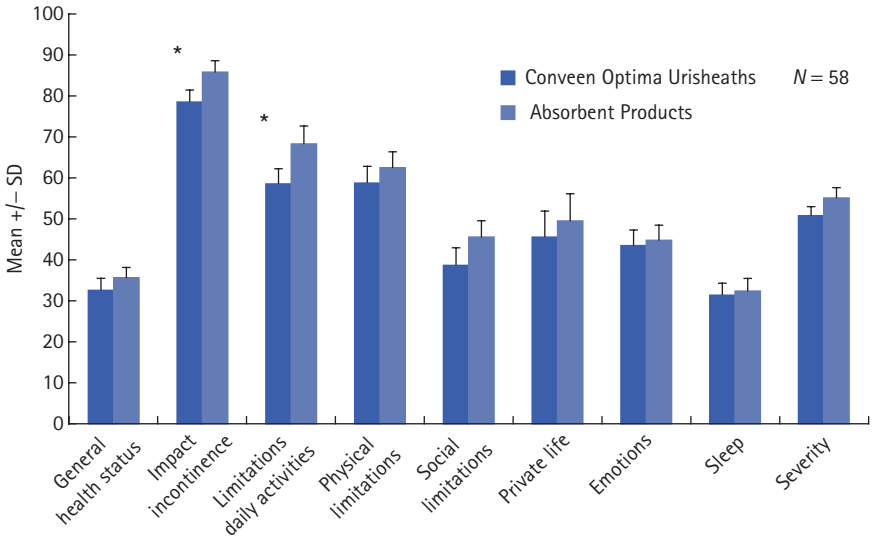


*FIG. 3. KHQ scores. The lower the score, the higher the QoL. *Significant difference (P < 0.05).*



The number of and reasons for study drop-outs were recorded, and safety was expressed as the number of local adverse events observed.

STATISTICAL ANALYSIS

The lack of published data regarding outcome measures made the sample size calculation difficult. We planned to include 60 patients in order to obtain 50 evaluable patients, as the study was expected to have a 20% drop-out rate, in a crossover design to enhance the study power. The analyses were performed with an α risk of 0.05. A fixed-effect ANOVA for crossover design with order, period and product effects was used for all questionnaires; the preference was tested using an asymptotic Wald test with the proportion = 0.5. The intent-to-treat (ITT) population was defined as all patients who tested both products and evaluated each one for the primary endpoint. A confirmation analysis was performed on the per-protocol (PP) population, defined as the subgroup of the ITT population who did not present a major protocol deviation (e.g. early withdrawal, products not used in the right random order, inclusion or exclusion criteria not fulfilled). Safety was evaluated for all patients who used the product at least once.

RESULTS

PATIENT CHARACTERISTICS

In all, 61 patients were recruited at 14 urology centres; 58 patients were included in the ITT population (Fig. 2). Three patients were excluded from the ITT population: two were lost to follow-up immediately after inclusion and one used both products simultaneously. The characteristics of the ITT population are summarized in Table 1. Patients' mean (range) age was 66.8 (25–83) years, they used a median of 3 APs per day and the majority (69%) had been suffering from UI for >1 year. The median 1-h pad test was 54.5 g at baseline. UI was mainly after prostate surgery (75.9%) (Table 2). Stress UI was the most common (74.1%), followed by mixed incontinence (22.4%). Seven patients (12.1%) took anticholinergic medications with unchanged doses during the study.

PRIMARY OUTCOME MEASURE

All dimensions of the KHQ scored lower with the urisheaths (Fig. 3), indicating an improvement in QoL, especially for 'limitations of daily activities' (mean score ±SD: 10.24 ± 3.99, $P = 0.01$), 'impact of incontinence' (mean score ±SD: 7.05 ± 3.45, $P = 0.045$) and 'social limitations' (–6.93 ± 3.56, $P = 0.057$) dimensions.

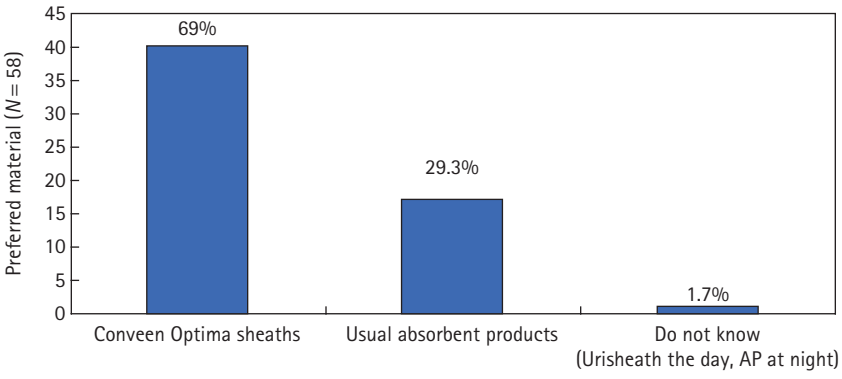
Patient characteristics	ITT population ($N = 58$)
Demographic data	
Mean (SD) age, years	66.8 (9.6)
<60 years, %	17.2
≥60 years, %	82.8
Clinical characteristics	
Type of UI, %	
Stress	74.1
Urge	3.4
Mixed	22.4
UI duration, %	
<1 year	31.0
1–3 years	39.7
3–5 years	17.2
>5 years	12.1
UI arises, %	
Mainly during the day	60.3
Day and night time	36.2
1-h pad test (g)	
Mean (SD)	105.5 (114.5)
Median (range)	54.5 (11–452)
Number of APs per day	
mean (SD)	4.1 (3.2)
median (range)	3.0 (1–20)
Comorbidities (at least one), %	84.5
Concomitant treatments (at least one), %	58.6
Genitor-urinary system, %	12.1
Concomitant faecal incontinence	0
History of UTIs treated with antibiotics, %	
Frequent	3.4
Occasional	34.5

TABLE 1 Patients characteristics at baseline for the ITT population

TABLE 2 Origin of UI in the ITT population

Origin	*N* (%)
Prostate surgery	44 (75.9)
Prostate surgery + radiotherapy	3 (5.2)
Prostate surgery + bladder surgery	1 (1.7)
Prostate surgery + Neurological	1 (1.7)
Neurological	4 (6.9)
Prostate radiotherapy	2 (3.4)
Bladder surgery	1 (1.7)
BPH	1 (1.7)
Other	1 (1.7)

FIG. 4. Patient preference.



SECONDARY OUTCOMES

The SF-12 scores were better with urisheaths for five of eight categories (physical function, physical pain, general health, vitality and mental health), but without a statistically significant difference. Incontinence had more impact on the psychological aspects of QoL (mean ± SD combined mental scores: urisheaths: 39.5 ± 1.51; AP: 39.0 ± 1.5), than on the physical aspects (mean ± SD combined physical scores: urisheaths: 44.3 ± 1.1; AP: 43.2 ± 1.1).

The majority of patients (69%) preferred urisheaths to their usual AP ($P = 0.002$) (Fig. 4). Participants rated the urisheaths significantly higher for all categories (efficacy, feeling of security, feeling of freedom, self-image, discretion, odour management and skin integrity) except for ease of use, which was significantly higher with the AP (Fig. 5). The 72-h leakage diary showed a significantly lower mean ± SD daily consumption of urisheaths (1.20 ± 0.28 vs AP: 3.12 ± 0.28, $P < 0.001$). Nine (15.5%) patients required more than one urisheath a day which was mainly related to urinary leakage necessitating urisheath change. At the end of the study, seven out of these nine patients preferred their usual AP. The mean ± SD number of leaks (urisheath: 3.65 ± 0.84 vs AP: 4.40 ± 0.84), daily physiotherapy exercises (urisheath: 0.49 ± 0.23 vs AP: 0.74 ± 0.23), and mean ± SD daily fluid intake (urisheath: 0.7 ± 0.03 L vs AP: 0.72 ± 0.03 L) were comparable.

Additional analyses were performed to attempt to characterize patients who preferred the urisheaths. Younger men and those with a larger amount of leakage at the 1-h pad test were more likely to prefer urisheaths, with a statistically significant difference for age (Table 3).

SAFETY

Five patients (8.3%) reported an adverse event which was considered to be possibly related to the urisheath: four cases of skin irritation that resolved in three cases within 1–3 days with better hygiene, and one case of

*FIG. 5. Product performance. *Significant difference in favour of urisheaths; **Significant difference in favour of APs.*

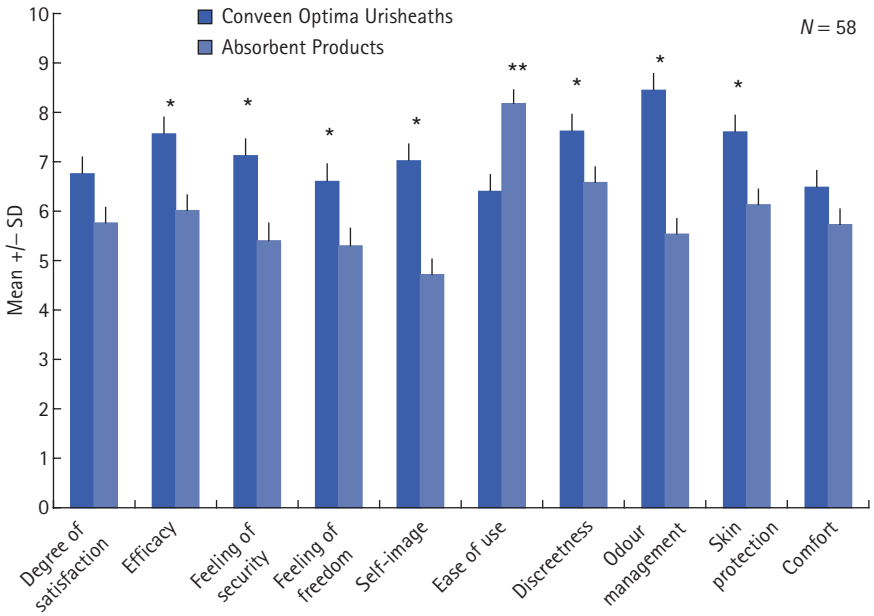


TABLE 3 Patient characteristics according to the preferred product

Patient characteristic		Preferred product: Urisheaths (*N* = 40)	Preferred product: APs (*N* = 18)	*P*
Age, years	Mean (SD)	65.1 (10.8)	70.9 (5.9)	0.044*
	Range	25–83	58–83	
	Median (Q1;Q3)	67.0 (61;72)	71.0 (68;74)	
UI type, %	Stress	80.0%	61.1%	0.122**
	Urge	5.0%	0.0%	
	Mixed	15.0%	38.9%	
UI duration, years	Mean (SD)	2.1 (1.0)	2.2 (1.0)	0.684*
	Range	1–4	1–4	
	Median (Q1;Q3)	2.0 (1;3)	2.0 (1;3)	
UI arises, %	Mainly during the day	60.0	61.1%	>0.999**
	Mainly at night	5.0	0.0%	
	Day and night	35.0	38.9%	
1-h pad test, g	Mean (SD)	116 (124)	76 (88)	0.272*
	Range	11–452	10–382	
	Median (Q1 ; Q3)	57.0 (30;159)	44.0 (33;67)	

**Wilcoxon rank sum test. **Fisher's exact test.*

maculopapular rash (urisheath use was discontinued).

Three UTIs were reported during the study. These were considered by the investigator to be unrelated to product use. One patient developed a UTI while using an AP during the second period and another patient developed a UTI during each study period, first using an AP then a urisheath.

DISCUSSION

This randomized, controlled, prospective, crossover study is the first to have been performed to date, measuring the impact on QoL of using a urisheath with a urine collecting bag vs the patient's usual AP in men with stable, moderate to severe UI. The methodology complies with ICI recommendations [1,13]. According to the ICI, the outcome measures must include instruments for QoL measurement and a patient questionnaire assessing patient overall preference, which should be the primary outcome variable, as well as the product impact on such dimensions as daily activities, hygiene, odour management, urinary infections and skin health. The present study showed that the Conveen Optima urisheath provides better results than the AP in terms of QoL (Fig. 3) and patient preference (Fig. 4).Patients also reported a significant improvement in efficacy, self image, odour management, discretion and skin integrity (Fig. 5). The incidence of UTIs appears comparable, but a larger sample size would be necessary for confirmatory conclusions.

The study was conducted in two periods of 2 weeks each. One can speculate that longer use would give similar findings in favour of urisheaths, since patients need to be trained in urisheath use and there is a decreased difficulty in use over time, especially if patient training and close follow-up by healthcare professionals is done in compliance with the ICI recommendations [1,13].

While urisheaths are most often used for men with spinal cord injuries [14], the population in this study mainly consisted of men with stable moderate to severe UI of urological origin, with no concomitant faecal incontinence, who were able to use urisheaths without assistance. The choice of comparator in this study was represented by the palliative system generally used by the patient. This was done to measure the impact of urisheaths on QoL under real-life conditions. Recent studies have shown that the preferred AP varied greatly from patient to patient, that the skin protection offered by different AP models was much the same, and that using different types of AP for different situations (day or night, at home or out) was more efficient and economical than wearing a standard AP [15,16].

This study confirmed an excellent safety profile of Conveen Optima urisheaths in the majority of patients (91.7%). Product-related adverse events, mainly skin irritations, were reported in only five patients (8.3%). In most

cases (three of five), these irritations could have been avoided by the patients' following simple hygiene measures.

It should be noted that urisheaths come in a variety of sizes to fit different penis lengths and diameters. If the urisheath is too small for the patient, urine collection problems may arise and blood supply to the penis may be reduced. Conversely, if the urisheath is too big, wrinkles may appear in the device, leakage may occur, and the device may slip off [17].

As it has been shown previously that the performance and acceptability of different urisheaths may vary [15,18,19] and that leg bag design has a considerable influence on urisheath performance [20], and considering the fact that this is the first study comparing urisheaths with APs, the observed results can apply only to the collecting device studied here (the Conveen Optima urisheath).

This study did not explore the health-economic aspects of urisheath vs AP use, although this was recommended by the ICI [1,13]. In incontinent male patients, product selection is strongly influenced by the patient's financial means and health reimbursement policies (for both urisheaths and APs) which vary considerably among countries. In France, urisheaths but not APs are reimbursed by Social Security; APs are paid for by the patient or, in a few cases, through private insurance and elderly people allowance. This could be an additional argument for wider use of urisheaths in France.

Male continence products must be reliable and must allow patients to deal with incontinence simply, discreetly and independently. In addition, they must provide a high standard of hygiene and odour management and protect both skin and clothing [21]. An inappropriate choice may force users to restrict their social and professional activities, may place undue stress on relationships, and may be detrimental to QoL [22]. Patients are influenced by several factors when selecting a continence product, including personal preference and needs, the patients' degree of independence, their activities and the time of day they are performed (day or night, at home or out), the nature of their UI, and the information given to them about the different methods available for managing UI [23–25]. Urisheaths are used as an alternative to an AP, and most specialists agree that their use enhances the physical and psychological well-being of incontinent patients [18,19,26]. According to ICI recommendations, improving patient QoL must be considered first and foremost before making any decisions [1,13].

In conclusion, compared with APs, Conveen Optima urisheaths showed a positive impact on QoL (according to the KHQ results) in moderate to severely incontinent men, without concomitant faecal incontinence, who were long-term users of APs. Participants largely preferred the urisheath over APs, listing its many advantages offered in real-life conditions. We believe that the results of the present study support a wider use of Conveen Optima urisheaths in preference to APs in moderate to severely incontinent men. We believe that healthcare professionals should make effective and informed decisions as they help their patients to choose between continence product categories and recommend the promotion of patient education related to urisheath use.

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CONFLICT OF INTEREST

Emmanuel Chartier-Kastler is a speaker and consultant for Coloplast; Loïc Le Normand is a speaker for Coloplast; Pierre Costa is a speaker and consultant for Coloplast. Source of Funding: Laboratoires Coloplast, France.

TRIAL REGISTRATION

Conveen Optima urisheaths and collecting bags vs APs in men suffering moderate to severe UI. NCT01056666. clinicaltrial.gov.

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Abbreviations: **QoL**, quality of life; **AP**, absorbent product; **UI**, urinary incontinence; **KHQ**, King's Health Questionnaire; **SF-12**, short form-12; **ITT**, intent to treat; **PP**, per protocol.