The first randomised, controlled trial compared how urinary sheaths with absorbent products affected quality of life in men with moderate to severe urinary incontinence.

**How urinary sheaths benefit quality of life**

In this article...
- The effects of urinary incontinence in men
- Designing a clinical trial to test urisheaths
- How urisheaths improved patients’ quality of life

Author: Emmanuel Chartier-Kastler is professor of urology, Pierre et Marie Curie medical school, Paris VI University, France.


Aim: To examine the effect on quality of life of urisheaths compared with absorbent products.

Method: A randomised, controlled, crossover trial was carried out in men with moderate to severe urinary incontinence.

Results: Two sections of the main quality-of-life questionnaire showed statistically significant improvements for urisheaths compared with absorbent products - “impact of incontinence” and “limitations of daily activities”. Most participants (69%) preferred urisheaths.

Discussion and conclusion: The results support wider use of this particular design of urisheath in men with moderate to severe urinary incontinence.

Unrinary incontinence is a debilitating and often overlooked condition that can affect up to 11% of men aged 60-64 and 30% of those over 85 (Shamliyan et al, 2009; Anger et al, 2006). It is often associated with a severe physical and psychological burden, and has a considerable impact on the ability to perform everyday tasks.

Inadequate management of urinary incontinence may lead to limited social and professional interactions. The condition can have a serious effect on independence and even lead to some older patients being institutionalised (Irwin et al, 2006; Cottenden et al, 2005).

Medical treatments are available for urinary incontinence, and surgical options may be appropriate for some patients (Fonda and Abrams, 2006). However, conventional treatment is often ineffective or inappropriate, and some men choose to manage the condition rather than attempt a cure, using containment measures instead to allow them to participate more fully in social and professional situations.

For these men, the choice of continence product is strongly influenced by individual preference and confidence in the product’s ability to manage their incontinence efficiently and discreetly. Options include penile/urinary sheaths (sometimes known as “urisheaths” or external catheters – see Fig 1) or absorbent products such as pads (Fonda and Abrams, 2006; Cottenden et al, 2005).

Many experts consider urisheaths to be the preferred method of containment care for urinary incontinence, as they have some theoretical advantages over absorbent products, in terms of comfort, hygiene, clothing protection and overall dryness. However, until recently, relatively few well-designed clinical trials have investigated the management of urinary incontinence so no real recommendations could be made in terms of product choice.

Without good-quality evidence to inform this decision, both patients and health professionals may not be convinced of the advantages of urisheaths; patients are sometimes deterred by their perceived complexity, and continence advisers may have misconceptions about the relative advantages and disadvantages of each method. Indeed, in 2005, the committee of the International Consultation on Incontinence identified the need for randomised, controlled trials comparing urisheaths with absorbent products to help fill the data gap (Cottenden et al, 2005).

An article published recently in *BJU international* described one such study designed to address these concerns, especially in terms of the effects of urisheaths and absorbent products on quality of life (Chartier-Kastler et al, 2011).

Method: This controlled crossover study was conducted from June 2007 to February 2009, enrolling men from 14 urology centres in France. To be included, participants had to be already using absorbent products to manage their moderate to severe urinary incontinence as outpatients, with a one-hour pad test measuring 10g or more of urine loss.

At baseline, participants were randomised in a crossover design to evaluate first either the urisheath (Conveen Optima) or the absorbent product of their choice, and asked to use the product without evaluation for one week. This “practice week” allowed participants to be correctly trained in fitting the urisheath and familiarise themselves with its collecting bag, which is attached to the calf or thigh using straps.

The products were then evaluated after a further week of use, and patients were then switched to the alternative product for a further two weeks.

The primary end point was the impact on quality of life in the previous week, as measured by the validated King’s Health Questionnaire (Okamura et al, 2009). This is specific to urinary incontinence and scored from 0-100, where 100 is the worst value and 0 best. Other outcome measures included the generic short form-12 (SF-12) acute...
Results from the second quality of life instrument, the SF-12 questionnaire, confirmed this conclusion; five of the eight categories scored better for urisheaths and improvements were seen in both the physical and psychological domains, although this was not statistically significant.

When asked about their preference, most participants (69%) preferred urisheaths to the absorbent products they had been using previously. In the 10-item patient questionnaire, the urisheath was rated significantly better than absorbent products in terms of efficacy, feeling of security, feeling of freedom, self-image, discreetness, odour management and skin protection. Absorbent products were rated significantly higher than the urisheath in only one of the 10 categories (ease of use).

Although 16% of participants needed more than one urisheath each day, their usage was significantly lower than that with absorbent products. Both type of products were well tolerated, with a good safety profile.

Discussion
As the first randomised, controlled, prospective crossover trial in patients with urinary incontinence comparing the effect of urisheaths and absorbent products on quality of life, this is a landmark study for managing urinary incontinence.

Importantly, the trial was designed following the recommendations of the committee of the International Consultation on Incontinence (Cottenden et al, 2008; 2005), which highlighted the importance of patient-focused outcome measures, particularly those relating to quality of life.

Two validated quality-of-life questionnaires were included, as well as a patient questionnaire which focused on product performance and preference. These assessments were able to directly demonstrate clear advantages for patients of using urisheaths over absorbent products. Another key part of the study design was the inclusion of a two-week crossover period for each comparator product, with only the second week being used as part of the patient efficacy assessment. This allowed participants to be correctly trained and followed up by health professionals with experience in using urisheaths; this is extremely important for their full efficacy to be recognised.

It is worth noting that design and therefore the comfort and performance of urisheaths varies considerably, particularly in terms of design of the leg bag (Paterson et al, 2003). This study only investigated the acceptability of one type of urisheath and leg-bag. As such, the results should not be applied to any other urisheaths; each design should be investigated individually.

Conclusion
The results support the wider use of this particular design of urisheath in men with moderate to severe urinary incontinence. These products improved patients’ quality of life and the majority preferred them over absorbent products.

Urisheaths should therefore be considered as a serious alternative to absorbent products, which may not offer the same level of benefits, especially in terms of quality of life.

References
Okamura K et al (2009) Reliability and validity of the King’s Health Questionnaire for lower urinary tract symptoms in both genders. BJU International; 103: 1673-1678.