A comparative study of two types of urinary sheath

Authors Pamela Pemberton, RGN, is continence team leader, Warrington PCT; Anthony Brooks, BSc, CertEd, RN, DEn, is continence nurse specialist adviser, Canterbury and Coastal PCT; Christina Mai Eriksen, is clinical trial manager; Sue Frost, RGN, is clinical research nurse, Coloplast A/S; Sue Graham, RGN, DN, DPsychN, is clinical nurse specialist, continence care, Solihull PCT; Linda Greenman, BSc, RGN, is clinical nurse specialist in continence, Halifax PCT; Helen Hannigan, RGN, is clinical nurse specialist in continence care, Solihull PCT; Dagnia Looms, PhD, MSc, is scientific clinical outcome manager, Coloplast A/S; Sandra Moran, BA, RGN, is highly specialist nurse, continence adviser, North Liverpool PCT; Pia Norup Nielsen, MD, is clinical development manager, Coloplast A/S; Debra Ollerhead, BSc, RGN, is clinical lead/continence nurse specialist, Bebington and West Wirral PCT; Judith Shaw, RGN, DN, Dip health promotion, is lead nurse for continence care, Rugby PCT; David Williams, BSc, RGN, is highly specialist nurse, continence adviser, North Liverpool PCT.


Aim The aim of this study was to compare the newly developed Conveen Optima urinary sheath with the established Clear Advantage urinary sheath in terms of patient satisfaction and preference.

Method This was a randomised, prospective, open, crossover study, in which each participant tested 10 urinary sheaths.

Results Conveen Optima provided a higher feeling of security, was easier to handle and apply and was more comfortable to wear than Clear Advantage. Furthermore, Conveen Optima was easier to apply with gloves. Finally, the overall product preference for the Conveen Optima sheath was 67 per cent.

Conclusion The new Conveen Optima urinary sheath was found to perform better than the well-established Clear Advantage sheath.

Declaration of interest This study was funded by Coloplast A/S.

Compared with absorbent continence products, urinary sheaths offer the advantage of diverting the urine to a bag, thus decreasing urine odour and protecting the skin from contact with urine. Compared with indwelling catheters, urinary sheaths reduce the risk of complications associated with instrumentation of the urethra.

Possible complications resulting from long-term use of indwelling urethral catheters (Simpson, 2001; Newman, 1998) include:

- Urinary tract infection;
- Encrustation and bladder stones;
- Urethral fistula;
- Erosion of the urethra;
- Urethritis;
- Epididymitis;
- Stricture formation;
- Urosepsis;
- Carcinoma of the bladder.

In spinal cord injury, for example, the incidence of urinary tract infection was reduced by more than sevenfold in patients who used urinary sheaths to manage continence problems compared with those patients who used indwelling catheters (Esclarín de Ruz et al, 2000).
**Reference**


**Literature review**

Overall, there has been a lack of research on urinary sheaths, with the few studies there have been focusing on the benefits and complications of urinary sheaths or comparisons of sheaths with other continence management methods such as indwelling urethral catheters. Much of this research is out of date and discusses problems encountered with the first generation of urinary devices. The complications reported are mainly the result of incorrect application of the devices or lack of ongoing assessment and the studies most commonly do not distinguish between different products (Jayachandran et al, 1985; Newman and Price, 1985).

There are few published studies that compare urinary sheath products. Continence care specialists have expressed a need for more research and evidence that will enable them to make informed choices on behalf of their patients (Bath et al, 1999). One article cited a need to compare the effect of different sheath systems on the penile shaft and ease of use, as well as improving sheath adherence (Newman et al, 2004).

The Medical Devices Agency has published two comparative clinical evaluations of urinary sheaths. The first (MDA, 1995) evaluated two-piece and one-piece products available in the UK. The results showed that self-adhesive, one-piece sheaths were more effective than two-piece sheaths in terms of overall performance and ease of application. In the second report (MDA, 2000) only self-adhesive, one-piece sheaths were evaluated. Substantial differences between self-adhesive sheaths were found, indicating that clinicians and consumers need to select products with care. The Clear Advantage urinary sheath was found to be particularly effective in an evaluation of the six self-adhesive sheaths that were available in the UK at that time.

**Method**

The aim of this study was to compare the new Conveen Optima urinary sheath with the established Clear Advantage urinary sheath to ascertain patient satisfaction and preference. The primary endpoint was urinary sheath product preference, and secondary endpoints were handling, application, comfort, leakage and skin reactions.

**Participants**

Seven centres in the UK participated in the study. At each centre, a continence adviser recruited participants for the study from patients within their
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primary care trust (community area). Males aged 18 years and over who were using at least one one-piece urinary sheath (30–35mm) a day were recruited into the study. Men with mental health problems and men participating in any other clinical studies were excluded.

ethical approval
Multicentre ethics approval was obtained from Sefton Local Research Ethics Committee. All seven centres involved in the study then gained site-specific approval from their local research ethics committee as well as from their relevant research and development departments. The project did not commence in each centre until both local approvals had been gained.

study design
In this randomised, prospective, open, crossover study, each participant tested 10 Conveen Optima sheaths and 10 Clear Advantage sheaths. Each sheath was to be worn for approximately 24 hours. Participants were randomised according to a block randomisation list produced electronically using Medstat version 2.1.

Products
The products tested in this trial were both one-piece silicone self-adhesive urinary sheaths, namely Conveen Optima (Coloplast A/S, Denmark) and the current market-leading sheath in the UK, Clear Advantage (Mentor, US, distributed in the UK by Coloplast Ltd).

Study procedure
The inclusion visit was made in the community by the continence advisers. Eligible participants were assessed for inclusion in the study by a continence adviser and after giving informed consent were randomised to use either Conveen Optima or Clear Advantage.

The continence adviser completed the initial study questionnaire on the patients' behalf. Each participant was then supplied with a box of 10 urinary sheaths from each brand and instructions for use. It was ensured that the participant understood which box he should start with. The participant or his carer was asked to complete further questionnaires after finishing each box.

When the trial had been completed the participants filled out a preference questionnaire. At a termination visit the continence adviser ensured that all questionnaires had been completed and returned them for inclusion in the study data.

Sample size
The study was designed to calculate a 95 per cent confidence interval for the expected preference for each product of 50 per cent and an estimated error of 15 per cent. The number of subjects needed to achieve these requirements was found to be 43, and it was therefore planned to include 50 patients to compensate for dropouts.

Statistical analyses
The criterion for including the data from a participant in the statistical analysis was that he had evaluated at least three urinary sheaths of each product type.

Data from the initial study questionnaire regarding demographics and problems experienced with urinary sheaths prior to entering the study was reported descriptively. The nurse/helper evaluation data was also reported descriptively. With regard to the primary parameter, 95 per cent confidence intervals were calculated for the results for product preference.

Analyses of the comparison of the two products with respect to the secondary parameters were performed using the Wilcoxon test and the Sign test where appropriate. All statistical analyses were performed using SPSS version 11.5 for Windows with a significance level of five per cent.

Results
Of the 53 men who took part in the study, 44 fulfilled the evaluation criteria and were included in the analysis. The demographics of the participants included in the statistical analyses are listed in Table 1 (p37). At the initial study visit the participants were asked which kind of problems they had experienced using urinary sheaths prior to entering the study (Table 2, p37).

references


FIG 1. OVERALL PRODUCT PREFERENCE
Out of the 36 participants who expressed a product preference, 67% (95% confidence interval 52–82%) preferred the Conveen Optima sheath, whereas 33% of the participants (95% confidence interval 18–48%) preferred the Clear Advantage urinary sheath.
Preference
The participants were asked whether they preferred either of the two urinary sheaths and if so, which one. Eighty-one per cent of the participants reported having a preference and of these 67 per cent preferred the Conveen Optima urinary sheath (Fig 1). Overall, 55 per cent of participants preferred the Conveen Optima, while 27 per cent preferred the Clear Advantage sheath.

Secondary endpoints
Table 3 (p40) summarises the participants’ responses relating to application and connection to a urine bag. With regard to handling and application, the participants found both the opening and the removal of the Conveen Optima urinary sheath from its packaging significantly easier than the Clear Advantage. Fewer participants experienced wrinkles or bubbles when applying the Conveen Optima urinary sheath compared with the Clear Advantage. In addition, more patients felt safe immediately after application of the Conveen Optima sheath and, as shown in Fig 2, participants rated their feeling of security more highly when using the Conveen Optima urinary sheath.

Nurses who applied the urinary sheaths were asked whether the sheath was easy to apply when wearing gloves. Overall, nurses found the Conveen Optima urinary sheath easier to apply than the Clear Advantage (Fig 3, p41).

The results regarding overall wear are summarised in Table 3 (p40). Participants felt that the Conveen Optima sheath was more comfortable to wear than the Clear Advantage sheath. In addition, more participants found that the drainage from the sheath into the urine bag was satisfactory.

With regard to packaging, the Conveen Optima was considered easier to carry around (Fig 4, p41).

Finally, the participants were asked about the ease of connection and disconnection to a urine bag. Significantly more found both connection and subsequent disconnection of the Conveen Optima product easier (Table 3, p40).

With regard to all the other questions asked, there was no statistically significant difference between the Conveen Optima and the Clear Advantage urinary sheaths although the tendency was that Conveen Optima received higher mean scores.

Discussion
The main problems experienced by study participants before taking part in the study were:
- The sheath falling off;
- Skin redness;
- Leakage;
- Problems with application;
- Problems with handling.

This reflects the fact that one of the most important requirements for a user of urinary sheaths is that they remain in place and do not leak. Only then can the men feel confident and free from worry about social embarrassment due to incontinence.

FIG 2. CONFIDENCE THAT THE SHEATH WOULD STAY IN PLACE

Participants were asked to rate their feelings of security when using the two products on a scale of 0 (very insecure) to 10 (very secure). Conveen Optima was rated significantly more secure (p=0.03, Wilcoxon test). As shown, three times as many participants gave their feeling of security with the Conveen Optima urinary sheath the top rating. In other words, the security rating 10 was given by 12 participants for Conveen Optima, whereas the rating 10 was given by four participants for Clear Advantage.

REFERENCES


TABLE 3. OVERALL RATINGS ON APPLICATION, WEAR AND CONNECTION TO URINE BAG

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Issues</th>
<th>Clear Advantage</th>
<th>Conveen Optima</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application</td>
<td>Ease of opening packaging</td>
<td>3.30</td>
<td>4.32</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Easy of removal from packaging</td>
<td>3.66</td>
<td>4.39</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Wrinkles/bubbles on sheath when applied</td>
<td>3.57</td>
<td>3.86</td>
<td>0.036</td>
</tr>
<tr>
<td></td>
<td>Confidence when wearing the sheath</td>
<td>3.36</td>
<td>3.69</td>
<td>0.043</td>
</tr>
<tr>
<td>Overall wear</td>
<td>Comfortable to wear</td>
<td>3.79</td>
<td>4.02</td>
<td>0.018</td>
</tr>
<tr>
<td></td>
<td>Drainage of urine into bag during use</td>
<td>3.89</td>
<td>4.14</td>
<td>0.033</td>
</tr>
<tr>
<td>Connection to urine bag</td>
<td>Ease of connecting sheath to urine bag</td>
<td>3.80</td>
<td>4.14</td>
<td>0.018</td>
</tr>
<tr>
<td></td>
<td>Ease of disconnection of the urine bag from sheath</td>
<td>3.82</td>
<td>4.32</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

This security depends on proper assessment, sizing and application of the sheath, as well as on the quality of the adhesive. The adhesive must be balanced so that it is strong enough to keep the sheath in place, is easy to remove and preserves skin integrity.

This study shows that the Conveen Optima sheath provides a greater feeling of security, meaning that the men using this sheath have more confidence that it will stay in place and keep the user dry until it is routinely removed. Furthermore, the Conveen Optima sheath was found to be easier to handle and apply in some of the aspects studied and at least as user-friendly as the Clear Advantage sheath in all the other aspects studied.

It is surprising that this increased feeling of security did not lead to significantly fewer leakages and roll-offs of the Conveen Optima urinary sheath. However, this may be explained by the study design, where only 10 of each sheath were tested. Sixty percent of participants had already used Clear Advantage before the trial and were therefore used to applying this product. Trying a new product for the first time will inevitably result in the first few sheaths being applied less optimally, until a familiarity with the product is built up. It is therefore reasonable to expect that with a longer trial period, a difference could have been seen for leakages and roll-offs.

Some men are unable to apply a urinary sheath for themselves and are dependent on a nurse or carer to apply it for them. This can cause embarrassment to both parties as it entails close physical contact that is often perceived as intimate. Wearing gloves can help nurses to overcome this and are also often used for reasons of hygiene. Nevertheless, wearing gloves when applying a urinary sheath may pose some practical problems, as the adhesive can stick to the gloves while unrolling and applying it.

Nearly all the nurses who were involved in this study agreed that the Conveen Optima sheath was easy to apply while wearing gloves. These results may benefit both men with continence problems and their carers who would otherwise not be offered sheaths.

The individual product packaging was considered to be another advantage of the Conveen Optima sheath, making it more convenient to carry around, easier to open and allowing for easier
The nurses/helpers were asked whether they strongly agreed, agreed, neither agreed or disagreed, disagreed or strongly disagreed that the urinary sheath was easy to apply while wearing gloves. There were 83 observations for Conveen Optima and 82 observations for Clear Advantage obtained from the nurses/helpers of 9 participants.

Conclusion
This is one of the first randomised clinical trials aimed at providing evidence to assist health care professionals and their patients in making informed choices about urinary sheath products. The study shows that the Conveen Optima sheath offers a greater feeling of security than the Clear Advantage. Furthermore, Conveen Optima was found to be easier to handle and apply as well as more comfortable to wear. Finally, the overall product preference for Conveen Optima was 67 per cent, indicating that it is more acceptable than the well-established product.

These results may have implications for practice, making urinary sheaths a viable solution for men to actively manage continence problems rather than depending on absorbent incontinence products.