

A comparative study of two types of urinary sheath:

A randomised, prospective, crossover clinical study

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1. Warrington PCT, UK
2. Canterbury and Coastal PCT, UK
3. Coloplast A/S, Denmark
4. Solihull PCT, UK
5. Calderdale PCT, UK
6. North Liverpool PCT, UK
7. Bebington and West Wirral PCT, UK
8. Rugby PCT, UK

Hypothesis/aims of study

To compare the new Conveen® Optima urinary sheath (Figure 1) with the established Clear Advantage® urinary sheath with regard to patient satisfaction and preference. The primary endpoint was urinary sheath product preference, and secondary endpoints were handling, application, comfort, leakage and skin reactions.

Study design, materials and methods

This randomised, prospective, open, crossover study at seven centres in the UK included males at least 18 years of age and using at least one one-piece urinary sheath a day. Exclusion criteria were mental health problems and participation in other clinical studies. Each participant tested 10 urinary sheaths of each product Conveen® Optima (Coloplast A/S, Denmark) and Clear Advantage® (Mentor, U.S.A.). Participants were randomised according to a block randomisation list.

In order to calculate a 95% confidence interval for the expected preference for each product of 50% and an estimated error of 15% the number of subjects needed was 43, thus, it was planned to include 50 patients to compensate for dropouts.

Data regarding demographics and nurse/helper evaluation was reported descriptively. 95% confidence intervals were calculated for the product preference results. Secondary parameters were analysed using the Wilcoxon test and the Sign test where appropriate (SPSS version 11.5 for Windows) with a significance level of 5%.

Results

Of the 53 men included in the study, 44 fulfilled the evaluability criteria and were included in the analyses. Eighty-one percent of the participants reported having a preference (Figure 2).

With Conveen® Optima more participants found that:

- It was easier to open and remove the sheath from the individual packaging
- They did not experience wrinkles or bubbles when applying the sheath
- They felt safe immediately after application of the sheath
- The sheath was comfortable to wear
- The drainage from the sheath into the urine bag was satisfactory
- The individual packaging of the urinary sheath enabled them to easily carry it around with them
- It was easier to connect and subsequently disconnect the sheath from the urine bag

The scores for these results are shown in Table 1.

- Participants felt more secure when using the Conveen® Optima (scale ranged from 0=very insecure to 10=very secure; $P=0.029$, Wilcoxon test).
- Where nurses applied the urinary sheaths wearing gloves, more nurses found Conveen® Optima easy to apply.
- For all other questions asked, there was no statistically significant difference between the Conveen® Optima and the Clear Advantage® urinary sheaths.

Reference

1. *BJU Int* (2001), 87: 367-372.

Concluding message

This is one of the first randomised clinical trials aimed at providing evidence for healthcare professionals in order to assist them and their patients in making informed choices concerning a urinary sheath product. The study shows that the newly developed Conveen® Optima urinary sheath provides a higher feeling of security than the well-established product, 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%, indicating that it is more acceptable than the well-established product.

Interpretation of results

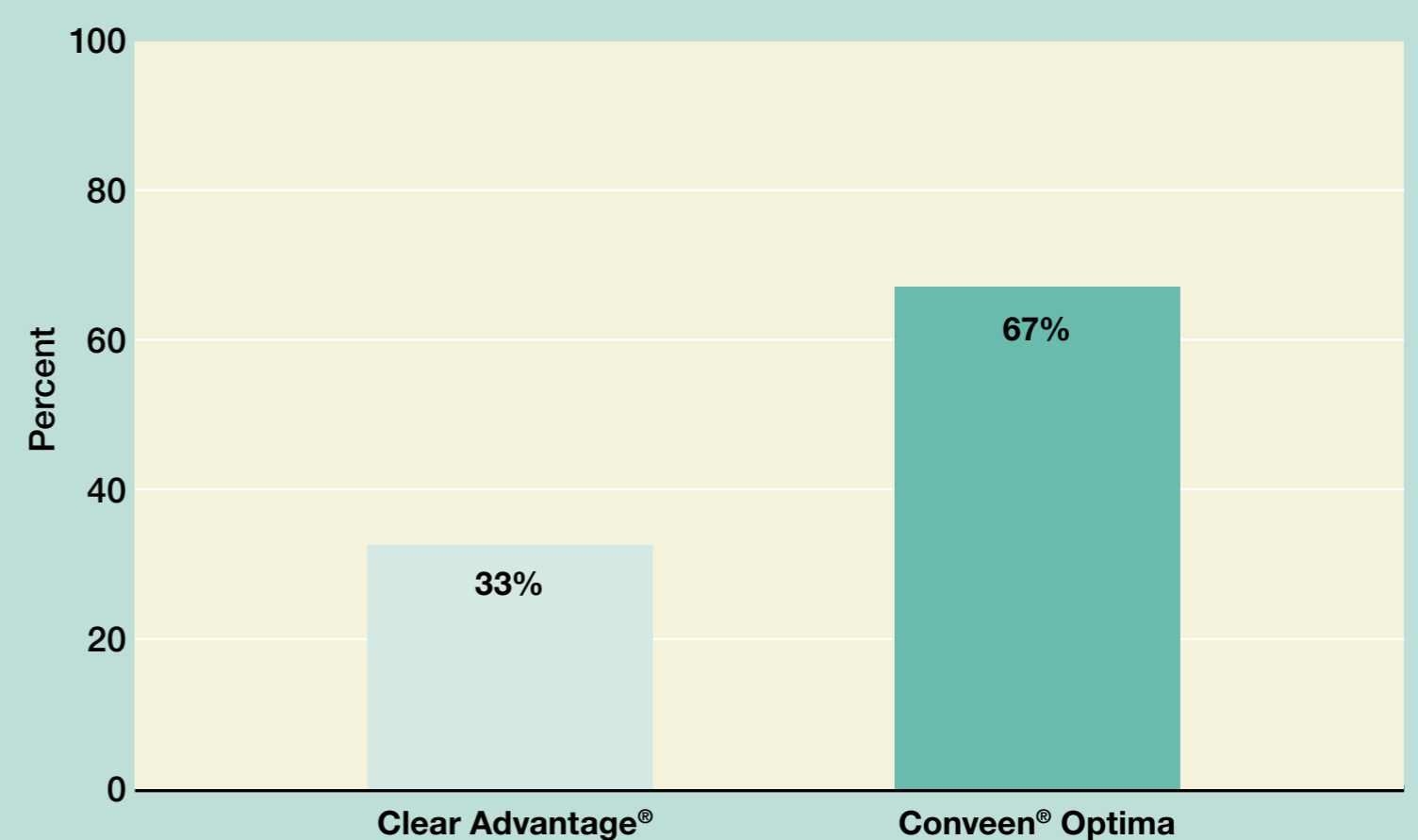
This study shows that the Conveen® Optima urinary sheath provides a higher feeling of security. Furthermore, the Conveen® Optima sheath was found to be easier to handle and apply in some of the aspects studied and importantly, it was found to be at least as user-friendly as the Clear Advantage® sheath in all the other aspects studied.

The study showed that 67% preferred the Conveen® Optima urinary sheath over Clear Advantage®, which was previously shown to perform significantly better than other self-adhesive urinary sheaths on the UK market at that time [1]. 60% of the participants were using Clear Advantage® before entering the study and must therefore be expected to favour Clear Advantage®. It is thus interesting to note that such a large proportion preferred Conveen® Optima. This large preference may be due to the improved feeling of security, the improved comfort and improved packaging of the product.

Figure 1: The Conveen® Optima urinary sheath



Figure 2: Product preference



67% (95% confidence interval 52% to 82%) preferred Conveen® Optima, 33% (95% confidence interval 18% to 48%) preferred Clear Advantage®.

Table 1: Handling, application, comfort, and packaging

Parameter	Issues	Clear Advantage	Conveen Optima	P value
Application	Ease of opening individual packaging	3.30	4.32	<0.001
	Ease of removal from individual packaging	3.66	4.39	<0.001
	No wrinkles/bubbles on sheath when applied	3.57	3.86	0.036
	Confidence when wearing the sheath	3.36	3.69	0.043
Overall wear	Comfortable to wear	3.79	4.02	0.018
	Drainage of urine into bag during use	3.89	4.14	0.033
Connection to urine bag	Ease of connecting sheath to urine bag	3.80	4.14	0.018
	Ease of disconnection of urine bag from sheath	3.82	4.32	<0.001
Packaging	Ease of carrying sheath around	3.21	4.30	<0.001

Issues were stated as questions and answered on the following scale: 1 strongly disagree; 2 disagree; 3 neither agree or disagree; 4 agree; 5 strongly agree. The differences between the products were all statistically significant at 5% (Wilcoxon test).