Fecal containment in bedridden patients: economic impact of 2 commercial bowel catheter systems


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study examined the clinical and economic impact of two indwelling bowel catheter systems in hospitalised adults with faecal incontinence. The authors concluded that a silicone catheter, with a collapse-resistant annulus, a low-pressure retention cuff, and collection bags, was cheaper and required fewer linen changes per patient per day than a soft silicone catheter tube assembly, with syringe and collection bags. The study was well presented, but had some methodological limitations that might have affected the validity of these conclusions.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study examined the clinical and economic impact of two indwelling bowel catheter systems in hospitalised adults, with faecal incontinence. The focus was on the costs of the two devices.

Interventions
Two catheter systems were compared.

Catheter A was a silicone catheter with a collapse-resistant annulus, a low-pressure retention cuff, and collection bags. It was used for the diversion of faecal matter, to facilitate the collection of faecal matter, to provide access for colonic irrigation, and to administer enemas or medications.

Catheter B was a soft silicone catheter tube assembly, with syringe, and collection bags. It was used for the faecal management of patients with little or no bowel control and liquid or semi-liquid stools.

Location/setting
USA/acute or critical care units.

Methods
Analytical approach:
The analysis was based on a single study with a 29-day time horizon. The authors did not explicitly state the perspective.

Effectiveness data:
The clinical evidence was from a multi-centre, open-label, non-randomised observational study of 146 patients, with 76 receiving catheter A (mean age 61.1 years; 42.1% women) and 70 receiving catheter B (mean age 62.3 years; 37.1% women). Patients were followed-up until they left the acute or critical care unit or until 29 days had elapsed from the catheter insertion. Clinicians completed a questionnaire on the ease of product insertion and other catheter characteristics. The endpoints of the analysis included the key outcome, which was rate of unscheduled bedding and dressing changes. The secondary outcome was incidence of skin or soft tissue and urinary tract infections, with ease of use being the tertiary outcome.

Monetary benefit and utility valuations:
Not considered.
Measure of benefit:
No summary benefit measure was used. The key outcome was rate of unscheduled bedding and dressing changes.

Cost data:
The economic analysis included the nursing time for unscheduled bedding and dressing changes and the cost of laundry services. The costs of the two devices were not included in the base case. The resource use data were derived from the sample of patients in the clinical study. The cost of nursing time was based on standard pay scales for intensive care unit personnel in the USA, while the laundry costs (processing, replacement, delivery, and stocking) were derived from the Bureau of Labor Statistics. All costs were in US dollars ($) and the price year was 2008.

Analysis of uncertainty:
Not investigated.

Results
Catheter A was $13.94 cheaper per patient per day than catheter B. When the cost of the catheter was considered, the analysis showed that only if the catheter was used for less than two or three days, would there be a cost advantage of using catheter B instead of catheter A.

The rate of bedding or dressing changes per day was 1.20 with catheter A and 1.71 with catheter B. This difference was statistically significant (p=0.004). There were two skin or soft tissue and four urinary tract infections with catheter A and six skin or soft tissue and one urinary tract infection with catheter B. This very low incidence of infection precluded the use of statistical tests.

The proportions of clinicians who were very satisfied with the overall performance of the catheter were 84% with catheter A and 80% with catheter B. Other outcomes, such as the probability of removal, the indwelling time, and the reinsertion of the initial device, also favoured catheter A.

Authors' conclusions
The authors concluded that catheter A was cheaper and required fewer linen changes per patient day in comparison with catheter B.

CRD commentary
Interventions:
The selection of the comparators was appropriate and the authors stated that each participating site used the type of catheter that was standard for that setting. A clear description of both catheters was given.

Effectiveness/benefits:
The clinical evidence came from a prospective observational study, which was appropriate for the study question, but the lack of randomisation might have introduced selection bias. Strong features of the study were its multi-centre design and the baseline comparability of the study groups in their clinical and demographic factors. Small differences in weight and age did not reach statistical significance. Limitations were the relatively small sample size and the lack of power calculations to justify the number of patients enrolled. The benefit measures were disease-specific and appropriate, but will not be comparable with other disease areas.

Note: correspondence with the authors subsequent to this abstract being written has indicated that a power calculation was carried out, but that details of this were not included in the original manuscript submitted for publication. This omission has now been corrected and, in due course, an addendum to the paper will be published. The addendum will read as follows: "A sample size of 67 subjects per group was required to determine a 25% difference between catheter A and catheter B (α=0.05, β=0.20, power is 0.80) when catheter B was not expected to exceed a 60% increase in linen change (less than 1 unscheduled change per day). The sample size was based on an alpha correction to accommodate the planned interim analysis, and also consisted of a 10% increase to accommodate drop out".

Costs:
The economic viewpoint was not stated, but only those costs borne by the service provider appear to have been
included. Some of the unit costs and quantities of resources used were presented and these reflected the sites enrolled in the study. The economic data were from official US sources. The price year was appropriately reported, which will allow reflation exercises to be carried out in other time periods. The costs were treated deterministically and the unit costs and quantities of resources used were not varied.

Analysis and results:
The costs and benefits were not synthesised, as a cost-consequences analysis was performed. The expected clinical and economic outcomes were clearly presented, with some diagrams. The issue of uncertainty was not investigated. The authors acknowledged some limitations of their study and these mainly related to the observational design that was needed to maintain the standard practices in the sites enrolled. These results should be corroborated by randomised trials.

Concluding remarks:
The study was well presented, but had some methodological limitations that might have affected the validity of the authors’ conclusions.

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