Hydrogel/silver ion-coated urinary catheter reduces nosocomial urinary tract infection rates in intensive care unit patients: a multicenter study


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.

Health technology
The use of a hydrogel catheter with a monolayer of silver metal applied to its inner and outer surfaces (Bardex I.C. catheter).

Type of intervention
Treatment (medical device).

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients admitted to critical care units, who required catheters.

Setting
The setting was a hospital. The economic study was carried out at the Graduate Hospital, Philadelphia, USA.

Dates to which data relate
No dates relating to effectiveness evidence or resource use were given. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
No power calculations to determine the sample size were performed. Patients admitted to medical, surgical and coronary care units in five institutions, and who required catheters, were included in the study. There was no information about the number of patients in the two groups, the sample characteristics, or about patients who refused to participate or were excluded from the analysis.

Study design
This was a non-randomised prospective study ("quasi-experimental") that was performed in five US hospitals. The study period averaged 8.4 months (range: 3 - 12) for the standard latex catheter (baseline group) and 9.7 months (range: 3 - 12) for the hydrogel catheter.
for the Bardex I.C. catheter (intervention group). No explicit information about the duration of follow-up was given. The loss to follow-up was not reported. The medical and nursing staff were not notified about the change of catheters, thus enabling a blind switch from the standard catheter to the Bardex I.C. catheter.

Analysis of effectiveness
It was not stated whether the basis of the analysis was intention to treat or treatment completers only. The primary health outcomes included in the analysis were the rates of device use, and adjusted and unadjusted catheter-associated infection rates. The device usage rates were calculated by dividing a daily manual count of catheters in the intensive care units by the total number of patients bed days. NUTIs were defined according to the Centers for Diseases Control criteria of the National Infections Surveillance System. The infection rates (unadjusted) were calculated as the number of infections per 1,000 catheter days. As the authors recognised, there was a lack of comparability between the two groups due to potential differences in the time of year, severity of illness, hospital size and type of intensive care unit. The NUTI rates were therefore adjusted for these factors.

Effectiveness results
There was no statistically significant difference overall in the device usage ratio (number of device days per number of patient days) between the intervention group (0.78) and baseline (0.76), (p=0.31).

The overall unadjusted catheter-associated infection rate was significantly lower for the intervention group (4.5) than the baseline (7.1), (p=0.01).

In particular, the unadjusted catheter-associated infection rate was significantly lower for the intervention group (4.9) than the baseline (11.0) in the Graduate Hospital, (p=0.03). However, it was not significantly different in the other institutions.

The overall adjusted catheter-associated infection rate was not significantly different between the intervention group (4.9) and the baseline (8.1), (p=0.13).

Clinical conclusions
The authors concluded that there was a trend in the reduction of NUTIs with the Bardex I.C. catheter, although this was not statistically significant in terms of the adjusted catheter-associated infection rate.

Measure of benefits used in the economic analysis
No summary benefit measure was used. A cost-consequences analysis was therefore carried out

Direct costs
Discounting was not conducted, or relevant, due to the short time horizon of the study. The unit costs were not systematically analysed separately from the quantities of resources used. The costs of the catheters, tests and hospitalisations in the intensive care units were included in the analysis. The costs were estimated only for the Graduate Hospital, where there was a statistically significant difference in the infection rates. The quantity/cost boundary was that of the hospital. Resource use data were derived from actual data obtained by monitoring the patients admitted to the hospitals. The unit costs were obtained from the hospital databases and from the literature. The dates during which the costs were incurred were not given and the price year was not reported.

Statistical analysis of costs
No statistical analyses of the costs were performed.

Indirect Costs
The indirect costs were not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were not carried out.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The total costs ranged from $2,471 to $3,391. With an estimated reduction of 41 infections per year, the use of the Bardex I.C. catheter would lead to cost-savings of $98,021 in one year, compared to the standard Foley catheter. The additional cost of the catheter was offset by the reduction in hospitalisations.

**Synthesis of costs and benefits**
Not relevant as a cost-consequences analysis was performed.

**Authors' conclusions**
The use of the Bardex ion-coated (I.C.) catheter would lead to cost-savings, by reducing the number of nosocomial urinary tract infections (NUTIs), as was demonstrated by one of the institutions studied.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. The new Bardex I.C. catheter was compared with the standard Foley catheter. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness analysis used a non-randomised prospective study. The authors stated that a randomised controlled double-blind trial of longer duration would have been the best study design for achieving statistical significance in some of the main outcome measures. The use of power calculations to ascertain sample size would also have enhanced the validity of the study results. The results for the unadjusted catheter-associated infection rate should be viewed with caution given the potential bias due to the different characteristics of the patients in the two study periods. More details on the sample characteristics would have been useful for judging the comparability of the two groups. Statistical analyses were performed to estimate the statistical significance of differences in the outcome results between the two groups. The internal validity of the results obtained is likely to be low given the potential for both bias and confounding.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the economic analysis, which was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**
The cost analysis was conducted from the hospital perspective and all the relevant categories of cost seem to have been included. However, only limited details on the cost categories were given and the unit costs were not reported separately from the resource use quantities. This reduces the external validity of the results. No statistical analyses were carried out.
out. Also, no sensitivity analyses of the costs were performed, probably due to the large difference in costs between the two study groups. It should be noted that since the costing was conducted at only one of the hospitals, caution should be exercised when generalising the results to other settings.

Other issues
The authors addressed the issue of generalisability by comparing their effectiveness results (and, in part, the costs) with several published studies. The main limitation of the study was that all the analysis was based on the difference in the unadjusted catheter-associated infection rate that, as the authors acknowledged, could be biased due to multiple factors.

Implications of the study
Further analyses using a study design with more internal validity (such as a randomised controlled trial) should be performed to confirm the advantage, in terms of the effectiveness and costs, of the Bardex I.C. catheter.

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