Effect of silver-coated urinary catheters: efficacy, cost-effectiveness, and antimicrobial resistance.

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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 technology considered was a silver alloy/hydrogel-coated urinary catheter (Bardex I.C.; C.R. Bard, Inc. Covington, GA) for the prevention of urinary tract infections (UTI). The comparator was an uncoated latex catheter produced by the same manufacturer.

Type of intervention
Primary and secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients in 10 units of the Nebraska Medical Center over the study period. The 10 units consisted of three medical or surgical intensive care units (ICUs), one paediatric ICU, one paediatric solid organ transplantation unit, one adult liver transplantation unit, one haematopoetic stem cell transplantation unit, one burn care unit, one rehabilitation unit and one transplantation cooperative care unit.

Setting
The setting was tertiary care. The economic study was carried out in the Nebraska Medical Center, Nebraska, USA.

Dates to which data relate
The effectiveness and resource use data were collected for the period 1999 to 2002. The price year was 2002.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used for the effectiveness study. It appears to have been conducted prospectively for the intervention group and retrospectively for the control group.

Study sample
The authors did not report the use of power calculations to determine the sample size. All patients with UTIs were included, and these comprised consecutive patients at the study institutions. Surveillance in the 10 special care units accounted for 20.5% and 19.9% of all patient-days at the institution for 2001 and 2002, respectively.
Study design
This was a prospective observational study matched with historic controls that was conducted at a single centre. The duration of the follow-up was 2 years.

Analysis of effectiveness
The analysis of effectiveness was conducted on the basis of treatment completers only. The primary outcomes were the rate of infection (expressed as UTI/1,000 catheter-days and UTI/1,000 patient-days) and the emergence of silver resistance in urinary microbial isolates. A Poisson regression model was used to estimate the number of infections. No adjusting for confounding factors was reported, although the model was adjusted by the addition of a dispersion parameter to account for high variation.

Effectiveness results
The model-estimated infection rates by year were similar for 1999 and 2000 (6.30/1,000 catheter-days and 6.01/1000 catheter-days, respectively; p=0.88) and also for 2001 and 2002 (2.37/1,000 catheter-days and 2.84/1,000 catheter-days, respectively; p=0.70).

The rate for 2001 - 2002 (2.62/1,000 catheter-days) was statistically lower than that for 1999 - 2000 (6.13/1,000 catheter days; p=0.002). This represented a 57% (95% confidence interval, CI: 27 to 75) reduction in the risk of UTI following the introduction of the silver alloy-coated urinary catheter.

The rates of infection per patient-day were similar in 1999 and 2000 (1.51/1,000 patient-days and 1.83/1000 patient days, respectively; p=0.39), as well as in 2001 and 2002 (0.89/1,000 patient-days and 1.03/1,000 patient-days, respectively; p=0.57).

The rate for 1999 - 2000 (1.67/1,000 patient-days) was statistically higher than that for 2001 - 2002 (0.97/1,000 patient-days; p=0.02).

All clinical isolates remained susceptible to silver and exhibited an MIC (minimum inhibitory concentration) of less than or equal to 16 microg/mL.

Clinical conclusions
The results of the study showed that the introduction of a silver alloy/hydrogel-coated urinary catheter was associated with a significant reduction in the rate of nosocomial UTI.

Measure of benefits used in the economic analysis
The authors used the number of prevented UTIs as the measure of benefits for the economic analysis.

Direct costs
The cost/quantity boundary adopted for the study appears to have been that of the hospital. The authors reported the cost of the most commonly used device during the study period (the 16 French Folley catheter tray with a 350 mL urinary meter), as well as a total direct cost for nosocomial UTI complications and secondary bacteraemia. Price data were collected from the manufacturer and from the literature. The costs were adjusted for inflation. The price year was 2002.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
No indirect costs were included.

**Currency**
US dollars ($).

**Sensitivity analysis**
No areas of uncertainty were identified or investigated.

**Estimated benefits used in the economic analysis**
The number of prevented UTIs was 110 in 2001 and 96 in 2002.

**Cost results**
The additional cost of the silver alloy/hydrogel-coated urinary catheter amounted to $64,281 in 2001 and $65,307 in 2002.

**Synthesis of costs and benefits**
The benefits and costs were combined by multiplying the number of prevented UTIs by the cost of nosocomial UTI, then adding the cost of bacteraemia associated with 2% of nosocomial UTIs and subtracting the additional cost of the coated urinary catheter.

The cost-savings ranged from $13,469 to $535,452 in 2001 and from $5,811 to $484,070 in 2002, based on the cost estimate range in the literature ($700 to $5,682 per episode of a nosocomial UTI).

**Authors' conclusions**
The introduction of a silver alloy/hydrogel catheter was associated with a significant decline in nosocomial urinary tract infections (UTIs), and cost-savings over a range of cost estimates.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. It represented standard practice in tertiary care and reflected general practice in the USA.

**Validity of estimate of measure of effectiveness**
In design terms, the study was a prospective observational trial with historic controls. Although there were no adjustments for potential confounding factors, the authors stated that the 2-year follow-up minimised the potential impact of short-term confounding variables such as the Hawthorne effect, concurrent outbreaks, and other limited clinical practice changes. It was unclear from the study whether the effectiveness analysis was handled credibly and whether the sample size was sufficiently large to obtain robust results. Adjustments were made in the model to deal with variance in the data, which suggests uncertainty in the source data.

**Validity of estimate of measure of benefit**
The summary measure of benefit used in the economic analysis appears to have been appropriate in comparison with those used in similar studies. However, given that it was an intervention-specific health benefit measure, it would not enable comparisons with different health care interventions.

**Validity of estimate of costs**
It was unclear from the paper whether all the appropriate cost categories were included given the hospital perspective. It would appear that the authors limited their analysis to some direct costs, so the total cost may not fully reflect the actual costs. The resource quantities and costs were not reported transparently, which limits the transferability of the findings to other settings. Further, the cost estimates are likely to be specific to the Nebraska Medical Center.

Other issues
The authors made extensive and detailed comparisons of their findings with those of other studies. They stated that this piece of research lends support to the conclusion that the product is effective in the reduction of catheter-associated UTIs. The authors acknowledged that confounding variables could not be excluded and that there was a wide fluctuation in cost analysis results when a range of published cost figures was used. Hence, the results of this study favoured the use of silver alloy/hydrogel-coated urinary catheters. However, because of the scope of the costing, the use of hospital prices and the lack of power calculations, the magnitude of the savings should be viewed with some caution.

Implications of the study
Within the limitations and caveats highlighted, the results of the study support the use of silver alloy/hydrogel-coated catheters, even when subjected to conservative estimates of cost-effectiveness.

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