A randomized crossover study of silver-coated urinary catheters in hospitalized patients

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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
Silver-coated urinary catheters in decreasing urinary tract infections (UTIs) in hospitalised patients requiring catheter use.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of adult patients throughout a university hospital with a wide variety of types and severity of underlying illnesses. Paediatric wards were not included since children's catheters were not available. Obstetrics, gynaecology, and psychiatry were excluded because of their low infection rates and infrequent catheter use in these specialties.

Setting
The setting was hospital. The economic analysis was carried out in the USA.

Dates to which data relate
Effectiveness and resource use data corresponded to the period between 1 November 1996 and 30 November 1997. The price year was 1997. Data on excess cost of UTI were from studies published in 1992 and 1993.

Source of effectiveness data
The evidence for the final outcomes was based on a single study.

Link between effectiveness and cost data
Catheter use was recorded retrospectively on the same patient sample as that used in the effectiveness analysis. The excess cost of UTI was obtained by combining the rate of infection from the study with the published data on cost per infection.

Study sample
Power calculations were used to determine the sample size. Based on the rate of 1.54 catheter-associated UTIs per 100 patients from July 1994 through June 1995, it was estimated that a sample size of 29,184 hospital admissions would be needed to detect a 25% significance level with 80% power at a significance level of 5%. A total of 11,032 catheters were used on the wards during the study period, 5,398 silver-coated and 5,634 uncoated.
Study design
The study took the form of a randomised-controlled trial, carried out in a single centre. The unit of randomisation was
the hospital ward. The hospital wards were categorised into 3 strata according to baseline infection rates (high, medium,
and low) between 1 May 1995 and 30 April 1996. Hospital wards were randomised into 2 groups (1 and 2) within each
stratum. During the first 6 months, wards randomised to group 1 were stocked with silver-coated catheters, and wards
randomised to group 2 used uncoated catheters. This was followed by a 1-month washout period during which all wards
were stocked with uncoated catheters. In the second 6 months of the study, group 1 wards used uncoated catheters and
group 2 wards had silver-coated catheters. Of the total 27,878 patients, wards randomised to silver-coated catheters
treated 13,945 versus 13,933 patients on wards randomised to uncoated catheters. The duration of the follow-up
appears to have been until discharge. No information was given regarding the number of patients who were lost to
follow-up, it was reported that of the 343 infections, 89 (26%) involved crossover catheters; 63 (70.8%) of the 89
occurred in patients on wards randomised to silver-coated catheters but who had uncoated catheters in place at the time
of infection, and 26 (29.2%) occurred in patients on wards randomised to uncoated catheters but who had silver-coated
catheters in place. Fifty-two of the 343 infections occurred in persons whose catheters had been placed on non-study
wards (2 silver-coated and 50 uncoated). Intensive care units and their step-down units were linked to minimise the
chance of duplicate data collection among patients transferring between wards. Hospital-wide surveillance for
nosocomial infections was conducted as described by Wenzel et al (1976).

Analysis of effectiveness
The principle used in the analysis of effectiveness was both intention to treat and treatment completers only. The
clinical outcome measures were nosocomial catheter-associated UTIs and secondary blood stream infections identified
and ascribed to particular hospital wards by infection control practitioners using definitions from the Centers for
Disease Control and Prevention. Hospital records of patients with secondary blood stream infections were reviewed to
determine whether any deaths appeared to be related to these infections. Rates were calculated for the number of
infections per 100 patients, per 1,000 patient-days, and per 100 catheters. Within the intensive care units, rates were
Calculated per 100 patients, per 1,000 patient-days, and per 1,000 catheter days. The proportion of infections attributed
to different organisms was also reported. The comparability of study patients was not investigated.

Effectiveness results
The effectiveness results were as follows:

The incidence of nosocomial catheter-associated UTI per 100 patient when analysed in terms of intention to treat
(analysis as randomised) was 1.10 in the silver-coated catheters versus 1.36 in the uncoated catheters, with a relative
risk of 0.81 (95% CI: 0.65-1.01), (p=0.07).

The corresponding values in terms of incidence of catheter-associated UTI per 1,000 patient-days were 2.66 and 3.35,
respectively, with a relative risk of 0.79 (95% CI: 0.63-0.99) (p=0.07).

The relative risk of infection with silver-coated catheters compared with uncoated catheters in intensive care units was
0.94 per 100 patients (95% CI: 0.64-1.38; p=0.80).

The incidence of nosocomial catheter-associated UTI per 100 catheter when analysed in terms of treatment completers
(analysis by actual catheter use) was 2.13 in the silver-coated catheters versus 3.12 in the uncoated catheters, with a
relative risk of 0.68 (95% CI: 0.54-0.86) (p=0.001).

Fourteen (4.1%) of the 343 infections were complicated by secondary blood stream infections.

The rate of secondary infection was 0.04 per 100 patients on units randomised to silver-coated catheters and 0.07 per
100 on units assigned to uncoated catheters, for a relative risk of 0.56 (95% CI: 0.19-1.66; p=0.42).

One death appeared to be related to secondary infection.

There were no statistically significant differences in the proportion of infections attributed to different organisms.
following use of silver-coated and uncoated catheters.

**Clinical conclusions**
Given this study's known crossover rate of catheters resulting in infection (26%), the finding of a significant decrease in infections as randomised offers strong evidence of the effectiveness of the silver-coated catheters for preventing infection.

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic analysis, indicating that a cost-consequences analysis (CCA) was carried out.

**Direct costs**
Costs were not discounted due to the short time frame of the cost analysis. Quantities were reported separately from the costs. Some cost items were reported separately. The cost analysis covered the costs of catheters and components, and excess cost of UTI infections. The perspective adopted in the cost analysis was not explicitly specified. The price year was 1997. The purchase costs of catheters and components were provided by the manufacturer. The lower estimate of cost per infection was based on an uncontrolled case series of 84 patients from 1975. The higher estimate was based on a 19-month case-control study with 675 cases and 5,337 control subjects matched in baseline characteristics. The estimates were adjusted for inflation (to 1997 prices) using the consumer price index for medical care.

**Indirect Costs**
Indirect costs were not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was conducted.

**Estimated benefits used in the economic analysis**
See effectiveness results above.

**Cost results**
Using the lower estimate of the excess cost of UTI, the total annualised catheter-related cost was $448,104 for the uncoated catheters versus $433,648 for the silver-coated catheters, resulting in cost savings of $14,456.

The corresponding values when the higher estimate of the excess cost of UTI was used were $2,190,135 and $1,616,842, resulting in cost savings of $573,293.

The cost of catheters and components was $68,795 for the uncoated and $176,020 for the silver coated.

**Synthesis of costs and benefits**
Costs and benefits were not combined since the use of the silver-coated catheters was the dominant strategy.

**Authors' conclusions**
The risk of infection declined by 21% among study wards randomised to silver-coated catheters and by 32% among patients in whom silver-coated catheters were used on the wards. Use of the more expensive silver-coated catheters appeared to offer cost savings by preventing excess hospital costs from nosocomial UTI associated with catheter use.

CRD COMMENTARY - Selection of comparators
No justification was provided for the choice of the comparator. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The internal validity of the effectiveness results is likely the be high given the randomised nature of the study design, the power calculations performed, and the fact that the effectiveness analysis was based both on intention to treat and on treatment completers only. However, a limitation of the study was perceived to be that hospital wards rather than individual patients were used as the unit of catheter randomisation, increasing the chances of bias by detection and management. The authors believed that an advantage of randomising to wards rather than individuals was that a larger number of subjects could be exposed to study and control catheters, thereby maximising the power of the study while limiting the necessary resources and workforce. The degree to which the study sample was representative of the study population cannot be fully evaluated as insufficient information was provided regarding the characteristics of the study patients.

Validity of estimate of measure of benefit
Not applicable.

Validity of estimate of costs
The following features of the analysis may have enhanced the validity of the cost analysis: quantities were reported separately from the costs; adequate details of methods of cost estimation were given; the price year was specified; and adjustment was made for inflation. However, the cost breakdown was not fully reported; it is not entirely clear whether the cost data were based on true costs or on charges; the perspective adopted in the cost analysis was not explicitly reported; statistical analyses were not performed on the cost data and the effects of alternative preventive methods on indirect costs were not addressed. The cost saving relies on the estimates for the excess costs due to infection, the validity of which is not verifiable given that they come from two other studies.

Other issues
With respect to limitations of the study design, and lack of sensitivity analysis and statistical analysis of the cost, some degree of caution should be exercised in interpreting the study results. Generalisability was not discussed. Appropriate comparisons were made with other studies.

Implications of the study
The observed concordance of significantly fewer UTIs and a trend toward fewer bloodstream infections on wards randomised to silver-alloy catheters might be clinically important and produce cost savings, indicating the need to consider further study.

Source of funding
None stated.

Bibliographic details
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Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
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