Prevention of central venous catheter-related bloodstream infection by use of an antiseptic-impregnated catheter: a randomized, controlled trial

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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
A standard catheter impregnated with chlorhexidine and silver sulfadiazine (antiseptic catheter) or a standard triple-lumen polyurethane catheter in preventing central venous catheter-related infection.

Type of intervention
Treatment; secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
All adult patients requiring a central venous catheter for short-term use and who were not allergic to chlorhexidine, silver, or sulfonamides. The catheters included in the final analysis of the outcomes had been in place for at least 8 hours, and could be cultured at removal.

Setting
Hospital. The economic study was carried out in Wisconsin, USA.

Dates to which data relate
The date to which the effectiveness data referred was not specified. The resource utilisation data were extracted from two studies published in 1994 and 1995. Prices refer to 1995.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was not performed on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The initial study sample consisted of 442 study catheters. A total of 8.8% of catheters were excluded from the initial study sample (9.3% of control catheters and 8.3% of antiseptic catheters). A total of 403 catheters from 158 patients remained in the study sample. The control group consisted of 195 randomly assigned catheters corresponding to 86 patients, whereas the antiseptic group comprised 208 randomly designated catheters corresponding to 72 patients. About 10% of the invited patients refused to participate in the study.
Study design
The study was a randomised controlled trial carried out in a single centre. The duration of the follow-up was until catheter removal. The average duration of catheterization was 6 days in each group. A central venous catheter was used as the main unit of analysis, but potential benefits of the intervention were also reported in terms of individual patient as experimental unit. The blinding method adopted by the study assured that the patients’ physicians and nurses, the principal investigator and the research microbiologist were kept blinded to each study catheter’s group. No loss to follow up was reported.

Analysis of effectiveness
The analysis of the clinical outcomes was based on intention to treat. The main health outcomes were colonization and catheter-related bloodstream infection at removal, mean composite inflammatory score (considering itching, pain, erythema, and tenderness) as the measure of tolerance, and the potential sources of catheter-associated bloodstream infection. The adverse effects and resistance to chlorhexidine-silver sulfadiazine were also investigated. A scoring programme was used in order to report the potential benefits of antiseptic catheter in terms of individual patient as the unit of analysis. Patients and catheters were shown to be comparable in terms of age and risk factors predisposing to nosocomial infection.

Effectiveness results
The colonization rate at removal was 13.5% for the antiseptic catheters against 24.1% for the control catheters (RR, 0.56; 95% CI: 0.36 - 0.89; P=0.005). The rate of bloodstream infection was 1% for the antiseptic catheters against 4.6% for the control catheters (RR, 0.21; 95% CI: 0.03 - 0.95; P=0.03) or 1.6 versus 7.6 infections per 1,000 catheter-days, respectively. Mean composite inflammatory score (considering itching, pain, erythema, and tenderness) as the measure of tolerance was 1.4 (SD, 1.2) for the antiseptic catheters versus 1.4 (SD, 1.2) for the control catheters (no clinically significant differences). With regard to the sources of infections, bloodstream infection rates with gram-negative bacilli, Staphylococcus aureus, enterococci, or Candida species was 0% in the antiseptic catheter group versus 4.1% in the control catheter group (95% CI: 0.02 - 0.65; P=0.003). No adverse effects from antiseptic catheter or cases of resistance in either group were discovered. When the potential benefits of antiseptic catheters in preventing colonization and bloodstream infection were analysed in terms of individual patient as the unit of analysis, the results confirmed the preventive role of the intervention (mean score for preventing colonization was 2.185; P=0.032; mean score for preventing bloodstream infection was 0.975; P=0.019). The overall rate of nosocomial bloodstream infection was 5.6% in the antiseptic catheter group against 10.2% in the control catheter group.

Clinical conclusions
In this study the main source of catheter-related bacteremia and candidemia was the skin around the insertion site (6 cases out of 11). The other origins of infection may have been contamination of catheter hub (2 to 6 cases) and contaminated infusate or hematogenous seeding from remote source (1 to 3 cases). The authors concluded that "for maximum benefit, preventive strategies must be designed to block microbial invasion from all possible sources".

Measure of benefits used in the economic analysis
Catheter-related bloodstream infection rate at removal was the main benefit measure.

Direct costs
Quantities were not reported separately from costs. The cost items were not reported separately(except for the added cost of antiseptic catheters). Direct hospital costs were considered in the cost analysis. The cost of one catheter-related bloodstream infection was reported. The perspective adopted in the cost analysis was not stated. The sources of cost data were two published studies. The date of the price data was 1995.

Indirect Costs
Not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
A sensitivity analysis was performed by investigating a range of values for a parameter (K) in the scoring programme adopted to identify the potential preventive benefits of antiseptic catheters in terms of individual patient as the unit of analysis. A threshold analysis was performed to identify the cut-off points in the range over which the intervention remains cost-effective.

**Estimated benefits used in the economic analysis**
The rate of bloodstream infection was 1% for the antiseptic catheters against 4.6% for the control catheters (RR, 0.21; 95% CI: 0.03 -0.95; P=0.03) or 1.6 versus 7.6 infections per 1,000 catheter-days, respectively.

**Cost results**
The cost of one catheter-related bloodstream infection was $29,000. The added cost of antiseptic catheters was $25.

**Synthesis of costs and benefits**
The incremental hospital cost per 100 catheters for the control group was $59,000 (for 2% rate of bloodstream infection or 3.3 infections per 1,000 catheter-days) or $87,000 (for 3% rate of infection or 5.0 infections per 1,000 catheter-days). The corresponding value for the antiseptic catheter group was $31,500 (for 1% rate of bloodstream infection or 1.7 infections per 1,000 catheter-days). It was calculated that if the rate of bloodstream infection in an institution is at least 2% (approximately 3 infections per 1,000 catheter-days) and the antiseptic catheter improves the risk of the infection by 50%, the use of the intervention remains cost-effective.

**Authors' conclusions**
The chlorhexidine-silver sulfadiazine catheter is well tolerated, reduces the incidence of catheter-related infection, extends the time that noncuffed central venous catheters can be safely left in place for the short term, and should allow cost savings.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the choice of the comparator. The triple-lumen polyurethane catheter was considered as the comparator since it was identified as the standard technique. You should consider whether this a widely used health technology in your own setting.

**Validity of estimate of measure of benefit**
The internal validity of the benefit results is likely to be assured given the randomised design adopted for the study.

**Validity of estimate of costs**
Resource utilisation was not reported separately from the costs. Adequate details of the methods of cost estimation were not given. As a comprehensive list of cost items included in the economic study was not given, it is not possible to identify any potentially important cost items which may have been omitted from the study (apparently it was assumed that, with the exception of the extra cost of coated catheters, all other costs were common to both strategies). The main factor weakening the internal validity of the cost results is the fact that the costing was not performed on the same patient sample as that used in the effectiveness study.
Other issues
Appropriate comparisons were made with other studies, however the issue of generalisability to other settings or countries was not addressed.

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