Technical and economic feasibility of reusing disposable perfusion cannulas

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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
Reuse (reprocessing) of single- and dual-stage venous and arterial perfusion cannulas.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Single- and dual-stage venous and arterial perfusion cannulas.

Setting
Hospital. The economic analysis was carried out in the USA.

Dates to which data relate
No dates were given.

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

Link between effectiveness and cost data
Costing was performed based on four times reuse of cannulas. It was not specified whether costing was performed prospectively or retrospectively.

Study sample
Power calculations were not used to determine the sample size. In material evaluation (dimensions) of the Research Medical Incorporated (RMI) dual-stage venous cannula, the number of cases tested was 12 for unused/unprocessed cannulas versus 21 for each of clinically-used/post 1 (sterilization) cycle, clinically-used/post 5 cycles, and clinically-used/post 10 cycles. The corresponding numbers in the material evaluation (dimensions) of RMI single-stage venous cannula were 3, 20, 20, and 20, respectively. The respective numbers in 3M/Sarns arterial cannula were 14, 21, 21, and 16, respectively. The number of cannulas involved in sterilization validation were 5 (a total of 30) for each of clinical use (one sterilization cycle), and simulated use (10 sterilization cycles) for each one of RMI dual stage, RMI single stage, and 3M/Sarns. In function testing of RMI dual-stage, single-stage, and 3M/Sarns arterial cannulas (at 22 degrees C), the numbers involved in the intervention (10-time processed with simulated use) versus control (new cannulas) group were 10 versus 5; 10 versus 5, and 10 versus 6, respectively. In the function testing of 3M/Sarns cannulas
involving assessing temperature sensitivity, the numbers were 11, 12, and 5 for controls (new), 1-time processed, and 10-time processed use, respectively. In vivo testing was performed in sheep undergoing cardiac valve replacement using two new cannulas and three used cannulas (with five total sterilization cycles).

**Study design**
This was a prospective non-randomised study with concurrent controls, carried out in a single centre. The duration of the follow-up was until the end of testing. No loss to follow-up was reported. An independent laboratory performed biocompatibility testing. Simulation of reuse was conducted employing end-to-end bending, coupling and uncoupling of the connectors, and two 1-hour soaks in plasma at 4 degrees and 40 degrees C, respectively.

**Analysis of effectiveness**
The principle (intention to treat or treatment completers only) used in the analysis of effectiveness was not explicitly specified. The clinical outcome measures were validity of sterilization (involving eradication Bacillus subtilis spores from the cannulas on each of five consecutive cycles), physical changes (tensile stiffness, yield strength, ultimate tensile strength, elongation-at-break, and energy-to-break), functional integrity, biocompatibility, and in vivo performance in sheep.

**Effectiveness results**
Sterilization was validated by showing no sign of the test organism post-sterilization. The mechanical properties showed less than 20% change in terms of all variables assessed with comparison to the new cannulas, such that experienced cardiac surgeons did not detect the changes in selective evaluation. In terms of functional testing at room temperature, the reused RMI dual-stage cannulas showed 15% change in body bending stiffness (p<0.001), 21% in tip bending stiffness (NS), and 13% in body tensile stiffness (p=0.004), compared to the use of new cannulas. The corresponding values for RMI single-stage cannulas were 9% (NS), 10% (NS), and 8% (NS), respectively. The reused 3M/Sarns showed no significant changes of wire-reinforced body hardness, nonreinforced body hardness, tip bending stiffness, body tensile stiffness, tip tensile stiffness, tensile yield strength, ultimate tensile strength, tensile elongation-at-break, tensile energy-to-break, shear (tip only) torsional stiffness, torsional yield strength, ultimate torsional strength, torsional angle-at-yield, and torsional energy-to-yield, while body bending stiffness changed by 5%, (p=0.03). New and reused cannulas were not significantly different in terms of clinical properties, even after nine simulated reuses. In vivo testing showed one infected in each of the intervention and control cases. Reused cannulas were successful in the other biocompatibility tests.

**Clinical conclusions**
The fact that the cannulas passed the other biocompatibility tests, including the muscle implantation test, and that no adverse reactions were observed in the animal model (one of the cannula models evaluated), showed that the reprocessed cannulas are safe.

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic analysis because of equal efficacy of the two alternatives, and only separate clinical outcomes were reported.

**Direct costs**
Costs were not discounted due to the short time frame chosen for the study. Quantities of resource use were not fully reported separately from the costs. Cost items were reported separately. Cost analysis covered the costs of sterilization cycle (including sterilant, consumable supplies, and capital equipment) and reprocessing costs including labour costs. Cost calculation for the reuse option was based on four-time cannula reuse. The source of cost data for reprocessing costs including labour costs was the Cleveland Clinic Foundation. The date of the price data was not explicitly specified.
Indirect Costs
Not applicable.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The cost/procedure was $53.13 (8,500 devices purchased per year) for the without-reuse option versus $18.64 (1,700 devices purchased per year) for the with-reuse option based on 3,200 procedures per year, amounting to a saving of $34.49 per procedure.

Synthesis of costs and benefits
Costs and benefits were not combined since the reuse option was the (weakly) dominant strategy based on the authors' assumption of equal efficacy between the two alternatives.

Authors' conclusions
Preliminary data suggest that the perfusion cannulas tested can be safely and efficaciously used five times. Limited reuse of these disposable cannulas is technically feasible and cost-effective. Cannula reuse would result in a small incremental saving. However, with more expensive devices and higher-volume sterilization procedures, the savings could be considerably greater. This programme provides a model for evaluation of other single-use medical devices for reuse.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear.

Validity of estimate of measure of benefit
The study design was appropriate but it is not clear whether the sample size was sufficient to detect differences between single use and multiple use of cannulas. The study should be classified as a cost-minimization analysis.

Validity of estimate of costs
Some quantities of resource use were reported separately from the costs. Insufficient details of the methods of cost estimation were given. Cost results may not be generalisable to other settings or countries.

Other issues
Sensitivity analysis was not used to address the uncertainties surrounding the cost and effectiveness variables. The issue of generalisability to other settings or countries was not addressed. Appropriate comparisons were made with other studies.
Implications of the study
The results of this testing suggest that a clinical trial can be designed and carried out to assess the clinical utility and overall economic impact of reuse of perfusion cannulas.

Source of funding
None stated.

Bibliographic details

PubMedID
9305199

Original Paper URL
http://www1.mosby.com/scripts/om.dll/serve?action=searchDB&artType=abs&id=a81392&nav=abs

Indexing Status
Subject indexing assigned by NLM

MeSH
Animals; Bacillus subtilis; Biocompatible Materials; Catheterization, Peripheral /economics /instrumentation; Cost-Benefit Analysis; Costs and Cost Analysis; Disposable Equipment /economics; Equipment Contamination; Equipment Reuse /economics; Feasibility Studies; Humans; Materials Testing; Perfusion /instrumentation; Sheep; Sterilization; Tensile Strength; Torsion Abnormality

AccessionNumber
21997001286

Date bibliographic record published
30/04/2000

Date abstract record published
30/04/2000