Safety and efficacy of hydrogen peroxide plasma sterilization for repeated use of electrophysiology catheters

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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 new technique for sterilising nonlumen electrophysiology catheters that uses hydrogen peroxide gas plasma was examined.

Type of intervention
Other: sterilisation procedures.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients suffering from a variety of arrhythmias who were being treated by an ablation procedure.

Setting
The setting was not stated, but it is likely to have been tertiary care. The economic analysis was conducted in New Mexico, USA.

Dates to which data relate
The dates to which the effectiveness data related were not reported. The resource data related to 1996. The price year was 1996.

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

Link between effectiveness and cost data
The costing was undertaken on the same sample as that used in the effectiveness study.

Study sample
No power calculations to determine the sample size were reported. Ten nonlumen electrophysiology catheters were extensively evaluated, of these five were quadripolar diagnostic catheters and five were deflectable thermistor-tipped ablation catheters.

Study design
The study was a prospective study where each electrophysiology catheter served as its own control. The study was conducted in a single centre. Each of the electrophysiology catheters was used 5 times and was sterilised after each use with hydrogen peroxide gas plasma. In addition to the 10 catheters used in the actual electrophysiology studies, 3 additional ablation catheters were sterilised a total of 20 times with aggressive manipulation of each catheter between cycles to simulate clinical use. The duration of follow-up was not reported, but it appears to have been less than one month.

**Analysis of effectiveness**

All of the catheters in the study were accounted for at analysis. The primary outcomes used in the analysis were the effects of sterilisation, in particular mechanical and electrical integrity, visual and microscopic inspection, sterility and chemical residuals remaining after the sterilisation process. Sterility testing included an evaluation of the sterilisation technique against resistant bacterial and viral organisms and both hydrophilic and lipophilic viruses, and an assessment of the sterility of the catheter used in the study.

**Effectiveness results**

Loss of electrical integrity or mechanical integrity was not observed in any catheter.

No evidence of microbial contamination was found.

Surface integrity was preserved except for one ablation catheter that exhibited fraying of the insulation at the insulation-electrode interface.

Surface inspection using standard magnification and electron microscopy revealed no significant change in the surface characteristics that could be associated with the sterilisation process.

Hydrogen peroxide was the only chemical residual noted, with an average concentration of 0.22% by weight. This was within the accepted limits set by the American Association for the Advancement of Medical Instrumentation.

**Clinical conclusions**

Hydrogen peroxide plasma sterilisation provided a safe and effective means of reusing electrophysiology catheters.

**Measure of benefits used in the economic analysis**

The authors did not develop a summary benefit measure. The analysis was therefore classified as a cost-consequences analysis.

**Direct costs**

The perspective adopted was not reported. Only the direct costs of the catheter and the sterilisation procedure were considered. The costs of the sterilisation procedure were for the sterilisation system (cost per procedure) and the chemicals necessary for each sterilisation cycle. The quantities and costs were estimated using data from the authors’ institution. The costs and the quantities were not reported separately. Discounting was unnecessary since the costs were incurred in less than one year. The price year was 1996.

**Statistical analysis of costs**

No statistical analysis of the costs was carried out.

**Indirect Costs**

The indirect costs were not included.
Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

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

Cost results
The cost of a standard electrophysiology catheter ranged from $200 to $800. The average cost was $500.

The average cost of one hydrogen peroxide sterilisation cycle was $10.

The reuse of each catheter five times would lead to a cost-saving of $2,000 per catheter.

With 3 to 5 catheters used for the average ablation procedure, a cost-saving of $6,000 to $10,000 could be realised for every five ablation procedures performed.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
Hydrogen peroxide gas plasma sterilisation may provide a cost-effective means of sterilising nonlumen electrophysiology catheters without the problem of potential harmful chemical residuals. In the absence of such residuals it may provide an alternative to ethylene oxide gas sterilisation.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was unclear. It appears that the authors have compared the outcomes of hydrogen peroxide plasma sterilisation with those of ethylene oxide gas sterilisation in the 'Introduction' and 'Discussion' sections, and concluded that the first intervention may be a better alternative to the second. However, the two interventions were not compared in terms of their respective costs. Ethylene oxide gas sterilisation would have been a more appropriate comparator for the cost-effectiveness analysis.

Validity of estimate of measure of effectiveness
The study design seems to have been appropriate for the study question. However, the sample size was very small (n=10) and may bias the result in favour of the intervention. An intermediate effectiveness outcome was evaluated. The authors acknowledged that a clinical end point would have been more appropriate for the study question.

Validity of estimate of measure of benefit
There was no summary measure of benefit.

Validity of estimate of costs
The perspective adopted in the analysis was unclear and, therefore, it is not possible to determine whether all the relevant costs were included. The costs and the quantities were not reported separately. In addition, no statistical analysis of the quantities or costs was performed. These factors hinder the reproduction of the results in other settings.
Other issues
The generalisability of the results was not discussed. Adequate comparisons were made with studies dealing with the same topic. The authors highlighted the limitations of their study. They do not appear to have reported the results selectively. The main limitations of the study were the definition of the comparator and the interpretation of the results of the cost-effectiveness analysis.

Implications of the study
The authors suggested that hydrogen peroxide plasma sterilisation may be particularly suitable for sterilising heat- and moisture-sensitive materials, such as electrophysiology catheters, since a low-temperature and low-moisture environment is used. Larger studies that address clinical outcomes will be necessary to evaluate the complete safety of this technique.

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Bibliographic details

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9809952

Other publications of related interest
Dunningan A, Roberts C, McNamara M, et al. Success of re-use of cardiac electrode catheters. American Journal of Cardiology 1987;60:807-10.


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