In vitro evaluation of integrity and sterilization of single-use argon beam plasma coagulation probes

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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
Reprocessing, through manual cleaning and ethylene oxide (ETO) sterilisation, of argon plasma coagulation (APC) probes (2.3 mm diameter, 220 cm length) manufactured by ERBE Inc. (Marietta, GA) for treatment of gastrointestinal bleeding.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The authors follow an ‘in vitro’ experimental approach, in which the patients were substituted with pieces of beefsteak placed on a grounding pad and each probe was used to coagulate a 1.5 x 1.5 cm square section of the meat for 60 seconds using a painting motion.

Setting
The setting was a medical centre. The economic study was carried out in Seattle, USA.

Dates to which data relate
The dates for the effectiveness evidence, resource use and cost data were not reported.

Source of effectiveness data
Evidence was derived from a single study.

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

Study sample
The study sample consisted of pieces of beefsteak placed on a grounding pad coagulated by ERBE APC probes for 60 seconds using a painting motion. All 10 probes completed 10 testing sessions.

Study design
The study was designed as a case series carried out in a single centre. Follow up was until probes were discarded. There
was no loss of follow up.

Analysis of effectiveness
The analysis of effectiveness was based on intention to treat. The primary outcomes used in the analysis were: physical and functional condition including electrical integrity in terms of mean depth of coagulation of the 10 probes after 10 testing sessions and presence of B. subtilis inoculation after manual cleaning and ETO sterilisation.

Effectiveness results
One probe fractured at its proximal length, however, its electrical integrity was intact and the probe completed the trial. No other probes suffered physical damages.

The white ceramic tips of the nine probes incurred grey to black discolouration after the 3rd trial. The latter had no relation to the function of the probes.

The probes did not suffer from any functional damages and their electrical integrity was intact. The mean depth of coagulation of the probes differed between some trials: between trial 1 (2.7 mm) and trial 5 (3.4 mm), (p=0.03), between trial 1 and trial 7 (3.5mm), (p=0.0003), and between trial 1 and trial 9 (3.6 mm), (p=0.002). According to the authors, this was due to external factors: 3-month duration of the experiment, different pieces of beefsteak used, variations of the angle and distance of the probe from the beefsteak at each trial.

After both the manual clean and ETO sterilisation no B. subtilis was found on the probes.

Clinical conclusions
The combination of a manual clean and ETO gas safely and efficiently sterilised ERBE argon plasma probes without significant loss of form or function.

Measure of benefits used in the economic analysis
Since the effectiveness analysis showed no difference in effectiveness/clinical benefit between the intervention and the comparator, the economic analysis was based on the difference in costs only. The analysis was therefore of cost-minimisation design.

Direct costs
Costs were not discounted due to the short duration of the trial. Some quantities and costs were analysed separately. Only hospital procedure costs were included in the study. Estimation of costs and quantities was based on the trial data. The date for the price data was not specified. The authors calculate the per-procedure costs of the probes by adding the initial purchase price of the probe to its processing costs divided by the number of uses. The processing costs of the probe included: costs of technician time needed to process a probe, supplies costs and ETO sterilisation charges.

Indirect Costs
Indirect costs were not considered.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.
Estimated benefits used in the economic analysis
Not applicable.

Cost results
The per-procedure costs of reprocessed APC probes used in the experiment were $24.25 (the reprocessing costs being $5.83 per probe), whereas the per-procedure costs of single use APC probes was $190.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
Reprocessing of ERBE APC probes through both manual clean and ETO sterilisation was effective and significantly more cost-efficient than the single use ERBE APC probes.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used, namely that the APC probes manufactured by ERBE inc. (Marietta, GA) had recently been approved for use in the USA as a possible treatment for gastrointestinal bleeding. You, as a user of the database, should decide if this is widely used health technology in your own setting.

Validity of estimate of measure of benefit
The analysis was based on a case series, which was appropriate for the study question. It was not clear whether the sample size was sufficient to detect differences in the effectiveness of the two approaches. This was an in vitro experiment and the authors acknowledged that in vivo studies might show that the number of reuses was an overestimation.

Validity of estimate of costs
All categories of costs relevant to the perspective adopted were included in the analysis. Costs and quantities were reported separately. As noted by the authors, the measure of per-procedure cost of reprocessed APC probes may be an underestimate. Correspondingly the cost-effectiveness of the technology may have been overestimated, because the results derived from the 'in vitro' methods used in the study, may differ from those derived from 'in vivo' methodology. Therefore, it is necessary to perform, in the future, an 'in vivo' study on the effectiveness of reusing APC probes. Cost results refer to the authors setting and might not apply elsewhere.

Other issues
The issue of generalisability to other settings was addressed and the authors made appropriate comparisons with other studies.

Implications of the study
The authors suggest that APC probes can, potentially, be safely and effectively reused up to 10 times with possible procedural savings.

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None stated.

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