A prospective study of the repeated use of sterilized papillotomes and retrieval baskets for ERCP: quality and cost analysis


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
Reusable papillotomes and retrieval baskets for endoscopic retrograde cholangiopancreatography (ERCP).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients attending an endoscopy unit for ERCP.

Setting
Hospital. The economic study was carried out in Toronto, Ontario, Canada.

Dates to which data relate
The effectiveness and resource use data corresponded to new reusable papillotomes and retrieval baskets bought between October 1995 and February 1996. 1995 price data were used.

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

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

Study sample
Only reusable instruments were assessed in the effectiveness study, comprising 25 papillotomes and 15 retrieval baskets. These numbers were not reported to be associated with prior power calculations. The quality of an instrument's function was assessed by a gastroenterologist, blinded to the number of prior uses of the instrument.

Study design
The study was of a case-series design, based at a single centre. Instruments were used 'in a random fashion' from central supplies. The quality of an instrument's function was assessed using a scale of 1 (useless) to 10 (excellent). Instruments were sterilised and reused if they passed the quality rating (assessed at 6 out of 10, or better). The duration of follow-up
for the complication rate was not reported. The loss to follow-up for the final culture assessment was 42.5%.

Analysis of effectiveness
The principle used in the analysis was not relevant. The principal outcome measures included the median and mean number of uses. Complication rates attributable to faulty or poor functioning were also recorded. At the end of their useful lives, instruments were sterilised and sent for bacterial and viral culture.

Effectiveness results
The median number of uses of the papillotomes, above the minimum quality rating was 8 (mean 9.8); the corresponding figures for the baskets were 13 (median) and 12.9 (mean) uses. All but three papillotomes were discarded once the rating dropped below 6 out of 10, while the baskets rated lower than 6 were routinely used afterwards only for stent removal and sweeping ducts. No complication was found to be attributable to poor functioning of the reusable instruments. All bacterial and viral cultures were negative except one basket, which yielded an anaerobic diphtheroid, believed to be handling contaminant.

Clinical conclusions
In this study, the papillotomes and baskets could be reused reliably and safely multiple times.

Modelling
A Kaplan-Meier model was used to estimate instrument survival rates.

Methods used to derive estimates of effectiveness
The authors referred to the theoretical advantages of single-use instruments, as documented in the marketing and medical literature.

Estimates of effectiveness and key assumptions
The authors assumed that disposable papillotomes and baskets would be safe and effective.

Measure of benefits used in the economic analysis
Since the benefits associated with both strategies were believed to be equivalent, the economic analysis was based on the differences in costs only.

Direct costs
Costs were estimated from the perspective of the hospital, and included the equipment, cleaning and disposal costs associated with the strategies. Purchasing prices were used to calculate costs associated with the instruments, while the cleaning, processing and sterilisation costs were obtained from actual operating times from the study and salaries at the institution (Toronto). Unit disposal costs were obtained from the 1995 charges to the hospital for waste disposal. Resource use estimates for the median number of (reusable) instrument uses were used to derive the number of disposable instruments required to perform the same number of procedures as the reusable instruments. The price date was 1995.

Statistical analysis of costs
Not performed.

Indirect Costs
Indirect costs were not included in the analysis.

**Currency**
US dollars ($). Canadian dollars were converted at the rate of $1.00 per US $0.72.

**Sensitivity analysis**
No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
The total annual cost for the reusable basket policy option was $19,192, whereas the figure for the disposable basket policy was $81,000. The results for the papillotomes were $19,792 and $113,887 respectively, for the reusable and disposal policies. The total annual cost saving was therefore $115,904 and the saving per case of ERCP was estimated to be $96.

**Synthesis of costs and benefits**
Not applicable.

**Authors' conclusions**
Papillotomes and retrieval baskets may be reused reliably and safely many times after cleaning and sterilisation. These reusable ERCP accessories become cost-effective by the second usage. Although the costs of proper cleaning and sterilisation are low, these steps are of critical importance to the safety of the practice of reusing instruments. Thorough quality control and procedures should be in place, and sufficient stocks of accessories need to be maintained to allow ample time for disinfection and sterilisation without causing procedure delays. At present, multiple reuse of papillotomes and baskets is more cost-effective than the practice of using disposable ERCP accessories.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of comparator is clear. The authors noted that the practice of one-use ERCP instruments is promoted for functioning and safety considerations.

**Validity of estimate of measure of benefit**
It was not stated whether those responsible for cleaning and sterilising the instruments were aware that their work was being monitored: their performance may have been affected by this knowledge, resulting in more thorough cleaning than would be achieved under non-study conditions. Similarly, the assessors' examination of instruments prior to use may have been more careful than might be the case in normal practice; this might have implications for the risks associated with reusable instruments. The size of the study, in terms of the number of cases of ERCP, was not clearly stated. The method by which complications were assessed was not specified, nor was the duration of follow-up for these patients. It is possible that unrecorded complications occurred at a later date. In the absence of a formal control in the clinical study, the effectiveness results are not justified.

**Validity of estimate of costs**
The report of the cost analysis gave adequate details about the methodology and elements included in it, with quantities of resource use analysed separately from the costs. Cost savings may not, however, be generalisable to other settings.
Other issues
The authors’ conclusions concerning cost savings within the study setting were justified. However, uncertainties in the effectiveness data cast doubt upon the conclusions regarding safety and efficacy.

Implications of the study
Further studies are needed in order to obtain a more reliable estimate of the cost-effectiveness of reusable instruments for ERCP.

Source of funding
None stated.

Bibliographic details

PubMedID
9040995

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Cholangiopancreatography, Endoscopic Retrograde /economics /instrumentation; Cost Control; Costs and Cost Analysis; Disposable Equipment; Equipment Contamination; Equipment Design; Equipment Reuse /economics /statistics & numerical data; Equipment Safety; Humans; Prospective Studies; Quality Control; Statistics, Nonparametric; Sterilization; Survival Analysis

AccessionNumber
21997000337

Date bibliographic record published
30/04/1999

Date abstract record published
30/04/1999