Prospective multicentre study comparing a standard reusable sphincterotome with a disposable triple-lumen sphincterotome

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
Endoscopic sphincterotomy with either a reusable single-lumen sphincterotome (Ultratome XL; Microvasive Endoscopy, Boston Scientific Corp., Natick, MA) or a disposable triple-lumen sphincterotome with a guidewire (KD 18; Olympus Corp., Hamburg, Germany).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients requiring endoscopic sphincterotomy for diseases of the bile duct and pancreas.

Setting
Secondary care (endoscopy units), in France.

Dates to which data relate
The study was received for publication in 1998, and was published in 2000. No other dates relating to effectiveness data were provided. Resource use was calculated for the trial patients, although no dates were given. Costs associated with reprocessing procedures were estimated on the basis of a study published in 1999. The price year was not stated.

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

Link between effectiveness and cost data
Resource use was calculated for the 77 patients requiring endoscopic biliary sphincterotomy who were recruited into the study. Resource use was recorded prospectively.

Study sample
Power calculations were not reported and no justification was provided for the choice of endoscopy units from which patients were recruited. The paper stated that the study sample used probably mirrors the spectrum of usual indications for sphincterotomy in routine practice. It would therefore seem to have been an appropriate group to study in order to address the study question. 38 patients were assigned to the standard reusable group (group A) and 39 patients were assigned to the disposable triple-lumen device (group B). No details were given on patients who refused to participate.
Study design
This was a multi-centred randomised controlled trial involving four endoscopy units. The method of randomisation was not described. Eighteen patients were enrolled from 3 of the units, with the fourth unit providing 23 patients. Patients were not followed up after the initial procedure was undertaken, therefore no follow-up data were collected. Since no follow-up was undertaken, loss to follow-up was not relevant. No blinding was reported.

Analysis of effectiveness
The analysis was presumably based on intention to treat, although this was not explicitly stated. The health outcomes assessed in the trial were: success of deep cannulation and specification of the bile duct, achievement of sphincterotomy, time required to achieve deep cannulation, time required to perform sphincterotomy after deep cannulation, and type of current used. The following parameters were rated by an endoscopist using a 4-point scale: fluoroscopic visualisation of the instruments, injection of the contrast medium, specification of the bile duct and positioning of the cutting wire. The endoscopist also gave an overall assessment of the procedure. The allocation between the two treatment groups was random, therefore adjustments for confounding factors were not undertaken. The characteristics of the two treatment groups were not compared at baseline.

Effectiveness results
Results were reported for each of the health outcomes. The only significant difference between the groups was in number of complications of sphincterotomy (mild or moderate pancreatitis): there were 5/38 in group A compared to 7/39 in group B, (p = 0.03). No other effectiveness results were statistically significant. In the opinion of the endoscopists, the overall assessment of the procedure (reusable sphincterotome without guidewire versus disposable triple-lumen device with a guidewire) was rated as excellent (32% versus 54%), good (37% versus 33%), medium (18% versus 5%) and poor (13% versus 8%). For fluoroscopic visualisation the device was rated excellent (37% versus 54%), good (46% versus 36%), medium (17% versus 8%), and poor (0% versus 2%). For injection of contrast medium and opacification of BD the results were excellent (42% versus 54%), good (45% versus 38%), medium (6% versus 5%), and poor (6% versus 3%). The position of the cutting wire during sphincterotomy was rated excellent (50% versus 65%), good (44% versus 27%), medium (3% versus 5%), and poor (3% versus 3%). None of these results were statistically significant.

Clinical conclusions
Although there were differences in some associated complication rates, the study showed no differences in the success rate. The time taken to perform the procedure and the frequency of complications were the same for both techniques. Therefore there is no evidence that the use of disposable instruments was more clinically effective.

Measure of benefits used in the economic analysis
No summary measure of benefit was used in the economic analysis, and, as such, a cost-consequences approach was undertaken.

Direct costs
Resource use items included in the analysis were restricted to the cost of instruments. Costs occurring as a result of complications were not considered. A per patient cost for the instruments was reported, along with a total cost for both treatment groups. Discounting was not performed which was appropriate given the time frame of the analysis. The estimation of resource use and the cost of instruments were based on actual data collected in the trial. The costs of reprocessing were estimated from a study by Koareck, conducted in 1999. The study did not report any differences between marginal and average costs.
Statistical analysis of costs
The two treatment groups were compared using Fischer's exact test and a chi-squared test. P-values were reported for results, where a significant difference was found.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out, and no justification for this was offered.

Estimated benefits used in the economic analysis
Outcomes were assessed separately, as shown in the effectiveness results reported above.

Cost results
The cost per patient in group A was $61 compared to $241 in group B, (p = 0.02). Overall costs were $2,332 in group A and $9,399 in group B. Incremental costs were not reported.

Synthesis of costs and benefits
Costs and benefits were not combined, due to the cost-consequences nature of the analysis.

Authors' conclusions
The outcomes assessed in this study did not differ significantly between groups. The extra cost of disposable instruments cannot be justified in terms of the improvement in success rates or reduced morbidity of sphincterotomy. As a first approach in unselected cases the authors concluded that sphincterotomy with standard reusable sphincterotomes should be used, as it gives satisfactory results and is substantially cheaper than disposable instruments.

CRD COMMENTARY - Selection of comparators
Standard versus reusable sphincterotome would seem an appropriate choice of comparator, given the difference in costs between the two instruments and the fact that many endoscopy units now use disposable instruments, and no evidence on increased effectiveness compared to reusable sphincterotomes was previously available.

Validity of estimate of measure of effectiveness
The measures of effectiveness included in the study were rated according to the opinion of endoscopists. Patients from four centres were studied, so it is likely that there will not be a consensus between endoscopists as to what constituted excellent/good/medium or poor. Additional clinical measures were recorded in the trial: stone in bile duct, stenosis of bile duct, stenosis or tumour of the papilla and miscellaneous indications. These are likely to represent valid measures given the randomised nature of the trial.

Validity of estimate of measure of benefit
No summary measure of benefit was recorded for the economic analysis, due to the cost-consequences approach adopted.

Validity of estimate of costs
The costs of the instruments were based on actual data collected in the trial. The costs of complications were not included, although these were included as a measure of effectiveness. No price year was reported and costs and
quantities were not reported separately, which limits the generalisability of the cost results.

**Other issues**
Generalisability was not discussed. Comparisons were made, however, with the results of other studies. The authors conclude that the population included in the study will probably be fairly representative of routine practice. They also conclude that the study provides evidence that, as a first approach in unselected cases, endoscopic biliary sphincterotomy, with a standard reusable sphincterotome should be attempted, as it gives satisfactory success and complications rates. The procedure also results in substantial cost savings.

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**Other publications of related interest**


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