Preoperative endoscopic sphincterotomy versus laparoendoscopic rendezvous in patients with gallbladder and bile duct stones
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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
The study compared classic sequential treatment with the laparoendoscopic rendezvous technique in patients with gallbladder and bile duct stones. Classic sequential treatment was preoperative endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES) followed by laparoscopic cholecystectomy (LC). The laparoendoscopic rendezvous technique was preoperative ERCP and ES during LC.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with symptomatic cholelithiasis and suspected common bile duct (CBD) stones, who had been admitted to a department of general surgery at a university hospital. The exclusion criteria included:

- patients with acute cholangitis or necrotising pancreatitis;
- under 18 years of age;
- ASA IV and V;
- suspected CBD malignancy;
- previous cholecystectomy;
- contraindications and/or absence of compliance with the diagnostic and/or therapeutic procedures, including magnetic resonance cholangiography (MRC) and ECRP;
- contraindications to laparoscopic surgery such as glaucoma, pulmonary emphysema and left heart failure; and
- patients treated by total or partial gastric resection.

Setting
The setting was inpatient tertiary care. The economic study was carried out at the II Division of General Surgery of the University of Turin, Italy.

Dates to which data relate
NHS Economic Evaluation Database (NHS EED)
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The effectiveness and resource use data were derived between May 2001 and August 2005. The price year was not reported.

**Link between effectiveness and cost data**
The costing was undertaken prospectively on the same patient sample that provided the effectiveness data.

**Study sample**
The authors reported that the appropriate sample size was calculated on the assumption of a 10% difference in failure rate between the two groups to improve the success rate from 85 to 95%. This required a sample size of at least 40 patients in each group to prove this difference at 80% power. All patients meeting the inclusion criteria were eligible. A total of 186 patients were admitted to hospital from May 2001 to August 2005, of which 130 (72%) cases had CBD diagnosed by MRC. After excluding patients who did not meet the inclusion criteria (i.e. 17 patients with ASA IV, 5 patients with a previous gastric resection, and 7 patients with contraindications to LAP or ERCP), and 10 who refused the protocol, 91 patients were included in the trial. Forty-five patients were randomised to preoperative ERCP followed by LC and 46 to the laparoendoscopic rendezvous technique. No patients were reported to have been excluded from the initial sample.

**Study design**
The study was a randomised controlled trial undertaken at a single centre, the II Division of General Surgery of the University of Turin, Italy. Eligible consenting patients were randomised to one of two groups using sealed opaque envelopes containing computer-generated random numbers. Blinding of the patients and clinicians does not appear to have been possible. Recruitment to the trial took place between May 2001 and August 2005. All patients were followed up for 60 days. There was no loss to follow-up.

**Analysis of effectiveness**
The primary outcome was the success or failure rate. Failure of ERCP was defined as an inability to visualise or to cannulate the CBD. Failure of ES and stone extraction was defined as the inability to obtain complete CBD stone clearance at the completion cholangiogram. Other outcomes were postoperative morbidity, the rate of clinical pancreatitis, mortality at 60 days and hyperamylasemia at 24 hours. The analysis was conducted on an intention to treat basis. The patient groups were found to be comparable in terms of their gender, age, ASA status and mean liver enzyme values.

**Effectiveness results**
The failure of complete duct clearance was 20% (n=9) in the preoperative ERCP+ES group, compared with 4.4% (n=2) in the group undergoing the laparoendoscopic rendezvous technique, (p=0.06).

There were no deaths in either group.

There were no significant differences in terms of morbidity, clinical pancreatitis or hyperamylasemia.

**Clinical conclusions**
The authors reported that the laparoendoscopic rendezvous technique allowed a higher rate of CBD stone clearance in comparison with preoperative ERCP+ES.

**Measure of benefits used in the economic analysis**
The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed (see 'Analysis of Effectiveness' for the clinical outcomes measured).
Direct costs
The study reported the direct costs to the health care provider. These included the use of endoscopic/operative room, the cost of surgical and endoscopic devices, and the costs of hospitalisation. The use of endoscopic/operative room covered the nurse, technical staff, surgical and endoscopic devices, and maintenance. The cost of surgical and endoscopic devices included disposable instruments, trocars, wires and papillotome. The resource use data were collected alongside the clinical trial. The unit costs were derived from the authors' settings. Discounting was not necessary, as the costs were incurred during a short time, and was appropriately not performed. Resource use was derived between May 2001 and August 2005. The price year was not reported. The study reported the average costs. The unit cost and quantity of each resource used were reported.

Statistical analysis of costs
Resource use and costs were treated in a stochastic manner. The authors reported that continuous variables, such as costs and resource use, were compared using Student's t-test or the Mann-Whitney U test, depending on the distribution. A p-value of less than 0.05 indicated statistically significant differences. Cost-differences were reported for all cost categories, including total, endoscopic room, endoscopic tools, operating room, laparoscopic tools and hospital stay costs.

Indirect Costs
Productivity losses were not considered.

Currency
Euro (EUR).

Sensitivity analysis
The examination of uncertainty was restricted to the statistical analyses of the quantities and costs reported above (see 'Statistical Analysis of Quantities/Costs').

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

Cost results
The authors reported the average costs for all categories of cost included in the analysis.

The average total cost per patient was EUR 3,834 in the preoperative ERCP+ES group and EUR 2,829 in patients undergoing the laparoendoscopic rendezvous technique, (p<0.05).

Synthesis of costs and benefits
The costs and benefits were not combined as the laparoendoscopic rendezvous technique was more effective and less costly than preoperative ERCP+ES.

Authors' conclusions
Compared with preoperative endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES) followed by laparoscopic cholecystectomy (LC), the laparoendoscopic rendezvous technique allowed a higher rate of common bile duct (CBD) stone clearance, a shorter hospital stay and a reduction in costs.

CRD COMMENTARY - Selection of comparators
A justification was given for using preoperative ERCP+ES followed by LC as the comparator. It has recently been proposed for the performance of CBD stone clearance in order to improve patient compliance and to improve clinical results. You should decide if this health technology represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a randomised controlled trial which, if appropriately performed, is the 'gold' standard study design for comparing health interventions. Power calculations were performed to ensure that the size of the study sample was adequate. The authors described the study sample in some detail, providing baseline characteristics for the two groups under investigation. This will enable readers to form a reasonable impression of the extent to which their own patients are comparable with those in this study. The study sample appears to have been representative of the study population and the two patient groups were shown to be comparable at analysis. The methods of randomisation, length of study and reasons for exclusion were all reported, which suggests that the internal validity of the study is likely to be good. Appropriate statistical analyses were undertaken to examine whether differences between the two groups were statistically significant.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed.

Validity of estimate of costs
The analysis of the costs was performed from the perspective of the health care provider (i.e. the hospital) paying for the surgery. All the relevant categories of costs, and all major relevant costs, appear to have been included in the analysis. Consequently, any possible omissions would be unlikely to have affected the authors' conclusions. Resource use was derived from the clinical study, while the unit costs were derived from the authors' settings. Appropriate statistical analyses of the costs and resource use were performed to establish whether differences between the two groups were statistically significant. Discounting was not relevant, as the costs were incurred during a short time, and was appropriately not performed. The authors reported the dates to which resource use related, and reported the costs and the quantities separately, which will enhance the generalisability and assist the transferability of the results to other settings. However, the price year was not reported, which will hamper any possible future inflation exercises.

Other issues
The authors did not compare their findings with those from other studies, so it is not possible to establish how far their results agree with other published results. They also did not explicitly address the issue of generalisability to other settings, and no sensitivity analysis was conducted in order to vary the unit costs. The authors do not appear to have presented their results selectively. In their conclusions, the authors reported that the laparoendoscopic rendezvous technique enabled a higher rate of CBD stone clearance in comparison with ERCP+ES. However, this difference did not reach statistical levels of significance, (p=0.06 as opposed to the p<0.05 set by the authors to define statistically significant differences). The authors did not report any further limitations to their study.

Implications of the study
The authors reported that the results from their study should lead to an increased use of the laparoendoscopic rendezvous technique, leading to improved clinical results and reduced patient discomfort.

Source of funding
None stated.

Bibliographic details
Other publications of related interest
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Subject indexing assigned by NLM

MeSH
Adult; Aged; Aged, 80 and over; Cholangiopancreatography, Endoscopic Retrograde; Cholecystectomy, Laparoscopic /adverse effects /economics; Female; Gallstones /radiography /surgery; Health Care Costs; Humans; Length of Stay; Male; Middle Aged; Prospective Studies; Sphincterotomy, Endoscopic /adverse effects /economics; Treatment Outcome

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