Laparoscopy-assisted versus balloon enteroscopy-assisted ERCP in bariatric post-Roux-en-Y gastric bypass patients

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.

CRD summary
This study examined the clinical and economic impact of endoscopic retrograde cholangiopancreatography (ERCP) with balloon enteroscopy versus ERCP with laparoscopy, for patients who had received Roux-en-Y gastric bypass. Balloon enteroscopy was preferred for patients with a Roux limb length of less than 150cm, in centres with expertise in deep enteroscopy, but laparoscopy was preferred when it was 150cm or longer. The analysis was retrospective, with a small sample, which might affect the validity of the conclusions.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study examined the clinical and economic impact of endoscopic retrograde cholangiopancreatography (ERCP) with balloon enteroscopy versus ERCP with laparoscopy, for patients who had received Roux-en-Y gastric bypass.

Interventions
ERCP using balloon enteroscopy for visualisation was compared with ERCP with laparoscopy. Patients for whom balloon enteroscopy failed received laparoscopy with ERCP as a second procedure.

Location/setting
USA/tertiary care.

Methods
Analytical approach:
The analysis was based on the retrospective review of a hospital database. A short time horizon was considered, covering the period in hospital until discharge. The authors stated that the perspective of the hospital was adopted.

Effectiveness data:
The clinical data were from the retrospective review of the medical charts of 56 patients who were treated at the authors’ institution between September 7, 2007, and May 13, 2011. There were 32 patients (mean age 53 years; 31 women) in the enteroscopy group and 24 patients (mean age 52 years; 19 women) in the laparoscopy group. A multivariate statistical analysis was carried out to identify the predictors of the model outcomes. The primary endpoint was the rate of therapeutic success, which was defined as biliary and/or pancreatic sphincterotomy, stone extraction, or pancreaticobiliary stent placement, and did not include the resolution of clinical symptoms, abnormal laboratory results, and abnormalities on imaging.

Monetary benefit and utility valuations:
Not considered.

Measure of benefit:
No summary benefit measure was used and the rate of therapeutic success was the primary endpoint. Other endpoints, such as the complication rates and cannulation rates were considered.

Cost data:
The analysis included the hospital charges for the entire procedure, including the operating room time, anaesthesia assistance, and the hospital stay. All the costs were from the sample of patients included in the clinical analysis, as reported above. The costs were in US $.

Analysis of uncertainty:
Not considered.

Results
The rate of therapeutic success for ERCP was 100% with laparoscopy and 59% with balloon enteroscopy (p<0.001). Most of other outcomes favoured the laparoscopy, but the total procedure time was significantly longer with laparoscopy (172 minutes) than with balloon enteroscopy (106 minutes). The complication rates were similar between the two groups.

The multivariate analysis showed that the only factor that was significantly associated with therapeutic success with balloon enteroscopy was the presence of a Roux limb plus biliopancreatic ligament of Treitz to jejunojejunal anastomosis, with a limb length of less than 150cm. In a subgroup of 20 enteroscopy patients, the success rate was 88% with a limb length less than 150cm, 33% with a limb length of 150 to 225cm, and zero with a limb length more than 225cm.

The total costs per patient were $8,514 with balloon enteroscopy then laparoscopy if it failed, and $9,529 with laparoscopy. For patients with a limb length of less than 150cm, balloon enteroscopy, compared with laparoscopy, led to cost savings of $2,388. For patients with a limb length of 150cm or longer, enteroscopy led to an additional cost of $593 over laparoscopy.

Authors’ conclusions
The authors concluded that balloon enteroscopy with ERCP was preferred for patients with a Roux limb length of less than 150cm, and in centres with expertise in deep enteroscopy, but laparoscopy with ERCP was preferred for patients with a Roux limb length of 150cm or longer.

CRD commentary
Interventions:
The selection of the comparators appears to have been appropriate and the procedures are likely to be relevant for other health care settings.

Effectiveness/benefits:
The clinical data had some drawbacks, due to their retrospective collection and no randomised allocation. The procedure was selected by the endoscopist, in consultation with the patient, and was not chosen according to a protocol. Another limitation was the small sample of patients analysed, which might affect the power of the analysis to capture statistically significant differences in the clinical outcomes between the two groups. The authors used an appropriate statistical analysis account for potential confounding factors, but the evidence came from one institution, which might not have been representative of other institutions, especially given the expertise needed for the procedures.

Costs:
The perspective of the hospital was adopted and the cost categories were appropriate. All the data were from the sample of patients used for the clinical analysis and the estimates were from a retrospective review of their hospital charts. The unit costs and resource use were not reported. The costs are likely to have been representative of a tertiary institution, but might not have been representative of other institutions; the centre had a high skill level for the procedures. The price year was not reported, which will hinder reflection exercises. In general, more information on the costs would have been useful.

Analysis and results:
The results were clearly reported, for the whole sample and for subgroups based on the length of the Roux limb. The costs and benefits were not synthesised. Sensitivity analyses were not performed, but regression analysis was used to determine the effects of multiple independent variables on the study outcomes. The authors acknowledged some limitations to their analysis, mainly due to the study design. These findings were specific to the authors’ institution and
do not appear to be transferable to other contexts.

Concluding remarks:
The analysis did not combine the costs and benefits, which were collected retrospectively, and it included a relatively small sample of patients, which might affect the reliability and validity of the authors’ conclusions.

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