Clipless laparoscopic restorative proctocolectomy using an electrothermal bipolar vessel sealer

Hasegawa H, Watanabe M, Nishibori H, Ishii Y, Kitajima M

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
Laparoscopic restorative proctocolectomy (LRP) using electrothermal bipolar vessel sealer (EBVS) was compared with LRP using ultrasonic coagulating shears and haemoclips (conventional LRP) for the treatment of ulcerative colitis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with ulcerative colitis who were eligible for LRP, although the eligibility criteria were not stated. The exclusion criteria were fulminant colitis, or prior emergency sub-total colectomy with an end ileostomy as an open procedure prior to RP at other institutions. Fulminant colitis was defined by at least two of the following: tachycardia (heart rate >120 beats/minute), temperature great than 38.0 degrees C, peritoneal sign, and white blood cell count of greater than 11,000/mL. Three patients were subsequently considered unsuitable for LRP and underwent open RP.

Setting
The setting was secondary care. The economic study was conducted in Japan.

Dates to which data relate
The effectiveness data for the EBVS-LRP group referred to 2002. Respective data for the control group were collected before 2002, but the exact dates were not reported. The resources used and prices possibly referred to 2002.

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

Link between effectiveness and cost data
The cost consisted only of the cost of disposable instrumentation for each intervention, and did not refer to each patient individually. Thus, there was no need for the costing to be conducted on the sample of patients participating in the study.

Study sample
The study sample comprised patients undergoing LRP in one hospital setting. No power calculations were used to
determine or assess the sample size. Patients with ulcerative colitis who were considered eligible for LRP were included in the study. The EBVS-LRP group consisted of 8 eligible patients (7 men and 1 woman) who attended the hospital in 2002 and subsequently underwent this procedure. Their median age was 33 years (range: 20 - 68). The control group consisted of 18 patients who had undergone conventional LRP in the hospital before 2002. No further details of their gender and age were reported. There was no evidence that the study sample was appropriate for the clinical study question.

**Study design**
The basis of the analysis was a prospective comparative study with a historical cohort, which was conducted in one hospital in Japan. The two groups were compared in terms of the costs and benefits incurred during the procedure. The median follow-up for the EBVS-LRP group was 7 months (range: 1 - 13), but such information (and likely health outcomes) was not provided for the conventional LRP group. No loss to follow-up was reported for the EBVS-LRP group.

**Analysis of effectiveness**
All the patients included in the study were accounted for in the analysis. The primary health outcome used in the analysis was the operative time. Further health outcomes were reported for the EBVS-LRP group. For example, the number of conversions to open procedure, the condition of seals, and intraoperative and postoperative haemorrhagic complications. The comparability of the groups at baseline was not discussed and no adjustments for confounding factors were reported.

**Effectiveness results**
The median operative time was 320 minutes (range: 300 - 400) for the EBVS-LRP group and 360 minutes (range: 290 - 500) for the conventional LRP group. The difference was 40 minutes, favouring EBVS-LRP, (p=0.0303, Mann-Whitney U-test).

In the EBVS-LRP group, no conversions to the open procedure were reported. In addition, none of the seals required an alternative ligation technique and in the one case in which oozing occurred, resealing with EBVS controlled it.

No intraoperative complications or postoperative haemorrhagic complications were observed.

**Clinical conclusions**
EBVS-LRP was a safe and feasible technique that did not need conventional ultrasonic coagulating shears and haemoclips.

**Measure of benefits used in the economic analysis**
There was no summary measure of benefit. In effect, a cost-consequences analysis was performed.

**Direct costs**
The study perspective was possibly that of the hospital. Only the costs of disposable instrumentation were examined. These included the costs of ultrasonic coagulating shears and haemoclips (for conventional LRP), EBVS (for EBVS-LRP), and also reimbursement from medical insurance for disposable instrumentation (for conventional LRP). All other costs (e.g. staff, operating theatres, other consumables, hospital stay, complications) were excluded from the analysis, probably because they were common to both alternatives. The costs and the quantities were reported separately where applicable. The quantities needed for each LRP were, presumably, based on data derived from the hospital where the study took place. Retail prices were used to estimate the costs. Discounting was not carried out, which was appropriate since the costs were incurred within one day. The year to which the prices referred was probably 2002.
Statistical analysis of costs
The costs were treated deterministically. No statistical analysis of the costs was performed.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
The costs were estimated in Japanese yen (Y) (figures not reported) and subsequently converted to US dollars ($). The conversion rate was $1 = Y120.

Sensitivity analysis
No sensitivity analysis was carried out.

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

Cost results
The cost of disposable instrumentation was $950 for conventional LRP and $600 for EBVS-LRP. EBVS-LRP was $300 less costly than the conventional procedure. These values probably reflected the costs of a routine procedure. It is not known whether potential complications might possibly increase the quantities of disposable instrumentation required and, consequently, the related costs.

Synthesis of costs and benefits
The estimated costs and benefits were not combined in a single cost-effectiveness ratio. However, this was not necessary as EBVS-LRP proved to be the dominant strategy in terms of the primary health benefit chosen and related cost (it reduced operative time and was also cheaper than conventional LRP).

Authors’ conclusions
Laparoscopic restorative proctocolectomy (LRP) using electrothermal bipolar vessel sealer (EBVS) was safe, feasible and cost-effective in selected patients with ulcerative colitis.

CRD COMMENTARY - Selection of comparators
The comparator used (conventional LRP with ultrasonic coagulating shears and haemoclips) reflected routine practice for the laparoscopic approach to RP. The new technique evaluated (EBVS-LRP) was practically identical to the conventional procedure, except that it used EBVS instead of ultrasonic coagulating shears and haemoclips.

Validity of estimate of measure of effectiveness
The basis of the analysis was a prospective comparative study with a historical cohort. This kind of study may have introduced biases into the analysis, such as selection bias, information bias and bias due to the different times when the strategies were evaluated. It is not known whether the study sample was representative of the patient population since the inclusion and exclusion criteria were basically not reported. It was not shown whether the patient groups were comparable in terms of their baseline characteristics. No statistical analysis to show the comparability of the groups, or to account for any potential biases and confounders, was provided.

Validity of estimate of measure of benefit
The estimation of benefits was obtained directly from the effectiveness analysis. The choice of estimate (operative time) was not explicitly justified, but it was implied that in all other terms (safety, frequency of complications, conversions to open procedure), the two interventions were equally effective.

**Validity of estimate of costs**
The study perspective was not stated. The costs were restricted to those of disposable instrumentation only, apparently from the viewpoint of the hospital. Other related costs (e.g. staff, operation, hospital stay and complications) were not considered, possibly because they were common to the two interventions compared. The costs and the quantities were reported separately, which improves the generalisability of the results. Discounting was, appropriately, not performed since all the costs were incurred in less than one year. The date to which the costs referred was not explicitly stated, which hinders the reproducibility of the results.

**Other issues**
The authors did not compare their findings with those of other studies. This approach may be justified since they evaluated a new intervention, possibly not widely used and assessed in other settings at the time this study was conducted. The issue of generalisability to other settings was not addressed. The authors acknowledged that the effectiveness results might be attributable to the fact that the surgeons performing LRP in the study had long experience, and thus they had progressed along the learning curve. The results of the analysis were adequately reported. The study should be considered as one of the first attempts to evaluate EBVS-LRP in comparison with the conventional method. The authors' conclusions reflected the scope of the study.

**Implications of the study**
The authors evaluated a new method of LRP and made some recommendations about its technical characteristics. The study results showed that LRP was safe, feasible and cost-effective when using new technology (EBVS). Thus, the authors recommended that laparoscopic surgery in general, using new technology, be promoted and become a standard procedure in the future.

**Source of funding**
None stated.

**Bibliographic details**

**MeSH**
Colitis, Ulcerative /surgery; Cost-Benefit Analysis; Disposable Equipment /economics; Electrocoagulation /instrumentation; Hemostasis, Surgical /instrumentation /methods; Japan; Laparoscopy; Proctocolectomy, Restorative /methods /economics; Surgical Instruments /economics; Surgical Stapling

**AccessionNumber**
22003008574

**Date bibliographic record published**
31/07/2004

**Date abstract record published**
31/07/2004