Operative time and other outcomes of the electrothermal bipolar vessel sealing system (LigaSure) versus other methods for surgical hemostasis: a meta-analysis

Macario A, Dexter F, Sypal J, Cosgriff N, Heniford T B

CRD summary
The authors concluded that electrothermal bipolar vessel sealing systems reduced operating time by approximately one quarter compared to conventional methods of haemostasis, without increased blood loss, pain and complications. In view of methodological limitations in the review, in particular the failure to adequately address heterogeneity between the studies, these conclusions may need to be regarded with some caution.

Authors' objectives
To evaluate the effects of using electrothermal bipolar vessel sealing systems (EBVS) for achieving haemostasis in surgical patients, versus other methods.

Searching
MEDLINE and The Cochrane Library were searched from 2000 to August 2007 without language restriction. Search terms were reported. The reference lists of articles retrieved were handsearched.

Study selection
Randomised controlled trials (RCTs) comparing electrothermal bipolar vessel sealing systems with conventional or ultrasonic-energy methods of haemostasis in surgical patients were eligible for inclusion. Conventional methods could include suture, clips, vascular/circular stapler and/or monopolar diathermy. Outcomes of interest were operating time, blood loss, length of hospital stay, complications and postoperative pain scores.

The included studies involved many different types of surgery, most commonly haemorrhoidectomy, hysterectomy and thyroidectomy. The outcome of complications included both minor and severe events. Pain, where reported, was measured on a 0 (no pain) to 10 scale. The median duration of follow-up was 30 days (with a range of one day to two years).

Assessment of study quality
The studies were assessed using the Jadad scale, which measures adequacy of randomisation, blinding, and management of withdrawals and dropouts. The use of a power analysis was also evaluated. Data on withdrawals, blinding and use of power analysis were extracted independently by two reviewers; differences were resolved by consensus.

Data extraction
Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated for dichotomous outcomes and mean differences for continuous outcomes. The percentage reduction in operating time was calculated by dividing the mean time difference between the two groups by the operating time in the control group.

Data were extracted independently by two reviewers; differences were resolved by consensus.

Methods of synthesis
Studies were grouped by comparator. Data from studies that reported standard deviations were combined using a random-effects model to calculate pooled ORs for binary data and weighted mean differences (WMDs) for continuous data, with 95% CIs. The mean percentage reduction in operating time (normalised mean reduction) was calculated from reported mean or median values, with the 95% CI. A vote-counting methodology was also used, using the sign test to calculate whether there was a significant difference in the number of studies with positive or negative findings with respect to operating time in the intervention group. Heterogeneity was apparently assessed using the χ² test.

Results of the review
Twenty nine RCTs were included (n was reported as 1,079, sample size range was 11 to 125). None were double-blinded. Eight studies used blinded data collection, 12 described withdrawals and 22 described randomisation adequately. Fourteen studies were unsuitable for meta-analysis as they did not report standard deviations.

Electrothermal bipolar vessel sealing systems versus conventional haemostatic methods (26 RCTs, n=2,186):

Among RCTs suitable for meta-analysis, the intervention was associated with statistically significant reductions in operating time (normalised mean reduction 28%, 95% CI: 18%, 39%, p<0.0001; 15 RCTs), blood loss (mean reduction 43 mL, 95% CI: 14 mL, 73 mL, p=0.0021; five RCTs) and pain score (WMD 2.8 units, 95% CI: 1.5, 4.1, p<0.0001; four RCTs), with statistically significant heterogeneity for the outcomes of operating time (p<0.00001) and pain (p<0.0001).

There were significantly fewer complications in the intervention group (OR 0.66, 95% CI: 0.47,0.92, p=0.02; 22 RCTs). No statistically significant difference was found between the groups in length of hospital stay (nine RCTs). Among haemorrhoidectomy studies only, the normalised mean reduction in operating time was 46 per cent (95% CI: 29%, 62%, p<0.0001; six RCTs), with significant heterogeneity (p<0.00001). All but two of the 26 studies reported shorter operating times in the intervention group (p<0.0001).

Electrothermal bipolar vessel sealing systems versus ultrasonic energy (reported as five RCTs in the text):

No statistically significant difference in complication rate was found between the two groups. No other data were suitable for meta-analysis.

Other results were reported in the review.

Cost information
Three studies reported costs, but the authors stated that data could not be pooled.

Authors’ conclusions
Electrothermal bipolar vessel sealing systems reduced operating time by approximately one quarter compared to conventional methods of haemostasis, without increased blood loss, pain and complications.

CRD commentary
The objectives and inclusion criteria were clear. Relevant sources were searched for studies without language restriction, although it did not appear that any specific attempts were made to retrieve unpublished studies. Some steps were taken to reduce the risk of error and bias in the processes of study selection, data extraction and validity assessment by involving more than one reviewer. However, important factors related to study quality were apparently not assessed (for example, use of allocation concealment) and no details were reported about the characteristics of individual studies (for example, sample numbers and Jadad score). This made it difficult to evaluate the reliability of the review findings. The statistical techniques used to calculate pooled ORs and WMDs appeared appropriate. However, in view of the clinical and methodological heterogeneity between the studies, the vote-counting method of combining studies did not appear appropriate. Similarly, it was questionable whether the normalised mean reduction in operating time was a reliable effect measure, as there was significant heterogeneity for this analysis (p<0.0001). In view of methodological limitations in the review, in particular the failure to adequately address heterogeneity between the studies, the authors’ conclusions may need to be regarded with some caution.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that each institution should evaluate the effects of electrothermal bipolar vessel sealing systems on overall hospital costs.

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