Meta-analysis of short-term outcomes of randomized controlled trials of LigaSure vs conventional hemorrhoidectomy

Tan E K, Cornish J, Darzi A W, Papagrigoriadis S, Tekkis P P

CRD summary
The authors concluded that LigaSure haemorrhoidectomy reduced operative time and blood loss when compared to conventional therapy. Overall, aspects of this systematic review were well conducted, but due to limitations of the data and some of the analysis the reliability of the results is uncertain.

Authors' objectives
To evaluate operative and postoperative parameters and adverse outcomes in patients undergoing LigaSure versus conventional haemorrhoidectomy.

Searching
MEDLINE, EMBASE and Cochrane Database of Systematic Reviews were searched between 2002 and May 2006; search terms were reported. The reference lists of relevant publications were checked. There were no language restrictions.

Study selection
Randomised controlled trials (RCTs) that compared LigaSure haemorrhoidectomy with conventional haemorrhoidectomy (including scissors and diathermy techniques) were eligible for inclusion. The operation technique had to be clearly documented, as well as the indications for operation for each group. Eligible studies had to report on at least one of the following outcome measures: operative parameters (including operative time and operative blood loss); complications (up to six months, including post-operative haemorrhage, faecal and flatus incontinence, constipation, poor wound healing and/or dehiscence, anal stenosis and urinary retention); and postoperative recovery (length of hospital stay and return to normal activity).

Patients included in the review had grade 3 or 4 haemorrhoids. Where reported, mean ages ranged from 41 to 52 years. All patients had a mixture of internal and external haemorrhoidal components treated at the time of operation.

The authors did not state how the papers were selected for the review.

Assessment of study quality
Study quality was assessed using a modified Jadad scale. Criteria assessed included: patient selection, comparability of the study groups and assessment of outcomes. Studies with a score of 3 or more out of a maximum of 5 were considered to be of higher quality. The authors did not state how many reviewers assessed the quality of the studies.

Data extraction
Data on the number of outcomes in the intervention and comparator groups were extracted and odd ratios and 95% confidence intervals (CIs) were calculated. For studies that presented continuous data as means and ranges, standard deviations were calculated using statistical algorithms and checked using bootstrap re-sampling techniques. Two reviewers independently extracted the data.

Methods of synthesis
Meta-analyses that examined pooled odd ratios (for dichotomous data) and weighted mean difference (for continuous data) were performed using the Mantel-Haenszel random-effects model. Heterogeneity was assessed using the $X^2$ and $I^2$ statistics. Publication bias was assessed using funnel plots. Sensitivity analysis was conducted by excluding poorer quality studies. Subgroup analyses compared LigaSure with open haemorrhoidectomy and LigaSure with closed haemorrhoidectomy.

Results of the review
Nine RCTs (n=525) were included in the review. The sample sizes ranged from 34 to 112 participants. It appeared that six studies were considered to be high-quality studies.

Operative time was significantly shorter in the LigaSure group compared with conventional haemorrhoidectomy (weighted mean difference -8.67, 95% CI: -15.34 to -2.00, p=0.01; nine trials). There was significant heterogeneity between the studies (p<0.001).

There was significantly lower operative blood loss in the LigaSure group (weighted mean difference -23.08, 95% CI: -27.24 to -18.92, p<0.001; four trials). There was no significant heterogeneity.

Participants who underwent LigaSure haemorrhoidectomy had significantly less pain on postoperative day one compared to patients who underwent conventional haemorrhoidectomy (weighted mean difference -2.31, 95% CI: -3.37 to -1.26, p<0.001; seven trials). There was significant heterogeneity between the studies (p<0.001).

There were no significant differences between the intervention and control groups for post-operative haemorrhage, faecal and/or flatus incontinence, constipation, poor wound healing and/or dehiscence, anal stenosis and urinary retention. No deaths were reported.

There were no significant differences in the length of hospital stay (six trials) or in the time to return to work or normal activity (four trials) between the LigaSure and control groups. There was significant heterogeneity between the studies for these results (p<0.001 for both).

Analysis of high-quality studies and of the subgroup LigaSure versus open haemorrhoidectomy showed similar results for operative time and blood loss.

Other secondary outcomes were also reported.

The funnel plots demonstrated some publication bias.

Authors' conclusions
The significant benefits of LigaSure haemorrhoidectomy included reduced operative time and blood loss, but it may not confer any advantage over conventional therapy for postoperative pain, length of hospital stay and time to return to work or normal activity.

CRD commentary
The review addressed a clear question and was supported by appropriate inclusion criteria. There were no language restrictions, which limited the potential for language bias. The authors did not attempt to search for unpublished studies, so some studies may have been missed. The authors appropriately evaluated publication bias. Some attempts were made to minimise reviewer bias and error, although this was not clearly reported for all stages of the review process. The studies were quality assessed using published criteria. Due to heterogeneity between the studies, meta-analysis may not have been appropriate for some of the outcomes. The conclusions regarding post-operative pain were inconsistent. Overall, aspects of this systematic review were well conducted, but due to limitations of the data and some of the analysis the reliability of the results is uncertain.

Implications of the review for practice and research
Practice: The authors stated that LigaSure haemorrhoidectomy was a safe, effective and fast alternative to the conventional operation.

Research: The authors stated that further RCTs were required to assess long-term success rates of the LigaSure haemorrhoidectomy.

Funding
No funding received.
Bibliographic details

PubMedID
18086990

DOI
10.1001/archsurg.142.12.1209

Original Paper URL
http://archsurg.ama-assn.org/cgi/content/full/142/12/1209

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Hemorrhoids /surgery; Humans; Ligation /instrumentation; Randomized Controlled Trials as Topic; Surgical Stapling; Suture Techniques; Treatment Outcome

AccessionNumber
12008000173

Date bibliographic record published
01/09/2008

Date abstract record published
16/09/2009

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.