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## Review

Pain after conventional versus Ligasure haemorrhoidectomy.  
A meta-analysis<sup>☆</sup>

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## ABSTRACT

**Background:** Haemorrhoidectomy is a frequently performed surgical procedure and associated with postprocedural pain. The use of the Ligasure may result in a decreased incidence of pain as coagulation with high frequency current and active feedback control over the power output results in minimal thermal spread and limited tissue charring.

**Methods:** A multi-database systematic search was conducted to identify trials randomizing conventional and Ligasure haemorrhoidectomy. Key journals were hand searched. There was no restriction on language. Two reviewers independently extracted data and assessed trial quality. Odds Ratios were generated for dichotomous variables. Weight Mean Differences were used for analysing continuous variables. Only random effects models were used. Heterogeneity was explored by sensitivity analysis.

**Results:** Twelve studies with 1142 patients met the inclusion criteria. The pain score at the first day following surgery was significantly less in the Ligasure group (10 studies, 835 patients, WMD  $-2.07$  CI  $-2.77$  to  $-1.38$ ). The benefit was diminished at day 14 (VAS pain score, 4 studies, 183 patients, WMD  $-0.12$  CI  $-0.37$  to  $0.12$ ). The conventional technique took significantly longer to complete (11 trials, 9.15 minutes, CI 3.21 to 15.09). Significantly less urinary retentions and less delayed wound healing were noted following Ligasure haemorrhoidectomy. There was no relevant difference in other postoperative complications, symptoms of recurrent bleeding or incontinence at final follow-up. Hospital stay was similar for both groups. Patients treated with the Ligasure-technique returned to work significantly earlier (4 studies, 451 patients, 4.88 days, CI 2.18 to 7.59). Sensitivity analysis in case of considerable heterogeneity distinguished closed from open conventional technique.

**Conclusion:** Since the usage of the Ligasure technique results in significantly less immediate postoperative pain after haemorrhoidectomy without any adverse effect on postoperative complications, convalescence and incontinence-rate, this technique is superior in terms of patient tolerance. Although there was a tendency for equal efficacy, more evaluation of the long-term risk of recurrent haemorrhoidal disease is required.

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## 1. Introduction

Haemorrhoidectomy is a frequently performed surgical procedure. The excisional technique is regarded to be the first choice for grade III and IV or recurrent haemorrhoids.<sup>1,2</sup> As conventional haemorrhoidectomy is associated with postprocedural pain, modifications have been proposed to diminish this complication. An example is the use of the Ligasure-TM (Valleylab, Boulder, CO), a bipolar electrothermal sealing device which uses a very high frequency current providing haemostasis by denaturing collagen

and elastin from the vessel wall and surrounding connective tissue. Due to this high frequency current and active feedback control over the power output it is postulated that sealing of haemorrhoidal tissue in between the Ligasure-forceps is achieved with minimal collateral thermal spread and limited tissue charring leading to a decreased incidence of postoperative pain. To test the validity of this hypothesis, the results of randomized trials comparing conventional to Ligasure assisted haemorrhoidectomy are evaluated. The primary goal was to ascertain whether the use of Ligasure results into less postprocedural pain.

## 2. Methods

A comprehensive search of different electronic databases using a combination of free text and MESH (Medical Subject Heading)

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terms was undertaken to identify potential studies for inclusion in the review. The full strategy for Medline has been published previously as a Cochrane Review.<sup>3</sup> In summary, terms used were haemorrhoids, diathermy, Milligan-Morgan, Ferguson, haemorrhoidectomy and Ligasure. Searched databases were Medline, EMBASE, The Cochrane Central Register of Controlled Trials and CINAHL. There was no restriction on language. Principal authors were contacted if possible for further information related to the study and any other studies published and unpublished. All reference lists were searched for additional studies. Hand-searches were performed on the following journals from 2000 and beyond: Annals of Surgery, British Journal of Surgery and Diseases of the Colon and Rectum.

All published randomized controlled trials comparing Ligasure assisted to conventional haemorrhoidectomy were included. Eligible techniques for conventional haemorrhoidectomy were the open (e.g. Milligan–Morgan) and the closed (e.g. Ferguson) technique. Length of follow-up was not a selection criteria. Pain measured with a visual analogue scale or verbal numeric scale at the first postoperative day as well as the amount and number of patients using analgesics were the primary outcome measures addressed in this review. The operative variables, complications, incontinence and patient related outcome were considered as secondary outcome measures. Operative variables were operating time in minutes and blood loss in millilitres. Complications were postoperative bleeding, urinary retention, constipation, incomplete wound healing, anal fissure, anal stenosis and late minor bleeding. Late minor bleeding was regarded as recurrent disease. Incontinence was defined as any grade of incontinence at follow-up. Patient related outcomes were length of hospital stay, return to work and satisfaction.

Full text of the eligible studies were obtained and two reviewers assessed independently whether the studies met the selection criteria. The quality of the included studies was assessed by using the modified Jadad score,<sup>4</sup> considering a score of four and more as high quality. For statistical analysis RevMan Analysis software in Review Manager 5.0.15 was used. Odd Ratios were generated for dichotomous variables. Weight Mean Differences type IV were used for analysing continuous variables. Both were presented with 95% confidence interval.

No covariates were added into the models. If studies reported medians instead of means, the difference of medians was assumed to be equal to the difference of means. If no measure of dispersion was given, these data were tried to be obtained from the authors or retrieved out of the confidence interval or range. Where there were sufficient data, a summary statistic for each outcome was calculated. If data were insufficient for statistical analysis, observational results were presented. Where appropriate, a formal meta-analysis was conducted with investigation of heterogeneity. Standard random effects model were used as the data resulted from surgical interventions from different centres. In case of considerable heterogeneity (test of inconsistency > 50%) a sensitivity analysis was performed for high quality studies (MJS > 3), conventional open and closed techniques.

### 3. Results

#### 3.1. Studies

Twelve original studies were included wherein 1142 patients were evaluated in total (Table 1).<sup>5–16</sup> Follow-up periods ranged from 1 to 37 months. In the trial of Muzi, reasons for loss to follow-up were noted, resulting in a total of 88% (250 out of 284 patients).<sup>11</sup> The other primary reports reached a 100% follow-up. Two of the included trials were subsequently re-published under different

**Table 1**  
Study characteristics.

Study	Evaluated patients (n)	Conventional technique	Follow-up (months)	Modified Jadad Score
Altomare	273	Loder and Phillips	1	4
Bessa	110	Milligan–Morgan	6	4
Chung	61	Ferguson	4	3
Franklin	34	Modified Ferguson	3	4
Jayne	40	Milligan–Morgan	3	4
Peters	30	As Jayne	36–37	n/a
Milito	56	Milligan–Morgan	6	4
Muzi	250	Milligan–Morgan	6–36	5
Palazzo	34	Milligan–Morgan	1.5	4
Lawes	30	As Palazzo	13–18	n/a
Pattana-Arun	45	Fansler	1	4
Tan	43	Milligan–Morgan	1.5	4
Thorbeck	112	Milligan–Morgan	6	1
Wang	84	Ferguson	2	3

authors with long-term follow-up for 75%<sup>17</sup> and 88%<sup>18</sup> of the original patients.

In most trials follow-up was carried out by interview or postal questionnaire. In the study of Jayne et al. a blinded surgeon assessed discharge and follow-up was performed by blinded nurse practitioners.<sup>9</sup> An independent observer was used in three trials.<sup>10–16</sup> In the trial conducted by Palazzo patients were kept unaware of what procedure had been performed until the consignment of the research data two weeks postoperatively.<sup>12</sup> Five studies applied the closed (Ferguson, Loder and Phillips and Fansler) technique,<sup>5,7,8,13,16</sup> the remaining applied the open Milligan-Morgan technique. In all method sections the use of diathermy was noted, only in the study of Pattana-arun the excision was by Metzenbaum scissors and bleeding stopped by electrocauterization.<sup>13</sup> The majority of the papers described patients with grade III or IV haemorrhoids. Two papers did not specify the grade of haemorrhoids and used the definition of symptomatic prolapsed haemorrhoidal disease requiring haemorrhoidectomy.<sup>10,12</sup>

#### 3.2. Pain

The pain score at the first day following surgery was significantly less in the Ligasure group ( $p < .00001$ ). Test for heterogeneity was significant ( $\text{Chi}^2 = 340$ ,  $p < .001$ ,  $I^2 = 97\%$ ). The sensitivity analysis revealed a higher impact of studies concerning the open than closed conventional techniques. The benefit was diminished at day 14 (Table 2).

#### 3.3. Operative variables

The Ligasure technique was performed in significantly less time (9.15 minutes,  $p = .0025$ ). Due to the 100% heterogeneity, a sensitivity analysis was performed. The difference with closed

**Table 2**  
Pain.

Outcome	Studies (n)	Patients (n)	Favours	Effect size [95% CI]	HE
Pain day 1 (VAS score)	10	835	Ligasure	-2.07 [-2.77, -1.38]	97%
MJS > 3	7	578	Ligasure	-1.71 [-2.53, -0.89]	88%
Open	6	611	Ligasure	-2.08 [-3.32, -0.83]	97%
Closed	4	224	–	-1.83 [-2.58, -1.08]	99%
Pain day 14 (VAS score)	4	183	–	0.12 [-0.37, 0.12]	0%

MJS = Modified Jadad Score, Effect size estimated by statistical method of inverse variance, analysis model of random effects, effect measure of mean difference, CI = Confidence Interval.

**Table 3**  
Operative parameters.

Outcome	Studies (n)	Patients (n)	Favours	Effect size [95% CI]	HE
Operating time (min)	11	869	Ligasure	−9.15 [−15.09, −3.21]	100%
MJS > 3	8	612	Ligasure	−7.42 [−9.86, −4.98]	92%
Open	7	645	Ligasure	−7.54 [−9.48, −5.59]	92%
Closed	4	224	Ligasure	−12.02 [−24.05, 0.01]	99%
Intra-operative blood loss (ml)	2	124	Ligasure	−22.33 [−26.46, −18.20]	71%

MJS = Modified Jadad Score, Effect size estimated by statistical method of inverse variance, analysis model of random effects, effect measure of mean difference, CI = Confidence Interval.

conventional procedures showed a larger effect size. Intra-operative blood loss was more with the conventional technique (22.33 ml,  $p < .00001$ ) (Table 3). Although there was a considerable heterogeneity, further analysis of two included studies only was not performed.

#### 3.4. Complications

Postoperative bleeding did not differ significantly between the techniques ( $p = .16$ ). Urinary retention occurred less frequently after a Ligasure procedure ( $p = .020$ ). There were also non-significant trends of less constipation, anal fissure and stenosis. Further analysis for the parameter of constipation showed no significant difference.

Delayed wound healing was seen in the conventional technique group, which was significant for wound dehiscence in days (2 studies, both with MJS > 3 and open conventional technique,  $p = .0021$ ) and non-significant for incomplete healing after 1 month (4 studies,  $p = .54$ ). Late minor bleeding was reported for 6 patients in the Ligasure-group versus 8 patients in the conventional one ( $p = .74$ ). Symptoms of incontinence at final follow-up was not significantly different ( $p = .58$ ) (Table 4).

#### 3.5. Patient related outcome

Hospital stay was similar for both groups for this comparison with a considerable heterogeneity. In the sensitivity analysis for studies with closed techniques hospitalization was significant longer for the conventional procedure group ( $p = .0027$ ). Patients treated with Ligasure returned to work significantly earlier ( $p = .0004$ ). There was a non-significant trend of more patients

being unsatisfied with the results in the conventional group ( $p = .29$ ) (Table 5).

#### 4. Discussion

Pain following haemorrhoidectomy is a well known complication. One possible explanatory factor is tissue damage by thermal spread of diathermy. Avoiding or minimizing extended thermal injury might result into decreased postoperative pain. It has been postulated that such minimal thermal injury can be achieved with the use of a bipolar electrothermal sealing device (Ligasure-TM, Valleylab, Boulder, CO). In contrast to diathermy or electrocautery, this device uses a very high frequency current providing haemostasis by denaturing collagen and elastin from the vessel wall and surrounding connective tissue. Furthermore, it has the potential to reduce thermal damage through use of active feedback control over the power output and the head of the device is heat-sink engineered to ensure a cool (below 45 degrees Celsius) surface. Negligible evidence of thermal damage has been shown in histological studies and in situ thermal imaging.<sup>19</sup> Ligasure has been used in haemorrhoidectomy. Reviewing the randomized controlled trials on this subject, this technique was related to less postoperative pain in comparison to conventional surgical techniques. Specifically, in the meta-analysis of the present review, the VAS pain score at day 1 was significantly lower. The results of pain measurement within the first postoperative week or by number of analgesics showed an association between Ligasure and less postprocedural pain. The effect size of less pain on the first postoperative day with the use of Ligasure was about one-third of the pain score in the conventional group. In the original Cochrane version this result was reflected by less pain with the first stool and less use of some medications. No difference however was seen with other analgesics or at any measure moment beyond day 1. Although data on possible explanatory factors such as preoperative pain or co-existing pain syndromes were not provided and parameters such as age, degree of haemorrhoids, duration of complaints, employment and the number of piles excised were not included in the meta-analysis, the results of less pain was found consistently. Posthaemorrhoidectomy pain is a complex phenomenon with thermal, mechanical and chemical stimuli all attributing to nociception. The surgical trauma does not solely consist out of these stimuli. Tissue damage releases mediators like to TNF- $\alpha$ , interleukins, cyclo-oxygenase, histamine and chemokines. They cause a cascade with anti- and pro-inflammatory effects. One effect is the release of cytokines and neurotransmitters and an altered function of the electrolytes-channels in the cells. This lowers the receptors' threshold, which is the

**Table 4**  
Complications.

Outcome	Studies (n)	Patients (n)	Favours	Effect size [95% CI]	HE
Postoperative bleeding (n)	11	1108	–	0.55 [0.24, 1.27]	0%
Urinary retention (n)	10	996	Ligasure	0.41 [0.20, 0.87]	0%
Constipation (n)	4	313	–	0.54 [0.19, 1.56]	97%
MJS > 3	1	56	–	1.93 [0.16, 22.55]	–
Open	2	168	–	0.44 [0.02, 10.42]	64%
Closed	2	145	–	0.55 [0.15, 1.98]	0%
Wound dehiscence (days)	2	306	Ligasure	−15.97 [−26.16, −5.78]	97%
Incomplete healing day 28 (n)	4	443	–	0.76 [0.32, 1.80]	4%
Anal fissure (n)	2	313	–	0.67 [0.15, 3.09]	0%
Anal stenosis (n)	9	931	–	0.95 [0.22, 4.09]	0%
Late minor bleeding (n)	6	765	–	0.72 [0.10, 5.24]	51%
Open	4	446	–	0.28 [0.02, 3.94]	40%
Closed	2	319	–	2.22 [0.42, 11.63]	–
Incontinence at follow-up (n)	8	896	–	0.69 [0.18, 2.61]	5%

MJS = Modified Jadad Score, Effect size estimated by statistical method of inverse variance, analysis model of random effects, effect measure of mean difference (continuous data) or odds ratio measure and mantel-haenszel method (dichotomous data), CI = Confidence Interval.

**Table 5**  
Convalescence.

Outcome	Studies (n)	Patients (n)	Favours	Effect size [95% CI]	HE
Hospital stay (days)	6	525	–	–0.19 [–0.63, 0.24]	100%
MJS > 3/Open	4	380	–	–0.02 [–0.45, 0.41]	99%
Closed	2	145	Ligasure	–0.57 [–0.94, –0.20]	66%
Return to work (days)	4	451	Ligasure	–4.88 [–7.59, –2.18]	87%
MJS > 3/Open	2	306	Ligasure	–7.01 [–12.79, –1.23]	91%
Closed	2	145	–	–2.66 [–7.62, 2.30]	88%
Patient unhappy with result (number)	2	70	–	0.53 [0.16, 1.70]	0%

MJS = Modified Jadad Score, Effect size estimated by statistical method of inverse variance, analysis model of random effects, effect measure of mean difference (continuous data) or odds ratio measure and mantel-haenszel method (dichotomous data), CI = Confidence Interval.

minimum of stimuli necessary to cause depolarisation. Thus, inflammatory mediators can amplify and spread pain or change non-painful stimuli into noxious signals. Furthermore, patients' factors and pain reducing actions will modulate the transmission of these nociceptive information to result in the experience of pain. As for pain mechanisms on local level, not only tissue damage has been studied. With regard to the effect of Botulinum toxin and topical metronidazole, spasm of the internal sphincter is also a pain contributing factor.<sup>20,21</sup> Whether or not less thermal damage by Ligasure is related to less spasm is unknown. Taken together, we conclude that treatment with Ligasure resulted in less pain. This may be related to the finding in this meta-analysis of significant less urinary retention and sooner return to work. A significantly shorter operation duration, less blood loss and shorter wound dehiscence found in the analysis could be addressed to effective sealing by Ligasure. For all these short-term parameters, the technique of Ligasure appeared to be superior to conventional haemorrhoidectomy. However, the clinical relevance may be questioned, since the difference in operation time was only 9 minutes and the difference in blood loss only 22 ml.

After two weeks, however, the surplus value seemed to be gone. No significant differences were found in pain measurement at day 14, complications such as anal stenosis, fissure or recurrences as late minor bleeding or incontinence at follow-up.

At least, there are some drawbacks of the present review. A few trials had only a low number of patients included and only three studies had a significant long-term follow-up.<sup>11,17,18</sup> Another drawback is the different techniques that were used. The Milligan-Morgan technique was applied in the majority, the closed technique was used with different alternatives. In the American Gastroenterological Association Technical Review on the Diagnosis and Treatment of Hemorrhoids four trials randomizing between open and closed technique were reviewed.<sup>22</sup> In three no difference in pain was found, one reported less pain following the open technique. In another RCT on this subject less pain was reported after the closed technique.<sup>23</sup> Based on these results, both open and closed techniques were initially considered to be equal in terms of postoperative pain in this review. However, in the sensitivity analysis whenever the primary analysis was affected by a considerable heterogeneity, there were some differences. In subgroup analysis of the closed conventional technique, less pain at day 1 was no longer significant and operating time longer. The significant longer hospital stay seemed to be in contrast with more or less comparable time for return to work. This is probably not only influenced by statistical however also by clinical heterogeneity between the studies.

The decrease in thermal spread is not unique to the Ligasure device. It can also be provided by sealing with ultrasonic

coagulating shears. In two studies there was no difference in thermal spread between these two devices.<sup>24,25</sup> An ultrasonic device (Harmonic Scalple-TM) has been used in haemorrhoidectomy and is compared to the Ligasure in one randomized controlled trial.<sup>26</sup> In this study, the use of an ultrasonic device was associated with more postoperative pain. The results for patients' tolerance favoured the Ligasure technique. Initially, comparable well tolerance was reported for another device, being the stapling device. However, due to a high long-term risk of recurrent haemorrhoidal disease and prolaps found in a review, the enthusiasm for this technique has diminished.

In the present review, effort was made to analyse long-term results. Only six trials included late minor bleeding as an endpoint. The definition for minor bleeding varied between the studies; from late bleeding to haemorrhoidal symptoms. Half the trials reported no recurrences. Altomare et al. reported 5 versus 2 bleedings and 2 versus 1 redo-surgery within 30 days for the Ligasure and conventional group respectively.<sup>5</sup> The remaining two studies had a follow-up of 3 years. Their combined results were 1 versus 6 recurrences in favour of the Ligasure technique. Based on the results of 8 trials, the symptoms of incontinence at final follow-up did not differ significantly.

Since the usage of the Ligasure-technique results in significantly less postoperative pain after haemorrhoidectomy without any adverse effect on postoperative complications, hospital stay and incontinence-rate this technique is superior in terms of patient tolerance. Although there was a tendency for equal efficacy, more evaluation of the long-term risk of recurrent haemorrhoidal disease and incontinence is required. In future studies on this subject a more comprehensive pain assessment could provide valuable additional information. If costs are taken into account, these should be analysed with general socio-economical aspects such as an earlier return to work as found in this review.

#### Conflict of interest

None declared.

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