

LigaSure-assisted versus diathermy day case haemorrhoidectomy: a randomized controlled trial

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Abstract

Aim: Milligan-Morgan haemorrhoidectomy is considered the best treatment for haemorrhoidal disease. The major drawback is severe post-operative pain. We postulate that using the LigaSure™ vessel sealing system to divide the haemorrhoidal pedicle may cause less postoperative pain.

Methods: This was a double-blinded randomised controlled trial in a single institution. Consecutive patients undergoing elective day-case haemorrhoidectomy were recruited. Patients were randomised into the diathermy (D) group or the LigaSure™ (L) group. The haemorrhoidal pedicle was coagulated with monopolar diathermy in D group or the LigaSure vessel sealing system in L group. Patients were seen in post-operative weeks 1, 3, 6 and 12 for assessment. Primary

outcome was post-operative pain by 10cm visual analog pain score. Secondary outcomes include operative time, complications and day discharge rate.

Results: 68 patients were recruited in this study (n=33 in D group versus n=35 in L group) with comparable demographic data. There was no significant difference in VAS pain score (median postoperative one-week cumulative pain score: D group = 40.2 versus L group = 39, p=0.93). More complications were observed in D group (5 versus 2, p=0.25) but this was not statistically significant. Day discharge rate was similar in the two groups at about 88%. **Conclusion:** LigaSure-assisted haemorrhoidectomy is not superior to diathermy haemorrhoidectomy. Day case haemorrhoidectomy is feasible and safe with both techniques.

Keywords: Haemorrhoidectomy; Post-operative pain; LigaSure; Faecal incontinence.

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Introduction

Milligan-Morgan haemorrhoidectomy is considered the best treatment for haemorrhoidal disease [1]. It is also renowned for its severe post-operative pain especially during the first post-operative week. It is postulated to be due to septic complications and sphincter spasm [2, 3]. Antibiotic regimens and topical nitrates have been used for minimizing post-operative pain, but the results are not conclusive [3-5]. LigaSure™ is a bipolar vessel sealing system using high current and low voltage electrical power to reform vessel collagen and elastin to seal the vessel. The instant feedback system adjusts energy delivery according to tissue reaction with a frequency of 200 times/sec and has minimal charring effect and thermal spread of 2-5mm [6, 7].

Based on the assumptions that precise and appropriate current delivery may provoke less thermal injury to the sphincter and its surrounding tissue and therefore produce less sphincter spasm, we postulated that using the LigaSure™ vessel sealing system in controlling the haemorrhoidal pedicle may cause less post-operative pain than the conventional diathermy technique.

Patients and method

This was a double-blinded randomised controlled trial in a single institution from 1 July 2002 to 30 June 2003 with the approval of the ethics committee. All patients undergoing elective day case haemorrhoidectomy were recruited to this study. Patients with a past history of haemorrhoidectomy, age older than 75 years, or with other concomitant anorectal pathology were excluded from the study. Eligible patients with informed consent were randomised using computer generated numbers in sealed opaque envelopes into two groups at the time of anaesthesia. Patients were blinded to the result of randomisation. All operations were performed

under spinal anaesthesia in the lithotomy position by colorectal surgeons. Anaesthetic technique and surgical technique on dissection of the haemorrhoidal pedicle were standardised in both groups. 2% lignocaine with 1:10000 adrenaline was infiltrated into the perianal skin to facilitate identification of the submucosal plane. Haemorrhoidectomy was performed using monopolar diathermy in cutting mode with the power of 25W. The haemorrhoidal pedicle was dissected from the internal sphincter to its apex. In the control group, the pedicle was coagulated with monopolar diathermy and divided with scissors. In the treatment arm, we used the medium-size LigaSure™ vessel sealing system to coagulate the pedicle which was then divided with scissors. A one centimetre mucocutaneous bridge between pedicles was ensured. Xylocaine jelly was applied to the wound at the end of the procedure. No wound packing was required in either group.

The operative time and the number of piles excised were documented by an independent assessor who was blinded to the randomisation results. Patients were discharged in the afternoon when they were ambulatory and able to pass urine. Dologesic (500mg 4 times daily as required for 28 tablets), Flayl 400mg three times 4 daily for 5 days, 4% potassium permanganate sitz bath and Metamucil 2 teaspoons three times daily as required were given upon discharge. Patients were asked to follow-up in our specialty clinic in post-operative weeks 1, 3, 6 and 12 and assessed by independent specialists.

The primary outcome was post-operative pain. Patients charted their pain score using 10cm visual analog scale from day 1 to day 7 after the operation. Patients were asked to bring back any remaining Dologesic tablets to their first follow up, where the analgesia consumption was counted and recorded. Complications including faecal incontinence, per-rectal bleeding, and readmission were compared. Faecal incontinence was assessed using the Pescatori score system [8].

Statistics

30 patients should be recruited in each group to identify an improvement of 50% in one-week cumulative pain score, with a power of 0.8 and p-value of 0.05. Continuous variables were analysed by Mann-Whitney U test and categorical variables were analysed by Chi-square test or Fisher Exact test as appropriate using SPSS 9.0 for window.

Results

A total of 68 patients were recruited in this study. (diathermy (D) group= 33, LigaSure™ (L) group =35). There was no significant difference between the two groups in respect of mean age, sex distribution or the number of piles excised. (Table 1). Median operative time was similar between two groups (D=20mins. [3–45] versus L=20mins. [4–37], $p=0.17$). There was no significant difference in the median post-operative one-week cumulative pain score between the two groups (D=40.2(1–35) versus L=39(1.3–68.8), $p=0.93$). The daily post-operative pain score and analgesia consumption were similar in the two groups (Table 2).

Table 1 Demographic of the Diathermy (D) Group and the LigaSure™ (L) group.

	Diathermy (D)	Group LigaSure™ (L) group	P value
Age	45.3	46	0.77
Sex (M:F)	1:2.8	1:2.2	0.55
Number of piles excised	2.76	2.57	0.17

Table 2 Post-operative VAS pain score and analgesia requirement.

	Diathermy (D) Group	LigaSure™ (L) group	P value
Day 1	5.0	5.2	0.96
Day 2	6.7	6.5	0.84
Day 3	6.5	6.4	0.31
Day 4	5.8	5.8	0.46
Day 5	5.3	5.8	0.72
Day 6	5.0	5.5	0.67
Day 7	4.9	5.0	0.61
Analgesia requirement (number of Dologesic tablet taken)	18	15.5	0.83

There were more post-operative complications observed in D group. (n=5, urinary retention=1, flatus incontinence=2, transient liquid incontinence=1 for 6 weeks). There were only 2 complications in the L group (urinary retention=1, faecal impaction=1). However, this did not reach the level of significance (D=5 versus L=2, $p=0.25$, Fisher's exact test). On subgroup analysis, the incontinence rate was higher in the D group but did not reach the level of significance (D=3 versus L=0, $P=0.11$, Fisher's exact test). Flatus or liquid incontinence subsided within 8 weeks in all patients with these complications. There was no re-bleeding in either group.

Most patients could be discharged on the same day in both groups. (D=29/33 versus L=31/35, $p=0.93$, Chi square test). One patient

in each group was re-admitted for urinary retention and faecal impaction respectively ($p=1.0$, Fisher's exact test).

Discussion

Despite the apparent short term success in stapled haemorrhoidectomy [9,10,11], the Milligan-Morgan haemorrhoidectomy remains the gold standard of piles treatment with a low recurrence rate [1]. The major drawback of this ablative perianal procedure is postoperative pain. Being one of the most common general surgical procedures, it is also graded as one of the most painful procedures in surgical practice. As in other perianal operations, two major explanations are proposed for the severe pain, namely perianal sepsis and anal sphincter spasm [2,3,4,5,12]. The theoretical advantages of the LigaSure vessel sealing system over convention diathermy are the reliable haemostatic effect and the short distance of current leak (less than 3 mm) which should cause less post-operative sphincter spasm and subsequent pain [6,7].

However, we did not demonstrate any significant advantage in post-operative pain in the LigaSure group. This is similar to past studies that have shown LigaSure offers no benefit in pain control in haemorrhoidectomy [13,15–17]. We believe that positive identification of the internal anal sphincter by conventional dissection of the submucosal plane can reduce anal sphincter injury, and thus the pain. A careful dissection and preservation of the anal sphincter is more important than the choice of instruments in haemorrhoidectomy. Stapled haemorrhoidectomy is a less painful operation compared with conventional hemorrhoidectomy [9–11]. This is probably due to the absence of an open wound and no dissection of the anal sphincter. Nevertheless, no benefit is shown in the day case setting in stapled haemorrhoidectomy [18,19]. In a study of 168 day case stapled haemorrhoidectomies, only 87.3% were discharged successfully on a day case basis [20]. In our study, a day discharge rate of 88% was achieved in both groups. Day case open haemorrhoidectomy with either LigaSure or diathermy is feasible with acceptable postoperative pain.

One study on long term follow up of LigaSure versus diathermy haemorrhoidectomy showed a significant lower internal anal sphincter thickness and a significant lower volume of rectal urge sensation in the diathermy group [15]. However, it was not clinically significant. The theoretical advantage of Ligasure in causing less sphincter damage and faecal incontinence is not shown in our study. There was no faecal incontinence in either group at 8 weeks after operation. Again, surgical technique in anal sphincter protection is the first priority in the prevention of incontinence complications.

Conclusion

LigaSure-assisted haemorrhoidectomy is not advantageous to diathermy haemorrhoidectomy with similar postoperative pain score and complications. Open haemorrhoidectomy performed with either techniques is feasible and safe as day-case setting. Considering the cost and benefit of LigaSure device, diathermy haemorrhoidectomy is the preferred choice of technique.

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