

Closed vs Ligasure Hemorrhoidectomy: A Prospective, Randomized Clinical Trial

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Objective: To compare the operative time, postoperative complications, and analgesic requirement between closed hemorrhoidectomy and Ligasure™ hemorrhoidectomy.

Material and Method: The study was conducted in a prospectively randomized controlled fashion. Forty-seven patients with grade 3 or 4 hemorrhoids plus external component or skin tag were operated on by either hemorrhoidectomy with Ligasure (24 patients) or closed hemorrhoidectomy (23 patients). One patient in each group was lost to follow up. The operative time, postoperative verbal numeric pain score, analgesic requirement, bleeding, and wound dehiscence between the two groups were compared. Unpaired t-tests, Mann-Whitney U tests, or Fisher's Exact tests were used where appropriate.

Results: Demographic and clinical data between two groups were comparable. Operative time for the Ligasure hemorrhoidectomy was significantly shorter than the closed hemorrhoidectomy group (21.70 ± 11.76 vs 35.68 ± 14.25 min, $p < 0.001$), while the number of resected hemorrhoids in the study group were 2.91 versus 2.18 in the control group. However, there were no differences in post-operative pain score, analgesic requirement, bleeding, or wound dehiscence between the two groups.

Conclusion: Ligasure hemorrhoidectomy is superior to closed hemorrhoidectomy in terms of reducing the operative time without affecting postoperative complications.

Keywords: Ligasure hemorrhoidectomy, Hemorrhoidectomy, Postoperative complication

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Hemorrhoids are one of the most common colorectal diseases. Anal bleeding, pain and mass at the anus are common presenting symptoms. Hemorrhoidectomy is still the treatment of choice for patients with symptomatic grade 3, 4 and combined hemorrhoids. Unfortunately, it may be accompanied by significant postoperative complications including pain or bleeding. Many studies have compared closed with open hemorrhoidectomy, the results show no differences between postoperative pain and complications. However, the healing time is shorter in the closed hemor-

rhoidectomy group than the open hemorrhoidectomy group^(1,2). Several surgical techniques or instruments have been used to reduce postoperative concerns especially pain, bleeding and wound dehiscence.

There are various techniques of closed hemorrhoidectomy such as Ferguson⁽³⁾ or Fansler⁽⁴⁾ techniques. At the Colorectal Division, King Chulalongkorn Memorial Hospital, the authors prefer closed hemorrhoidectomy (Fansler's technique). In the present study, hemorrhoidectomy using Ligasure was compared with closed hemorrhoidectomy (Fansler's technique). Ligasure (Valleylab, Boulder, Colorado, USA), a hemostatic device, can seal the pedicle of the hemorrhoidal plexus and automatically stop the energy delivery when tissue sealing is complete. The device can coagulate with minimal thermal spreading and limited tissue charring.

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Material and Method

47 patients with symptomatic grade 3 or 4 hemorrhoids with external component were recruited to the trial according to the profile in Fig. 1, from March to December 2004 in King Chulalongkorn Memorial Hospital. The present study was designed as a prospective, randomized, clinical trial and ethics committee approval was obtained. Exclusion criteria included complicated hemorrhoid (thrombosed or strangulated hemorrhoid), coexisting perianal disease, previous perianal surgery, compromised patients, pregnancy and history of bleeding tendency. Randomization was performed at the outpatient department by closed envelope allocation. One patient in each group was lost to follow up.

Thirty minutes before the operation, all patients were injected with 50 mg of pethidine, intramuscularly. Patients were positioned in prone jack-knife. Then 1% xylocaine with adrenaline 20 cc. diluted with 0.9% NSS 20 cc. was infiltrated into perianal area as local anesthesia. The technique of surgical hemorrhoidectomy was standardized in each case. The Ligasure procedure was performed using a modified Fansler retractor. External component was incised by large Metzenbaum upto the dentate line, then the Ligasure

device was applied from the dentate line to just above the apex of the hemorrhoidal plexus and coagulated. The tissue above the upper border of the coagulated strip was cut and removed. The anodermal wound was approximated with a continuous Rapid Vicryl 4-0 suture. This procedure was followed for each bundle of hemorrhoids.

Patients in the control group (the elective group) were treated in the same manner, involving using modified the Fansler retractor, Metzenbaum excision of the hemorrhoid complexes starting from the external component to just above the hemorrhoidal plexus, bleeding was stopped by electrocauterization. The wound was closed with Rapid Vicryl 4-0 continuously. Operating time was defined as the time from insertion of the modified Fansler retractor to placement of the dressing. All procedures were documented by colorectal fellows and staff.

After the operation, all patients were prescribed an adequate dose of oral acetaminophen, according to their body weight immediately and every four hours. They were also allowed intramuscular injection with pethidine (1 mg/kg each time), as requested. Bulk forming agent (Mucilin) was prescribed in a sachet twice daily.

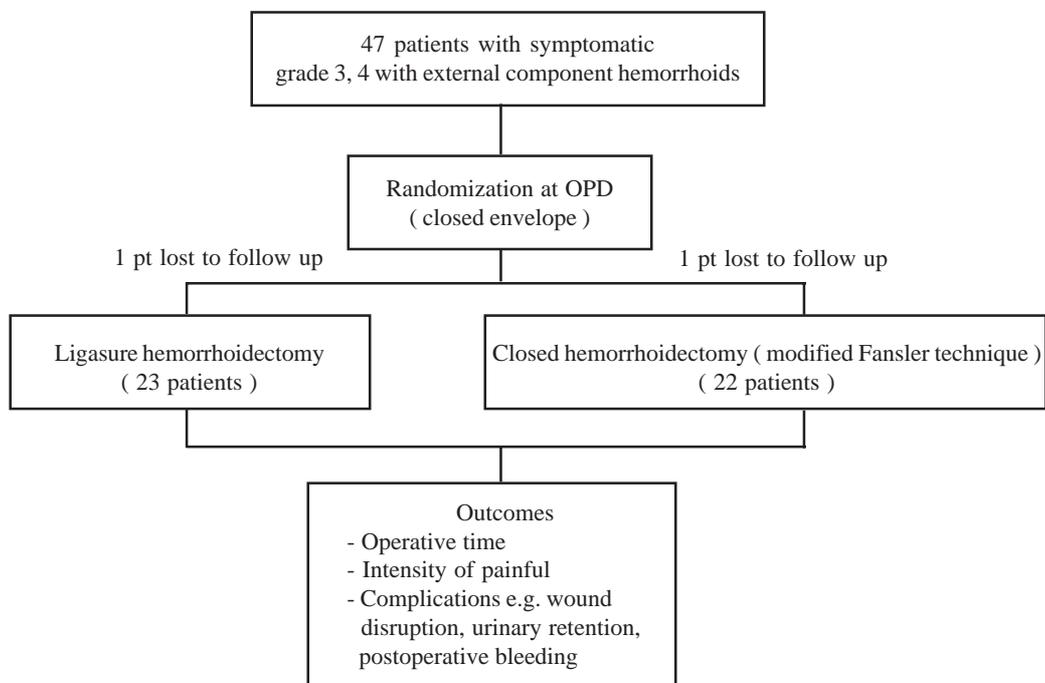


Fig. 1 Schematic profile of randomized controlled trial comparing Ligasure against closed hemorrhoidectomy

Postoperative pain was evaluated by means of a verbal numeric pain score^(13,14) in the postoperative period at 6, 24 hours and 14, 28 days. The position and number of hemorrhoids excised, together with associated skin tags were recorded for both groups in addition to analgesic requirement and any complications. Follow-up was scheduled at 2 and 4 weeks.

Statistical analysis

Initial power calculations suggested that a minimum of 22 patients were required in each group to detect the difference of one standard deviation in mean operating time and pain score, with statistical significant difference at the $P < 0.05$ level. All data analysis was performed with the SPSS version 11.2 statistical software package (SPSS Inc., Chicago, IL). Continuous variables were compared using unpaired t-test and the Mann-Whitney U test, categorical variables using the χ^2 or Fisher's exact test.

Results

Forty five patients were randomized in two groups to the trial. The demographic data, in terms of age and gender distribution, were comparable. Similarly, there was no statistically significant difference between the two groups (Table 1). The extent of hemorrhoidal disease was similar between the two groups. Statistically significant difference was observed in the operating time. Mean operating time was 21.7 minutes in the study group and 35.68 minutes in the control group

($p = 0.001$), while the number of hemorrhoids resected in both groups (2.91 versus 2.18 in the control group) showed no statistical difference (Fig. 2, 3).

Analysis of the postoperative pain gave the median score of the Ligasure group as 6, 3.65, 1.35 and 0.48 in 6, 24 hours, and 2 and 4 weeks postoperative, while 4.82, 3.14, 1.5, 0.45 in the closed group. This showed no statistically significant difference between the two groups (Fig. 4). The mean total dose of pethidine requirement was 65 mg in the Ligasure group and 75 mg in the closed group ($p = 0.729$).

Concerning to postoperative wound dehiscence on post operative day 14, there was no statistically significant difference between the two groups ($p = 1.0$). In both groups, complete wound healing was achieved in patients after four weeks. Three patients, one in the Ligasure group and two in the closed group, experienced postoperative urinary retention which responded to temporary bladder catheterization. There was no postoperative bleeding in both groups.

Discussion

In recent years, many new treatment modalities have been developed which aim to reduce postoperative pain after hemorrhoidectomy. None is clearly superior to the other, and the primary concern remains reduction of postoperative pain and operating time⁽⁵⁻⁸⁾.

Staple hemorrhoidectomy showed benefit above conventional techniques but can not get rid of the external component, which may be the most

Table 1. Patient characteristics and operative variables

Variables	Closed hemorrhoidectomy	Ligasure hemorrhoidectomy	p value
Age (year)	45.7 ± 14.6	41.9 ± 12.9	0.365
Gender			
Male	12	12	1.000
Female	10	11	
Weight (kg)	58.8 ± 8.5	59.0 ± 7.5	0.933
Height (cm)	164.0 ± 6.5	162.5 ± 6.8	0.461
Number of hemorrhoids	2.2 ± 0.9	2.9 ± 1.4	0.039
Grade of hemorrhoids			
III	21	20	0.608
IV	1	3	
Operative time (min)	35.7 ± 14.3	21.7 ± 11.8	0.001
Total dose of pethidine (mg)	75.0 ± 50.0	65.0 ± 33.5	0.729
Complications			
Urinary retention	2	1	0.608
Bleeding	0	0	
Wound dehiscence (2 wk)	4	5	1.000

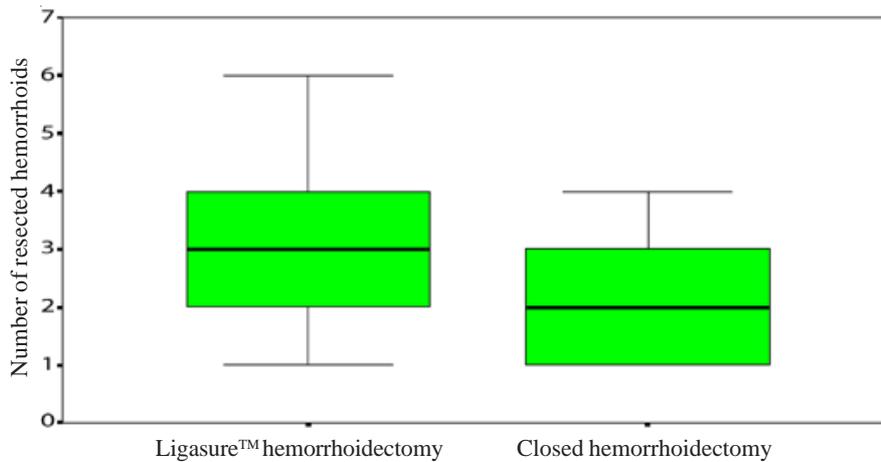


Fig. 2 Box plot showing number of resected hemorrhoids in each of the two groups

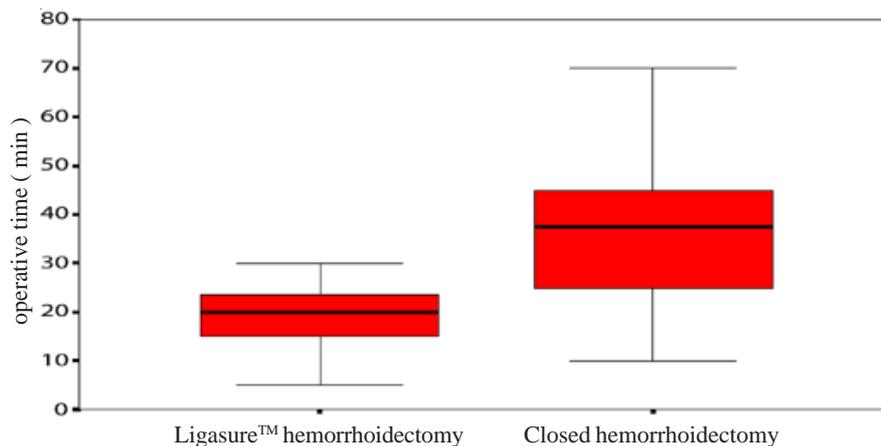


Fig 3 Box plot showing operating time in minutes in each of the two groups

concern for the patients^(9,10). The Ligasure diathermy system offers an excellent method for achieving bloodless dissection of vascular tissues. This system confines thermal spread to within 2 mm of the adjacent tissue. The combination of localized coagulation with minimal collateral thermal spread makes it an ideal instrument for hemorrhoidectomy. A randomized, clinical trial has been performed so far comparing Ligasure with closed hemorrhoidectomy (Ferguson's technique). That study showed that the Ligasure system reduced postoperative pain and operating time⁽¹¹⁾.

The present study shows that this technique offers several advantages over closed Fansler hemorrhoidectomy. Technically, it is simple and reproducible. Although the Harmonic Scalpel has the same advantage of producing less lateral thermal injury, the Ligasure

system required shorter operating time^(12,13). Number of hemorrhoids resected in the cases of Ligasure hemorrhoidectomy were more than in case of closed hemorrhoidectomy but the operation times were shorter than the other group.

Pain after conventional surgery continues to be a major problem for hemorrhoidectomy patients, and any strategy to reduce pain is desirable. The present study has shown that there was no significant reduction in postoperative pain in Ligasure hemorrhoidectomy as analgesic requirement was the same as closed hemorrhoidectomy.

Complications such as urinary retention and wound dehiscence experienced by the Ligasure patients occurred with the incidence similar to that found after conventional operations. However, no early

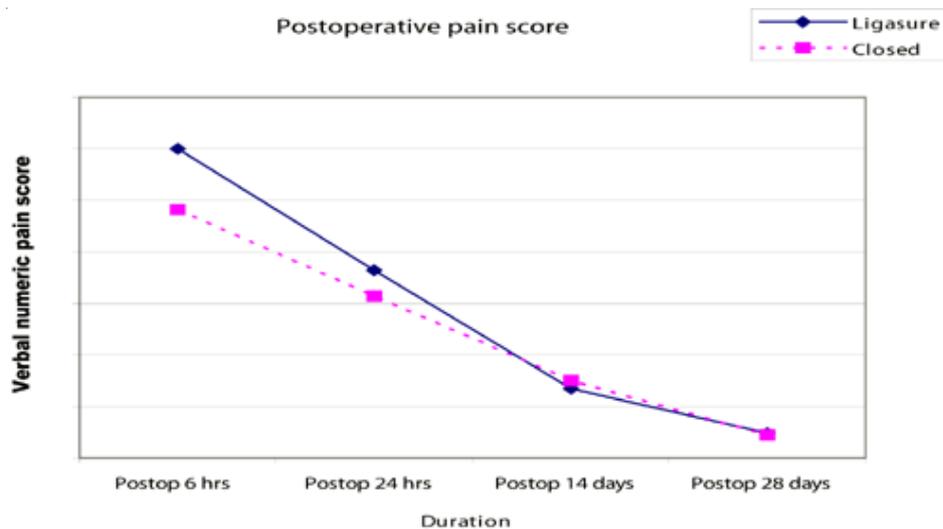


Fig. 4 Postoperative pain score between Ligasure and closed hemorrhoidectomy group

or late postoperative bleeding occurred in the present study.

Ligasure hemorrhoidectomy is superior to closed hemorrhoidectomy in terms of reducing the operative time without affecting postoperative complications but more cases are required for the further study.

Conclusion

Ligasure™ hemorrhoidectomy is an easy-to-learn technique that takes less operative time than the closed technique, with no difference in the complication rate (urinary retention, bleeding and wound dehiscence).

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การผ่าตัดริดสีดวงทวารแบบปิดเปรียบเทียบกับการใช้ Ligasure: การศึกษาทางคลินิกแบบ prospective randomized trial

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วัตถุประสงค์: เพื่อเปรียบเทียบระยะเวลาที่ใช้ผ่าตัด, ภาวะแทรกซ้อนจากการผ่าตัด และความต้องการใช้ยาาระงับปวด ระหว่างการผ่าตัดริดสีดวงทวารแบบปิดและการผ่าตัดริดสีดวงทวารโดยใช้อุปกรณ์ ligasure

วัสดุและวิธีการ: ศึกษาแบบ prospective randomized controlled trial ในผู้ป่วย 47 รายที่เป็นริดสีดวงทวาร grade 3 หรือ 4 ร่วมกับริดสีดวงทวารชนิดภายในหรือติ่งเนื้อ โดยแบ่งผู้ป่วยเป็นสองกลุ่ม กลุ่มที่หนึ่ง 24 ราย ได้รับการผ่าตัดริดสีดวงทวารด้วยอุปกรณ์ ligasure และกลุ่มที่สอง 23 รายได้รับการผ่าตัดริดสีดวงทวารแบบปิด ผู้ป่วยกลุ่มละหนึ่งรายไม่มาติดตามรักษา เปรียบเทียบข้อมูลเกี่ยวกับระยะเวลาที่ใช้ในการผ่าตัด, ความเจ็บปวดหลังผ่าตัด (ประเมินด้วย verbal numeric pain score และความต้องการใช้ยาแก้ปวด), ภาวะเลือดออกหลังผ่าตัดและแผลแยก ระหว่างสองกลุ่มด้วยวิธีการทางสถิติ Unpaired t-tests, Mann-Whitney U tests, หรือ Fisher's Exact tests ตามความเหมาะสม

ผลการศึกษา: ข้อมูลลักษณะของผู้ป่วยสองกลุ่มใกล้เคียงกัน ระยะเวลาที่ใช้ในการผ่าตัดด้วยอุปกรณ์ ligasure สั้นกว่าการผ่าตัดริดสีดวงทวารแบบปิด (21.70 ± 11.76 vs 35.68 ± 14.25 นาที, $p < 0.001$), จำนวนหัวริดสีดวงทวารในกลุ่มที่ผ่าตัดด้วยอุปกรณ์และผ่าตัดแบบปิดมี 2.91 และ 2.18 ตามลำดับ อย่างไรก็ตามไม่มีความแตกต่างกันเรื่องความเจ็บปวดหลังผ่าตัด, ความต้องการยาแก้ปวด, ภาวะเลือดออก และแผลแยก

สรุป: การผ่าตัดริดสีดวงทวารด้วยอุปกรณ์ ligasure ดีกว่าการผ่าตัดแบบปิดในด้านการลดระยะเวลาที่ใช้ในการผ่าตัดโดยไม่ทำให้ภาวะแทรกซ้อนหลังการผ่าตัดเพิ่มขึ้น