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Original Article

Hand-Made Silk Loop Versus Hem-O-Lok Clip in Single Port Laparoscopic Appendectomy: A Randomized Controlled Trial

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Abstract

Background: Instruments used for closing the appendicular stump contribute to the high cost of laparoscopic appendectomy. In the present study a hand-made Roeder loop made of 3-0 silk to be placed on the appendicular stump and tightened by a plastic tube was created to reduce operative costs.

Objective: The objective of the present study was to compare the operative time in single port laparoscopic appendectomy, when using hand-made silk loop and when using hem-o-lok clip, a commercial instrument, in the closure of the appendicular stump in patients diagnosed with acute appendicitis.

Methods: Patients who were diagnosed as having uncomplicated acute appendicitis at Hatyai Hospital in Songkhla, Thailand were enrolled from January 2018 to September 2019. The primary outcome was operative time. Patients were randomized to either the hand-made silk loop group or the hem-o-lok clip group. Data collected included age, gender, body mass index, operative time, pathological report, operative cost, pain score at 4, 8, 12, and 24 hours after operation, hospital stay, and 30-day postoperative complications.

Results: Thirty-eight patients were included in the study. There were no significant differences between the two groups in terms of age, gender, body mass index, and American Society of Anesthesiologists classification. The mean operative time ± SD was 41.4 ± 14.8 minutes in the hand-made silk loop group and 50.2 ± 19.8 minutes in the hem-o-lok clip group, which were not significantly different ($p = 0.14$). The cost of 3 hand-made silk loops used for each operation was 17 baht, and for the 3 hem-o-lok clips was 795 baht. The pain score at 4, 8, 12, and 24 hours, and hospital stay, were similar in both groups. No 30-day postoperative complication was observed in both groups.

Conclusion: The use of hand-made silk loop to close the appendicular stump in single port laparoscopic appendectomy resulted in a similar operative time as that with the use of hem-o-lok clip. Hand-made silk loop is safe, simple and effective for the closure of appendicular stump, and may help reduce operative cost.

Keywords: Acute appendicitis, Appendicular stump, Hand-made silk loop, Hem-o-lok, Single port laparoscopic appendectomy

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Introduction

Acute appendicitis is one of the most common abdominal emergencies. In1983, Semm introduced three-port laparoscopic appendectomy for the treatment of acute appendicitis[1]. Since then, laparoscopic appendectomy has been accepted as a standard for the treatment of acute appendicitis. Its advantages include less postoperative pain, faster postoperative recovery, shorter hospital stay, and fewer postoperative complications, when compared with open appendectomy[4,12]. Single port laparoscopic appendectomy (SPLA) was introduced in 1998[3]. Recent meta-analyses have shown similar postoperative morbidity and wound infection rates for SPLA as for conventional laparoscopic appendectomy[15,16,19].

Techniques for appendicular stump closure include the use of staples, commercial endoloops (e.g., Endoloop(R) Ligature Ethicon Endo-surgery, Johnson & Johnson, Cincinnati, OH, USA), titanium clips, non-absorbable polymer clips (hem-o-lock(R) Surgical Instruments, Teleflex Medical, Durham, NC, USA), extracorporeal sliding knot, and intracorporeal ligature[20]. The staple technique results in the safest closure, even when the appendiceal base is inflamed or considerably enlarged, but it is also the most expensive[11]. Endoloop is safe for closing the appendix stump, and its cost is lower as compared to staplers [10]. Hem-o-lok clips appear to be superior to the endoloop in terms of shorter operative time, while maintaining comparable safety.

The hand-made Roeder silk endoloop in the present study was made of 3-0 silk, and autoclaved before use. The knot of the loop can be placed on the appendicular stump and tightened by a plastic tube (Figure 1). The silk loop was made solely with the aim to reduce operative costs. The hem-o-lok clip (Weck Closure Systems, Research Triangle Park, NC, USA) used in the present study is a V-shaped clip made of nonabsorbable material in XL size. During application, two loops or clips are placed at least 3 to 4 mm apart (Figures 2 to 3).

In the present study, we performed a randomized controlled study of SPLA for uncomplicated appendicitis, to compare the total operative time when using the hand-made silk endoloop, with that when using the hem-o-lok clips, for the closure of appendicular stump. The hope is that, with comparable ease of use and safety, the hand-made silk loop stump closure may be a viable, cheaper option in laparoscopic appendectomy.

Patients and Methods

The study was conducted at Hatyai Hospital in Songkhla, Thailand, and was registered on clinicaltrials.in.th, with number TCTR 21080718004, and approved by the Research Ethics Committee of Hatyai Hospital (REC-HY, No10/2561), Songkhla. The sample size was estimated to be at least 20 patients per group, based on a similar study by Delibegovic[7]. Forty-eight patients with a diagnosis of acute appendicitis were enrolled into the present study from January 2018 to September 2019. Written informed consent was obtained from all patients before randomization.

Figure 1 Hand-made silk endoloop instrument

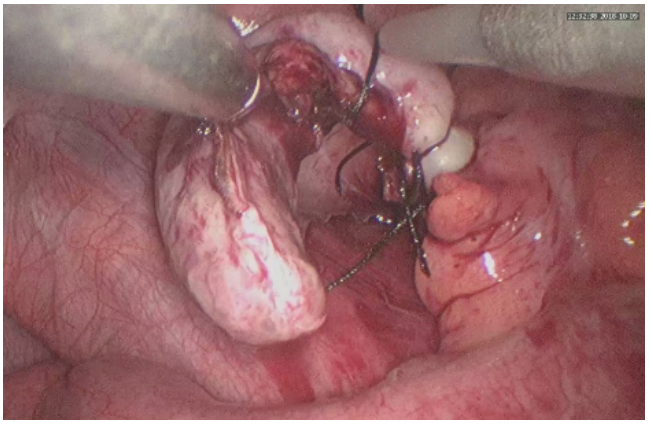

Figure 2 Hand-made silk endoloop ligation technique

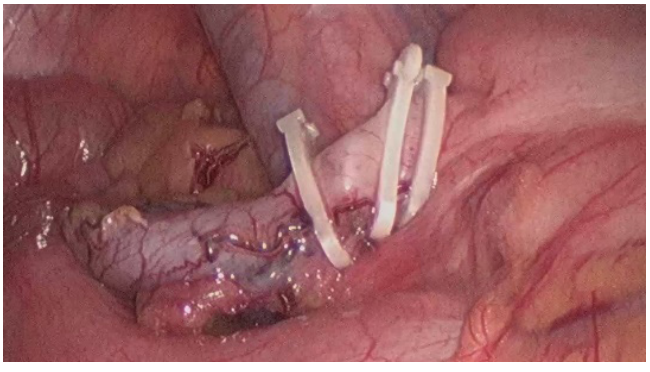

Figure 3 Hem-o-lok clip technique

Exclusion criteria included: age less than 14 years, pregnancy, presence of perforated appendicitis or appendiceal mass, classified as the American Society of Anesthesiologists class 4 or 5, and contraindications to general anesthesia. Patients undergoing laparoscopic appendectomy (available only from 8.30 a.m. to 16.30 p.m. at our institution) were randomly allocated via computer-generated randomization to the hand-made silk loop group (SL) or the hem-o-lok group (HL).

All patients in the study received 500 milligrams of metronidazole and 2 grams of ceftriaxone 2 grams intravenously within 30 minutes before incision. All patients were instructed to void urine prior to anesthesia, so no urinary catheters were used.

After induction of general anesthesia, a skin incision of length 1.5 to 2.0 cm was made at the umbilicus by a surgeon who had performed over 200 laparoscopic appendectomies. The glove port (Nelis, Gyeonggi-do, Korea) was introduced through the umbilical incision. The patient was placed in the Trendelenburg position with the right side rotated up. Pneumoperitoneum was established with CO_2 insufflation, and the intra-abdominal pressure was kept below 15 mmHg. A rigid zero degree 10-mm laparoscope was used to visualized the intra-abdomen. We used two 5 mm laparoscopic graspers to mobilize the appendix. A laparoscopic bipolar electrothermal instrument (LigaSure™ 5mm blunt tip, Covidien, Mansfield, Massachusetts, USA) was used to divide the mesoappendix.

In the SL group, two proximal and one distal hand-made silk loops were applied to close the stump of the appendix (Figure 2). In the HL group, the appendiceal stump was closed with two proximal and one distal XL-size hem-o-lok clips (Figure 3). The appendix was transected with LigaSure™ between proximal and distal loops or clips, in both groups. After checking for bleeding and contamination, the transected appendix was removed together with the glove port to reduce contamination of the abdominal wall. The fascia was closed with interrupted 1-0 absorbable sutures. The skin was closed with 4-0 absorbable, subcuticular sutures.

Patients were seen in the out-patients clinic at the first week and 30 days after operation. They were evaluated by the same surgeon for any signs of complications. Data collected included age, gender, body mass index (BMI), operative time, pathological report, operative cost, pain score at 4, 8, 12, and 24 hours after surgery (scored from 1 to 10), length of hospital stay, and 30-day postoperative complications. The latter included wound infection, wound abscess, intra-abdominal abscess, lung atelectasis, re-operation for any reason, postoperative adhesion or postoperative bleeding. Operative time was defined as the duration in minutes between skin incision to skin closure.

Statistical analysis was performed using Stata version 13 (Stata Corp LLC, Texas, USA). Two groups were compared using Student's t-test for continuous variables. Categorical variables were compared using Chi-square test or Fisher's exact test. Numerical data were presented as mean ± S.D. and categorical data were expressed as counts and proportion (in percent). Statistical significance was defined as a p-value ≤ 0.05.

Results

Forty-eight patients diagnosed with acute appendicitis were included in the present study. Ten patients were excluded, due to the presence of ruptured appendicitis in 6, and misdiagnosis in 4 (neuroendocrine tumor, corpus luteal cyst, ruptured gallbladder and cecal mass). There were 18 patients in the SL group, and 20 patients in the HL group. The final, pathological, diagnosis in all patients was acute appendicitis.

Of the 38 patients, 28 (74%) were men and 10 (26%) were women. The mean age (S.D.) was 36.2 (14.4) years in the SL group and 34.5 (16.4) years in the HL group. There were no differences in age, gender, BMI and ASA class between the 2 groups (Table1). No conversion from laparoscopic to open technique occurred, and neither additional ports nor intra-abdominal drains were required. The mean operative time was shorter in SL group (41.4 ± 14.3 minutes) than in the HL group (50.2 ± 19.8 minutes) but not significantly so. The pain score at 4, 8, 12, and 24 hours after surgery and the length of hospital stay were similar in both groups. No 30-day postoperative complication was observed in both groups (Table 2). There was no leakage of the appendiceal stump and no ligature or clip dislodgement in both groups. The cost of 3 hand-made silk endoloops was 17 baht, while the 3 hem-o-lok clips cost 795 baht in Thailand.

Discussion

Laparoscopic appendectomy has several advantages over open appendectomy. This includes more complete examination of the abdominal cavity, less pain, shorter hospital stay, more rapid recovery, fewer complications and better wound cosmesis[4,12].

Table 1 Characteristics of patients in the study

Characteristics	SL (n=18)	HL (n=20)	*p*-value
Age, years: mean ± SD	36.1±14.4	34.5±16.4	0.69
Male/Female: number	14/4	14/6	0.59
BMI, kg/m^2: mean ± SD	24.3±4.2	23.8±5.6	0.72
ASA class I: number	1	2	0.62
ASA class II: number	16	16	0.46
ASA class III: number	1	2	0.62

SL=hand-made silk endoloop; HL=hem-o-lok clip; BMI=body mass index; ASA class=American Society of Anesthesiologists classification

Table 2 Postoperative outcomes (mean ± SD)

Outcomes	SL (n=18)	HL (n=20)	*p*-value
Operative time, minutes	41.4 ± 14.3	50.2 ± 19.8	0.14
Pain at 4 hours	5.4 ± 3.3	4.2 ± 3.0	0.22
Pain at 8 hours	4.2 ± 3.0	4.0 ± 2.6	0.81
Pain at 12 hours	2.4 ± 2.4	2.5 ± 2.4	0.94
Pain at 24 hours	3.0 ± 2.6	2.2 ± 2.1	0.27
Hospital stay, hours	78.3 ± 38.9	81.2 ± 41.2	0.82

SL=hand-made silk endoloop; HL=hem-o-lok clip; Pain is scored on a numeric scale from 1 to 10

Disadvantages include longer operating time, higher cost, and the need for laparoscopic experience. With advances in laparoscopic technique and equipment, the SPLA procedure was introduced, which further decreases incision length, reduces postoperative pain, with even more rapid recovery and smaller scar[15,16,19].

One important component of the cost of laparoscopic appendectomy is the laparoscopic equipment and technique of securing the appendiceal stump. Closure of the appendicular stump is an important step in laparoscopic appendectomy because, if not done properly, serious complications from stump leakage including fecal fistula, intra-abdominal abscess and sepsis may occur.

Stapling is the safest method to close the appendiceal stump but it is also the most expensive[2,6,7]. Advantages of staplers include ease of use, shorter learning curve, shorter operative time, and is safe even when the appendiceal base is inflamed or is rather large. Staples can also prevent mucosa protrusion, spillage of fecal material or pus, and with complete closure of the appendiceal stump, should result in a lower risk of intra-abdominal abscess or collection[11].

The endoloop is also safe for closing the appendiceal stump, and is much cheaper, but requires longer operative time as compared to staplers[8,14,17]. A few studies seem to show higher risks of surgical-site infection and unplanned readmission when using the endoloop, compared with using staples[9]. This may be due to the presence of the exposed appendiceal mucosa, some spillage of fecal material during the division of the appendix, or fecal dislodgement from the appendiceal stump. Also, the endoloop may not be safe for the closure of inflamed appendiceal stump, and if the endoloop is tied too tightly, stump breakdown from suture cut-through with leakage may occur. The endoloop technique requires dexterity, and some experience in tying different appendiceal stump sizes before a surgeon can use the technique safely.

The advantages of the hem-o-lok clips include simplicity of application, shorter operative time, and its relative cheapness[7,11,13,21]. One disadvantage is the failure to safely secure bulging or severely inflamed appendicular base (e.g., when diameter size is more than 1 cm). The locking mechanism of a hem-o-lok clip is key to safely secure the stump, and the clip must fit tightly around the appendiceal stump prior to closure of the locking mechanism, as slipping off the stump may

result in stump leakage. XL-size hem-o-lok also requires size 12-mm trocar to employ, and even then, it cannot secure large, inflamed appendices.

In our study, the operative time of SPLA when using hand-made silk endoloop was shorter even than that when using hem-o-lok clip, but this difference was not significant. The shorter operative time may reflect the extensive experience of the surgeon in using the endoloop. The postoperative pain scores, the lengths of hospital stay were not significantly different between the 2 groups. No 30-day postoperative complications were seen in both groups. This was similar to our previous study[22], in which SPLA using hand-made silk loops was compared to open appendectomy, and only 2 patients in the SPLA group had superficial surgical site infection but no intra-abdominal abscesses. Controlled contamination during the division and securing the appendiceal stump is an important step to prevent intra-abdominal infection.

The endoloop technique and can be used for appendiceal stump of all sizes but requires experience. A limitation of hem-o-lok clip is a higher risk failure if applied to severely inflamed or enlarged appendicular stump, but these were excluded from the present study. The cost of 3 hand-made silk endoloops was 17 baht, and in comparison, 3 hem-o-lok clips cost 795 baht in Thailand. Therefore, the cost of laparoscopic appendectomy can be reduced by more than 778 baht per case if hand-made silk loops were used instead of the hem-o-lok clips. In the present study, as in some other studies, hand-made silk loop is a safe and cheaper method for closure of the appendicular stump[6,14,21-22].

Conclusion

The use of hand-made silk endoloop to close the appendicular stump in single port laparoscopic appendectomy resulted in a similar operative time as that with the use of hem-o-lok clip. Hand-made silk loop is safe, simple and effective for the closure of appendicular stump, and may help reduce operative costs.

Funding Sources and Conflicts of Interests

No competing financial interests exist.

Acknowledgements

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What Is Already Known On This Topic?

There are many studies comparing appendicular stump closure techniques in laparoscopic appendectomy. Some studies appeared to show hem-o-lok clips to be superior to endoloops in terms of shorter operative time and cost, while being similarly safe.

What This Study Adds?

This study shows that hand-made silk endoloop is cheaper than hem-o-lok clip when used to secure appendicular stumps in single port laparoscopic appendectomy, with similar outcomes.

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บทคัดย่อ **การศึกษาสุ่มเปรียบเทียบการใช้ลูปไหมประดิษฐ์ขึ้นเองเทียบกับอุปกรณ์ Hem-o-lok ในการผ่าตัดไส้ติ่งผ่านกล้องส่องช่องท้องรูเดียว**

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กลุ่มงานศัลยกรรม โรงพยาบาลหาดใหญ่ จังหวัดสงขลา

ความเป็นมา: การผ่าตัดไส้ติ่งเป็นการผ่าตัดที่พบบ่อยและการผ่าตัดแบบส่องกล้องช่วยลดความเจ็บปวดแต่ยังมีค่ารักษาแพง. อุปกรณ์ที่ใช้ในการผ่าตัดปิดต่อไส้ติ่งเป็นปัจจัยหนึ่งที่ทำให้ค่าผ่าตัดสูงขึ้น อุปกรณ์ hand-made silk endoloop เป็นการดัดแปลงอุปกรณ์ที่มีอยู่มาใช้เพื่อลดค่าใช้จ่ายและเวลาในการผ่าตัด การศึกษานี้ต้องการเปรียบเทียบระยะเวลาที่ใช้ในการผ่าตัดในการผ่าตัดผู้ป่วยที่ได้รับการวินิจฉัยว่าเป็นไส้ติ่งอักเสบเฉียบพลันโดยการใช้ hand-made silk endoloop กับ hemolock เพื่อปิดตอของไส้ติ่งในการผ่าตัดไส้ติ่งแบบส่องกล้องรูเดียว

วิธีการศึกษา: ผู้ป่วย 48 รายที่ได้รับการวินิจฉัยว่าเป็นไส้ติ่งอักเสบเฉียบพลันในโรงพยาบาลหาดใหญ่ จังหวัดสงขลา ประเทศไทยเข้าร่วมการวิจัยตั้งแต่เดือนมกราคม 2561 ถึงเดือนกันยายน 2562 จุดประสงค์หลักของการศึกษาเพื่อเปรียบเทียบระยะเวลาที่ใช้ในการผ่าตัดไส้ติ่งอักเสบเฉียบพลันโดยการใช้ hand-made silk endoloop กับ hemolock เพื่อปิดตอของไส้ติ่งในการผ่าตัดไส้ติ่งแบบส่องกล้องรูเดียว ผู้ป่วย 6 รายที่ได้รับการวินิจฉัยว่าไส้ติ่งอักเสบแตกทะลุและ 4 รายที่ได้รับการวินิจฉัยว่าเป็นโรคอื่น (neuroendocrine tumor, corpus luteal cyst, ruptured gallbladder and cecal mass) ได้ถูกคัดออกจากการศึกษา ผู้ป่วยทั้งหมดได้รับการสุ่มโดยการใช้คอมพิวเตอร์เข้ากลุ่ม hand-made silk endoloop หรือ hem-o-lock ข้อมูลที่ถูกเก็บ อายุ ดัชนีมวลกาย ระยะเวลาที่ใช้ในการผ่าตัด การรายงานผลชิ้นเนื้อ ราคาอุปกรณ์ ระดับความปวดแบบตัวเลข ระยะเวลาที่อยู่ในโรงพยาบาล ภาวะแทรกซ้อนที่เกิดขึ้นหลังผ่าตัดภายใน 30 วัน

ผลการศึกษา: ผู้ป่วย 38 ราย ได้เข้าร่วมการศึกษา ไม่มีความแตกต่างอย่างมีนัยสำคัญ ในเรื่องอายุ เพศ ดัชนีมวลกายและ ค่า ASA ระหว่าง 2 กลุ่ม ระยะเวลาเฉลี่ยที่ใช้ในการผ่าตัดของทั้ง 2 กลุ่ม ไม่มีความแตกต่างกัน ระยะเวลาที่ใช้ในการผ่าตัด 41.4 ± 14.8 นาที ในกลุ่ม SL ระยะเวลาที่ใช้ในการผ่าตัด 50.2 ± 19.8 นาที ในกลุ่ม HL ราคาอุปกรณ์ hand-made silk loops 3 ชิ้น เท่ากับ 17 บาท ราคาอุปกรณ์ hem-o-lok clips 3 ชิ้น เท่ากับ 795 บาท ระดับความปวดหลังผ่าตัดที่ 4, 8, 12, 24 ชั่วโมงหลังผ่าตัด ระยะเวลาที่นอนโรงพยาบาลหลังผ่าตัดและภาวะแทรกซ้อนหลังผ่าตัด 30 วัน

สรุปการศึกษา: ระยะเวลาเฉลี่ยที่ใช้ในการผ่าตัดเฉลี่ยในกลุ่มที่ใช้ hand-made silk Endoloop และ hemo-lock เพื่อปิดตอไส้ติ่งผู้ป่วยไส้ติ่งอักเสบที่ผ่าตัดโดยการส่องกล้องแบบรูเดียวไม่มีความแตกต่างอย่างมีนัยสำคัญ สำหรับการศึกษานี้ hand-made silk Endoloop สามารถใช้ในการผ่าตัดส่องกล้องแบบรูเดียวได้ปลอดภัยด้วยราคาที่ต่ำกว่ามาก