

A COMPARATIVE STUDY BETWEEN THE USE OF NON-ABSORBABLE POLYMER CLIPS (HEM-O-LOK CLIPS) VERSUS ROEDER'S KNOT FOR APPENDICEAL STUMP CLOSURE IN LAPAROSCOPIC APPENDICECTOMY

J John Kennedy¹, H. Syed Ahamed Kamil², D. Nirmal Raj³

Received : 06/01/2023
Received in revised form : 06/02/2023
Accepted : 19/02/2023

Keywords:

Non-absorbable polymer clips; Hem-o-Lok clips; Roeder's knot; Appendiceal stump; Laparoscopic appendectomy.

Corresponding Author:

Dr. H. Syed Ahamed Kamil
Email: kamilmadurai@gmail.com

DOI: 10.47009/jamp.2023.5.2.91

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5 (2); 433-437



¹Assistant Professor, Department of General Surgery, Madurai Medical College, Tamilnadu, India.
²Assistant Professor, Department of General Surgery, Madurai Medical College, Tamilnadu, India.
³Senior Resident, Department of General Surgery, Vinayaka Mission Medical College, Karaikal, Puducherry, India.

Abstract

Background: Appendiceal stump closure is an important step during a laparoscopic appendectomy. The present study attempted to evaluate the ease of use and safety of HEM-O-LOK polymer clips compared to Roeder's knot in the appendiceal stump closure in patients undergoing laparoscopic appendectomy. **Materials and Methods:** This prospective randomized controlled trial was done in the Department of General Surgery, Madurai Medical College and Govt. Rajaji Hospital, for one year. A total of 60 patients diagnosed with acute appendicitis and undergoing laparoscopic appendectomy were enrolled. These patients were divided into groups of 30 each, Group-R, in whom the stump closure was done by Roeder's Knot and Group-H, in whom Hem-o-lok polymer clips did the stump closure. **Result:** In the present study, 53.33% of the patients in group R were females compared to 56% in group H (p=0.796). The mean age in group R (27.0 ± 6.19 years) and group H (27.20±11.91 years) were comparable (p=0.935). Group H (53.33%) required a lower operative Time (45 to 60 minutes) compared to group R 73.33% of the cases required operative time between 61 to 75 minutes. The mean operative time is significantly higher in group R (63.07±12.00min) than in group H (55.67±9.58min). The mean hospital stay in group R was (3.8 ± 0.80min) and in group H was (3.73±0.73min). **Conclusion:** Appendiceal stump closure with Hem-o-Lok clips is advantageous for ease of use and safety. It has less operative time than Roeder's knot in appendiceal stump closure during laparoscopic appendectomy.

INTRODUCTION

Acute appendicitis is one of the most common clinical presentations requiring emergent intervention. The lifetime incidence of this condition is about 8%.^[1] People between 10 and 20 years of age are the most affected.^[2] A male preponderance exists, with a male-to-female ratio of 1.4:1 and the overall lifetime risk is 8.6% for males and 6.7% for females.^[3] Obstruction of the lumen is the dominant factor for acute appendicitis, and faecoliths are the usual cause of obstruction. Other causes of obstruction are worms, tumors, lymphoid hyperplasia and others.^[4-5]

Since its first description by Fitz in 1886, there have been many papers about acute appendicitis, and the consequences include perforation.^[6] The surgical management of appendicitis has recently advanced from open techniques to minimally invasive methods

like laparoscopic and Robotics. The gold standard for appendectomy is Laparoscopic Appendectomy (LA), even for complicated appendicitis. Studies have shown that LA has varied advantages.^[7] Patients undergoing LA experience reduced wound infections and required less intra-operative and post-operative analgesia, a reduced hospital stay, an early return of normal bowel function, and a good cosmetic tool to avoid large laparotomy scars.^[8] Intra-abdominal abscesses, higher costs and lengthy procedure time are some disadvantages. The technique of stump closure influences the chances of abscess formation.^[9] Although the surgical technique of laparoscopic appendectomy has been well established, concerns and controversy exist regarding the closure of the appendiceal stump during surgery, which is a key point in the procedure. During laparoscopic appendectomy (LA), an important step in the procedure is the closure of the appendiceal

stump. Post-operative complications can occur from its inappropriate closure. The development of dangerous occurrences such as enterocutaneous fistulas, peritonitis, and sepsis is feared and undesirable.^[10]

Several changes to the original procedure with newer modalities have been introduced for optimizing and controlling the appendiceal stump closure, such as ultrasonically activated scalpel, instrument-assisted knotting, bipolar coagulation, slipknot tying, metal clip, Hem-o-lok clip, endoloop, double endoloop and linear endo staplers. Polymeric clips, pre-knotted loops and staplers are currently used for stump closure. The finest method is not known, and that topic is debatable.^[11-12]

Roeder's knot tying is the most commonly used procedure for ligating the Appendiceal stump. Controversies about the efficacy and safety of these novel materials still exist, and the need to evaluate this through new research has become important.^[13]

An innovative appliance for appendicular stump closure is the Hem-o-Lok clip. Recently, some studies have reported the safety of using the Hem-o-Lok clip to close the appendicular stump. Additionally, the safety of using Hem-o-Lok clips for the ligation of vessels, ureters, and bile ducts has been documented in over 1,000 surgical procedures. Thus, it is well known that using Hem-o-Lok clips is safe, and its application is easy and fast.^[10,12]

This study was conducted to assess the ease of use and safety of Hem-o-Lok clips compared to Roeder's knot in the appendiceal stump closure and to compare intraoperative and post-operative complications and hospital stay among patients undergoing laparoscopic appendectomy.

MATERIALS AND METHODS

This prospective randomised control trial was conducted on patients diagnosed with appendicitis undergoing Laparoscopic appendectomy in the General Surgery Department of General Surgery, Madurai Medical College, for one year. Institutional ethical committee approval and written consent were taken before the start of the study.

The preoperative diagnosis of acute appendicitis was confirmed by ultrasound abdomen & pelvis, revealing either probe tenderness in the Right Iliac Fossa or an aperistaltic, tubular Appendix. The patients were divided into two groups: In Group H, Hem-o-lok clips were used, and in Group R, Roeder's Knot was used.

Both groups explained the details of the surgical procedure & written informed consent was taken. The same surgeon performed laparoscopic appendectomies. Chromic catgut suture was used to carry out Roeder's knot in Group R. The sample size of each group was calculated as 30 patients.

Inclusion criteria: Patients of either sex aged from 18 to 60 who are diagnosed with uncomplicated

Appendicitis cases are willing for Laparoscopic appendectomy. Ages between 18 to 60 years were included.

Exclusion criteria: Patients with acute perforated appendicitis and local or diffuse peritonitis and unfit/contraindicated for Laparoscopic Surgeries. Patients who refused to participate were excluded.

The patient was placed in a supine position, combined with the Trendelenburg position and left lateral position (10–15°, inclined towards the surgeon). The surgeon and an assistant stand on the left side, and the monitor is on the patient's right side. The surgical procedure is performed under general anaesthesia. The bladder was decompressed with a Foley catheter to avoid injury during the insertion of the suprapubic ports.

Through the umbilicus, a 10mm port was inserted, pneumoperitoneum was created & another 10 mm port was inserted in the midline lower pelvic region, and one 5-mm trocar was inserted in the right lower quadrant. After that, the abdominal cavity was inspected. The mesoappendix was skeletonized from the top to the base using cautery placed through the left lower quadrant port. The base of the appendix was then isolated. In group H, Hem-o-lok clips are passed through the 10mm port and secured at the base of the appendix. Two more clips are placed 5 mm apart & a third one is 1cm distal from the two. In group R, a Roeder's Knot (Chromic catgut suture) is introduced similarly through the same port. The appendix is transected between the ties, leaving two loops/clips on the caecal end. After resectioning the appendix, it is retrieved through a 10 mm trocar. The diagnosis was correlated with the Histopathology report. Post-operative management was monitored for any complications till discharge from the hospital. The skin sutures were removed between post-operative days seven to ten. All patients followed up for the first two months after surgery.

Student unpaired t-tests and Chi-square tests were used to compare both groups, and a p-value < 0.05 was accepted as statistical significance. Diagnosis of acute appendicitis was based on disease history (Right Iliac Fossa pain, vomiting, nausea, anorexia, fever) and clinical signs (Mc-Burney's point tenderness, Rebound Tenderness), and laboratory tests (elevated leukocyte count).

RESULTS

A total of 60 Patients of either sex, aged from 18 to 60 years, were selected and divided into two equal groups Group-H, in which Hem-o-lok clips were used and Group-R, in which Roeder's Knot was used. Female predominance was reported in both groups. The maximum number of patients was reported in the age group of 18 to 30 years, with a mean age of 27±6.2 years in group R and 27.2±27.2 years for Group H patients [Table 1].

Table 1: Observation of demographic and other variables of patients in both groups

Variables	Group R	Group H	p-value by 't-test
Gender			
Female	16 (53.3%)	17 (56.7%)	0.796
Male	14 (46.7%)	13 (43.3%)	
Age Group			
18 to 30	22 (73.3%)	22 (73.3%)	0.064
31 to 40	8 (26.7%)	3 (10.0%)	
41 to 50	0	3 (10.0%)	
51 to 60	0	2 (6.7%)	
Mean Age years \pm SD	27.0 \pm 6.198	27.20 \pm 11.915	0.935
Weight (Kg \pm SD)	64.40 \pm 11.40	65.93 \pm 12.98	0.629
Height (cm \pm SD)	151.07 \pm 12.37	154.60 \pm 15.15	0.327
Pulse rate(min \pm SD)	92.80 \pm 17.81	92.30 \pm 20.632	0.92
Respiratory rate (min \pm SD)	14.30 \pm 1.11	14.10 \pm 1.29	0.525
Temperature ($^{\circ}$ C \pm SD)	99.01 \pm 1.42	98.99 \pm 1.59	0.946
Haemoglobin (g % \pm SD)	11.63 \pm 1.47	11.58 \pm 1.33	0.898
Urine analysis			
Pus cell	2 (6.7%)	0	0.150
No abnormalities	28 (93.3%)	30 (100.0%)	
Appendicitis			
Acute appendicitis	25 (83.33%)	22 (73.3%)	0.347
Recurrent appendicitis	5 (16.67%)	8 (26.7%)	

The mean weight, height, pulse rate, respiratory rate, temperature and haemoglobin were comparable in both groups. The pus cells in urine were reported in 2 (6.7%) patients in group R, whereas in Group H, no patients were found with pus in urine [Table 2].

Table 2: Observation of operating time and hospital stay in patients of both groups

Variables	Group R	Group H
Operating time (min)	45 to 60	5 (16.67%)
	61 to 75	22 (73.33%)
	76 to 90	3 (10.0%)
Hospital stays (Days)	3	7 (23.3%)
	4	11 (36.7%)
	5	10 (33.3%)
	6	1 (3.3%)
	7	1 (3.3%)

The incidences of acute appendicitis were higher in Group R 25 (83.3%) than in Group H, with 22 (73.3%) patients. The hospital stay and operating time were also higher in Group R patients than in Group H patients. The intraoperative and post-operative complications were similar in both Groups [Table 3].

Table 3: Observations of intra-operative and post-operative complications in patients of both groups

	Group R	Group H
Intra-operative complications	Observation N (%)	
Subcutaneous emphysema	1 (3.3%)	1 (3.3%)
Absent	29 (96.7%)	29 (96.7%)
p-value	0.754	
Post-operative complications		
Abdominal pain	3 (10.0%)	3 (10.0%)
p-value	1.000	
Surgical site infection	2 (6.7%)	4 (13.3%)
p-value	0.389	
Absent	25 (83.3%)	23 (76.7%)

DISCUSSION

A total of 60 patients diagnosed with acute, chronic, or recurrent appendicitis scheduled for laparoscopic appendectomy were studied. Based on the method of appendiceal stump closure, these patients were divided into groups of 30 each by COIN TOSE METHOD as GROUP R (Patients underwent

appendiceal stump closure with Roeder's Knot) and GROUP H (Patients underwent appendiceal stump closure using Hem-o-lok clips). The patients were evaluated for operative time, intra-operative and post-operative complications, hospital stay and follow-up period.

In the present study frequency of females was slightly high in both groups. In group R, 53.33% of the patients were females; in group H, 80 females

constituted 56.7%. The female-to-male ratio in group R was 1.14:1 compared to 1.50:1. In group H. Though the appendix was common among females in both groups, the difference was statistically insignificant ($p=0.796$).

The incidence of appendicitis gradually rises from birth, peaks in the late teen years, and gradually declines in the geriatric years.^[14] In this study, the commonest age group was 18 to 30 years in group R (73.3%) and group H (73.3%) ($p=0.064$). The mean age in group R (27.0 ± 6.19 years) and group H (27.20 ± 11.95 years) were comparable ($p=0.935$). These findings suggest that most patients who presented with appendicitis were young. Most earlier studies 28,31 in the literature have observed that appendicitis is common in the younger age group.^[15]

Overall the demographic characteristics of the study population were comparable in group R and group H ($p>0.050$). Further, the history of associated illness (including diabetes mellitus, hypertension and previous surgery), clinical signs (guarding, rebound tenderness, and Rovsing's sign) and symptoms (including fever, pain migration to RIF, anorexia, nausea and vomiting) did not differ significantly in groups R and group H ($p>0.050$). The comparison of anthropometric variables (Height and weight), vitals (pulse rate, respiratory rate, temperature) and haemoglobin levels and urine analysis were also comparable. The majority of patients in group R (83.33%) and group H (73.3%) were diagnosed to have acute appendicitis ($p>0.050$).

An important step to avoid post-operative infectious complications is appendiceal stump closure. Endoloops, endoclips and endo staplers are used for this procedure. With each method having its advantages and disadvantages, various methods are being studied and tried for the same.

Any one of the methods cannot be preferred as the literature is mixed in this context. There are many studies where staplers are compared to endoloops. In two reviews, routine use of endostapler is preferred, especially in the case of an inflamed appendix base, because complications were lesser compared to endoloops.^[16-17] In contrast, endoloops were considered superior because of complication rates compared to staplers. Still, much lower costs in another review, consisting of five RCTs having 622 patients.¹¹ Longer operation time associated with endoloops led to higher costs in these studies. Also, placement and tightening the loop around the appendiceal base experience are required, and this can be counted as a disadvantage.^[18]

More than 20 years ago, the use of endoclips for appendicular stump closure was described. Despite this, it is less investigated and less commonly used. The diameter of the appendix base and the severity of inflammation limits the use of the endoclips. Clips can be used safely to close the appendiceal base in selected cases shown in small studies.^[9]

In the present study, a significantly higher number of patients in group H (53.33%) had lower operative times, that is, 45 to 60 minutes, compared to group R

as the majority of the patients, i.e. (73.33%) had operative time between 61 to 75 minutes ($p<0.05$). These findings suggest that appendiceal stump closure during laparoscopic appendectomy requires significantly lower operative time using Hem-o-lok clips compared to Roeder's knot. Large cohort studies reported shorter operation times when endostaplers were used (51.7 to 58 min) compared to endoloops (53.4 to 60 min). Findings of the present study were also comparable when metal clips were used instead of intracorporeal knotting techniques in two recent small randomized trials with shorter operative time. In several studies, polymeric non-metal clips have been used, resulting in reduced costs, shorter operation times and comparable complication rates. The optimal device for appendiceal stump closure should offer maximum patient safety and result in a safe stump closure with a low rate of complications. In this study, 3.33% of the patients in group H and 3.33% in Group R had intraoperative complications of SE (Subcutaneous Emphysema). However, this difference was statistically not significant ($p=0.300$). Post operatively, in Group H, complications of AP (Abdominal Pain) were noted in 10%, while in group R, 16.67%. Though the frequency of post-operative complications in group R is high, the difference was statistically insignificant ($p=0.754$). These findings suggest that the frequency of intraoperative and post-operative complications is less likely using Hem-o-lok clips. But comparable with appendiceal stump closure with Roeder's knot.

Only a few studies are available on polymer or metal clips for appendix stump closure. The rate of intra-abdominal Abscess in these studies ranges from 1% to 1.6%.⁹ Recently, two randomized trials found comparable complication rates when clips were used instead of intracorporeal knotting techniques.^[19]

In the present study, the mean operative time is significantly high in group R (63.07 ± 12.00 min) compared to group H (55.67 ± 9.58 min) with a p-value of ($p=0.011$), which is statistically significant. The mean hospital stay in group R was (3.8 ± 0.80 min), and in group H was (3.73 ± 0.73 min) with a p-value of ($p=0.725$) with no significance statistically. However, the mean follow period in both groups was two months. The 2 to 5.9 days was the median hospital stay found in other recent studies, with no significant differences between the different methods of appendiceal stump closure.^[18, 20]

Overall the result of this study suggests that Hem-o-lok clips are safe, and they shorten the operative time and simplify the procedure. Thus the Hem-o-lok clips can be a useful alternative to Roeder's knot for appendiceal stump closure. However, this study's limitation is that the follow-up period was insufficient to discuss the long-term side effects of Hem-o-lok clips.

CONCLUSION

The present study concluded that Hem-o-lok clips were safe and easy to apply compared to Roeder's knot tying. Moreover, Hem-o-lok clips also require less operative time than Roeder's knot.

REFERENCES

1. Addiss DG, Shaffer N, Fowler BS, Tauxe RV. The epidemiology of appendicitis and appendectomy in the United States. *Am J Epidemiol* 1990; 132:910-25.
2. Humes DJ, Simpson J. Acute appendicitis. *Br Med J* 2006; 333:530-4.
3. Sirikurnpiboon S, Amornpornchareon S. Factors Associated with Perforated Appendicitis in Elderly Patients in a Tertiary Care Hospital. *Surg Res Pract* 2015:Article ID 847681:6 pages.
4. Machado NO, Chopra P, Pande G. Appendiceal tumour-retrospective clinicopathological analysis. *Trop Gastroenterol* 2004; 25:36-9.
5. Arca MJ, Gates RL, Groner JI, Hammond S, Caniano DA. Clinical manifestations of appendiceal pinworms in children: an institutional experience and a review of the literature. *Pediatr Surg Int* 2004; 20:372-5.
6. Estrada J, Petrosyan M, Barnhart J, Tao M, Sohn H, Towfigh S, et al. Hyperbilirubinemia in appendicitis: a new predictor of perforation. *J Gastrointest Surg* 2007; 11:714-8.
7. Guller U, Hervey S, Purves H, Muhlbaier LH, Peterson ED, Eubanks S, et al. Laparoscopic versus open appendectomy: outcomes comparison based on a large administrative database. *Ann Surg* 2004; 239:43-52.
8. Ruffolo C, Fiorot A, Pagura G, Antoniutti M, Massani M., Caratozzolo E, et al. Acute appendicitis: what is the gold standard of treatment? *World J Gastroenterol*. 2013; 19:8799-807.
9. Rickert A, Bönninghoff R, Post S, Walz M, Runkel N, Kienle P. Appendix stump closure with titanium clips in laparoscopic appendectomy *Langenbecks Arch Surg* 2012; 397:327-31.
10. Caglià P, Tracia A, Spataro D, Borzi L, Lucifora B, Tracia L, Amodeo C. Appendix stump closure with endoloop in laparoscopic appendectomy. *Ann Ital Chir* 2014; 85:606-9.
11. Kazemier G, Hof KH, Saad S, Bonjer HJ, Sauerland S. Securing the appendiceal stump in laparoscopic appendectomy: evidence for routine stapling? *Surg Endosc* 2006; 20:1473-6.
12. Sajid MS, Rimple J, Cheek E, Baig MK. Use of endo-GIA versus endoloop for securing the appendicular stump in laparoscopic appendectomy: a systematic review. *Surg Laparosc Endosc Percutan Tech* 2009; 19:115-8.
13. Ates M, Dirican A, Ince V, Ara C, Isik B, Yilmaz S. Comparison of Intracorporeal Knot-tying suture (Polyglactin) and Titanium Endoclips in Laparoscopic Appendiceal Stump Closure: A Prospective Randomized study *Surg Laparosc Endosc Percutan Tech* 2012; 22:226-31.
14. Lohar HP, Asger Calcuttawala MA, Nirhale DS, Athavale VS, Malhotra M, Priyadarshi N. Epidemiological aspects of appendicitis in a setup. *Med J DY Patil Univ* 2014; 7:753-7.
15. Buckius MT, McGrath B, Monk J, Grim R, Bell T, Ahuja V. Changing of 1993 epidemiology of acute appendicitis in the United States: Study peri 2008. *J Surg Res* 2012. 175:185-90.
16. Gorter RR, Heij HA, Eker HH, Kazemier G. Laparoscopic appendectomy: State of the art. The tailored approach to the application of laparoscopic appendectomy? *Best Pract Res Clin Gastroenterol* 2014; 28:211-24.
17. Browne DS. Laparoscopic-guided appendectomy. A study of 100 consecutive cases. *Aust N Z J Obstet Gynaecol*. 1990; 30:231-3.
18. Beldi G, Vorburger SA, Bruegger LE, et al. Analysis of stapling versus endoloops in appendiceal stump closure. *Br J Surg*. 2006; 93:1390-3.
19. Gonenc M, Gemici E, Kalayci MU, Karabulut M, Turhan AN, Alis H. Intracorporeal knotting versus metal endoclip application for the closure of the appendiceal stump during a laparoscopic appendectomy in uncomplicated appendicitis. *J Laparoendosc Adv Surg Tech A* 2012; 22:231-5.
20. Swank HA, van Rossem CC, van Geloven AW, Hof KH, Kazemier G, Meijerink WJHI, et al. Endostapler or endoloops for securing the appendiceal stump in laparoscopic appendectomy; a retrospective cohort 103 study. *Surg Endosc* 2014; 28:576-837.