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Comparison Between Hem-O-Lok Clips Versus Roeder's Knot in Laparoscopic Appendiceal Stump Closure

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Abstract: ***Purpose**: The closure of the appendiceal stump, a crucial step in the process, has generated controversy and concerns despite the well-established surgical method of laparoscopic appendectomy. Several modifications to the original technique with new materials have been introduced for enhancing and controlling the appendiceal stump closure, such as endoloop, double endoloop, ultrasonically activated scalpel, instrument-assisted knotting, bipolar coagulation, slipknot tying, metal clip, Hem-o-lok clip, and linear endostaplers. The present study was an attempt to evaluate the ease of use and safety of Hem-o-lok clips compared to Roeder's knot in the appendiceal stump closure in patients undergoing laparoscopic appendectomy by comparing complications (intraoperative and postoperative), hospital stay and follow up period. **Methods**: 100 patients with appendicitis who underwent laparoscopic appendectomy were selected. Depending on the intervention, these patients were split into two groups of 50 each: Group R (which underwent laparoscopic appendiceal stump closure using Roeder's Knot) and Group H (which underwent laparoscopic appendiceal stump closure using Hem-o-lok clips). **Results**: 54.00% of patients in group R and 60% of patients in group H were female in the current study (p=0.6023). Groups R and H had similar mean ages (30.06 ± 9.04 years and 28.23 ± 11.23 years, respectively; p=0.372). Groups R and H's preoperative characteristics were similar to each other in terms of other factors (p>0.050). A considerably greater proportion of patients (54.00%) in group H needed less time during surgery (45 to 60 minutes), while 74.00% of cases in group R needed more time during surgery (61 to 75 minutes). When comparing group R to group H, the mean operative duration was substantially higher (p<0.05). On the other hand, both groups' intraoperative complications (p=0.300) and postoperative complications (p=0.601) were similar (p>0.050). **Conclusion**: Hem-o-lok clips are beneficial for appendiceal stump closure because they need less time to operate on, and are simpler to use.*

Keywords: Appendiceal stump closure; Roeder's knot; Hem-o-lok clips

1. Introduction

One of the most common clinical presentations that need immediate medical attention is acute appendicitis. The condition has a life time incidence of approximately 8% [1,2]. Most individuals affected are between the ages of 10 and 20 [2]. There is a 1.4:1 male- to-female ratio, suggesting a higher proportion of male. The overall lifetime risk is 6.7% for female and 8.6% for male [1-3]. Acute appendicitis is mostly caused by lumen obstruction, with faecoliths being the most common source of this obstruction. Tumours, intestinal worms, lymphoid hyperplasia, and other diseases may also be the cause of the obstruction [4,5].

Many articles about acute appendicitis and its effects, including perforation, have been written since Fitz's 1886 first description of the condition [6]. Minimally invasive procedures have replaced open procedures in the surgical therapy of appendicitis throughout time. Laparoscopic Appendectomy (LA) is currently the gold standard for appendicitis. Research has demonstrated the many benefits of LA [7,8].

Less wound infections, shorter hospital stays, less need for postoperative analgesics, a prompt recovery of normal bowel function, and an excellent cosmetic result are all experienced by patients undergoing laparoscopic procedures [8]. Its drawbacks include longer surgery times, increased expenses, and intra- abdominal abscesses [9,10]. It appears that the stump closure method affects the likelihood of an abscess formation [11].

The closure of the appendiceal stump, a crucial step in the process, has generated controversy and concerns despite the well- established surgical method of laparoscopic appendectomy. Closing the appendiceal stump is an essential step in the laparoscopic appendectomy process. Inappropriate sealing of the wound may result in post-operative problems. It is anticipated and unwanted when harmful events like sepsis, peritonitis, and enterocutaneous fistulas emerge

Several modifications to the original technique with new materials have been introduced for enhancing and controlling the appendiceal stump closure, such as endoloop, double endoloop, ultrasonically activated scalpel, instrument-assisted knotting, bipolar coagulation, slipknot tying, metal clip, Hem-o-lok clip, and linear endostaplers. For stump closure, staplers, pre-knotted loops, and polymeric clips are now in use. The best approach is unknown and a contentious topic [13-15]. For ligation of the appendiceal stump, Roeder's knot tying is the method most frequently applied. It is now essential to assess the ongoing debates on the safety and effectiveness of these innovative materials with additional study [16].

The Hem-o-lok clip is a novel device for appendicular stump closure. The safety of closing appendicular stumps with the Hem- o-lok clip has been documented in a few recent studies [6-9]. Furthermore, over a thousand surgical procedure

shave demonstrated the safety of Hem-o-lok clips for the ligation of arteries, ureters, and cystic ducts [12-14]. Therefore, it is already widely recognized that using Hem-o-lok clips is safe and that applying them is simple and quick.

The purpose of this study was to compare intraoperative and postoperative challenges, hospital stays, and the simplicity of use and safety of Hem-o-lok clips over Roeder's knot in the appendiceal stump closure among patients undergoing laparoscopic appendectomy.

2. Methods

Study design and settings

The present randomized controlled trial was done in the Department of General Surgery, more than 1000 bedded Shree Krishna hospital, attached to Pramukh Swami Medical College, Karamsad over a period of 12 months from February 2023 to February 2024. The institution's ethics committee approved the study on 30.09.2023.

Inclusion criteria

- Diagnosed Appendicitis cases, willing for Laparoscopic
- Appendectomy, Age between 12 to 70 years. Clinically diagnosed as uncomplicated appendicitis.

Exclusion criteria

- Patients who refuse to participate. Patients unfit/ contraindicated for Laparoscopic Surgery.

Objectives

Primary objective was to analyze the simplicity of use & safety of Hem-o-lok clips compared to Roeder's knot in the Appendiceal Stump closure in Laparoscopic Appendectomy. Secondary objective was to compare Intra operative complications, Post operative complications, and Hospital stays.

Sampling procedures

Due to the lack of proven data on prevalence, the exact size cannot be calculated. Therefore, purposive sampling is used for feasibility of this study. According to the rule of thumb, sample size of 100 divided into two groups of 50 each was planned. 100 patients with appendicitis age group between 12 to 70 years who underwent laparoscopic appendectomy were selected. Depending on the intervention, these patients were split into two groups of 50 each: Group R (which underwent laparoscopic appendiceal stump closure using Roeder's Knot) and Group H (which underwent laparoscopic appendiceal stump closure using Hem-o-lok clips). Observations were made in each group and compared to the other group.

Sample size

The exact size cannot be determined because there is no evidence of established prevalence. As a result, 50 samples from each group are examined, resulting in a sample size of 100 according to the general rule.

Statistical analysis

Student unpaired-t test and Chi-square tests were used to compare both groups, A p-value <0.05 was accepted as statistically significance. Diagnosis of acute appendicitis was based on disease history (Right Iliac Fossa pain, vomiting, nausea, anorexia, fever) and clinical signs (McBurney's point tenderness, Rebound Tenderness), and laboratory tests (elevated leukocyte count). The preoperative diagnosis of acute appendicitis was confirmed by ultrasound abdomen & pelvis revealing either probe tenderness in the Right Iliac Fossa orana peristaltic, tubular Appendix. Both the groups were explained the detail of the surgical procedure & a written informed consent was taken. Laparoscopic appendectomies were performed by the conventional method (2-(5mm) ports and 1-(10mm) port). Vicryl 1-0 suture was used to carry out Roeder's knot in Group R.

3. Result

54.00% of patients in group R and 60% of patients in group H were female in the current study (p=0.6023). Groups R and H had similar mean ages (30.06 ± 9.04 years and 28.23 ± 11.23 years, respectively; p=0.372). Groups R and H's preoperative characteristics were similar to each other in terms of other factors (p>0.050). A considerably greater proportion of patients (54.00%) in group H needed less time during surgery (45 to 60 minutes), while 74.00% of cases in group R needed more time during surgery (61 to 75 minutes).

When comparing group R to group H, the mean operative duration was substantially higher (p<0.05). On the other hand, both groups' intraoperative complications (p=0.300) and postoperative complications (p=0.601) were similar (p>0.050).

4. Discussion

Even though the surgical technique for laparoscopic appendectomy has been well established, there is still debate over closure of the appendiceal stump. During a laparoscopic appendectomy, pre- knotted loops, also known as Roeder loops or endoloops, were first placed to the stump. After its introduction, the use of linear staplers in laparoscopic appendectomy became "en vogue," especially for perforations at the base of the appendix. Loop slippage may be the cause of post-operative infections. Loops are not safe if the appendix's base is punctured or if the inflammation has affected the caecum. Tight loops can produce stump leaking, which can rip through tissues due to tissue necrosis [17-22].

Because they are affordable, safe, and simple to use, hem-o-lok clips are the most often used clips in minimally invasive surgery. However, they have not been routinely utilised for appendiceal stump closure in laparoscopic appendectomy.

The frequency of females in both groups in the current study was somewhat higher than average. While females made up 60% of patients in group H, 54.00% of patients in group R were female. In group R, the female to male ratio was 1.14:1, while in group H, it was1.50:1 within group H. Despite the fact that both groups' female members shared an appendix, the difference was not statistically significant (p=0.602).

From birth, the incidence of appendicitis climbs steadily, peaks in late adolescence, and then progressively falls as people age.17,18 The study found that group R (64.00%) and group H (70%) had the highest age group, which was 12 to 25 years old (p=0.253). Group R's mean age was 30.06 ± 9.04 years, while group H's mean age was 28.23 ± 11.23 years. These results imply that a large proportion of the appendicitis patients were young. The majority of past research investigations [17,18] in the literature have noted that appendicitis is more common in younger people.

Overall, group Rand group H's demographic characteristics were similar to those of the study population overall (p>0.050). Additionally, groups R and H did not significantly differ in the history of concomitant illnesses (diabetes mellitus, hypertension, and prior surgery), clinical signs (guarding, rebound tenderness, and Rovsing's sign), or symptoms (fever, pain migration to RIF, anorexia, nausea, and vomiting). Anthropometric factors (weight and height), vital signs (haemoglobin levels, systolic and diastolic blood pressure, temperature, pulse rate, breathing rate), and urine analysis were also compared. It was determined that the majority of patients in groups R (84.00%) and H (80%) had acute appendicitis (p>0.050).

Since there is a lack of consistency in the literature, it is impossible to favour one strategy over another. Staplers and endoloops are compared in numerous studies. According to two reviews, routine use of endostaplers is preferable since there were fewer difficulties with them than with endoloops, particularly in cases of an inflamed appendix base [15,21]. In contrast, a different evaluation that included five RCTs with 622 patients found that endoloops were preferable due to decreased costs and complication rates when compared to staplers [13]. In these investigations, longer operation times related to endoloops resulted in greater expenditures. Experience is also necessary for the positioning and tightening of the loop around the appendiceal base. One could consider this a drawback [20].

Compared to group R, a considerably larger proportion of patients in group H (54.00%) had surgical times between 45 and 60 minutes, whereas the majority of patients in group R (74.00%) had operative times between 61 and 75 minutes (p<0.05). Compared to group R, group H's mean operating time was substantially shorter (60.76 ± 11.07 *vs.* 67.6 ± 8.98 minutes; p<0.050). These results imply that, when utilising Hem-o-lok clips instead of Roeder's knot for appendiceal stump closure during laparoscopic appendectomy, operating time can be greatly reduced (Figure 1).

The study found that there was no significant difference in the mean hospital stay between groups H and R (3.73 ± 0.73 days *vs.* 3.80 ± 0.80 days, p=0.725). Nonetheless, for both groups, the average follow-up period was two months. Other recent studies indicated a median hospital stay of 2 to 5.9 days, with no statistically significant differences between the various techniques for appendiceal stump closure [19,20,23,24] (Table 1-3).

Overall, the study's findings point to the safety, simplicity, and reduction in operating time of Hem-o-lok clips. With appendiceal stump closure, the Hem-o-lok clips can therefore be a helpful

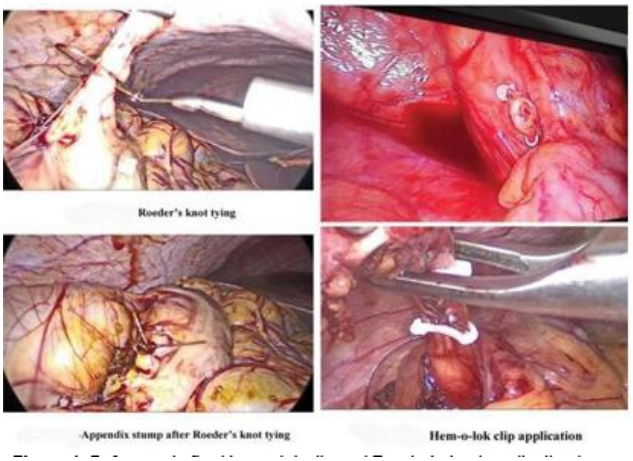

Figure 1: Before and after Hem-o-lok clip and Roeder`s knot application in appendiceal stump.

Table 1: Comparison of operative time.

Operative time (min)	Group R (n-50)		Group H (n=50)	
	No.	%	No.	%
45 to 60	8	16	27	54
61 to 75	37	74	20	40
76 to 90	5	10	3	6
Total	50	100	50	100

In the present study, the 54% of the patients in group H, the duration of operation ranged between 45 to 60 minutes while in group R 74 % of the cases required operative time between 61 to 75 minutes. This difference was statistically significant (p<0.050).

Table 2: Comparison of intraoperative complications

Complications	Group R (n=50)		Group H (n=50)	
	No.	%	No.	%
Subcutaneous Emphysema (SE)	45	90	48	96
No Complications	50	100	50	100
Total	5	10	2	4

In the present study intra operative complications of Subcutaneous Emphysema were noted in 10% of the patients in group R compared to 4% of the patients in group T but statistically, the difference was not significant (p=0.300).

Table 3: Comparison of postoperative complications.

Complications	Group R (n=50)		Group H (n=50)	
	No.	%	No.	%
Abdominal pain (AP)	8	16	5	10
Surgical site infection (SSI)	4	8	2	4
No Complications	38	76	43	86
Total	50	100	50	100

In this study, postoperatively, abdominal pain and Surgical Site Infection were present in 16.00% and 8.00 % of the patients in group R compared to 10% and 4.00 % in group H respectively. However, this difference was statistically not significant (p=0.6013). Substitute for Roeder's knot. This study's weakness, though, is that there was insufficient follow-up time to address the long-term adverse

consequences of Hem-o-lok clips.

5. Conclusion

Overall, the current study comparing Roeder's knot with Hem- o-lok clips in laparoscopic appendiceal stump closure revealed that Hem-o-lok clips were superior to Roeder's knot in a number of ways. These are the following: They were safe to use. Hem-o- lok clips were simpler to use and required less time to tie than Roeder's knots.

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