https://doi.org/10.21608/zumj.2023.245252.2984

Volume 30, Issue 1, January 2024

Manuscript ID ZUMJ-2310-2984 (R1) DOI 10.21608/ZUMJ.2023.245252.2984

## **ORIGINAL ARTICLE**

Hem-o-Lok clip versus extracorporeal sliding knot during Laparoscopic appendectomy, A prospective randomized clinical trial.

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Submit Date 2023-10-28 Revise Date 2023-11-02 Accept Date 2023-11-05

#### **ABSTRACT**

**Background:** The most common surgical disease is acute appendicitis. Appendicular stump closure is the most crucial part in appendectomy. The aim of the present study was to compare outcomes of Hem-o-lok clip and extracorporeal sliding knot in appendicular stump closure during L-APPE.

**Methods:** This study was designed as prospective randomized clinical trial for evaluation of the outcomes of appendix stump closure with Hem-o-lok clip or extracorporeal sliding knot during L-APPE. This study was carried out in Zagazig University Hospitals, Egypt. All patients diagnosed as acute appendicitis patients and operated by L-APPE at Zagazig University Hospital during the period from 1<sup>st</sup> of September 2020 till 31<sup>st</sup> of March 2022 were assessed for study eligibility.

**Results:** In total, 160 patients (80 patients in each arm) were enrolled into the study. No difference in hospital stay in both groups but operative time was noted in the hem-o-lok group (group I) of patients  $35.45 \pm 9.24$  minutes in Hemo-lok group, but in the extracorporeal knot group (group II) it was  $44.15 \pm 7.51$  minutes. Regarding postoperative complications, 2 patients (2.5%) within group I had superficial infection versus three patients (3.8%) within group II. While two patients (2.5%) within group I had one patient (1.2%) deep infection

versus within group II overall 3 cases (1.8%) of deep infection in both groups  $\,$ 

**Conclusions:** Hem-o-lok clip is safe and effective method in appendicular stump closure during L-APPE with less operative time.

**Keywords:** Laparoscopic appendectomy, Acute Appendicitis, appendicular stump closure, hem-o-lok clips, appendectomy.

#### INTRODUCTION

The most common surgical disease is acute appendicitis with 7–8% lifetime risk. The first laparoscopic-assisted appendectomy was performed by Hans de Kok in 1977, but Semm is the first one to publish about laparoscopic appendectomy (L-APPE) in 1983. [1]

Many studies have shown that L-APPE is better than open appendectomy due to reduced intensity of postoperative pain, surgical site infection rate, hospital stay length, and L-APPE also associated with better quality of life. [2] Appendicular stump Closure is the most crucial part of L-APPE. For prevention of serious complications postoperatively e.g. sepsis, abscesses and peritonitis, safe and effective closure of the stump is required. [3]

The exemplary technique for appendicular stump closure should be easy to use, accessible, safe, and inexpensive. A lot of various technique have been invented for closure of appendicular stump, included: Endoloop, non absorbable polymer clips (Hem-o-lock), titanium clips, staplers,

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extracorporeal sliding knot, intracorporeal ligation, Ligasure. [4]

The utilization of the nonabsorbable hem-o-lok clips which are polymer structures for ligation of bile ducts, ureters, and vessels, has been documented in over 1,000 surgical procedures. [5]

Closure of appendicular stump with Hem-o-lok clip has been investigated in some studies which reported the safety of its use, which is easy and cheap. [4]

We conducted this study to compare the use of Hem-o-lok clip and extracorporeal sliding knot for appendicular stump closure during L-APPE. The study is a single-center prospective randomized trial.

Our aim in this study is to compare outcomes of Hem-o-lok clip and extracorporeal sliding knot in appendicular stump closure during L-APPE. Our primary outcome is the stump leak and operative time, secondary outcome is other measures like hospital stay length.

#### **METHODS**

This study was designed as prospective randomized clinical trial for evaluation of the outcomes of appendix stump closure with Hem-olok clip or extracorporeal sliding knot during L-APPE. This study was carried out in Zagazig University Hospitals, Egypt. All patients diagnosed as acute appendicitis patients and operated by L-APPE at Zagazig University Hospital during the period from 1<sup>st</sup> of September 2020 till 31<sup>st</sup> of March 2022 were assessed for study eligibility.

Study approval was obtained from ethical committee of Faculty of Medicine, Zagazig University, (ref. number ZU-IRB #9906/27-9-2020). The study was performed in consonance with the Declaration of Helsinki (1964) and its subsequent amendments ethical standards.

Patients with age ≥12 years diagnosed with acute appendicitis and were candidate for L-APPE were included in the study. Patients with advanced inflammatory changes in the area of the appendicular stump or necrosis and patients who converted to laparotomy due to diffuse peritonitis were excluded from the study.

## **Randomization:**

Research Randomizer Version 4.0 at https://www.randomizer.org, an online software used for randomization of patients who fulfil the inclusion criteria and agree to participate in the study after signing of written consent. An unlabeled blue or black sealed envelope was given to each patient. The medical team know the code

of each color. The group A (Hem-o-lok clip) color code is blue while black color referred to the group B (extracorporeal sliding knot).

One of limitations in our study was sample size as not all cases of acute appendicitis performed via laparoscopy in our institution, as a result of these limitation, the trial sample size of 160 patients (80 patients in each trial arm).

## Surgical technique

Under general anesthesia laparoscopic appendectomy was performed in all patients by surgeons who had experience in advanced laparoscopic surgery. The patient position was supine with Trendelenburg position with slit tilt to the left. Three ports were placed (in periumbilical region a 10-mm port for the camera, a 5-mm port in suprapubic region and a 10-mm port in the left iliac fossa). The procedure started with proper exploration of the abdominal cavity; the appendectomy decision was made started with mesoappendix dissection using a bipolar diathermy. In the first group (group A) 2 Hem-olok clips size XL (Click'aV Plus<sup>TM</sup> Ligating Clips , GRENA ®) , were used for closure of the appendix base (two clips proximally) (Figure 1).

In the second group (group B) closure of the appendicular stump was done using a total of three vicryl extracorporeal sliding knot (two knots proximally and one distally) (Figure 2).

The appendix was removed via left iliac fossa port. Drain placement was done according to the inclination of the main surgeon which mostly in gangrenous appendicitis cases. The sheath of the umbilical port was closed under vision using vicryl 1. Broad-spectrum antibiotics were prescribed for 7 days in gangrenous appendicitis cases.

## **RESULTS**

One hundred sixty patients were included in this study, eighty patients in each group. Group (I) included the patients underwent stump closure using Hem-o-lok while group (II) included patients underwent stump closure using extracorporeal knot. Group (I) included 44 (55%) females and 36 (45%) males while in group (II) males and females were equal. The average age in group (I) was 25.55 years, in group (II) it was 26.65 years. As shown in table (1).

Regarding the operative time it was  $35.45 \pm 9.24$  minutes in Hem-o-lok group , but in the extracorporeal knot group it was  $44.15 \pm 7.51$  minutes this is statistically significant higher in group (II) as shown in table (2). The pathological

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subtype table (3) affected the operative time as shown in Figure (3) Within each group, there is statistically significant relation between appendicitis type and operative time. On doing Tukey HSD post hoc test, the difference is significant between each two types where patients with gangrenous type had significantly longer operative time followed by phlegmon then catarrhal types.

Regarding postoperative complications, 2 patients (2.5%) within group I had superficial infection versus three patients (3.8%) within group II. While two patients (2.5%) within group I had one patient (1.2%) deep infection versus within group II overall 3 cases (1.8%) of deep infection in both groups table (2).

**Table 1 :** Comparison between the studied groups regarding baseline data:

	Group I (Hem-o-lok group) N=80(%)	Group II (Extracorporeal knot) N=80 (%)	Т	P
Gender:				
Female	44 (55%)	40 (50%)	0.4018	0.527
Male	36 (45%)	40 (50%)		
Age (year):				
Mean $\pm$ SD	$25.55 \pm 8.45$	$26.65 \pm 8.43$	-0.824	0.411
<b>BMI</b> ( <b>kg/m</b> <sup>2</sup> ):				
Mean $\pm$ SD	$26.84 \pm 4.83$	$27.26 \pm 4.98$	-0.548	0.584
<b>Appendicitis:</b>				
Catarrhal	53 (66.3%)	55 (68.8%)	0.148§	0.929
Phlegmon	19 (23.8%)	17 (21.3%)		
Gangrenous	8 (10%)	8 (10%)		

t Independent sample t test \Schi square test

**Table 2 :** Comparison between the studied groups regarding operative and postoperative data:

	Group I (Hem-o-lok group) N=80(%)	Group II (Extracorporeal knot) N=80 (%)	t	P
Operative time (min)				
Mean ± SD	$35.45 \pm 9.24$	$44.15 \pm 7.51$	-6.537	<0.001**
Intraoperative	0 (0%)	0 (0%)		
complication				
LOS (hour)				
Mean ± SD	$39.9 \pm 9.88$	$41.55 \pm 8.53$	-1.131	0.26
Infection (SSRI):				
No	76 (95%)	76 (95%)	0.061§	0.805
Superficial	2 (2.5%)	3 (3.8%)		
Deep	2 (2.5%)	1 (1.25%)		

t Independent sample t test <sup>§</sup>Chi square for trend test \*\*p≤0.001 is statistically highly significant

Table 3: Relation between appendicitis pathology and operative time among the studied groups:

Type	Group I	Group II	t	P
	(Hem-o-lok group)	(Extracorporeal knot)		
	Mean ± SD	Mean ± SD		
Catarrhal	$30.3 \pm 4.08$	$40.58 \pm 3.22$	-14.558	<0.001**
Phlegmon	$41.32 \pm 4.36$	$47.06 \pm 3.09$	-4.508	<0.001**
Gangrenous	$55.63 \pm 5.63$	$62.5 \pm 5.35$	-2.505	0.025*
p§	<0.001**	<0.001**		

<sup>§</sup> p for One Way ANOVA test t independent sample t test \*\*p≤0.001 is statistically highly significant \*p<0.05 is statistically significant

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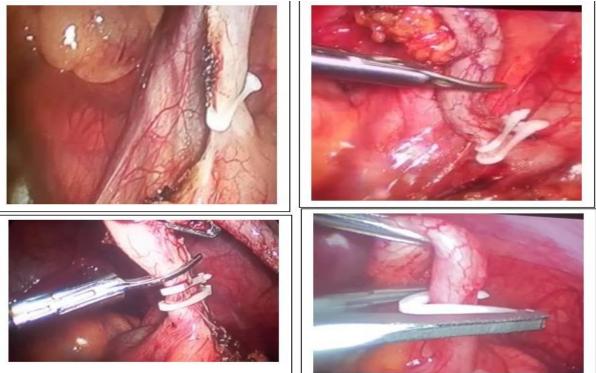
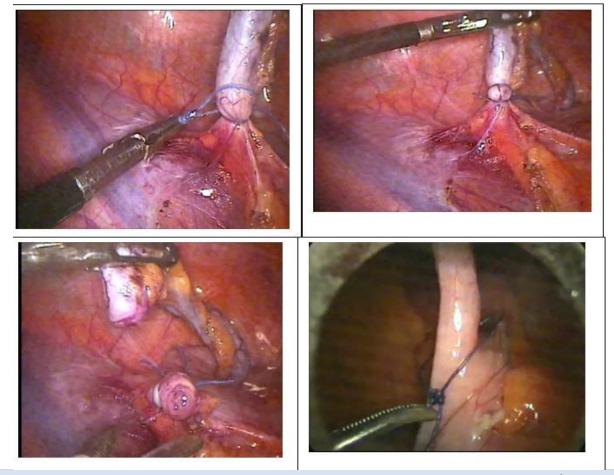
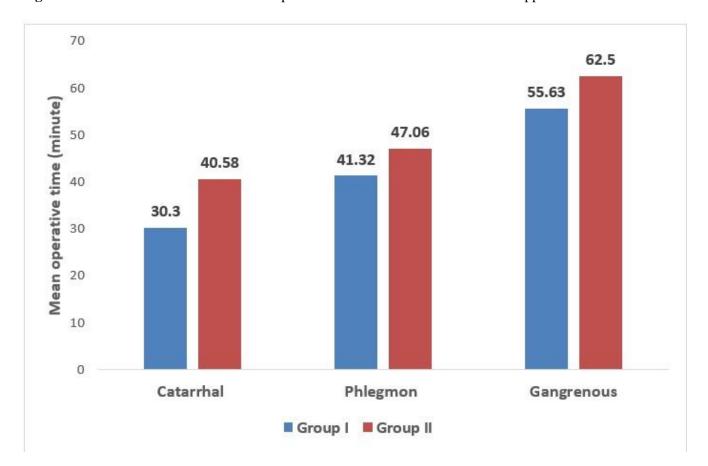


Figure 1: Different cases in which Hem-o-lok clips size XL were used for closure of the appendix base.



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**Figure 2:** Different cases in which extracorporeal knot were used for closure of the appendix base.

**Figure 3:** Multiple bar chart showing relation between operative time and type of appendicitis among studied groups.

#### DISCUSSION

Techniques for mesoappendix transection during Surgical management of acute appendicitis exhibits great heterogeneity also appendix base transection showed great variations. There is no evidence that a certain surgical technique provides better outcome or decreases postoperative complications [6].

In spite of paucity the studies, they conculded that the stump of the appendix can be safely closed with extracorporeal sliding knots, clips, or with hand-made loops.[7]

Postoperative morbidity after L-APPE with different methods of appendix stump closure includes deep SSI. Which is the most important postoperative complication directly associated with the technique of stump closure [3]. In this study was noted this complication in 1.8% of patients (whom appendix was gangrenous intraoperatively) in all study subgroups 2 in Hem-o-lok clip group and one in extracorporeal knot but without statistical significant difference. All

patients with deep infection CT scan showed no leak from the stump, so they were treated by antibiotics and inserting pigtail catheter by Intervention radiology (IR) doctors without need for reoperation. Therefore, we conclude that there are no differences in terms of the safety of stump closure between hem-o-lok and extracorporeal knot. However, it must be emphasized that our study sample size was limited

There is a growing body of evidence suggested that surgical duration is potentially and an independent modifiable risk factor for complications such as venous thromboembolism (VTE), surgical site infection (SSI), hematoma formation, bleeding, and necrosis [8]. Similarly, a systematic review by Visser et al. identified, categorized, and ranked various patient- and surgery-related risk factors for complications; prolonged operative duration was among the top three surgery-related factors. [9]. The operative time is less in the Hem-o-lok clip group which is caused by its ease of use which is a positive point regarding Hem-o-lok

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clip usage. The longer operative time in the extracorporeal knot is caused by the time taken to form the knot.

The cost is not calculated in our study but in general the usage of vicryl knot is cheaper than the Hem-o-lok clip but both were cheaper than the use of endoloop or stapler without affecting the outcome of the L-APPE.

#### **CONCLUSION**

Hem-o-lok clip is safe and effective method in appendicular stump closure during L-APPE with less operative time.

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## To Cite:

habib, F., Elgazzar, M., Sallam, A. Hem-o-Lok clip versus extracorporeal sliding knot during Laparoscopic appendectomy, A prospective randomized clinical trial.. *Zagazig University Medical Journal*, 2024; (89-94): -. doi: 10.21608/zumj.2023.245252.2984

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