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Research Article

From ENDOLOOP® Ligature to Hem-o-lok® Polymer Locking Ligation System Clips in Laparoscopic appendectomy: Effects of a Treatment Paradigm Shift in a Swiss Secondary Hospital

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Abstract

Purpose: Hem-O-lok® polymer clips are an alternative to the use of ENDOLOOP® for the closure of the appendicular stump during appendectomies. They have shown some reduction in the rate of postoperative intra-abdominal abscesses in some studies. In our institution, after reviewing the literature, we decided to introduce Hem-O-lok® instead of ENDOLOOP®. The aim of this study is to evaluate the impact of this change in terms of Organ/Space surgical site infection rate.

Method: The outcomes of patients operated for acute appendicitis during 2 consecutive years (1 year before the change of technique and 1 year after) were analyzed. Baseline patient characteristics and the rate of postoperative complications, including intra-abdominal abscess, were compared between the 2 periods.

Results: 162 patients were included the year before 1 December 2019 (1st group) and 163 patients the year after (2nd group). Patient's basic characteristics were similar in both groups. The rate of Organ/Space surgical site infection was significantly different, with 8 patients (4.9%) in the 1st group and 1 patient (0.6%) in the 2nd group (p = 0.018).

Conclusion: With this change from ENDOLOOP® to Hem-O-lok® for securing the appendicular stump in appendectomy for acute appendicitis, we have significantly reduced the rate of intra-abdominal abscesses, which was our primary objective.

Keywords: Acute appendicitis; Appendectomy; Clip; Endostapler; Postoperative abscess

Introduction

Although conservative treatment of acute appendicitis is gaining popularity, appendectomy remains the first line treatment. Indeed, according to the 2020 guidelines of the World Society of Emergent Surgery (WSES), non-operative management with antibiotics is not the gold standard but can be seen as a safe alternative to appendectomy in patients with uncomplicated acute appendicitis (confirmed by CT scan) and absence of appendicolith [1]. Failure and misdiagnosing complicated appendicitis, thus necessitating emergent operation, are problems that must be discussed with patients. They also must be aware of the risk of recurrence of up to 39% after 5 years [2]. In addition, non-operative treatment presupposes the systematic performance of a CT scan to exclude complication. However, the most appropriate first-line imaging in adults and children with clinical suspected appendicitis

is ultrasonography [1]. This is the method of first choice in our institution. Laparoscopic appendectomy is the current operative gold standard. Indeed, laparoscopy shows advantages over open appendectomy in terms of pain intensity on day one, length of hospital stays (adults and children), wound infections (adults and children) and time until return to normal activity in adults [3].

However, the higher rate of intra-abdominal abscess in adults remains an issue [3]. It can be suspected that the way the appendicular stump is closed may have an influence on this rate of abscess. ENDOLOOP® ligatures and endostaplers are the most commonly used devices [4-7]. More recently, it has been shown that Hem-o-lok® Polymer Locking Ligation System clips can be used safely in place of ENDOLOOP® in uncomplicated appendicitis [8-10]. Moreover, it can even replace the endostapler if the appendicular base is not severely inflamed or measures more than 1 cm in diameter, without increasing the postoperative infection rate [11-13], even in complicated appendicitis [14]. In our institution, the standard for stump closure in appendicitis was ENDOLOOP® ligatures until November 2019. We decided to use Hem-o-lok® from December 2019. The aim of this quality control study is to compare appendectomies performed in the year before this change with those performed in the year after, to measure the effect of this paradigm shift.

Material and Method

All consecutive patients requiring emergency appendectomy for acute appendicitis between December 2019 and November 2021 were retrospectively included. Identification of patients for inclusion was based on a search of all discharge letters mentioning acute appendicitis, and then cases were confirmed by a review of the actual operative schedule, allowing for full inclusion. Adults and children were included. Patients were divided into two groups according to the timing of appendectomy, i.e., the year before or after 1 December 2019. Appendectomies performed in an elective setting, remotely after conservative treatment or during other procedures were excluded. The method of stump closure was ENDOLOOP® before the 1st of December 2019 and Hem-O-lok® XL after. In case of large and/or inflamed appendix base, stapler were used at the discretion of the operator.

Data were extracted from the patient's computerized hospital record and ambulatory follow-up records. Only readily available data were collected, thus requiring no additional intervention compared to the usual course of patient management. Since the change in management was decided after a review of the literature and the study presented here is actually a quality control of this change, no specific request to the local ethics commission was necessary, in agreement with them. Primary outcome was the development of post-operative organ/space surgical site infection (SSI) according to the Center of Disease Control (CDC) definition, i.e., intra-abdominal abscess. Secondary outcome was operative time. Continuous variables are reported as median and interquartile range and discrete variables as percentage. Pearson's chi-square test or Fisher's exact test (dichotomous data) and the Mann–Whitney U test (categorical data) were applied.

Results

A total of 325 patients were included. 162 patients the year before 1 December 2019 (1st group) and 163 patients the year after (2nd group). The patient's basic characteristics were similar between both groups regarding gender, American Society of Anesthesiologists (ASA) scores, diabetes mellitus, rhythmic heart disease, ischemic heart disease, chronic lung disease, tobacco use, alcohol abuse and BMI. 1st group was younger than 2nd group (29 (17-45) vs 36 (21-53), p = 0.019) and had a little higher blood pressure (9.3% vs 3.7%, p = 0.041) (see Table 1).

Laparoscopy was used in all patients, with the need for conversion in 2 patients in the 1st group and 1 in the 2nd (1.2% vs 0.6%, p = 0.558). ENDOLOOP® were used in 130 patients (80.2%) and endostapler in 29 (17.9%) in the 1st group (Hem-O-lok® in 1.2%). Hem-O-lok® were used in 73 patients (44.8%) and endostapler in 81 (49.7%) in the 2nd group (ENDOLOOP® in 5.5%) (see Figure 1). The rates of perforated appendicitis (22.2 % vs 22.1%, p = 0.976), purulent peritonitis (12.3% vs 12.3%, p = 0.983) and stercoral peritonitis (1.9% vs 1.8%, p = 0.994) were nearly identical in both groups. The correct timing of antibiotic prophylaxis (meaning <60 min before incision) was achieved with the same rate in both groups (69.8% vs 71.8%, p = 0.69). Antibiotics were given as a therapy after the operation (>24h) with no significant rates differences in both groups (28.4% vs 37.4%, p = 0.083) (see Figure 2). A drain was left in place without difference in both groups (8% vs 10.4%, p = 0.454). Operative time was not significantly different between groups (70 min (53-86) vs 66 min (56-83), p = 0.646) (see Table 2).

The rate of Organ/Space SSI was significantly different, with 8 patients (4.9%) in the 1st group and 1 patient (0.6%) in the 2nd group (p = 0.018). Superficial (1.9% vs 0%, p = 0.081) and deep SSI (0.6% vs 1.2 %, p = 0.57) did not show significant differences between 1st and 2nd group (see Figure 3). Other complications as post-operative bleeding and post-operative ileus were similar in both groups, as were the need of post-operative intensive care and re-operation (see Table 3).

Variable	1 year before 01.12.2020 (n=162)	1 year after 01.12.2020 (n=163)	All patients (n=325)	P value
Gender				
Male % (n)	46.3 (75)	56.4 (92)	51.4 (167)	0.067
Female % (n)	53.7 (87)	43.6 (71)	48.6 (158)	0.067
ASA I % (n)	54.9 (89)	51.5 (84)	53.2 (173)	0.539
ASA II % (n)	41.4 (67)	42.9 (70)	42.2 (137)	0.772
ASA III % (n)	3.7 (6)	5.5 (9)	4.6 (15)	0.435
ASA IV % (n)	0 (0)	0 (0)	0 (0)	-
Diabetes mellitus % (n)	3.8 (6)	1.8 (3)	2.8 (9)	0.297
Rhythmic heart disease % (n)	3.7 (6)	1.8 (3)	2.8 (9)	0.306
Ischemic heart disease % (n)	1.2 (2)	3.1 (5)	2.2 (7)	0.255
Chronic lung disease % (n)	8.6 (14)	6.1 (10)	7.4 (24)	0.388
High blood pressure % (n)	9.3 (15)	3.7 (6)	6.5 (21)	0.041
Tobacco use % (n)	21 (34)	22.1 (36)	21.5 (70)	0.810
Alcohol abuse % (n)	2.5 (4)	3.1 (5)	2.8 (9)	0.742
Age median (interquartile range)	29 (17-45)	36 (21-53)	31(19-51)	0.019
BMI median (interquartile range)	23 (19.4-27)	24 (21-27.2)	23 (20-27)	0.144

Table 1: patient's basic characteristics.

Variable	1 year before 01.12.2020 (n=162)	1 year after 01.12.2020 (n=163)	All patients (n=325)	P value
Antibiotics given max. 60 min before % (n)	69.8 (113)	71.8 (117)	70.8 (230)	0.688
Antibiotics > 24h post-op % (n)	28.4 (46)	37.4 (61)	32.9 (107)	0.083
Laparoscopy % (n)	98.8 (160)	99.4 (162)	99.1 (322)	0.558
Laparotomy % (n)	0 (0)	0 (0)	0 (0)	-
Conversion % (n)	1.2 (2)	0.6 (1)	0.9 (3)	0.558
No appendicitis % (n)	1.2 (2)	1.2 (2)	1.2 (4)	0.995
Perforated appendicitis % (n)	22.2 (36)	22.1 (36)	22.2 (72)	0.976
Purulent Peritonitis % (n)	12.3 (20)	12.3 (20)	12.3 (40)	0.983
Stercoral Peritonitis % (n)	1.9 (3)	1.8 (3)	1.8 (6)	0.994
Endoloop % (n)	80.2 (130)	5.5 (9)	42.8 (139)	< 0.001
Hem-o-lok % (n)	1.2 (2)	44.8 (73)	23.1 (75)	< 0.001
Stapler % (n)	17.9 (29)	49.7 (81)	33.8 (110)	< 0.001
Ligature (open) % (n)	0.6 (1)	0 (0)	0.3 (1)	0.315

Drain % (n)	8 (13)	10.4 (17)	9.2 (30)	0.454
Operative time minute median (interquartile range)	70 (53-86)	66 (56-83)	68 (55-85)	0.646

Table 2: Surgery associated variable.

Variable	1 year before 01.12.2020 (n=162)	1 year after 01.12.2020 (n=163)	All patients (n=325)	P value
Surgical site infection % (n)	6.8 (11)	1.8 (3)	4.3 (14)	0.028
Superficial SSI % (n)	1.9 (3)	0 (0)	0.9 (3)	0.081
Deep SSI % (n)	0.6 (1)	1.2 (2)	0.9 (3)	0.566
Organ/Space SSI % (n)	4.9 (8)	0.6 (1)	2.8 (9)	0.018
Post-operative bleeding % (n)	0 (0)	0 (0)	0 (0)	-
Post-operative ileus % (n)	3.7 (6)	5.5 (9)	4.6 (15)	0.435
Post-operative intensive care % (n)	1.2 (2)	1.2 (2)	1.2 (4)	0.995
Re-operation % (n)	1.2 (2)	0.6 (1)	0.9 (3)	0.558

Table 3: Complications.

Figure 1

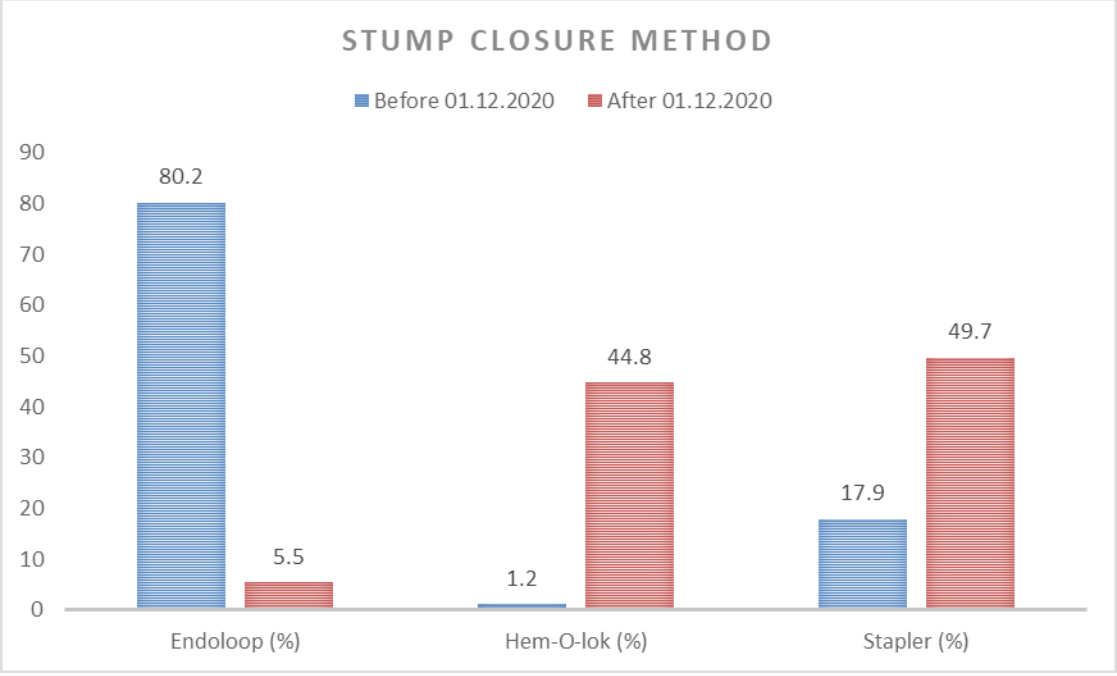


Figure 2

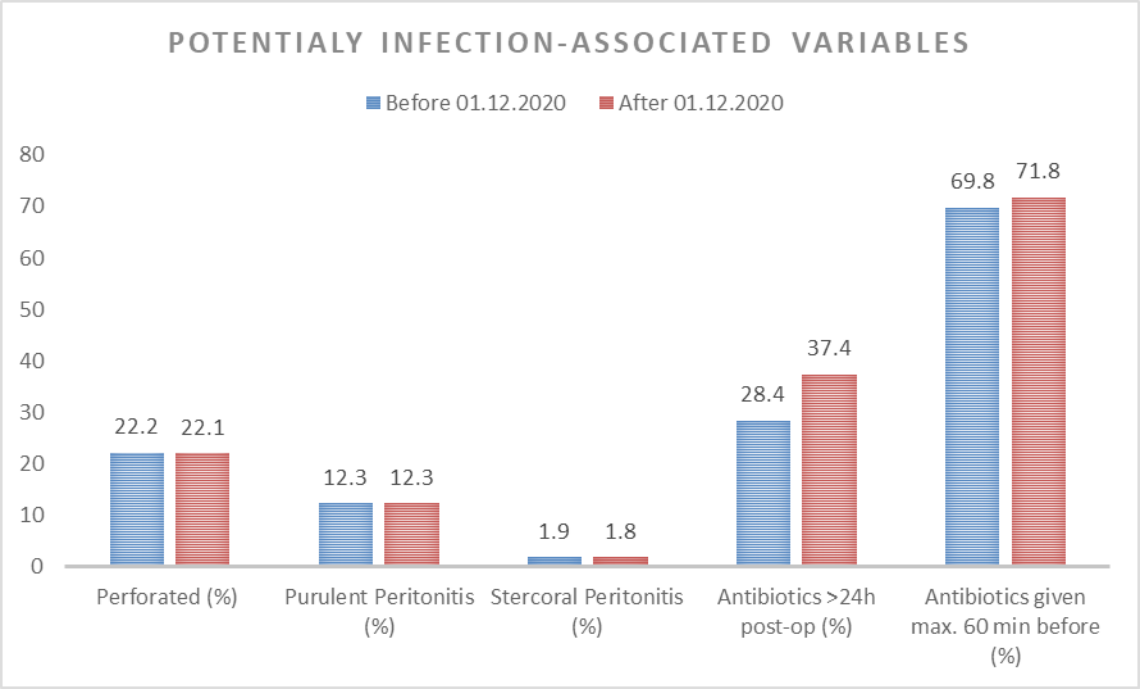
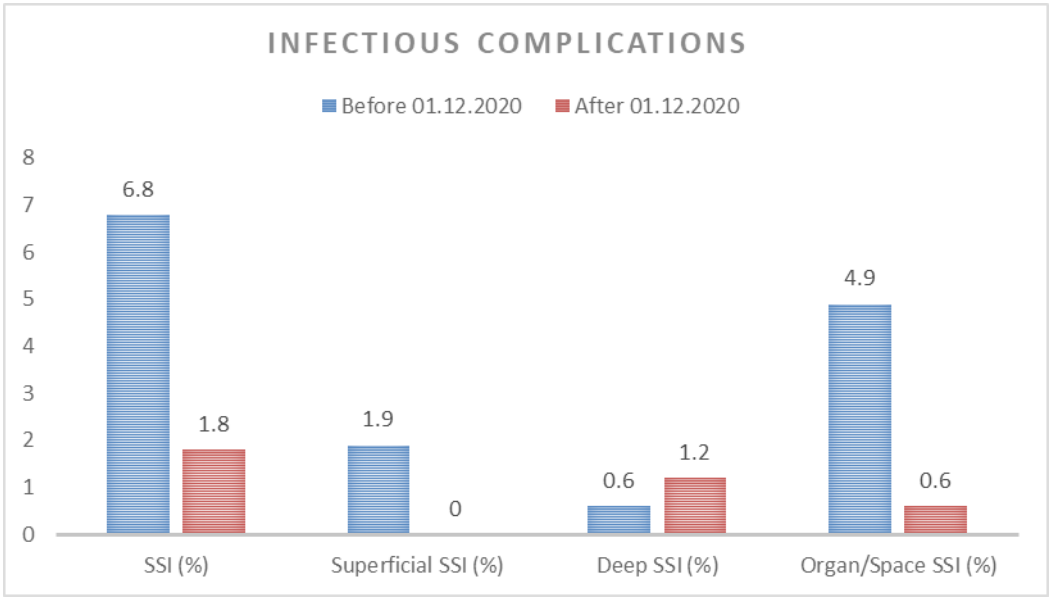


Figure 3



Discussion

Our audit study evaluated the outcomes of patients who underwent emergency appendectomy according to the timing of the procedure in relation to a change in the management paradigm at our institution, i.e., before 1 December 2019 or after, when we decided to change our 1st choice stump closure method from ENDOLOOP® to Hem-O-lok®. Our aim was to decrease postoperative intra-abdominal abscess rates and operative time with this change. Indeed, as shown by Vuille-dit-bille in 2019 [14], the rate of abscesses is

significantly higher in the ENDOLOOP® group than in the Hem-O-lok® group (4% vs 1%, p = 0.012). It should be noted that the percentage of postoperative antibiotics administration as well as the percentage of perforated appendicitis were equivalent in the two groups in this study. The application of ENDOLOOP® was identified as a predictive factor of postoperative abscess in the multivariate analysis, and the application of Hem-O-lok® presented a significant decrease in the risk of postoperative abscess (OR 0.25; 95% CI 0.09 - 0.69; p <0.008). Our own results clearly show that the aim of our paradigm change was achieved. Indeed, the rate of abscess was significantly different between groups, with 8 patients (4.9%) in the 1st group and 1 patient (0.6%) in the 2nd group (p = 0.018). However, no conclusion can be drawn concerning the safest stump closure method. Indeed, we did not directly compare ENDOLOOP® and Hem-O-lok®, but two different periods. It should be noted, however, that during these two periods of time, the population is comparable, as are the variables that may have a clear link with the rate of infections (rate of perforated appendicitis, peritonitis, correct timing of prophylactic antibiotics, postoperative antibiotics therapy, drainage).

The only significantly different variable that was not necessarily assumed to be different was the rate of stapler use. Indeed, the paradigm shift has resulted in much more frequent use of the stapler. There are several possible explanations for this finding. It is possible that surgeons felt less comfortable with Hem-O-lok® than with ENDOLOOP® and therefore preferred the use of the stapler at the slightest concern regarding the appendicular base. Hem-O-lok® can only safely close appendicular bases measuring less than 1 cm in diameter, which is the internal diameter of the clip, whereas ENDOLOOP® can be tied on virtually any base [12]. However, it could be hypothesized that if the Hem-O-loks® are too small to close the appendicular base, it could mean that the appendicular base is too enlarged and therefore too inflamed for the ENDOLOOP® as well, and that the use of the stapler should also be preferred in this type of situation over the placement of an ENDOLOOP®. This may mean that the use of Hem-O-loks® will require the surgeon to use the stapler when necessary, which is not necessarily the case with the ENDOLOOP®. This can be beneficial in a context where appendectomy is often performed by surgeons in training, thus with little experience, as it is the case in our institution. Indeed, as a teaching hospital, over the 2 years analyzed, appendectomies were performed as first operator by resident in training in 30.5% of the cases, by chief resident in 66.7% of the cases and by attending surgeons in only 2.8% of the cases.

Concerning the operative time, we did not find a significant difference (70 min (53-86) in the 1st group vs 66 min (56-83) in the 2nd group, p = 0.646). However, the fact that there is no statistically significant difference does not necessarily mean that there is no clinical or financial significance. With regard to costs, the stapler (GoldenStapler Lapath® Appendix) is of course the most expensive method (280.- CHF). The ENDOLOOP® (Ethicon PDS II EndoLoop Ligature) used in our institution cost 20.50 CHF each, which represents a minimum of 41.00 CHF per appendectomy. Using Hem-O-loks® (Weck® Hem-O-lok® Polymer Ligation System) with a pack of 5 costing 23.60 CHF, is the cheapest method in terms of material. The Hem-O-loks® is thus a cost-effective method compared to the ENDOLOOP®. However, in our study, the fact that the paradigm shift resulted in greater use of the stapler is rather unfavorable in terms of cost. It remains to be seen whether, with practice, the rate of stapler use will decrease in favor of Hem-O-loks®. The fact that this is a "quality control" study presupposes several limitations. Firstly, this is a retrospective monocentric study. Secondly, the choice of the closure method used between Hem-O-loks®/ ENDOLOOP® or stapler is left to the subjective per-operative assessment of the operator. The number of Hem-O-loks®/ ENDOLOOP® left in situ (1 or 2) is also operator dependent. Nevertheless, it has been shown that 1 or 2 Hem-o-lok® left in place did not show any difference [12].

Conclusion

Our primary endpoint with this change in method of securing the appendicular stump in the context of appendectomy for acute appendicitis was to reduce the rate of post-operative infections, particularly intra-abdominal abscesses. Without being able to conclude definitely which method of stump closure is the safest as we did not compare two methods but two periods, our datas show a statistically significant reduction in the abscess rate between the ENDOLOOP® and Hem-O-loks® periods. A review of the literature can therefore help to change our clinical practice which can be beneficial in term of complications, especially in a time when new technologies are constantly emerging and costs represent an issue.

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