Langenbeck's Archives of Surgery (2019) 404:711–716
https://doi.org/10.1007/s00423-019-01814-w

ORIGINAL ARTICLE

A comparison of non-absorbable polymeric clips and staplers for laparoscopic appendiceal stump closure: analysis of 618 adult patients

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Received: 12 March 2019 / Accepted: 15 August 2019 / Published online: 24 August 2019

Abstract

Purpose The aim of this long-term study was the comparison of appendiceal stump closure with polymeric clips or staplers with respect to perioperative costs and surgical outcome under routine conditions in a university centre.

Methods For this retrospective chart review, a total of 618 patients undergoing laparoscopic appendectomy for suspected acute appendicitis between 2010 and 2017 were reviewed: 410 patients in the stapler group and 208 patients in the clip group. The database contained demographic data, operation time, inflammation parameters, closure method of the stump, surgeon status, length of hospital stay, and complications as well as histology reports. The costs were also compared.

Results Clip application was more likely among younger patients (mean age 33.6 years vs. 41.7 years). Histopathological evidence for appendiceal pathology was found in 96.6% of patients in the clip group and 99.5% of patients in the stapler group. Laparoscopic appendectomy in the clip group was more frequently performed by resident physicians (69.2%) than in the stapler group (57.8%). The mean postoperative stay was 2.9 days in the clip group and 3.7 days in the stapler group. The use of the polymeric clip resulted in considerable cost savings (19.94€ vs. 348.70€).

Conclusions The use of polymeric clips for appendiceal stump closure during appendectomy is safe and effective. The base of the appendix is amenable to clipping in 32% of appendectomies in adult patients. This study supports the use of polymeric clips over staplers to decrease cost and environmental impact.

Keywords Laparoscopic appendectomy · Acute appendicitis · Appendicular stump closure · Stapler · Polymeric non-absorbable clip

Introduction

During the 36 years since its initial description in 1983 by Semm [1], laparoscopic appendectomy has gained increasing acceptance in the surgical community. However, while this procedure has been proven to be safe and effective [2, 3] and has been included in the guidelines for the treatment of acute appendicitis as first choice [4], a large prospective multicentre observational study describes that only slightly more than every second patient with acute appendicitis is treated by the laparoscopic approach [5]. Possible drawbacks of the laparoscopic technique are the increased treatment costs [6] and a slightly increased rate of intra-abdominal abscesses [7]. The technique of appendiceal stump closure is thought to influence the incidence of postoperative infectious complications [8]. Many different techniques have been developed for laparoscopic appendectomy as a function of the general progress of laparoscopic techniques. The most commonly used techniques include endoligatures (endo-loop), endostaplers, and absorbable and non-absorbable polymeric clips [9, 10]. Other methods comprising metal clips, bipolar endocoagulation, and intra-corporeal knots have been described but are not currently used [10–12]. All of these alternative techniques offer distinct advantages and disadvantages at various clinical stages of acute appendicitis. Although there have been some prospective randomised trials assessing the effectiveness of the different techniques for appendiceal stump closure, the patient

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numbers in these studies are low, and the evidence for one or the other technique is considered "very low" [10, 13]. Given the huge number of laparoscopic appendectomies, a safe and cost-saving technique for the closure of the appendicular stump is required to reduce the elevated in-hospital costs of laparoscopic appendectomy. The use of a polymeric clip appears to be easier, faster, and at least as safe as the loop. It is also cheaper than an endostapler. Following the first publications on this technique, polymeric clips have found an increasingly broader application in daily practice [6, 9, 14–16]. However, it remains to be defined in which clinical conditions the polymeric clip can be used safely without increasing the frequency of complications, and thus, treatment costs.

After an initial assessment period reported in our previous paper on the feasibility of clip closure of the appendiceal stump, we have introduced the polymeric non-absorbable clip into the clinical routine in our department [9]. The aim of this observational follow-up study is the assessment of the safety and effectiveness of this technique under routine conditions. We report the results in comparison with staplers, with respect to the complexity of the technical application, the safety, and the costs of laparoscopic appendiceal stump closure.

Material and methods

Between January 2010 and December 2017, all patients undergoing laparoscopic appendectomy were identified and clinical, paraclinical, and intraoperative data were retrieved from the electronic records and included in this retrospective chart review. Of the initially identified 624 patients, six patients who received a resorbable clip were excluded (Fig. 1).

In case of suspicion of acute appendicitis, the decision for surgery was always made by a board-certified surgeon. The surgical procedure followed a standardised protocol. Before starting anaesthesia, patients received a single dose of antibiotics (cefuroxime 1.5 g i.v. and metronidazole 500 mg i.v.). After preparation of the appendiceal base, either staplers or non-absorbable clips were used for closure of the appendicular stump. The proximal base of the appendix was closed using a single non-absorbable polymeric clip (Hem-o-lok MLX polymeric clips, Weck Closure Systems, NC, USA). A second clip was placed distally into the appendix followed by its transection between the clips. Clips for the closure of the appendicular stump were not used in cases of severe inflammation at the base of the appendix and findings evoking malignancy. The same was true for appendices with diameters larger than the inner diameter of the closed clip, i.e. 10 mm. In all of these cases, a stapler was used. If the largest diameter of the appendicular stump was inferior to 10 mm and safe closure of the clip could be obtained under visual control, the clip was used. In all other cases, staplers were used (Endo GIA™ Triple, Medtronic, USA). Both devices require a 12-mm trocar. The choice of the closure method was always approved by a board-certified surgeon.

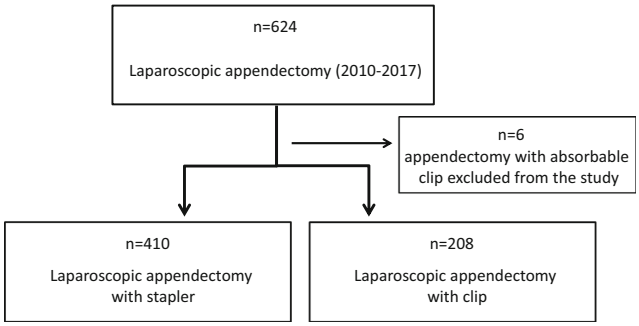

Fig. 1 Flow chart of the analysed patients undergoing laparoscopic appendectomy from 2010 to 2017

All relevant data were documented in a database including the patients' age and sex, BMI, duration of operation, inflammation parameters (white cell count, C-reactive protein), closure method of the stump, surgeon status, hospital stay, and complications during hospitalisation, as well as, histology reports and final diagnosis. The histological stages of inflammation were divided into six groups: (1) no microscopic signs of acute inflammation, (2) catarrhal appendicitis, (3) ulcero-phlegmonous appendicitis, (4) gangrenous appendicitis, (5) chronic inflammation appendicitis, and (6) malignant growth. Severe inflammation was defined as ulcero-phlegmonous appendicitis and gangrenous appendicitis.

Statistical analysis was performed using the GraphPad Prism version 4.02 (GraphPad Software Inc., San Diego, CA, USA). For comparison between the two groups, the unpaired t test was used to test for differences between means and Fisher's exact test was used to test for differences between proportions. A p value of less than 0.05 was considered to be statistically significant.

Results

Altogether, 618 laparoscopic appendectomies using a stapler or a polymeric clip were performed. The demographic and paraclinical data of the study population are summarised in Table 1. It was noteworthy that the clip application was more likely to be seen among younger patients (mean age of 33.6 years vs. 41.7 years in the stapler group). This difference was statistically significant ($p < 0.0001$).

Although differences in the preoperative white blood cell count (WBC) and the C-reactive protein (CRP) were statistically significant, the absolute differences were clinically negligible. The mean operating time was 55.3 min (range 11 to 177 min) in the stapler group and 51.0 min (range 8 to 146 min) in the clip group. This difference was statistically significant ($p = 0.0347$).

Table 1 Characteristics of the stapler and polymeric clip groups

	Stapler	Endoclip	*p* value
Number of patients	410	208	
Age in years	Median 39.0 (IQR 26–54) Mean 41.7 (range 15–90)	Median 28.0 (IQR 22–41) Mean 33.6 (range 17–81)	< 0.0001
Women, *n* (%)	211 (51.5%)	127 (61.1%)	0.0262
Men, *n* (%)	199 (48.5%)	81 (38.9%)	
WBC, ($\times 10^9$/L) (mean, SEM)	13.91 (± 0.23)	12.30 (± 0.31)	< 0.0001
CRP, (mg/L) (mean, SEM)	61.12 (± 3.99)	33.05 (± 3.75)	< 0.0001
Operative time in minutes	Median 51.0 (IQR 36.0–69.0) Mean 55.3 (range 11–177)	Median 49.5 (IQR 39.0–63.0) Mean 51.0 (range 8–146)	0.0347
Hospital stay in days (mean)	Median 3 (IQR 2–4) Mean 3.7 (range 1–32)	Median 3 (IQR 2–3) Mean 2.9 (range 1–11)	0.0001
Intraoperative complications, *n* (%)	9 (2.2%)	3 (1.4%)	0.7593
Postoperative complications, *n* (%)	31 (7.6%)	5 (2.4%)	0.0101
Costs per unit (€)	348.70	19.94	n. a.

Three intraoperative complications were observed in the clip group and nine in the stapler group. In more detail, three bleedings occurred in the clip group, and three bleedings and four lesions of the small intestine developed in the stapler group. All complications were laparoscopically managed. In the stapler group, two patients experienced intraoperative respiratory complications.

Surgery-related postoperative complications were observed in five cases in the clip group, including one prolonged intestinal paralysis, one wound infection, and one intra-abdominal abscess. Surgery-unrelated complications in the clip group were a respiratory failure in one case and one vaginal bleed. In the stapler group, 26 surgery-related postoperative complications were registered, including six intra-abdominal abscesses, 11 cases of prolonged intestinal paralysis, four ileuses, four wound infections, and one haematoma. Five surgery-unrelated complications were observed in the stapler group: one acute cholecystitis, one acute renal failure, one diarrhoea, one urinary tract infection, and one case of arrhythmia absolute. An overview of the postoperative complications and their severity according to the Clavien–Dindo classification is given in Table 2.

The results of the histopathological analysis of the specimen are summarised in Fig. 2. Intraoperatively, local inflammation was judged to be severe in 107 patients including nine patients with perforated appendicitis and 23 with abscess formation. In the stapler group, severe inflammation was found in 327 patients (79.7%), including 63 patients with perforated appendicitis and 44 with abscess formation.

In 237 cases, laparoscopic appendectomies (38.3%) were performed by board-certified surgeons ($n = 8$), while 381 laparoscopic appendectomies (61.7%) were performed by surgical trainees (first to the fifth year of training, $n = 12$) supervised by one of the eight above-mentioned board-certified surgeons. The proportion of laparoscopic appendectomy performed by resident physicians was higher in the clip group (144/208, 69.2%) than in the stapler group (237/410, 57.8%). There were no intraoperative technical problems both in the clip group and the stapler group. The mean postoperative stay was 2.9 days (range 1 to 11 days) in the clip group and 3.7 days (range 1 to 32 days) in the stapler group ($p = 0.0001$). The costs for one unit containing six polymeric clips (one set per operation) remained stable during the study period (19.94€). The stapler price increased during the study period; the average price was 348.70€ (including one magazine).

Discussion

Acute appendicitis is one of the leading causes of acute abdominal pain and is the most common surgical emergency requiring urgent surgery, with a reported lifetime incidence of 8% [17, 18].

The different techniques for laparoscopic closure of the appendiceal stump derive from the open procedure. The secure closure of the appendiceal stump is thought to be the most important step because of potential severe postoperative complications ensuing from its inappropriate management, e.g. postoperative peritonitis, sepsis, fistulas, and reoperations are feared and must be avoided. The appendiceal stump closure by a single ligature with an invaginating safety suture used in open appendectomy was replaced by alternative techniques in the laparoscopic procedure. For years, most surgeons either preferred a stapler [19] or a loop [20] to close the appendiceal stump. However, the loop requires an advanced level of laparoscopic training. The use of a stapler is simple and safe, but quite expensive. Furthermore, lost stapler clips have been shown to cause peritoneal adhesions leading to complications like small-bowel obstruction or ileus [21]. The use of clips to close the appendicular stump was first described by Cristalli

Table 2 Postoperative complications according to the Clavien–Dindo classification (five cases in the clip group and 31 cases in the stapler group)

Clavien–Dindo classification	Patients with clip (%)	Patients with stapler (%)
Grade II	2 (0.96%)	15 (3.66%)
Grade IIIa	2 (0.96%)	10 (2.44%)
Grade IIIb	1 (0.48%)	5 (1.22%)
Grade IVa	0	1 (0.24%)

et al. in 1991 who used metal clips [22]. In recent years, a new titanium double-shanked clip (DS-Clip) came into use. The studies suggest that titanium DS-Clip is a safe and cost-effective technique for securing the appendix base in laparoscopic appendectomy [11]. However, metal clips have not gained general acceptance. More recently, the use of simple non-absorbable clips for the closure of the appendicular stump (Hem-o-lok MLX polymeric clips, Weck Closure Systems, NC, USA) has been suggested by Hanssen et al. [23] and Delibegović et al. [24]. The clip was designed with a special tooth-like surface to prevent the slipping of the device. A lock was manufactured at the end of the clip to assure safe closure. Advantages of these clips include easy application, low cost, and firm and safe closure.

Studies describing the use of polymeric clips for appendiceal stump closure are sparse and mostly describe this technique in a paediatric population [6, 16, 25, 26]. However, the incidence of acute appendicitis is highest in the second to the fourth decades of life [17]. Moreover, secondary to the demographic trend towards older patient populations, the absolute number of adult patients requiring treatment for acute appendicitis is also increasing [27]. Thus, the usage of polymeric clips in an adult population will become more important from a clinical and economic point of view in the future. Many studies have demonstrated significantly higher costs for minimally invasive appendectomies compared with open surgery [28–33]. The price of the stapler is responsible for a considerable percentage of the total cost of the laparoscopic procedure. In our study, the total cost for simple laparoscopic appendectomies was reduced by 336.49€ per application if a clip rather than a stapler was applied. In the seven-year period, the total cost in the stapler group was 142.967€ but only 4.147€ in the clip group. The use of disposable staplers also means large amounts of medical waste, and thus, constitutes a significant environmental impact. The disposal costs were not included, but are an important factor for the total costs in the hospital system.

The comparison of demographic, paraclinical, and histopathological data of both patient groups showed clear differences. First, the age of the patients showed significant differences between the groups. In general, patients receiving the clip were younger (Table 1). The reason for this observation is unknown. It contrasts with the findings of a recent study on the usage of various closure methods in complicated appendicitis [34] where staplers were used more frequently in younger patients. The authors gave no explanation for this finding. This difference may stem from the fact that in our study, cases with more severe inflammation were older and clustered to the stapler group since the decision for or against one specific closure technique was predominantly influenced by the severity of inflammatory changes at the base of the appendix. Accordingly,

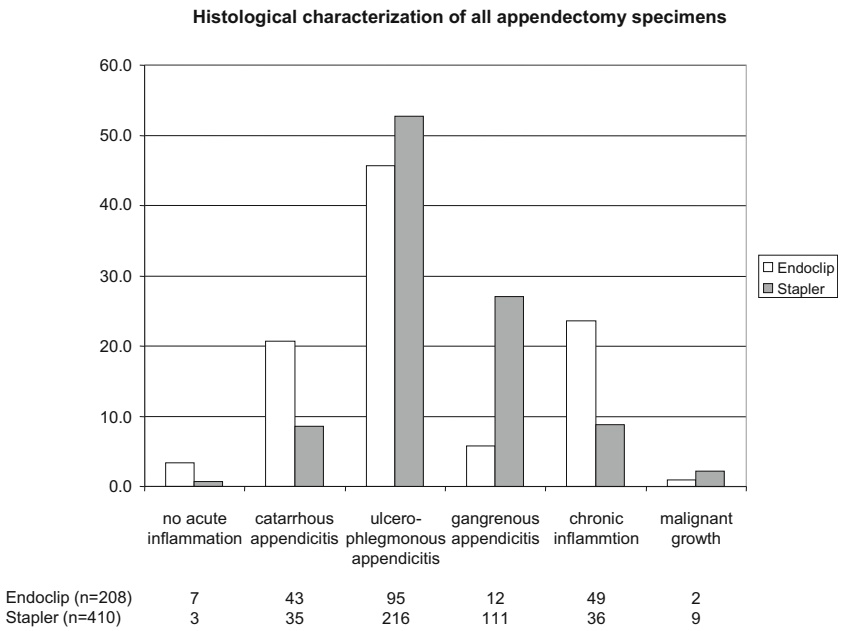

Fig. 2 Histological characteristics of appendectomy specimens (clip group and stapler group)

patients in the clip group were, on average, discharged one day earlier than those of the stapler group, indicating a less severe form of the disease in this patient group.

The decision to use a stapler in inflamed appendices was predominantly justified by severe inflammation up to the base of the appendix. However, in 107 cases showing severe inflammation (ulcero-phlegmonous/gangrenous appendicitis), with potential involvement of the base of the appendix, the clip was still successfully used. This finding corresponds to the observation of a Polish-German study group comparing clips, or staples for stump closure [34]. These investigators showed that clip closure of the appendiceal stump could be used even in cases of complicated appendicitis without an increased incidence of intra-abdominal abscesses. However, while usage of the stapler is not limited to the diameter of the inflamed appendix, the use of the clip can be hampered by the diameter of the inflamed base of the appendix exceeding the inner diameter of the closed clip (10 mm).

Laparoscopic appendectomy is usually performed as one of the first laparoscopic procedures in the surgical training programs. As expected, the proportion of laparoscopic appendectomies performed by resident physicians was higher in the clip group than in the stapler group, most probably due to less pronounced inflammatory changes and adhesions in the operation field. Interestingly, although the majority of procedures in the clip group was performed by residents, the operation time was slightly shorter than in the study of Lasek et al. [34]. In contrast to the results of this group, where the usage of a clip resulted in slightly longer operation time, this ratio was inverted in our study, probably indicating that for surgeons at the beginning of their career, the use of a clip is easier to perform than that of more complex stapler devices.

Postoperative morbidity was more frequent in the stapler group, which was the group with more severe inflammation. However, postoperative morbidity in the total patient cohort was comparable with that reported by other investigators [34].

Nonetheless, there are several limitations to our study. Due to its non-randomised design and the allocation to one or the other treatment arm as a result of the individual decision of the treating surgeon, both patient groups differed in disease severity. Thus, no conclusions concerning the equivalence of stump closure by the stapler or clip in the same disease stage could be drawn. However, the aim of this study was to assess the effectiveness of the clip closure in the routine setting, which also implies the individual decision of the surgeon. This limitation should be kept in mind when interpreting the results of this study. Moreover, it would have been interesting to document the main criteria for the individual decision to use one or the other method on a case by case basis. However, this has not been done due to the retrospective nature of this study.

The promising results in our study justify the further development of clip technology. Clips with larger diameters can expand the range of indications, allowing the closure of appendiceal stumps with a diameter greater than 10 mm. The development of an absorbable or partially absorbable clip might increase the acceptance of this technique by surgeons and patients.

Summary

The use of polymeric clips for an appendectomy is safe and effective, and results are comparable with those of stapling. Our data clearly show that a considerable percentage (32%) of routine appendectomies is amenable to clip closure without an increase in intra- and postoperative complications. This results in significantly reduced treatment costs. Our study supports the use of non-absorbable clips in cases of less severe inflammation of the appendiceal base to decrease treatment costs.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The study was carried out after approval by the ethics committee of the University Medicine Greifswald.

Informed consent Informed consent was obtained from all individual participants included in the study.

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