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Polymeric clips are a quicker and cheaper alternative to endoscopic ligatures for securing the appendiceal stump during laparoscopic appendicectomy

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ARSTRACT

INTRODUCTION The use of polymeric clips in securing the appendiceal stump has been increasingly reported as a viable alternative to current methods in emergency laparoscopic appendicectomy. We evaluated the operative outcomes following the use of polymeric clips versus endoscopic ligatures. The primary endpoint was operative time, with secondary outcomes including complications, inpatient stay, and cost analysis.

MATERIALS AND METHODS Operative records were retrospectively analysed to identify patients undergoing laparoscopic appendicectomy between January 2014 and June 2015. Data collected included age, gender, body mass index, duration of surgery, length of hospital stay, antibiotic use, preoperative haematological and biochemical parameters, 30-day readmission rate and complications.

RESULTS A total of 125 patients were included within the study, with 78 within the endoloop group and 47 in the polymeric clip group. There were no differences in age, gender, body mass index, hospital stay, antibiotic use, 30-day readmission rates or postoperative complications. Operative time was significantly reduced in the polymeric clip group (59 vs. 68 minutes, P = 0.00751). The use of polymeric clips cost £21 compared with £49 for endoloops per operation, which rose to £70 if both clips and endoloops were used during the procedure.

DISCUSSION Polymeric clips are a safe, viable and economical method for securing the appendiceal stump during laparoscopic appendicectomy. The clinical significance of nine minutes of reduced operating time in the polymeric clip cohort warrants further study with an adequately powered randomised controlled trial.

KEYWORDS

Appendicitis – Laparoscopic appendicectomy – Polymeric clips – Endoscopic ligature – Endoloop

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Introduction

Acute appendicitis is the most common indication for emergency abdominal surgery with a lifetime incidence of 8–16%. ^{1,2} Laparoscopic appendicectomy is now widely accepted as the first line method of choice for the surgical management of acute appendicitis in the developed world. ⁵ A crucial step in this procedure is securing the appendiceal stump. The most commonly employed methods include endoscopic ligatures (Endoloop, Ethicon) ⁴ or gastrointestinal laparoscopic stapling. ⁵ Other methods include the use of a harmonic scalpel, ⁶ bipolar coagulation, ⁷ metal clips ⁸ or the LigaSure system (Medtronic). ⁹ In our institution, Endoloop is the most commonly employed method of appendiceal stump closure.

An alternative method for securing closure of the appendiceal stump has been increasingly reported and involves the use of polymeric clips. ^{10,11} These clips are reported to be as safe as, cheaper and quicker to apply than Endoloops. Endoloops are limited by the fact that they can be technically difficult to apply and require the acquisition of skills to apply efficiently. However, they are significantly cheaper than laparoscopic staplers. Staplers, on the other hand, are expensive but easy to apply and this skill can be learned quickly.

A number of case series using polymeric clips have been reported in the literature, $^{10-15}$ with only one randomised controlled trial reported. The trial compared polymeric clips with Endoloops and reported reduced operating times in the Hem-o-lok cohort (64.7 \pm 19.2 vs 75.4 \pm 23 minutes),

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which failed to reach statistical significance. There was no difference in hospital stay or postoperative complication rates. Previous studies have failed to report outcomes based on the operative experience of the primary surgeon and we aimed to address this in our study.

The aim of our study was to analyse outcomes following laparoscopic appendicectomy in our institution comparing patients in whom polymeric clips were used to secure the appendiceal stump with those in whom Endoloops were used. The primary outcome was operating time, with secondary outcomes being complication rates, 30-day readmission rates and outcomes presented for surgical trainees performing the procedure as primary surgeon. We also undertook a cost analysis comparing the two methods.

Material and methods

We undertook a retrospective analysis of outcomes following laparoscopic appendicectomy between January 2014 and June 2015. Patients were included in the study if they had undergone emergency laparoscopic appendicectomy with the use of either polymeric clips (Hem-o-lok, Teleflex) or endoscopic ligatures (Endoloop, Ethicon) to secure the appendiceal stump. Patients were excluded if they had undergone an open appendicectomy (primary or laparoscopic to open conversion) or if alternative methods of appendiceal stump closure had been employed. The study was registered with the local Caldicott guardian.

In our institution, laparoscopic appendicectomy is the standard of care for acute appendicitis. There are some minor variations in practice between surgeons. The use of antibiotics (preoperative, intraoperative and postoperative) varies depending on the perceived severity of the appendicitis. However, either a 5-mm or 10-mm camera is used with standard port placements, subumbilically, suprapubically and in the left iliac fossa. Port sizes may vary between surgeons. In those who use a 5-mm camera, one 10-mm port in the left iliac fossa is used. In those who use a 10-mm camera, two 10-mm ports are required (subumbilical and left iliac fossa). Five millimetre cameras are used with greater frequency in paediatric cases and 10-mm cameras in adult cases, but this is influenced by surgeon preference. The decision to close the fascia of the 10-mm left iliac fossa port is down to surgeon preference, but subumbilical fascia is routinely closed.

When using Endoloops, typically three are applied to the appendix base and, following ligation, two Endoloops are left in place on the appendix stump. If polymeric clips are used then three 15-mm (gold) clips are placed across the appendix base. Following ligation, two are left in place on the appendix stump. Control of the mesoappendix and appendicular artery may involve diathermy alone, the application of a polymeric clip or an Endoloop. It is the practice of some of our surgeons to favour polymeric clips for the mesoappendix and Endoloops for the appendix stump. Depending upon the intraoperative severity, the use of laparoscopic washout and the need for placement of a drain is left in the hands of the primary surgeon.

A number of hospital databases were accessed to obtain relevant clinical data. The operative database was used to identify those who underwent emergency appendicectomy, date and time of surgery, grade of operating surgeon and American Society of Anesthesiologists (ASA) grade. The hospital admission database was used to determine date of admission, date of discharge and subsequent 30-day readmissions. The electronic discharge database was used to determine the duration of postoperative antibiotics. The method of securing the appendiceal stump, degree of peritoneal contamination, body mass index and use of antibiotics preoperatively and intraoperatively were all obtained from the clinical notes. The trusts' integrated clinical environment system was used to record preoperative white cell count, C-reactive protein, lactate and albumin levels. Pathology reports were also accessed using the same system.

Statistical analysis was performed using SPSS version 21.0. Fisher's exact test was used for categorical data, while continuous data were analysed using the Mann-Whitney U test. Tests were two-sided and a *P*-value of less than 0.05 was deemed statistically significant.

Results

During the study period, 136 laparoscopic appendicectomies were performed in our institution. Eleven patients were excluded due to the use of a laparoscopic stapler, leaving a final cohort of 125 patients; 47 (37.6%) in the polymeric clip cohort and 78 (62.4%) in the Endoloop cohort. Demographic data for each cohort are shown in Table 1. Age at presentation, male to female ratio, body mass index and ASA grade were similar between the two cohorts. There was no significant difference in antibiotic use (Table 2) or preoperative haematological or biochemical parameters (Table 3) between the two cohorts.

Length of in-patient stay and perioperative complications were also similar (Table 4). However, operative time was shorter in the polymeric clip cohort (59 minutes) compared with the use of Endoloops (68 minutes; P = 0.00751). Some 86.4% of procedures were performed by surgical trainees, with no significant difference between the two cohorts (P = 0.79).

Table 1 Demographic data.					
	Polymeric clip (n = 47)	Endoloop (n = 78)	<i>P</i> -value		
Mean age (years)	32.1 (range 6–79)	28.2 (range 4–91)	0.137		
Male : female ratio	1.19:1	1.22 : 1	1		
Body mass index (kg/m²)	25.6 (range 17-43)	25.9 (range 18–39)	0.731		
ASA grade n (%)			0.327		
I	37 (78.7%)	67 (85.9%)			
II	10 (21.3%)	11 (14.1%)			

Table 2 Perioperative antibiotic use.			
	Polymeric clip ($n = 47$)	Endoloop ($n = 78$)	<i>P</i> -value
Antibiotics pre-theatre	32 (68.1%)	63 (80.8%)	0.132
Antibiotics intraoperatively	30 (63.8%)	39 (50.0%)	0.143
Antibiotics postoperatively	14 (29.8%)	24 (30.8%)	1
Duration of postoperative antibiotics (days)	6.9	6.0	0.302

Table 3 Preoperative haematology and biochemistry.				
	Polymeric clip (n = 47)	Endoloop (n = 78)	<i>P</i> -value	
White cell count	13.1 (5.0–24.2)	14.5 (4.3–40.4)	0.265	
C-reactive protein	60.1 (4–329)	66.6 (4–297)	0.351	
Lactate	1.2 (0.4–3.3)	1.3 (0.5–4.9)	0.870	
Albumin	40.5 (31–50)	40.4 (27–48)	0.921	

Cost analysis

Three endoloops cost £49, with two being left proximally on the appendix stump following ligation. A single packet of six polymeric clips costs £21 in our institution. Three clips are required to secure the appendiceal stump. Following ligation, two are left proximally on the appendix stump. This represents a cost saving of £28 per procedure. If polymeric clips were employed in all 125 cases, this would represent a maximal cost saving of £3,500.

Discussion

Our results demonstrate that the use of polymeric clips to secure the appendiceal stump is a safe and cost-effective alternative to Endoloops when performing emergency laparoscopic appendicectomy. We report no significant difference in the complications, readmission rates, length of stay, or postoperative antibiotic use. In our study, the duration of surgery was significantly shorter (59 versus 68 minutes) in

the polymeric clip cohort. Further, the use of polymeric clips would represent a cost saving compared with the use of Endoloops.

In our institution, laparoscopic appendicectomy is the method of choice for patients presenting as an emergency with acute appendicitis. Owing to cost constraints, we have favoured the use of Endoloops over laparoscopic gastrointestinal staplers to secure the appendiceal stump. Laparoscopic staplers are reserved for the most severe cases, often perforated appendicitis with significant peritoneal contamination or in the presence of a necrotic appendix base that precludes the use of Endoloops. The use of drains and retrieval bags is down to surgeon preference. Patients are typically discharged 24–72 hours post-surgery.

More recently, the use of polymeric clips to secure the appendiceal stump during appendicectomy has been reported in the literature. Our findings add to the growing body of evidence that polymeric clips are a viable alternative to endoloops with equivocal complication rates. ^{10,15–16} Operating time is significantly quicker in some studies, ^{10,14,15} but comparable in the only randomised controlled trial to date. ¹⁶ The perceived benefits of polymeric clips are that they are cheaper when compared with Endoloops and this is certainly the case in our study. ^{10,15,14,16}

In our institution, we would typically use three Endoloops to secure the appendiceal stump, with ligation of the stump to leave two Endoloops in place. The cost of three endoloops is £49. However, a number of our surgeons may also opt to use a polymer clip(s) to secure the mesoappendix and prevent bleeding from the appendicular artery. Clips come in a packet of six and cost £21. If Endoloops are used to secure the appendiceal stump and a polymer clip used for the

Table 4 Admission, intra- and postoperative data.				
	Polymeric clip (n = 47)	Endoloop (n = 78)	<i>P</i> -value	
Surgical trainee as primary surgeon	40 (85.1%)	68 (87.2%)	0.791	
Duration of surgery (min)	59 (20-175)	68 (25-160)	0.00751	
Length of hospital stay (days)	3.2 (0-15)	2.9 (1-9)	0.374	
Postoperative stay (days)	2.4 (0-13)	2.3 (0-8)	0.081	
Complications:				
Intraoperative	-	_	_	
Postoperative	Collection (1), port site hernia (1)	Ileus (2), collection (1) Port site hernia (1)	1	

mesoappendix then the total cost is £70. In our Endoloop cohort, polymeric clips were used in 43 of 78 cases (55.1%). In our cost analysis, we estimated a £3,500 saving if polymeric clips were used for all cases of Endoloops. In the 43 cases where polymeric clips were used for the mesoappendix and Endoloops to the appendix stump, this would have cost £3,010. However, if polymeric clips alone had been used the total cost would have been £903, representing a total cost saving of £2,107.

It is worth debating the significance of the reduced operating time (nine minutes) in the polymeric clip cohort in our study. There are a number of possible explanations for this finding. The reduced operating time may be due to the clips simply being easier to apply than Endoloops, which has been reported previously.¹⁴ There is certainly an element of dexterity and skill required to adequately deploy three Endoloops, whereas polymer clips appear to require less surgical skill. Other explanations involve patient selection. One hypothesis is that surgeons would preferentially select the easiest method (i.e. polymer clips) for the more straightforward cases such as simple appendicitis with no evidence of perforation or peritoneal contamination. This does not appear to be the case in our study as there were no significant differences in the preoperative inflammatory markers between the two cohorts (Figure 4). However, we would always caution against the use of both polymer clips and Endoloops where the appendix base is necrotic. Instead, we would opt for the use of a laparoscopic stapling device across a healthy and viable portion of caecum. Our findings are corroborated by the recent Cochrane review on stump closure methods, which reported that the use of mechanical devices on the appendix stump is nine minutes quicker than Endoloops. 17

To date, there has been one randomised controlled trial comparing Endoloops to polymeric clips for the appendix stump during emergency appendicectomy. The authors of this study report no significant differences in operating time (64.7 vs 73 minutes, P = 0.072), complications or postoperative hospital stay. All previous studies had reported a significantly reduced operative time in the polymeric clip cohort. However, by failing to report a power calculation and with just 26 cases in the Hem-o-lok and 27 in the Endoloop cohorts the study is likely to have been underpowered. To definitively conclude that polymeric clips are as good as Endoloops in terms of complications and readmission rates, and indeed whether they result in a reduced operating time, an adequately powered randomised controlled trial is required. We would suggest a primary endpoint of postoperative intra-abdominal abscess with secondary endpoints to include; duration of surgery and 30-day readmission rates. To determine whether the clips are easier to apply, data capturing the time to apply polymer clips to the appendiceal stump versus an equivalent number of Endoloops are also required.

The strengths of our study are that there was no significant difference in age, gender, body mass index, inflammatory markers and ASA grade before surgery. There were no significant differences in antibiotic or hospital stay use in either cohort. Each cohort was therefore broadly similar

apart from the method employed to secure the appendiceal stump.

Our study is limited by its retrospective nature and the fact that it was undertaken within a single institution. We were unable to stratify our data by the operative experience (with appendicectomy) of the primary surgeon due to the retrospective nature of the study. However, we were able to determine that surgical trainees performed the majority of appendicectomies with no significant difference between the two cohorts. Our cost analysis is also limited in that we did not consider the cost of the applicator required for the polymer clips and the cost of cleaning the applicator after use. It was considered that the cost of the applicator required a large initial outlay. It would be reused multiple times in its lifetime and its use would not be restricted to laparoscopic appendectomies. The cost of cleaning the applicator were also considered to be negligible since it would be sterilised alongside the other instruments on the diagnostic laparoscopy tray, which would be the same regardless of whether clips or endoloops had been used to secure the appendiceal stump.

Conclusion

In summary, our study adds to the growing body of evidence that polymeric clips are a safe and viable method for securing the appendiceal stump during emergency appendicectomy. We report the outcomes of the largest case series in a Western population. Our study demonstrates homogeneity between the two cohorts for age, gender, ASA grade and bosy mass index. Further, we are the first to report homogeneity in terms of preoperative inflammatory markers (white cell count, C-reactive protein, lactate and albumin) and similar outcomes with the majority of procedures undertaken with surgical trainees as primary surgeon.

Our cost analysis demonstrates significant potential monetary savings if polymeric clips are used, particularly in those cases where polymeric clips are currently applied to the mesoappendix in conjunction with Endoloops to the appendix stump. We report a reduced duration of surgery in the polymeric clip cohort and this is an area for further study as a number of factors may have contributed to this result. We recommend an adequately powered randomised controlled trial of polymeric clips to Endoloops with data capture times of their deployment.

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