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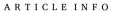


Quality Improvement Study

Endoloops in laparoscopic appendicectomy: A retrospective, cost effectiveness analysis

Jonathon R.C. Sheen ^{a,1,*}, Joel M. Bowen ^{b,1}, Kirk K. Bowling ^b

- ^a Department of Trauma & Orthopaedics, Torbay and South Devon NHS Foundation Trust, UK
- ^b Department of Upper G.I. Surgery, Torbay and South Devon NHS Foundation Trust, UK



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ABSTRACT

Background: Over 50,000 appendicectomies are performed in the UK annually. Despite this highvolume. status, and the endoloop being commonly employed, there is a scarcity of literature studying differences in outcomes depending on numbers used. The aim of this study was to investigate whether a significant difference in complication rate exists where different numbers of endoloop ligatures have been applied to the appendiceal base during laparoscopic appendicectomy, and to analyse for potential cost saving.

Methods: We performed a retrospective analysis of appendicectomies at our centre in one year, providing a sample of 254 patients. Each was followed up for complications in the 30 days post discharge and graded using the Clavien-Dindo system. Our null hypothesis of no difference in complication rate was tested using Fisher's exact test

Results: Of 254 patients, 59 were excluded due to open approach, non-endoloop method, or lack of available record, leaving a population of 195. The result of the two-tailed P value equalled 1.000, indicating no statistically significant difference in complication rate whether one or two endoloops were used. An endoloop costs £13.59. If the 62 cases in which 2 endoloops were used to secure the base had utilised a single endoloop, this would amount to a saving of £842.58.

Conclusion: Our study set out to assess whether the complication rate differs in cases where one or two endoloops have been applied. Retrospective statistical analysis found no significant difference between groups. Therefore, we recommend use of one endoloop to secure the base in laparoscopic appendicectomy.

1. Introduction

Acute appendicitis is the most common intra-abdominal surgical emergency in the world. Appendicectomy remains the mainstay of treatment, and in the UK, over 50,000 are performed per year [1]. The lifetime likelihood of undergoing this procedure has previously been calculated at 12% in males and as high as 23% in females, although this rate has been decreasing in the UK over recent years [2]. As such, it remains a high volume procedure, with significant associated costs to the healthcare system.

This study was conducted with the intention of highlighting whether the method of closure of the base of the appendix could provide an opportunity for real world cost reduction in laparoscopic appendicectomy. There are a number of recognised methods for securing the base, and a 2017 Cochrane review of uncomplicated cases found insufficient

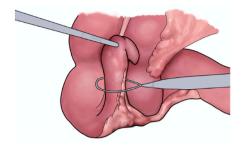
evidence to draw any conclusions regarding recommendation of one method over another [3]. However, existing literature has shown a cost reduction when introducing endoloops as the standard device for base closure (See Fig. 1) [4].

Review of the current literature found only one paper, by Beldi et al. [5], which directly investigated the use of one vs two proximal endoloops, to secure the appendiceal base. The findings of this paper showed no significant difference between the two, in terms of post-operative complications.

Given the sparsity of studies in this area, we felt that there was an opportunity to review current practice at our centre (a District General Hospital), where endoloop ligation is the standard method for securing the base. The particular device used at our centre is the Ethicon ENDOLOOP® Ligature made with PDS® II (See Fig. 2) - costing our Trust £13.59 per item.

^{*} Corresponding author. Department of Trauma & Orthopaedics, Torbay Hospital, Torquay, Devon, TQ27AA, UK. *E-mail address:* jonathon.sheen@nhs.net (J.R.C. Sheen).

¹ Co-first author for this study.



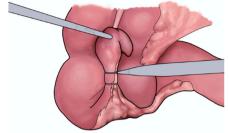


Fig. 1. PDS endoloop placement on appendix (Illustrations by Dr Ramiz Ahmed-Man).

The aim of this study was to investigate whether a significant difference in complication rate exists where different numbers of endoloops have been applied, and to analyse for potential of cost saving.

2. Methods

2.1. Study design

We performed a retrospective analysis of appendicectomies performed at a single centre between January 1st and December 31st, 2020.

Initial patient identifiable data was pulled from our online theatre system, before a review of the patient notes was performed. The initial population was all patients who had undergone open or laparoscopic surgery, including both emergency and interval operations.

The review of patient notes included admission documents, operation notes, radiology reports and histology reports. Complications were defined as those occurring either during the admission in which the appendicectomy was performed or within 30 days of discharge from the admission in which the appendicectomy was performed. A target of 30 days was used due to this being the most commonly cited timing in literature [6]. Complications were rated using the Clavien-Dindo system of grading surgical complications [7].

Patients were excluded from statistical analysis if the procedure was performed open or laparoscopic converted to open, there was no operation note, a method other than endoloops were utilised, and if the number of endoloops was not mentioned in the operation note.

2.2. Statistical analysis

Anonymised data was collated into a single document in spreadsheet format using Microsoft Excel 2019. Our null hypothesis of no difference in complication rate was tested using Fisher's exact test, tested against a p value of <0.05.

2.3. Ethical consideration

Given the nature of this study, ethical approval was not required or sort. Our work has been reported based on Standards for Quality Improvement Reporting Excellence Guidelines (SQUIRE 2.0) and the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement.

3. Results

At our institution, 254 patients underwent appendicectomy during the year 2020. Of these, 219 were laparoscopic, with the other 35 being open or laparoscopic converted to open. Of these, 212 were performed with endoloops and 4 were stapled, whilst 3 had no operation note to analyse. Of the 212 performed with endoloops, 133 had one proximal loop left on the appendiceal base, 62 had two loops, and in 17 cases the number used was not stated. Therefore, of the 254 cases, 59 were excluded, leaving the study population at 195 patients (See Fig. 3).

Using the 30 day definition for post-operative complications outlined

in the Methods section, 10 patients of the 133 having one endoloop at the appendiceal base sustained a complication, and 4 of the 62 having two endoloops. We then further analysed these complications, utilising the Clavien-Dindo system. Of the 10 in the one endoloop group, there were 7 grade I (x5 post-op pain, x2 post-op collection), 2 grade IIIa (x2 post-op collections requiring radiologically-guided drainage) and 1 grade IIIb (a post-op collection requiring laparotomy and washout). Of the 4 in the two endoloop group, there were 3 grade I (x1 post-op pain, x1 post-op ileus, and x1 post-op collection) and 1 grade V (death). No intraoperative complications were recorded in either group.

To assess our null hypothesis, we utilised Fisher's Exact test. The result of the two-tailed P value equalled 1.000 indicating that there was no statistically significant difference, at p < 0.05, in complication rate whether one or two endoloops were used for appendiceal base closure (See Table 1).

We also analysed the histology of the appendicectomies, to assess whether a surgeon utilising two endoloops may have elected to do so due to being faced with a more technically challenging pathology. The results showed that out of the 133 operations with one endoloop left on the base, 105 were for perforated appendix or appendicitis (78.9%), compared to 47 out of 62 (75.8%) for two endoloops, thus suggesting a similar mix of pathology across the two groups. Of note, the 'Others' were made up of mucinous neoplasms and pin worms.

Regarding the issue of cost effectiveness, a single endoloop costs £13.59. Therefore, if the 62 cases in which 2 endoloops were used to secure the appendiceal base had utilised a single endoloop, this would amount to $62 \times £13.59 = £842.58$.

4. Discussion

The use of endoloops to ligate the base is a more technically demanding approach than use of a stapler, as it is necessary to first skeletonise the appendix by careful dissection of the mesoappendix [5, 8]. Manoeuvring the endoloops into a satisfactory position also requires a level of laparoscopic dexterity. We consulted a body of experts (consisting of 10 surgeons each with well over 100 laparoscopic appendicectomies in their logbooks) on the time taken to place an additional endoloop. Their estimates provided an average figure rounded to an additional 7 min. This allowed for non-technical factors such as waiting for equipment in the operating theatre, as well as the 'active' time placing the endoloop. This part of the procedure is also frequently used as a training opportunity and performed by junior surgeons, potentially adding further time to the operation. It should of course be considered, however, that the immediate 'costs' of using a more technically demanding method, and the involvement of trainee surgeons may be a long-term investment, with an eventual return that is difficult to quantify. Attempts have been made in existing literature to quantify operative time when different methods of base fixation have been employed; however, the likely heterogeneity of the cases involved makes reasonable interpretation of the data troublesome [9].

The endoloop carries some inherent drawbacks, not least of which is the requirement of a healthy appendiceal base to allow for safe ligation. As with much of surgery, this is a judgement call made by the operating



Fig. 2. Ethicon ENDOLOOP® Ligature made with PDS® II.

surgeon upon inspection of the tissue. This requirement will undoubtedly have some bearing upon operative results as there is likely to be a skew towards the use of endoloops in less severe cases of appendicitis [4]. However, as cases being compared within this study were by definition judged to be suitable for use of endoloop ligation by the operating surgeon, this possible inherent skew will not impact upon our results.

A further purported limitation of endoloop ligation is a possible higher rate of stump insufficiency, as found in some published studies by Beldi et al. [5], who reported a rate of intra-abdominal surgical site infection at 1.7% with endoloop use, compared to 0.7% in their stapler group. However, a subsequent study by Sahm et al. did not reproduce these results, and reported no significant difference in relevant complications when comparing endoloops to a stapler [10].

Resources are finite and increasingly stretched, and marginal savings should be made wherever this is achievable without an apparent downside. The calculated overspend of £842.58 due to the use of an additional endoloop with no measurable benefit is an example of such a potential saving. This figure is also purely a materials costing, and does not include additional costs such as the accumulative additional operating time spent on the placement of an apparently superfluous ligature. Using the average endoloop placement time of 7 min as quoted by our body of experts, across the 60 cases of 'double fixation' of the base, $(7 \times 62 =)434$ min of additional operating time was used due to use of this method. With theatre time both costly and often sparse, this additional expense should be factored in when considering the potential saving that can be made [11].

There were some limitations to our study, and we will discuss the major two, with the first being incomplete data. Of the cases in our population data, 3 had no operation note, meaning we were unable to include them in the review. In 17 of the operations where endoloops were utilised, the number of endoloops left on the base was not stated, and therefore they could not be included in our full; though with only 3 minor complications (two post-op pain and one maternal concern re wound healing) in this group, we feel it is unlikely this would have impacted our findings.

Secondly, follow-up conducted was limited to the post-operative hospital stay, and any readmissions to our centre within 30 days. The data available to us, and our subsequent analysis, did therefore not include any presentation to other hospital centres or to GP practices. Those presenting to their local GP are likely to present with minor grade complications on the Clavien-Dindo system, but any presenting to other centres may have suffered higher grade complications - though it is important to note that no other deaths were recorded.

Finally, we accept that our study population of 254 is small, and therefore caution must be applied for the generalisability of these results.

Further research should be carried out to strengthen the findings of this study, with a multi-centred randomised controlled trial the ideal way forward. Further research should be also be carried out to assess for the cost effectiveness of using endoloops for appendiceal base closure vs other laparoscopic methods, such as such as stapling devices and electrothermal devices.

5. Conclusion

Our study set out to assess whether the complication rate differs in cases where one or two endoloops have been applied to the appendiceal base. Retrospective statistical analysis of these cases found that there was no significant difference between the two groups. Thus based on these findings, we can conclude that it is acceptable to use one endoloop to secure the base in laparoscopic appendicectomy.

Looking purely at equipment cost, in our centre this would have led to a cost saving of £842.58 in the year 2020. This is a small change, but in a high volume procedure, can have an accumulative impact.

Compliance with ethical standards

This work has been reported based on Standards for Quality Improvement Reporting Excellence Guidelines (SQUIRE 2.0) and the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement.

Ethical approval

Given the nature of this study, ethical approval was not required, nor sought.

Sources of funding

The authors declare that sponsors had no involvement in this study.

Author contribution

JRCS: study conception, data collection, interpretation and analysis, manuscript preparation. JMB: data collection, interpretation and analysis, manuscript preparation. KKB: study conception, critical revision of manuscript.

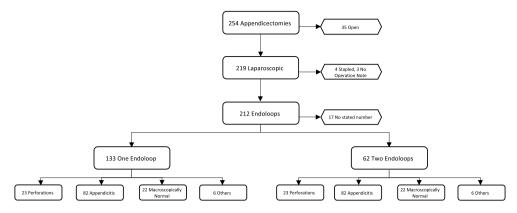


Fig. 3. Flow diagram of patient selection.

Table 1Fisher's Exact data for calculation.

	No Complication	Complication	Total
One Endoloop	123	10	133
Two Endoloops	58	4	62
Total	181	14	195

Consent

Given the retrospective nature of the study and anonymised data presentation, informed consent was not required or obtained.

Registration of research studies

N/A, as per Torbay Research & Development Director and the NHS HRA decision tool, not classified as research requiring registration.

Guarantor

Jonathon Sheen.

Declaration of competing interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.

org/10.1016/j.amsu.2021.102364.

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