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ORIGINAL ARTICLE

A standardized use of intraoperative anastomotic testing in colorectal surgery in the new millennium: is technology taking over? A systematic review and network meta-analysis

E. Rausa[1] · M. A. Zappa[2] · M. E. Kelly[3] · L. Turati[1] · A. Russo[1] · A. Aiolfi[4] · G. Bonitta[1] · L. G. Sgroi[1]

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Abstract

Background Anastomotic leakage (AL) remains the most challenging complication following colorectal resection. There are several tests that can be used to test anastomotic integrity intraoperatively including air leak testing (ALT) and intraoperative colonoscopy (IOC). Indocyanine green (ICG) can be used to visualise blood supply to the bowel used in the anastomosis. However, there is no consensus internationally regarding routine use and which technique is superior. The aim of this study was to determine which intraoperative anastomotoic leak test (IALT) was most effective in reducing AL.

Methods A systematic review and network meta-analysis were performed. An electronic systematic search was performed using Pubmed, CENTRAL, and Web of Science, of studies comparing ALT, IOC, and ICG. The inclusion criteria were as follows: (a) patients must have had colorectal surgery with formation of an anastomosis; (b) studies must have compared one or more IALTs; (c) and studies must have clear research methodology.

Results Eleven articles totalling 3844 patients met the inclusion criteria and were included in this meta-analysis. Point estimation showed that the AL rate in the control group (no IALT) was significantly higher when compared to the ICG group (RR 0.44; Crl 0.14–0.87) and higher, but without reaching statistical significance, when compared to ALT (RR 0.53; Crl 0.21–1.30) and IOC (RR 0.49; Crl 0.10–1.80). Indirect comparison showed that the AL rate in the ICG group was lower, when compared to both ALT (RR 0.44; Crl 0.14–0.87) and IOC (RR 0.44; Crl 0.14–0.87).

Conclusions This study suggests that intraoperative testing for a good blood supply using ICG may reduce the AL rate following colorectal surgery.

Keywords Postoperative complication · Anastomotic leak · Colonoscopy · Indocyanine green

Introduction

Anastomotic leakage (AL) remains the most challenging complication following colorectal resection, with considerable associated morbidity and/or mortality. Despite the introduction of improved stapler devices and minimally invasive techniques, the symptomatic AL rate is 5–19%, depending on the site and type of anastomosis [1].

As a result, surgeons have developed several intraoperative anastomotic leak tests (IALT) to try to detect anastomotic defects and reduce the incidence of AL. However, there are little data or consensus on which techniques are best. Lazorthes and Chiotassol highlighted the potential benefit that intraoperative air leak testing (ALT) could have in reducing AL following colorectal resection in the 1980s [2].

Since then, ALT has remained the most popular intraoperative technique for identifying AL. In recent decades,

✉ E. Rausa
emarausa@yahoo.it

1 Surgical Oncology Unit, Treviglio Hospital, Piazzale Ospedale 1, 24047 Treviglio, Bergamo, Italy

2 Division of General Surgery, Fatebenefratelli Hospital, Milan, Italy

3 Department of Colorectal Surgery, St James Hospital, Dublin, Ireland

4 Department of Biomedical Science for Health, Division of General Surgery, Istituto Clinico Sant'Ambrogio, University of Milan, Milan, Italy

other tests have been proposed including direct anastomotic assessment with intraoperative colonoscopy (IOC) or the use of indocyanine green (ICG) to assess integrity of anastomotic blood supply [3]. Both ALT and IOC methods are based on the macroscopic evaluation of the integrity of the anastomosis, while ICG allows real-time angiography during surgery to evaluate the perfusion of the anastomosis. Specifically, this technique is based on direct visualization of the fluorescence emitted by ICG under near-infrared light that can be identified using dedicated cameras and scopes [4].

Recently, several studies have reported promising results with ICG and reduced AL rates [5]; however, there remains little consensus on its routine use. The aim of this network meta-analysis was to determine which IALT was most effective in reducing AL.

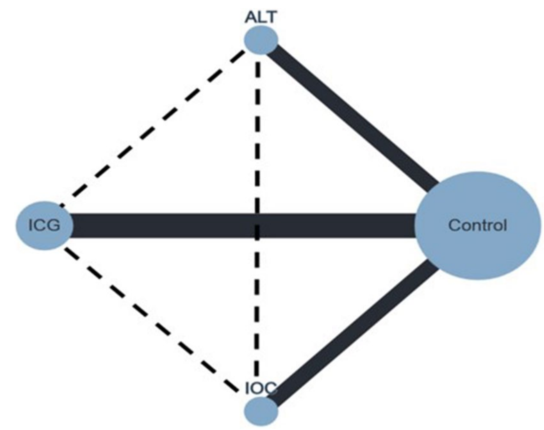

Fig. 1 Network geometry for studies reporting symptomatic AL in Control, ALT, IOC, and ICG groups. Solid lines indicate direct comparisons and dotted lines indirect comparisons

Materials and methods

Search strategy

A systematic review was performed according to the guidelines from the preferred reporting items for systematic reviews and meta-analyses checklist (PRISMA-NMA) [6]. Institutional review board approval was not required. According to the recommendations made by Goossen et al, we conducted an electronic systematic search using MEDLINE, CENTRAL and Web of Science [7]. We searched for papers published in English between January 1, 2000 and, October 1, 2019. We used the following search headings: IALT, anastomotic leak, colorectal resection, colorectal surgery, intraoperative colonoscopy, indocyanine green fluorescence, laser fluorescence angiography. All titles were initially screened and suitable abstracts were reviewed. Finally, each of the eligible publication reference section was also checked for other potential papers (Fig. 1).

Study inclusion criteria

According to Stroup et al. recommendations only randomized controlled trials (RCTs) or non-controlled clinical trials (non-RCTs) were included in this study [8]. To be included, the articles had to meet the following criteria: (a) patients have had colorectal surgery with an anastomosis; (b) studies have compared one or more IALTs; (c) and studies have clear research methodology.

Data extraction

The following data were retrieved from the selected publications and entered into a data set independently by two investigators (LT and ER). Recorded details included author information, study details; year, country, design, and patients details; gender, age, body mass index (BMI). In addition, primary diagnosis, type of surgery, type of IALTs, and AL rate were also recorded. Data entered were only compared at the end of the reviewing process to reduce the selection bias. A third author (MK) reviewed the database, with duplicates being erased and discrepancies clarified.

Study quality assessment

Assessment of risk of bias of included studies was performed using the Risk of Bias In Non-randomized Studies—of Interventions (ROBINS-I) tool [9], which categorises risk of bias as low, moderate, serious, critical and unclear, with the risk of bias category for each study being reported. If a study's risk of bias was categorised as serious, critical or unclear, the effect of removing this study was tested and the relevant outcome(s) reported.

The methodological quality of the selected RCTs was appraised using the Cochrane risk-of-bias tool [10]. Trials were graded as follows: L = low risk, H = high risk, U = unclear risk. The quality of all included studies is depicted in Table 1.

Clinical leak

According to Rahbari et al., AL was defined as a defect of the intestinal wall at the anastomotic site leading to a communication between the intra- and extraluminal compartments. Severity of AL was graded as: (a) no changes in patients' management required, (b) requiring active intervention, but not relaparotomy, and (c) requiring relaparotomy [11]. Eight studies [12–19] included in this network meta-analysis defined ALs on both clinical and radiological bases, two studies [20, 21] did not specifically report it, and one study [22] defined it only on clinical terms.

Table 1 Quality assessment of the included studies

Author	Con-founding bias	Selection bias	Classifica-tion bias	Interven-tion bias	Missing data bias	Measure-ment bias	Reporting bias	Bias
Observational studies[a]								
Allaix et al. 2018, Italy [12]	n	y	n	pn	n	pn	pn	Moderate
Ricciardi et al. 2009, USA [14]	n	y	n	pn	n	pn	pn	Moderate
Boni et al. 2016, Italy [15]	n	y	n	py	pn	n	pn	Moderate
Kim et al. 2015, Korea [16]	pn	py	n	py	n	pn	py	Serious
Kin et al. 2015, USA [17]	n	py	n	n	n	n	pn	Moderate
Jafari et al. 2013, Korea [18]	n	y	n	pn	n	pn	pn	Moderate
Li et al. 2009, USA [19]	n	py	n	pn	n	n	pn	Moderate
Lanthaler et al. 2008, Austria [20]	py	py	n	n	n	n	py	Serious
Shamiyeh et al. 2011, Austria [21]	n	y	pn	n	n	pn	py	Serious
Kudszus et al. 2010, Germany [22]	pn	py	pn	py	pn	py	py	Serious
Randomized clinical trial[b]								
	1	2	3	4	5	6	7	
Ivanov et al. 2011, Serbia [13]	H	H	L	U	H	U	L	

Each domain is evaluated with one of the following: y "yes", py "probably yes", pn "probably no", and n "no". The categories of judgement for each study are low, moderate, serious, and critical risk of bias

ALT air leak test, *IOC* intraoperative colonoscopy, *ICG* indocyanine green

[a]The quality of observational studies was performed using ROBINS-I tool

[b]The quality of the randomized clinical trials was assessed by Cochrane risk of bias tool (L = low risk, H = high risk, U = unclear risk). 1 = random sequence generation; 2 = allocation concealment; 3 = blinding of participants and researches; 4 = blinding of outcome assessment; 5 = incomplete outcome data; 6 = selective reporting; 7 = other bias

Outcomes of interest

Outcomes of interest were AL rate in the control group (no IALT), versus AL in patients who had ALT, IOC, and ICG testing.

Statistical analysis

We performed fully Bayesian arm based random effect network meta-analysis, in particular mixed treatment comparison. Briefly, the network meta-analysis simultaneously synthesizes data from all available trials within a consistent network and combines direct evidence (comparison of treatments within head-to-head trials) with indirect evidence (comparison of treatments across trials against a common comparator) [23].

We preferred the Bayesian approach because that takes into account all sources of variation and reflects these variations in the pooled result. Furthermore, the Bayesian approach can provide more accurate estimates for small samples. An ordinary consistency model was adopted with the binomial/log model as likelihood was used. Non-informative priors distribution included in this analysis were Normal (0, 1000) for log of Relative Risk (RR) and relative effects, Gamma (0.001, 0.001) distribution for random effect precision. Pairwise comparison were performed using unrelated mean effects model [24]. To provide valid indirect inferences we considered the transitivity assumption (i.e. studies comparing different sets of interventions needed to be sufficiently similar). To assess transitivity, we generated descriptive statistics and we compared the distributions of baseline participant characteristics across studies and treatment comparisons. We assumed a common heterogeneity parameter across the various treatment comparisons. To evaluate statistical heterogeneity, we calculated between-trial variances and I2–index, assuming a common estimate for the heterogeneity variance across the different comparisons. I2–index value of 25% was defined as low heterogeneity, 50% as moderate heterogeneity, and 75% as high heterogeneity [25]. To assess local inconsistencies we used the nodesplitting method [26].

The inference was performed using mean and relative 95% credible intervals (Crl), based on draws from marginal posterior distribution in Monte Carlo Markov chain, simulating 350,000 iterations after a burn-in period of 30,000 iterations. We consider the estimated parameter significance when its 95% Crl encompass null hypothesis value. Sensitivity analysis regarding the choice of prior distribution of random effect precision was considered.

Model convergence was assessed by analysing history, running means density and Brooks-Gelman-Rubin diagnostic plots In addition, autocorrelation plots were assessed to detect the presence of auto-correlation in the chains [27]. We plotted rank probabilities against the possible ranks for all competing treatments. All statistical analyses were carried out using Jags [27] and R-Cran [28].

Results

Literature search and study characteristics

One thousand three hundred and sixty-two publications were found using the search criteria. After removing duplicates, 172 publications were further examined. Further screening revealed that only 11 articles [12–22] met the predefined inclusion criteria. Six studies were prospective [12, 14–16, 20, 21], 4 were retrospective [17–19, 22], and 1 study was a randomized control trial [13] (Fig. 2).

Patient characteristics and follow-up

Three thousand eight hundred and forty-four patients were included in this analysis. One thousand seven hundred and sixty-eight patients (46%) were in the control group (no IALT), 1253 patients (32.5%) had ATL, 555 patients (14.5%) had ICG assessment, and 268 patients (7%) had IOC assessment. The gender of 3231 patients was specified; 1989 (61.5%) were male and 1242 (38.5%) were female. The median age was 61.4 years (range 50–69 years) and the median body mass index 25.7 kg/m^2 (range 23.2–27 kg/m^2). One thousand four hundred sixty-six patients (62%) had surgery for neoplasia. All patients had either colonic or rectal resection (Tables 2, 3).

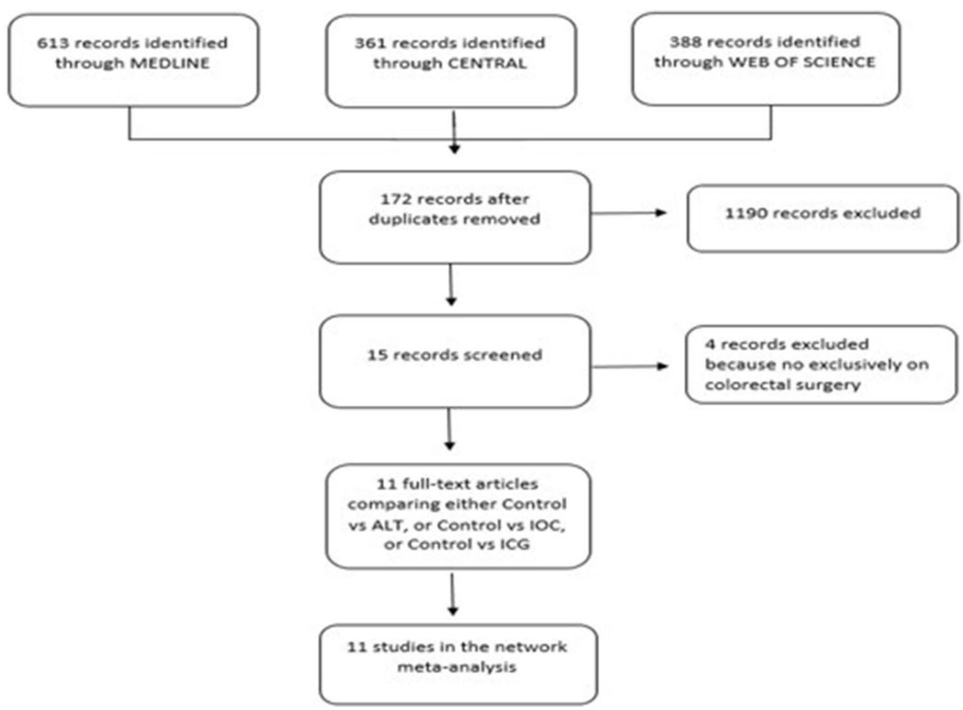

Fig. 2 Flowchart of studies retrieved from literature search

Table 2 Demographic and clinical characteristics of patients in the four groups

	Control $n=1768$	ALT $n=1253$	ICG $n=555$	IOC $n=268$
Median age (years)	61.2 (50–69)	66 (53.8–66)	62.2 (48–71)	58 (50–70)
Median BMI (kg/m^2)	24.7 (23.2–27)	25 (23–26)	26 (22.8–26.7)	26 (24.4–26.1)
Gender				198 (53.5%
Male	811 (62.7%)	728 (65.8%)	252 (54.5%)	198 (53.5%)
Female	482 (37.3%)	378 (34.2%)	210 (45.5%)	172 (46.5%)
AL documented both clinically and radiologically	106 (6%)	47 (3.7%)	22 (3.9%)	7 (2.6%)

ALT air leak testing, *ICG* indocyanine green, *IOC* intraoperative colonoscopy, *BMI* body mass index, *AL* anastomotic leak, *ALT* Air leak test, *IOC* Intraoperative colonoscopy, *ICG* indocyanine green

Table 3 Main findings of the included studies

Author	Study	Group	No. patients	Median age, years	Male	AL	Neoplasia	Left hemi-colectomy	Sigmoid resection	Anterior resection	Other
Allaix et al. [12]	Prospective	ALT	398	66	217 (54%)	10	295 (74%)	102	183	113	0
		Control	379	65	179 (47%)	22	276 (73%)	105	152	122	0
Ivanov et al. [13]	RCT	ALT	30	58	20 (66%)	3	NR	0	14	5	11
		Control	30	62	18 (60%)	6	NR	0	17	4	9
Ricciardi et al. [14]	Prospective	ALT	825	NR	NR	34	NR	NR	NR	NR	0
		Control	173	NR	NR	14	NR	NR	NR	NR	0
Boni et al. [15]	Prospective	ICG	42	69	28 (66%)	0	42 (100%)	0	0	42	0
		Control	38	67	22 (83%)	2	38 (100%)	0	0	38	0
Kim et al. [16]	Prospective	ICG	123	57	73 (59%)	1	123 (100%)	0	0	123	0
		Control	313	58	192 (61%)	17	313 (100%)	0	0	313	0
Kin et al. [17]	Retrospective	ICG	173	58	54 (31%)	13	98 (56%)	113	40	20	0
		Control	173	58	54 (31%)	11	98 (56%)	110	43	20	0
Jafari et al. [18]	Retrospective	ICG	16	58	12 (75%)	1	16 (100%)	0	0	16	0
		Control	22	63	16 (73%)	4	22 (100%)	0	0	22	0
Li et al. [19]	Retrospective	IOC	107	52	49 (45%)	0	24 (22%)	1	70	16	20
		Control	137	53	62 (45%)	2	23 (17%)	8	96	13	18
Lanthaler et al. [20]	Prospective	IOC	73	62	67 (91%)	4	49 (67%)	6	41	26	0
		Control	49	NR	NR	2	NR	2	24	21	0
Shamiyeh et al. [21]	Prospective	IOC	85	62	44 (51%)	1	14 (16%)	NR	NR	NR	0
		Control	253	60	133 (52%)	4	35 (14%)	NR	NR	NR	0
Kudszus et al. [22]	Retrospective	ICG	201	69	85 (42%)	7	NR	NR	NR	NR	NR
		Control	201	67	85 (42%)	15	NR	NR	NR	NR	NR

ALT air leak test, *IOC* intraoperative colonoscopy, *ICG* indocyanine green, *RCT* randomized controlled trial, *NR* not reported

Anastomotic leak

The point estimation showed that the AL risk in the control group was significantly higher when compared to the ICG group (RR 0.44; Crl 0.14–0.87) and higher but not significant when compared to ALT (RR 0.53; Crl 0.21–1.30) and IOC (RR 0.49; Crl 0.10–1.80). Moreover, the indirect comparison showed that AL risk in patients who had ICG was lower, though not significantly so, when compared with both ALT (RR 0.44; Crl 0.14–0.87) and IOC (RR 0.44; Crl 0.14–0.87) (Fig. 3a). Table 4 is a league table showing all pairwise comparisons in the network meta-analysis.

A rank plot illustrating empirical probabilities for AL with each assessment ranked first through fourth (left to right) is provided in Fig. 3b. The global heterogeneity was low ($I^2 = 13.0\%$). The sensitivity analysis regarding the choice of prior distribution for τ showed robustness of findings and the leverage plot did not show a potential outlier.

Discussion

This network meta-analysis observed that among all the IALT currently available, assessment with ICG offers the greatest reduction in symptomatic AL risk following colorectal surgery.

AL still remains the most feared complication following colorectal surgery. Its incidence is affected by several elements including preoperative factors (age, neoadjuvant chemotherapy, nutrition, and type of neoplasm), intraoperative factors (fluid replacement, hypothermia, type and length of surgery and surgical technique) and postoperative factors (medications and postoperative care) [1].

Ultimately, AL is multifactorial, and due to modifiable and non-modifiable factors. Historically, the role of IALT was to assess the structural integrity of the colorectal anastomosis, and out-rule a technical error. The use of ICG has been advocated in recent years to assess the actual perfusion of the new anastomosis and assess for vascular compromise. Concerns over ICG significantly increasing

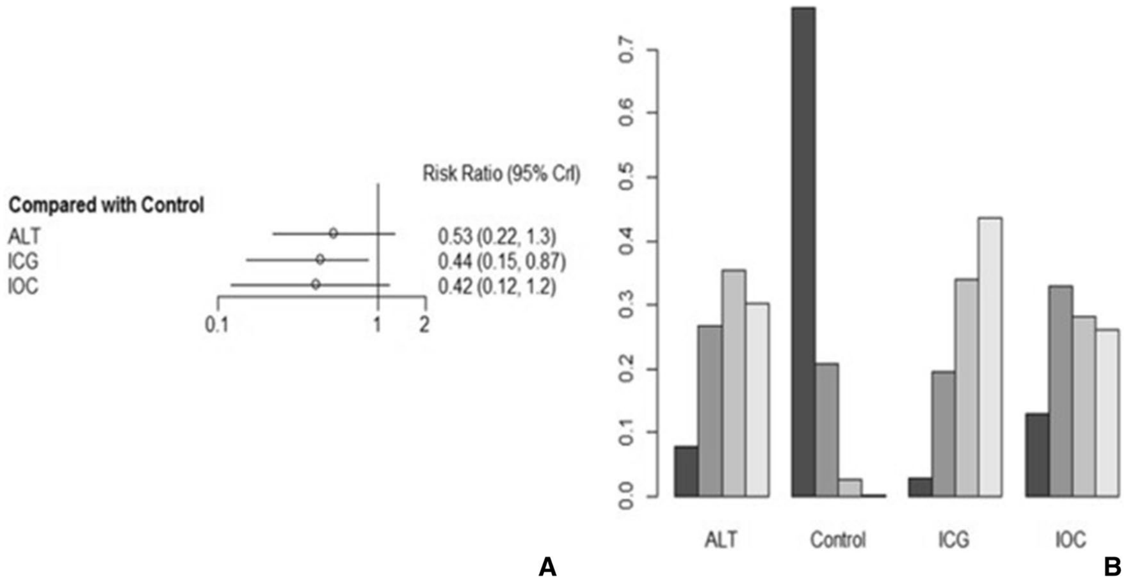

Fig. 3 **a** Forest plots of network meta-analysis estimates the RR for symptomatic AL. **b** Rank plot created using the rankogram function from the gemtc R package applied to the four groups illustrating empirical probabilities that each treatment is ranked first through fourth (left to right) for symptomatic AL

Table 4 League table

ALT	1.49 (0.80, 2.40)	0.92 (0.42, 1.83)	1.05 (0.46, 2.27)
0.66 (0.75, 0.99)	Control	0.62 (0.38, 1.05)	0.71 (0.38, 1.32)
1.07 (0.83, 1.10)	1.60 (0.94, 2.62)	ICG	1.14 (0.52, 2.51)
0.98 (0.43, 2.16)	1.40 (0.75, 2.57)	0.87 (0.39, 1.91)	IOC

Values are expressed as Risk Ratio (RR) and 95% Credible Intervals (95%CrI)

ALT air leak test, *IOC* intraoperative colonoscopy, *ICG* indocyanine green

operative times have been refuted in recent studies [15]. However, there is a lack of case-matched RCT evidence to adequately assess if ICG assessment does impact on AL and associated morbidity and mortality. Only with this, can consensus be reached on whether or not ICG assessment should be a standardized step for testing blood supply to all colorectal anastomosis. Without it, the cost of acquiring the necessary equipment to perform ICG will always remain an issue for institutions, given the increased costs of healthcare and the healthcare budget constraints.

We acknowledge that this review has some limitations. The lack of large-volume RCT evidence to date is a significant issue, plus there is some heterogeneity in study populations, selection bias and surgical techniques in the included studies. However, this is the first meta-analysis of current IALT techniques.

The confidence interval crosses null value or includes values favouring either treatment. Including observational studies may be considered a limitation; however, the a priori exclusion of these studies in systematic reviews would be inappropriate and internally inconsistent with an evidence-based approach [29].

The confidence in the estimates was assessed using CINeMA and was found to range from moderate to very low primarily due to the quality of the included studies [30]. Regarding the interpretation of the treatment ranking, caution is needed regarding the confidence level. In fact, the treatment ranking does not consider the magnitude of differences in effects between treatments and therefore chance may explain any apparent difference between treatments. Thus, that our results suggest surgeons should choose the IALT technique, which best suits their expertise and the equipment available at their institution.

Conclusions

Surgical technology has been rapidly evolving, and this review highlights the change in thinking regarding prevention of AL. Historically, assessment of anastomotic integrity was based on structural evaluation and ensuring there were no technical issues with the anastomosis. ICG represents a change in assessment, and surgical philosophy. However, there is a need for better RCTs, to strengthen our results, especially regarding the impact on AL and subsequent morbidity. In addition, cost analysis should be assessed to support its universal acceptance amongst colorectal surgeons.

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Compliance with ethical standards

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

Ethical approval Not applicable.

Informed consent Not applicable.

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