The impact of indocyanine green fluorescence angiography in changing the planned surgical site resection on the rates of colorectal anastomotic leak: our early experience

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Background
Anastomotic leak (AL) is one of the most serious complications of colonic resection with a mortality rate of ~12–21%. Despite the advances in laparoscopic systems and anastomotic techniques, the AL rate is still high (6–15%). Poor perfusion at the anastomotic site is a major cause of AL. Indocyanine green fluorescence angiography (ICG-FA) can be used to ensure good perfusion at the resection site to construct secure anastomosis.
Aim
To evaluate the impact of ICG-FA on changing the surgical site resection and its impact on colorectal AL rate compared with traditional white light assessment of the resection site.
Patients and methods
This is a prospective interventional comparative study that included patients who underwent successful laparoscopic colectomy during the period between August 2020 and February 2022. In all, 39 patients were included in the study and were divided into two groups: The ICG-FA group included 16 patients in which we used ICG-FA to assess the perfusion at the resection site before performing anastomosis. The control group included 23 patients in which the perfusion of the anastomotic site was assessed under white light.
Results
The assessment of the perfusion using ICG-FA led to a change in the surgical plan in two (12.5%) patients. The leak rate was 6.3% (one patient) in the ICG-FA group compared with 8.7% (two patients) in the control group. The decrease in AL was not statistically significant and we cannot prove that changing the surgical plan using ICG-FA reduced the leakage rate because of the small sample size. So, larger prospective, randomized controlled trials are recommended to prove its efficacy.

Keywords:
indocyanine green fluorescence angiography, indocyanine green, laparoscopic colectomy

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Introduction

Anastomotic leak (AL) is one of the most serious complications of open or laparoscopic colon resection. It ranges from minor controlled leakage with mild peritonitis to serious morbidities including perianastomotic abscess, peritonitis, septic shock, and mortality. It has a mortality rate of about 12–21% with an average of about 16.3% depending on the general condition of the patient and the location of anastomosis [1,2].

AL may also adversely affect colorectal cancer oncologic outcome in terms of increased local recurrence, delaying postoperative chemotherapy or radiotherapy, and reduced survival. For this reason, the prevention of colorectal AL is of extreme importance [3].

Despite significant advancements in laparoscopic systems, including high-definition and three-dimensional systems, the leak rate during laparoscopic colectomy remains high [2].

The patient's general state, malnutrition, receiving preoperative chemotherapy or radiotherapy at the distal location of the anastomosis, prolonged operating time, peritoneal infection, technical mistake, or poor perfusion of the anastomotic site are all risk factors for AL [4].

The leak rate varies since the definition of AL is variable. It is characterized as disruption of the anastomotic suture line, which can be felt with digital

rectal examination, seen with a sigmoidoscope, or seen with contrast extravasation following a contrast study [5].

AL rate varies according to the anastomosis site; the rate of AL in ileo-colic anastomosis ranges between 1 and 4%), whereas AL in colocolic ranges between 2 and 3% with the greatest risk of AL in colorectal or colo-anal anastomosis reaching about 5–19% [6].

Despite several studies on the risk factors for AL and advances in surgical techniques, the incidence rate of AL has not decreased much [7].

Good surgical technique ensuring integrity and securing good perfusion for the anastomotic site may improve healing and reduce leakage rate. The air leak test or endoscopic examination of anastomosis can be done to ensure the integrity of the anastomosis [8].

Traditional subjective methods for determining adequate perfusion include the color of the mucosa, bleeding after cutting the edges, and feeling mesenteric pulsations. Traditional approaches can give a good judgment for the perfusion at the planned resection site, but they are subjective and rely on the surgeon's experience, and are ineffective in some cases [9].

Doppler for mesenteric arteries, tissue oxygen tension, and oxygen spectroscopy are among the objective tests that can be used. Doppler has been used since 1987, but it is ineffective, and other technologies are expensive and cannot be utilized with a laparoscope [5].

Indocyanine green (ICG) can be used in the assessment of anastomotic perfusion with near-infrared (NIR) fluorescence camera and this is called indocyanine green fluorescence angiography (ICG-FA). It is suitable for both open and laparoscopic surgeries. It allows us to see the mesenteric flow to the anastomosis site, which is crucial in laparoscopic procedures [10].

Visualization of the mesenteric perfusion is critical because it may lead to intraoperative alterations in the planned resection site and anastomosis construction dependent on the vascularity of the anastomotic site. This would enable us to perform anastomosis in a well-perfused location [10].

Patients and methods

It is a prospective interventional comparative study that included patients who underwent laparoscopic colorectal surgery at the Department of Colorectal Surgery at Ain Shams University Hospitals between August 2020 and February 2022. In all, 39 patients were included.

Patients who refused to participate in the study, those who had an unfavorable reaction to ICG or iodine in the past, and pregnant and lactating women were all included in the control group instead of the ICG-FA group.

The eligible patients for our study were divided into two groups: the ICG-FA group (16 patients) in which we used ICG-FA to assess the perfusion at the resection site before performing anastomosis. And the control group included 23 patients in which perfusion of the anastomotic site was assessed under white light.

Ethical approval was obtained from the Ethics Committee of Ain Shams University Hospitals and all patients signed informed consent for the surgery, and patients in the ICG-FA group signed detailed informed consent about the ICG and the technique.

Indocyanine green

ICG is an anionic sterile hydrophilic dye with a molecular weight of 776 D. It was developed by Kodac Laboratories for NIR photography in 1955 and was FDA approved for clinical use in 1959 [11].

It binds to intravascular lipoproteins after injection and is secreted entirely by the liver with no metabolites. After around 8 min from the injection, it will be excreted in bile [11].

The dose of ICG is variable and the majority of studies used a dose of 0.1–0.5 mg/kg of ICG, whereas some studies used a fixed dose of 5–25 mg, not based on body weight [12]. In our study, we used a fixed dose of 12.5 mg regardless of body weight.

It appears fluorescent after injection and can be seen with NIR light at wavelengths of around 829 nm or longer. A specially built camera can detect it and will enable real-time monitoring of mucosal perfusion [13].

Laparoscopic equipment

A laparoscopic system (Karl Storz GmbH & Co. KG, Tuttlingen, Germany) was used. The imaging is generated by the high-end full high-definition camera system (IMAGE 1 SPIESTM, Karl Storz) connected to a laparoscope with a 30° field of direction and 10 mm diameter equipped with a specific filter for optimal detection of the NIR fluorescence and white light without manual switching. The powerful Xenon light source (D-LIGHT P SCB; Karl Storz) provides both

visible and NIR excitation light. Switching from standard light to NIR is controlled by the surgeon using a pedal.

Statistical analysis

Statistical analysis was performed with SPSS software, version 25.0 for Windows (SPSS Inc., Chicago, Illinois, USA). Quantitative variables are presented as mean and SDs and qualitative data as the number and its percentage. Quantitative variables are compared with Student's *t* test and qualitative variables are compared with the χ^2 test. *P* values of less than 0.05 were considered statistically significant.

Surgical technique

All patients were placed in the supine 'Lloyds Davie' position under general anesthesia, and four ports were implanted using our approach, which differed in position depending on the tumor site. The principle of complete mesocolic excision was used to mobilize relevant colons from their retroperitoneal attachments. The laparoscopic vessel sealer 'Ligasure' was used to isolate and ligate vessels.

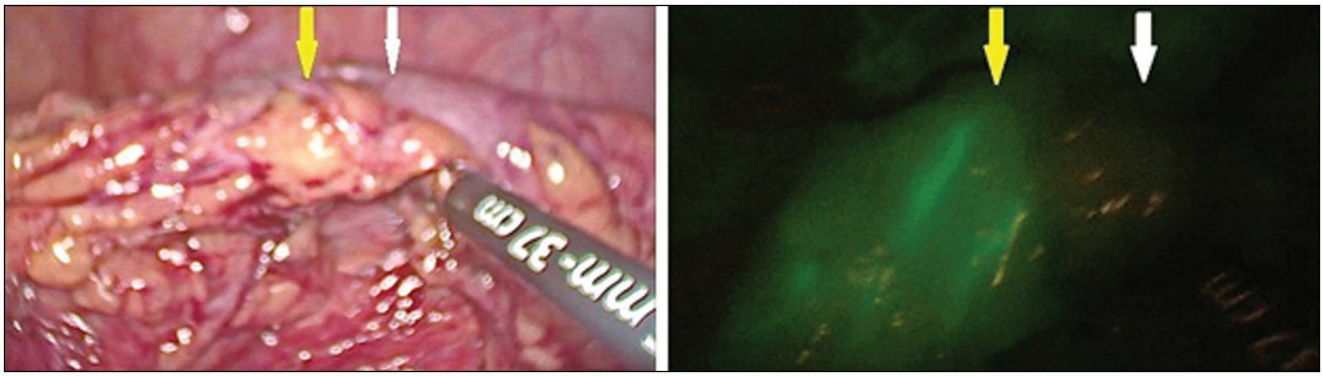
In the ICG-FA group, a dose of 12.5 mg ICG was given intravenously after the mesentery was divided at the level of the planned transaction under white light. Following injection, the xenon light is converted to NIR, and the camera filter that detects fluorescence is activated. Fluorescence appears on the colonic wall within seconds of injection, confirming intestinal perfusion. If the intestinal perfusion was inadequate (weak fluorescence), a resection to a well-perfused region (high fluorescence) would be performed (Fig. 1).

Because external light hinders fluorescence detection by the camera, the operative room should be fully darkened in cases when bowel division was performed extracorporeally.

A right transverse incision is used to deliver the specimen for right colon cancers, while a Pfannenstiel incision is used to deliver the specimen for left and rectal tumors.

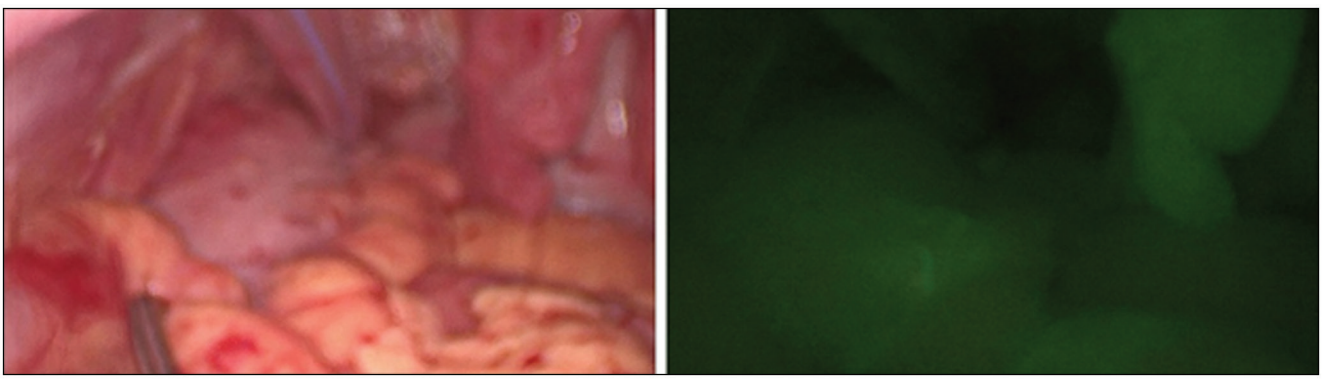
After that, the colon was separated within a well-perfused tissue area (high fluorescence). The bowel continuity was restored via ileo-transverse, colocolic, or colorectal anastomosis, and after the anastomosis was completed, an air leak test was done in the left-sided anastomosis, and a second evaluation of perfusion was performed (Fig. 2).

Figure 1



Assigned site for resection under white light (white arrow). Revision of the site to a well-perfused area guided by ICG-FA (yellow arrow). ICG-FA, indocyanine green fluorescence angiography.

Figure 2



Rechecking of the perfusion at the anastomosis after completion of anastomosis and performing air leak test.

The control group used the same anastomotic procedure without ICG injection, and the bowel perfusion was assessed by its color and its bleeding edges under white light or by feeling pulsations when performed extracorporeally.

Results

Our study included 39 patients who underwent laparoscopic colectomy. They were split into two groups: the ICG-FA group (16 patients), who had ICG utilized to assess anastomotic perfusion, and the control group (23 patients), who had conventional laparoscopic colectomy.

Characteristics of the tumors and demographics of the patients are presented in Table 1. There were no significant differences between the ICG-FA and control groups in terms of age, sex, BMI, ASA scores, tumor location, previous abdominal operation history, or preoperative chemotherapy (P>0.05).

All the participants in this study had effective laparoscopic surgery. In Table 2, surgical and pathological data are presented. The mean operative time in the ICG-FA group was 195 ± 10 min, which is marginally less than the control group which was 202 ± 14 min. In the ICG-FA group, there were no adverse responses.

Table 1 Demographic data of the patients and preoperative assessment

	ICG-FA group (N=16)	Control group (N=23)	P value
Sex [n (%)]			0.06
Male	7 (43.8)	11 (47.8)	
Female	9 (56.2)	12 (52.2)	
Age (year) (mean±SD)	49.3 ± 8.1	51.1 ± 10.4	0.63
BMI (kg/m^2) (mean±SD)	28.6 ± 1.5	27.7 ± 1.7	0.09
ASA score [n (%)]			0.88
I	9 (56.2)	14 (60.9)	
II	6 (37.5)	7 (30.4)	
III	1 (6.3)	2 (8.7)	
Previous abdominal operations [n (%)]			0.75
Yes	10 (62.5)	13 (56.5)	
No	6 (37.5)	10 (43.5)	
Preoperative neoadjuvant therapy [n (%)]			0.99
NACT	8 (50)	10 (43.5)	
No	8 (50)	13 (56.5)	
Tumor location [n (%)]			0.77
Cecum	2 (12.7)	5 (21.7)	
Hepatic flexure	2 (12.7)	2 (8.7)	
Descending colon	1 (6.3)	4 (17.4)	
Sigmoid	3 (18.8)	3 (13)	
Upper rectum	3 (18.8)	5 (21.7)	
Lower rectum	5 (31.3)	4 (17.4)	

ICG-FA, indocyanine green fluorescence angiography.

Due to insufficient intestinal perfusion, two (12.5%) patients in the ICG-FA group had additional 'resection' up to the 'fluorescent' area. One experienced descending colon cancer that required a left hemicolectomy, while the other was a low rectal cancer that required a low anterior resection.

After ICG administration, the average time for fluorescence was 49.5 ± 9.5 s.

All of the patients in both groups had negative resection margins, and their pathological results were equivalent.

A temporary diverting ileostomy was used in all patients with low anterior resection, and no anastomotic disruption was detected after ileostomy closure.

The ICG-FA group's mean postoperative stay was 5 ± 1.2 days, whereas the control group's postoperative stay was 5.3 ± 1.3 with no significant differences (P=0.69). To detect delayed leaking, every patient was followed up for 1 month following discharge.

Minor postoperative complications such as wound infection and ileus were similar in both groups (P=0.91). On postoperative day 5, one of the patients in the ICG-FA group who had sigmoidectomy had a minor AL that was observed in the drain and confirmed by a computed tomography scan. The patient was treated conservatively and discharged on the ninth postoperative day.

One of the patients in the control group who had left hemicolectomy had an AL that was diagnosed on

Table 2 Surgical and pathological details

	ICG-FA group (N=16)	Control group (N=23)	P value
Operation time (min) (mean±SD)	195 ± 10	202 ± 14	0.3
Operation [n (%)]			0.73
Right hemicolectomy	4 (25)	7 (30.4)	
Left hemicolectomy	1 (6.3)	4 (17.4)	
Sigmoidectomy	3 (18.8)	3 (13)	
Anterior resection	3 (18.8)	5 (21.7)	
Low anterior resection	5 (31.3)	4 (17.4)	
ICG allergy	0	–	
Changing assigned resection margin	2 (12.5)	–	
Diverting stoma [n (%)]			0.31
No	11 (68.8)	19 (82.6)	
Yes	5 (31.3)	4 (17.4)	
pTNM stage [n (%)]			0.5
I	1 (6.3)	3 (13)	
II	6 (37.5)	5 (21.7)	
III	9 (56.3)	15 (65.2)	

ICG-FA, indocyanine green fluorescence angiography.

Table 3 Outcome of the patients

	ICG-FA group (*N*=16)	Control group (*N*=23)	*P* value
Postoperative hospital stay (days) (mean±SD)	5±1.2	5.3±1.3	0.64
Postoperative complications [*n* (%)]			0.91
Anastomotic leakage	1 (6.3)	2 (8.7)	0.79
Wound infection	2 (12.5)	3 (13)	
Ileus	2 (12.5)	2 (8.7)	
Reoperation	0	1 (4.3)	0.4
Readmission	0	1 (4.3)	0.4
Mortality	0	0	

ICG-FA, indocyanine green fluorescence angiography.

postoperative day 5 by a computed tomography scan and was managed effectively by ultrasound-guided pigtail insertion. Another AL was identified after the patient was discharged on the 10th postoperative day; the patient was readmitted and required a laparoscopic peritoneal lavage and a diverting stoma.

However, the difference in leakage rate was insignificant in both groups (*P*=0.79). The difference in readmission and reoperation in both groups was insignificant (*P*=0.4). The mortality rate in both groups was 0% (Table 3).

Discussion

Laparoscopic colectomy has become the gold standard for colonic resection in patients with cancer colon or any other cause for resection. AL is one of the most serious complications of colectomy either open or laparoscopic [14].

AL following colorectal anastomoses can be related to several factors, the most important of which is possibly the insufficient blood supply [15].

Traditional methods such as feeling pulsation of the marginal artery, active bleeding from the edges, or lack of discoloration may make assessing perfusion at the anastomotic site easier in open surgery or extracorporeal resection in laparoscopic surgery, but these methods are subjective and unreliable [9].

Due to the lack of stereoscopic vision, assessing bowel perfusion under laparoscopy can be difficult, but it can be done by visual inspection under the white light of laparoscopy, looking for bowel color, bowel peristalsis, pulsation of the marginal artery, if possible, and bleeding at the resected bowel's margins. This approach is still subjective, although these are valuable clinical indications of adequate perfusion [12].

ICG is a water-soluble, nontoxic substance that fluoresces when exposed to NIR light. As a result, it might be considered a more reliable and simple way of determining perfusion [16].

The recently developed ICG-related equipment made intraoperative fluorescence angiography simple and has been utilized to assess the resection margin's real-time perfusion during laparoscopic surgery [17].

The beneficial effect of ICG-FA in reducing leak rates is mostly attributed to its ability to detect areas of low or absent perfusion, and thus guide the surgeon to revise the transection/anastomosis level to be done in a better perfused area [12].

Many studies have been performed to assess the effectiveness of ICG fluorescence in visualizing the perfusion pattern at the anastomotic site and its role in decreasing the AL rate.

Based on those findings, we evaluated the feasibility, safety, and short-term effects of using ICG in laparoscopic surgery for colon cancer. It is one of the first studies in Egypt to evaluate the efficacy of ICG-FAs in colorectal surgery.

We utilized ICG-FA to evaluate intestinal perfusion during laparoscopic surgery for cancer colon, and the mean operation time was 195±10 min which is slightly shorter than the control group, but not significantly (*P*=0.3). After ICG injection, the average time for perfusion in our study was 49.5±9.5 s, which was comparable to other studies such as 48.4±14 [18] and 43±4 [19].

We assumed that the difference in surgery time was attributable to the quick and precise assessment of intestinal perfusion as well as the procedure's simplicity. It is also a real-time procedure that can compensate for laparoscopic surgery's absence of tactile sense.

We found that the assessment of perfusion at the proximal and distal resection margins by ICG-FA was associated with revision of the surgical plan in two cases (nearly 12.5% of patients). Although we consider that standard methods of assessment may miss the microperfusion insufficiency of the transected bowel and planned site of anastomosis, it is impossible to prove that changing the anastomotic site prevented leakage in those circumstances.

One of the two cases in the ICG-FA group that required reresection intraoperatively was a descending colon cancer undergoing left hemicolectomy, and the other case was a low rectal cancer undergoing

low anterior resection. Both patients were above the age of 65 years and one of them had ischemic heart disease.

This could be explained by a recent study by Guo *et al*. [20], who discovered that ligating the left colic artery reduced blood pressure in the marginal artery by 30% and that in roughly 10% of patients, unstable blood flow to the left colon occurred after IMA ligation.

As a result, we confirmed that insufficient bowel perfusion is more common in patients with left colon cancer, and we urge that in laparoscopic left hemicolectomy and anterior resection, especially for the proximal margin, more attention be paid to bowel perfusion.

The leakage rate was also reduced from 8.7 to 6.3%. Although the results were statistically insignificant (P=0.79), they may encourage us to conduct a larger scale study.

The reoperation rate also reduced in the ICG-FA group, from 4.3% in the control group to 0% in the ICG-FA group, but the difference was statistically insignificant (P=0.4). In addition, the ICG-FA group's mean postoperative stay was shorter (5 ± 1.2 days) due to decreasing the complication rate, but not significant (P=0.46).

When we compare our findings with those of other studies, we find that they are similar, as shown in Table 4.

In their study, Kudszus *et al*. [21] found that using ICG-FA methods reduced and decreased postoperative hospital stay. Also, we found that the use of ICG-FA decreased the leakage rate by 2.4% and decrease the hospital stay, but the results were statistically insignificant may be due to the small sample size

According to Jafari *et al*. [17] and Boni *et al*. [19] removing poor perfusion from an anastomosis can reduce the rate of AL and thus improve outcomes, but it cannot eliminate patient factors that influence the rate of AL, and the technical integrity of the anastomosis is dependent on the surgeon's judgment. The findings were not statistically significant, thus randomized control studies were suggested instead. And their conclusion was similar to ours.

Aside from proper tissue perfusion, a wide range of factors influence anastomotic healing, including the patient's overall health, the level of anastomosis, the type of anastomosis, and the surgeon's experience. Kin *et al*. [22] discovered that the level of anastomosis and the surgeon's experience were the most important factors in reducing leakage rates.

Kim *et al*. [23] discovered that ICG-FA aids in maintaining adequate perfusion at the anastomotic location. And this will aid in reducing postoperative anastomotic issues like leakage or stricture, as well as avoiding difficulties like marginal artery injury, a short mesocolon, older patients, or poor general condition. So we think those cases (elderly, cardiac patients, and distal colon or rectal cancers) are more eligible for the use of ICG-FA in institutions that do not use ICG-FA routinely in all cases.

In their study, Su *et al*. [18] discovered that ICG-FA helps ensure excellent perfusion at the anastomotic site and that it is a simple procedure with a short learning curve, but that no leakage occurred in either the control or ICG-FA groups.

To evaluate the influence of ICG-FA in colorectal anastomosis assessment, Emile *et al*. [12] conducted a large meta-analysis that comprised 27 trials and 8786 participants. ICG-FA was found to reduce leakage rates significantly.

They also discovered that patients who had a plan change based on ICG-FA had a greater rate of AL than patients whose ICG-FA showed acceptable perfusion

Table 4 Comparison between our results and similar previous studies

The study, year (*N*)	Country	Leakage (%)			Reduction in leakage rate (%)	Changing anastomotic site (%)
		ICG-FA	Control	*P*		
This study (39)	Egypt	6.3	8.7	0.79	2.4%	12.5%
Kudszus *et al*. (402) [21]	Germany	3.5	7.5	0.04	4	16.4
Jafari *et al*. (38) [17]	USA	6	18	0.28	12	19
Boni *et al*. (80) [19]	Italy	0	5	0.13	5	4.7
Kin *et al*. (346) [22]	USA	7.5	6.4	0.67		4.6
Kim *et al*. (657) [23]	South Korea	0.6	5.5	0.006	4.9%	–
Su *et al*. (84) [18]	China	0	0		0	4.8
Emile *et al*. (8786) [12]	Multicentric meta-analysis	3.8	7.5	0.03	3.7	9.1

ICG-FA, indocyanine green fluorescence angiography.

and did not warrant revision of anastomosis, thus it is recommended that such patients be closely monitored to detect AL early if it occurs [12].

The explanation might be that anastomoses that require revision due to poor perfusion may remain a high risk and susceptible to delayed, postoperative ischemic changes [24].

Some of the technique's limitations stem from the fact that it relies on the surgeon's subjective assessment of the intensity of the produced fluorescence. The angiography effect, a determining marker of perfusion, can be utilized to overcome this limitation. The quick emergence of the fluorescence signal during the initial seconds after injection is referred to as this effect [12]. Diana *et al*. [25] created a quantitative, software-based analysis of the fluorescence signal that allowed an objective real-time display of perfusion values.

Furthermore, it is not a completely standardized technique as there are variables related to the dose of injected ICG (0.1–0.25 mg/kg), the proximity of the laparoscope to the colic wall, the number and type of checks performed, and differences in the equipment available on the market [26].

Also, even without an ICG-FA assessment, surgeons may alter their surgical strategy based on their visual inspection and perception of the anastomosis under white light.

Limitation of the study

The small sample size in this preliminary study was insufficient to identify a 1–2% difference in leak rates at 80% power, which was the study's drawback.

Conclusion

ICG-FA is a simple, safe, and effective approach for verifying adequate perfusion at the anastomosis site that is less subjective than standard visual evaluation under white light.

It is more effective in patients with descending colon and rectal malignancies, as well as the elderly and cardiac patients.

Because of the small sample size recruited in this study, the efficacy of ICG-FA in reducing leakage rate was insignificant, and we cannot confirm that modifying the surgical decision was advantageous. To establish its efficacy, larger prospective, randomized controlled studies are required.

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Conflicts of interest

There are no conflicts of interest.

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