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ORIGINAL ARTICLE

The Value of Intraoperative Indocyanine Green Angiography to Assess Anastomotic Perfusion and Leakage in Patients Undergoing Laparoscopic Colorectal Resection: A Randomized Controlled Clinical Trial

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Abstract

Background and aim: **Anastomotic leaking (AL) is a significant obstacle in colorectal surgery, with potentially life-threatening consequences. Insufficient perfusion during surgery is one factor that can contribute to AL. Intraoperative angiography with indocyanine green (ICG) is a noninvasive imaging procedure that can monitor perfusion. This randomized controlled trial will investigate whether ICG angiography can decrease the frequency of AL and improve patient outcomes following laparoscopic colorectal resection.**

Patients and methods: **The clinical trial involved adult cases with a tumor located between 2 and 15 cm from the anal verge who had colorectal anastomosis performed during colectomy or laparoscopic anterior rectal resection. The study group received ICG intravenously to aid in assessing of bowel perfusion, while the control group received subjective evaluation. The adequacy of bowel perfusion was assessed during surgery to judge the level of colonic resection.**

Results: **There was no significant distinction in demographics between the study and placebo groups. Wound infection and rectal bleeding were higher in the control group. Age, malignant disease, and diabetes were correlated with Clavien–Dindo severity, while neoadjuvant therapy was linked to higher scores. BMI and coronary artery disease had no association with Clavien–Dindo. The intervention reduced AL occurrence.**

Conclusion: **Insufficient perfusion at the resection margins during colorectal resection can be successfully demonstrated with intraoperative fluorescence angiography with ICG, which is safe and not time-consuming.**

Keywords: Anastomosis perfusion, Angiography, Indocyanine green, Laparoscopic colorectal resection

1. Introduction

The potentially life-threatening complications of anastomotic leakage (AL) affect between 4 and 30% of individuals following colorectal surgery. Although the recent advancements in operation methods and equipment, AL is still a significant problem. This is attributable to an elevated hazard of morbidity and mortality, as well as more extended hospital stays, higher expenses and the possibility of a local recurrence of rectal cancer.[1]

Moreover, the appearance of AL was linked to a variety of factors, and insufficient perfusion was one of those factors. During surgery, patient's perfusion assessment may often be based on the surgeon's best-educated judgment. Nevertheless, objective approaches have been developed to enhance accuracy.[2] Owing to the high cost, complicated nature, and limited reproducibility, it is unattainable to utilize objective techniques to monitor perfusion regularly. Indeed, intraoperative angiography performed with indocyanine green (ICG) has been

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increasingly common in recent years as a valuable objective tool for determining perfusion.[3]

ICG angiography is a noninvasive, instantaneous imaging method that uses a luminescent dye. It can be used during surgery to monitor tissue perfusion following various surgeries, such as those involving the esophagus and colon.[4] Even though ICG angiography was identified as a significant method for measuring perfusion in previously conducted systematic reviews, well-designed randomized controlled trials are yet deficient.[5] AL is defined as anastomotic disruption, leading to peritoneal cavity leakage.[6]

This study aimed to determine if ICG angiography can help lower the frequency of AL occurrence and improve patient outcomes following laparoscopic colorectal resection.

2. Patients and methods

This study was performed in Al-Azhar University Hospitals from January to October 2022. The study included 101 participants. Everyone was observed at the General Surgery Units, Faculty of Medicine, Al-Azhar University. The clinical trial is a prospective, controlled (1:1), single-blinded, randomized trial. The study was carefully designed and approved by local ethics committees.

The University's Ethics Committee approved the investigation, and written informed consent was retrieved from every person involved. This research was done in concordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for human participants.

The trial included cases diagnosed with rectal cancer who required either left colectomy combined with colorectal anastomosis or laparoscopic anterior rectal resection. The tumor is positioned at 2–15 cm from the anal verge. In addition, patients with abdominoperineal rectal removal or restricted sigmoid excision without inferior mesenteric artery constriction, and those with a history of allergy to ICG or iodine were not incorporated in the research. Pregnant or breastfeeding candidates were also excluded.

Information on patient's demographics, medical history, and previous surgeries were collected before surgery. A computer-generated random number list was used to allocate them into one of two groups. There was no classification in the allocation procedure, and all cases were kept blind about which method they would get. Therefore the research could be validated. After receiving written informed permission from the patient, the surgical team was given a sealed envelope with the randomization arm just before surgery began. Neither the patient nor the surgical team knew which therapy they would receive until the envelope was opened right before the procedure.

The G*Power 3.1.0 program was used for sample size calculation. Measuring an effect size of 0.4 in the main result of interest, a sample size of 50 cases in each research group is required, considering a type I error of 0.05, 80% power, and 95% confidence interval. This is after accounting for a 10% drop out rate according to the statistical analysis.

2.1. Procedure

During surgery, the surgeon and the first assistant checked to ensure the bowel was getting enough blood flow. Accessing the abdominal cavity utilizing a mini-laparotomy usually in the supra-pubic region, a basic visual examination of the intestine was performed to establish whether or not the bowel was receiving an adequate supply of blood. This involved observing for active bleeding from the marginal artery and the intestinal edge. Appropriate perfusion was indicated by a pink, healthy bowel, pulsating arcade vessels, and rapid blood flow in the marginal vasculature of the proximal gut mesentery.

Following a positive initial visual evaluation, participants in the study group received an intravenous injection of ICG before resection. This was done to help evaluate bowel perfusion, allowing for a more accurate assessment of the adequacy of bowel perfusion. Perfusion may be assessed during medical operations using of the fluorescent dye ICG. It's safe to use and has a brief half-life of about 3–4 min. Serious adverse effects are more likely to occur in people with chronic renal illness.[7] To achieve the desired effect, 0.3 mg/kg was delivered intravenously twice: once before the colon resection and once following the anastomosis was completed. The surgical team was, therefore, able to assess the level of blood flow to the remnants of the colon and its edges.

Near-infrared (NIR) light was used to trigger fluorescence to study colonic vascularization.[8] NIR wavelength and conventional light were employed for this, both provided by a xenon light source attached to a specialized scope and camera. The transition from visible to NIR light was manually initiated by the physician. After injecting ICG, the surgical team waited 1 min for luminescence to develop and a good perfusion signal to be obvious before verifying the degree of colonic resection decided by standard visual assessment.

Once the resection site had been located, the perfusion was considered ‘good’ if fluorescence was

distributed uniformly up to the degree of proximal colon resection that had been decided upon. Perfusion was deemed 'poor' if fluorescence was not uniformly distributed to the intended degree of proximal colon excision. It was determined that perfusion was 'absent' if there was no fluorescence in the 10 cm near the edge of the colon excision. After 180 s, if inadequate or nonexistent perfusion was still present, the gut was inspected again, and resection was repeated. The entire process usually takes between 2 and 4 min.

If the fluorescence findings indicated that more intestine needed to be removed, the length of the additional bowel removed was noted, and an ICG injection was performed again after the anastomosis was complete to determine whether or not the margins were receiving adequate blood flow. Analyses and recordings of intraoperative angiography were conducted.

2.2. Surgical technique

Patients undergoing a colorectal operation were given 200 ml phosphate enema around 12 h before the procedure. Oral bowel preparation, similar to colonoscopy, was performed on patients 2 days before surgery. Antibiotic prophylaxis in 500 mg of metronidazole and 2 g of cefazolin was given to all cases before surgery.

The procedure included regular mobilization of the splenic flexure, ligation of the high vessels, and excision of the proximal loop beginning from the medial to the lateral side. The circular anastomosis was performed manually, and every colorectal anastomosis was subjected to a standard pneumatic leak test, in which air was insufflated transanally while the anastomosis was immersed in water. Adverse occurrences and consequences during surgery were documented.

A trained surgical team, which had no involvement in the research, gathered data on postoperative consequences and categorized leakage using the Clavien–Dindo system.[9] In addition, the rates of readmission and reoperation within 30 days were tracked. To be considered an AL, the intestinal wall defect must allow passage among the intraluminal and extraluminal spaces. The following clinical signs were indicative of leakage, including fever, purulent rectum discharge, abdominal pain, worsening of the clinical state, pelvic infection, peritonitis, and laboratory findings like leukocytosis or leukopenia, elevated C-reactive protein or procalcitonin throughout the hospital stay and for a minimum of 30 days following the procedure.[10] Leakage was established by abdominal computed tomography scan, barium enema, endoscopy, or surgical intervention after clinical suspicion.

AL rate 30 days after surgery was the major outcome measure. Overall consequences, variation in the extent of bowel excision, and complications following ICG administration were considered secondary outcomes.

2.3. Statistical analysis

IBM-SPSS, version 24 (IBM Corp., Armonk, New York, USA), was utilized for statistical analysis. To assess statistical significance, the Kruskal–Wallis and Wilcoxon tests, as well as Spearman's correlation and logistic regression analysis, were utilized. Every variable was analyzed depending on the data type included (parametric or not). If the P values were below 0.05, we deemed the results statistically significant.

3. Results

Regarding demographics, there was no significant distinction among the research and placebo groups, as shown in Table 1. Table 2 represents the comparison of the postoperative complications. Wound infection and rectal bleeding were significantly higher in the control group. Moreover, the rate of AL was significantly higher in the control group. In addition, when contrasting the two groups on the

Table 1. Demographic and clinical characteristics of the involved patients.

	Control ($N = 51$) [n (%)]	Study ($N = 50$) [n (%)]	P value
Age (years)	65.1 ± 11.3	66.1 ± 12.8	0.678
BMI (kg/m^2)	25.6 ± 8.7	25.2 ± 7.2	0.801
Sex			
Male	28 (54.9)	25 (50)	0.621
Female	23 (45.1)	25 (50)	
Disease			
Benign	15 (29.41)	14 (28)	0.875
Malignant	36 (70.59)	36 (72)	
ASA score			
1	3 (5.88)	4 (8)	0.675
2	38 (74.51)	35 (70)	0.612
3	10 (19.61)	11 (22)	0.767
Surgery			
Left colectomy	29 (56.86)	26 (52)	0.623
LAR	22 (43.14)	24 (48)	0.623
Neoadjuvant chemotherapy	12 (23.53)	14 (28)	0.607
Neoadjuvant radiotherapy	12 (23.53)	14 (28)	0.607
Diabetes	11 (21.57)	9 (18)	0.652
CAD	16 (31.37)	13 (26)	0.550

ASA, American Society of Anesthesiology; CAD, coronary artery disease; LAR, low anterior rectal resection.

Table 2. Postoperative complications in the two study groups.

	Control ($N = 51$) [n (%)]	Study ($N = 50$) [n (%)]	P value
Ileostomy leakage	2 (3.92)	1 (2)	0.569
Urinary fistula	4 (7.84)	1 (2)	0.175
Wound infection	7 (13.73)	1 (2)	0.029*
Rectal bleeding	7 (13.73)	1 (2)	0.029*
Paralytic ileus	3 (5.88)	3 (6)	0.981
Mechanic ileus	2 (3.92)	1 (2)	0.569
Colic perforation	4 (7.84)	1 (2)	0.175
Ileal perforation	3 (5.88)	1 (2)	0.317
Urinary infection	4 (7.84)	1 (2)	0.175
Lung infection	4 (7.84)	1 (2)	0.175
Fever without any diagnosis	2 (3.92)	4 (8)	0.385
Abdominal bleeding	3 (5.88)	1 (2)	0.317
Anastomotic stenosis	3 (5.88)	1 (2)	0.317
Anastomotic leakage occurrence	16 (31.37)	7(14)	0.037*
Grade A	3 (5.88)	1 (2)	0.317
Grade B	5 (9.8)	2 (4)	0.250
Grade C	8 (15.69)	4 (8)	0.232

*P value, statistically significant.

Clavien–Dindo classification, there was no significant distinction, as shown in Table 3.

Moreover, Table 4 showed a significant positive correlation between age, malignant disease and diabetes with Clavien–Dindo classification severity. Also, cases taking neoadjuvant chemotherapy and radiotherapy were significant to have a higher Clavien–Dindo scores. BMI and coronary artery disease had no association with Clavien–Dindo classification. In addition, this study reported that intervention was significantly effective in the reduction of AL occurrence independence of age, Sex, BMI, disease, and neoadjuvant therapy (Table 5; Fig. 1).

4. Discussion

Numerous patient-specific hazards, comprising low-level anastomosis, male sex, and smoking, were identified for AL.[11] Excessive stress at the fusion site, technical malfunction of the stapler, and inappropriate perfusion are the most important additional variables that could delay anastomotic healing. Indeed, anastomotic restoration relies on blood flow. Thus surgeons do many checks before and after an operation to ensure the wound has been properly closed.[12]

Studies are ongoing to find a more robust approach to accurately quantify tissue perfusion, as visual evaluation of the excision edges has been demonstrated to be erroneous in certain settings.[13] Microperfusion may be accurately measured during cardiac, plastic, reconstructive, and organ transplant procedures with intraoperative angiography utilizing ICG by deploying a NIR system to detect tissue fluorescence.[14]

Currently, there is a dearth of research on the topic of ICG angiography for evaluating fluorescence in the context of colorectal surgery. Nevertheless, no randomized controlled trials were found that particularly investigate this problem, and most of them are retrospective and report only small series. Some studies provide outcomes for both right and left colon resections and rectal operations performed by open or laparoscopic techniques, adding to the already substantial heterogeneity within the published research.[14,15]

Rectal resections with AL varied from 7 to 10% in the randomized multicenter CLASSIC II research contrasting open versus laparoscopic-assisted surgery, and increased to 15% after conversion.[16] In addition, the PILLAR II trials, a prospective

Table 3. Clavien–Dindo classification in the two study groups.

	Control ($N = 51$) [n (%)]	Study ($N = 50$) [n (%)]	P value
CD 1	3 (5.88)	1 (2)	0.317
CD 2	6 (11.76)	2 (4)	0.148
CD 3a	3 (5.88)	1 (2)	0.317
CD 3b	4 (7.84)	3 (6)	0.715

CD, Clavien–Dindo.

Table 4. Correlation between different parameters and Clavien–Dindo classification.

	r	P value
Age (years)	0.214*	0.033*
BMI (kg/m^2)	0.113	0.265
Sex (male)	−0.036	0.721
Benign disease	−0.300*	0.002*
Malignant disease	0.463*	<0.001*
Neoadjuvant chemotherapy	0.318*	0.001*
Neoadjuvant radiotherapy	0.216*	0.031*
Diabetes	0.201*	0.045*
CAD	0.049	0.629

CAD, coronary artery disease.
*P value, statistically significant.

Table 5. Odds ratio for reducing the incidence of anastomotic leakage between control and study groups.

	OR (95% CI)	P value
Age (years)	0.31 (0.24–0.61)	0.033*
BMI (kg/m^2)	0.37 (0.2–0.66)	0.021*
Sex (male)	0.36 (0.22–0.6)	0.022*
Neoadjuvant therapy	0.3 (0.25–0.61)	0.055
Diabetes	0.38 (0.22–0.8)	0.001*
CAD	0.49 (0.22–0.9)	0.032*

CAD, coronary artery disease.
*P value, statistically significant.

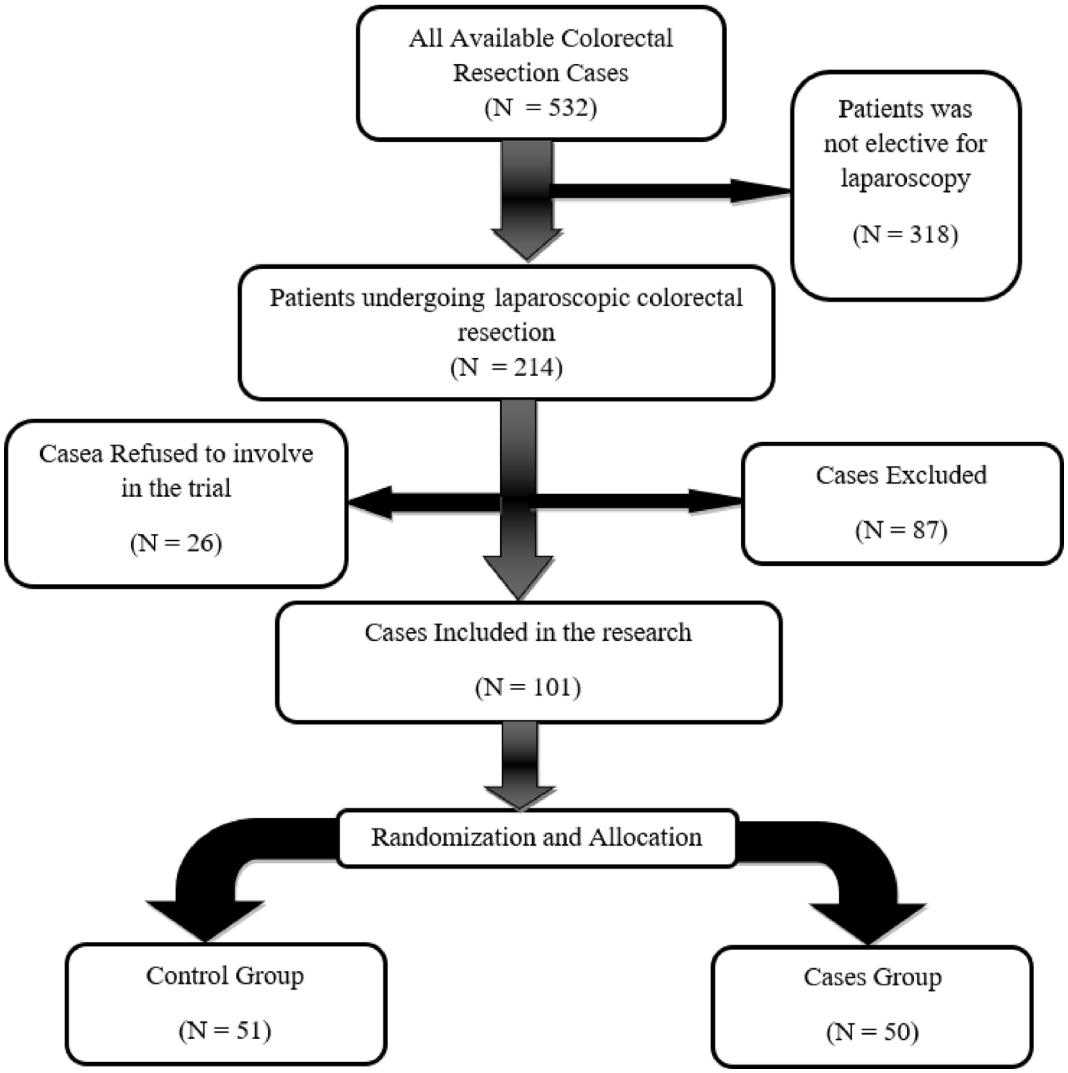

Fig. 1. Consort flow of study participants.

multicenter study conducted in the United States that included left-sided colon and anterior rectal resections, recently published an AL incidence rate of 1.4%.[17] However, the previously mentioned research lacked a control group. A large proportion of cases underwent surgery for benign colorectal disease. Just 25% of patients had rectal cancer, and of those, just 10% received preoperative chemoradiation, and cases with anastomosis less than 5 cm from the anal verge were excluded. All of these variables are known to increase the likelihood of developing AL, which may help to explain the disparities in leak rates among the two investigations.[18,19]

Similar to our findings, De Nardi *et al.*[6] found that in 11% of cases, inappropriate perfusion at the proximal resection margin was detected by ICG angiography while appearing normal on ocular examination and active bleeding assessment. This finding agrees with the 10.9% found in a previous comprehensive study of 516 cases.[20]

Using intraoperative luminescence angiography, Kudszus and colleagues, contrasted 201 cases conducting colon or rectal excision to the placebo group. However, the authors did not contrast the actual leak rate, but rather AL needed surgical reintervention and after surgery hospitalization, making their research hardly comparable to others.[21] In general, they found a decrease in the total likelihood of revision for AL and a substantially lower hospital stay, leading them to conclude that intraoperative luminescence angiography decreases the frequency of serious side effects in colorectal operations. However, 13.9% of cases in the intraoperative angiography group had tissue perfusion deemed inadequate, leading to sustained resection.

Intraoperative angiography with ICG has been used in robotic operation; for example, in research on left-sided colon excision, the authors repositioned the site of loop excision in 17 of 40 cases; however, two cases in this study still experienced an AL despite the repositioning.[22] In rectal cancer, laparoscopic LAR has been linked to a much lower incidence of AL, according to more recent studies.

AL can be reduced by using ICG fluorescence imaging to monitor the permeation of a colorectal anastomosis, as shown in research by Arezzo *et al.*[23] Like our research, the authors found that luminescence imaging substantially lowered the frequency of AL (odds ratio 0.341; 95% confidence interval 0.220–0.530; $P < 0.001$), even after taking into account confounding factors like age, sex, BMI, tumor, anastomotic distance from the anal verge, and neoadjuvant treatment. ICG luminescence imaging can be a useful technique for lowering the likelihood of AL during colorectal operations.

4.1. Conclusion

Objective assessment of the anastomotic perfusion may be efficiently shown with intraoperative luminescence angiography with ICG, which is safe and not time-consuming. This allows the surgeon to alter the operation technique and alter the point of bowel transection at a better-perfused area.

Conflicts of interest

There are no conflicts of interest.

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