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The influence of fluorescence imaging on the location of bowel transection during robotic left-sided colorectal surgery

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Abstract

Background Hypoperfusion is an important risk factor for anastomotic leakage in colorectal surgery. This study was designed to evaluate the impact of fluorescence imaging on visualization of perfusion and subsequent change of transection line during left-sided robotic colorectal resections.

Methods Patients scheduled for robotic left-sided colon or rectal resections were enrolled in this prospective, multicenter study. Resections were performed as per each surgeon's preference. After complete colorectal mobilization, ligation of blood vessels, and distal transection of the bowel, the mesocolon was completely divided to the planned proximal or distal transection line, which was marked in white light. Indocyanine green was injected intravenously and the transection location(s) and/or distal rectal stump, if applicable, were re-assessed in fluorescent imaging mode. Imaging information, perioperative, and early postoperative outcomes were recorded. An independent video review of the surgeries was performed.

Results Data for 40 patients (20 female/20 male) with a mean age of 63.9 years and a mean body mass index of 27.6 kg/m^2 were analyzed. Fluorescence imaging resulted in a change of the proximal transection location in 40 % (16/40) of patients. There was one change in the distal transection location in a patient with benign disease. The use of fluorescence imaging took an average of 5.1 min of the mean overall operative room time of 232 min. Two patients (5 %) with a change in transection line developed an anastomotic leak at postoperative days 15 and 40.

Conclusion Fluorescence imaging provides additional information during determination of transection location in left-sided colorectal procedures. This results in a significant change of transection location, particularly at the proximal transection site. Further research needs to be conducted with larger patient cohorts and in comparative design to determine actual effect on anastomotic leak rate.

Keywords Fluorescence imaging · Colorectal · Resection · Firefly · Robotic surgery · Da Vinci

Anastomotic leaks are a relatively frequent complication of colorectal surgery, occurring in 1.2–19.2 % of all operations [1–3], with rates reaching 39 % for rectal cancer cases requiring low or ultra-low anastomosis [4–8]. Despite technical advances that have led to an overall reduction of other complications, anastomotic leaks remain problematic, prolonging the clinical course and increasing hospitalization times [9, 10]. Anastomotic leaks require re-operation in 95 % of cases and result in significant mortality [4, 9, 11]. Additionally, more than half of all patients

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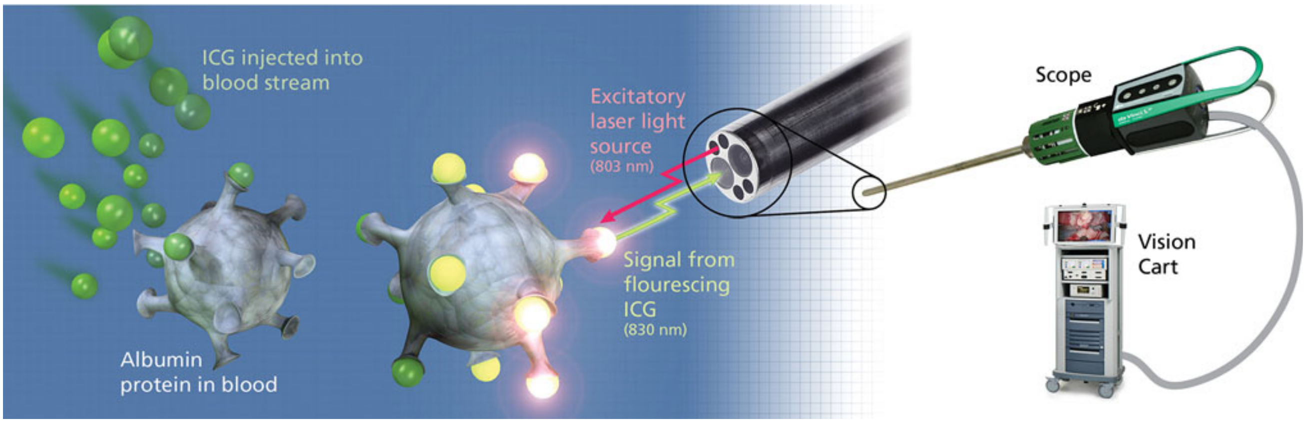

Fig. 1 The da Vinci fluorescence imaging system. *ICG* indocyanin green

who experience an anastomotic leak will live with a permanent stoma [12].

The etiology of anastomotic leaks is a multifactorial problem. Besides technical aspects, adequate bowel perfusion is the main factor in ensuring the integrity of an anastomosis [13–17]. Adequate perfusion of the resection margins and the anastomosis is usually determined using clinical judgment alone. The surgeon observes the color of the tissue, checks for bleeding from the cut edges, and palpates for arterial pulses and evaluates peristalsis. This method of assessment is subjective, difficult to quantify, and can be inaccurate, making it a poor predictor of the risk of anastomotic leakage [8].

Currently available literature on open and minimally invasive surgery, although small in numbers, suggests that additional visualization of tissue perfusion with fluorescence imaging can add relevant information for determining a well-perfused location for colonic and rectal transections, thus leading to fewer anastomotic leaks [18, 19]. Recently, near-infrared (NIR) light technology has been cleared by the US FDA to visualize blood flow and related tissue perfusion using indocyanine green (ICG; Akorn, Lake Forest, IL, USA) as the fluorescent agent with the da Vinci Si Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA, USA) (Fig. 1).

The aim of this study was to systematically evaluate the impact of fluorescence imaging on the location of colonic and rectal transection lines based on evaluation of perfusion with indocyanine green (ICG) + NIR imaging during left-sided robotic colorectal surgery.

Materials and methods

Each institution in this prospective, multicenter study obtained review board approval and each patient provided informed consent before study inclusion. Patients who underwent robotic left-sided colon or rectal resections at the participating sites between October 2012 and May 2013 for benign or malignant indications were included in this analysis. All surgeries were performed as per the clinical practice of each of the respective surgeons. All surgeons routinely use fluorescence imaging in their practice, including procedures performed outside of this study, and have performed more than 200 robotic procedures each.

Surgical technique, including assessment of transection location

Both completely robotic and laparoscopic-robotic hybrid techniques were performed per surgeon preference. Robotic-assisted low anterior resection (LAR) was conducted in a manner similar to the technique previously described by Pigazzi et al. [20, 21].

For malignant cases, all surgeons performed a medial to lateral mobilization with high ligation of the inferior mesenteric/superior rectal or sigmoidal arteries, as determined by the location of the cancer. For benign cases (primarily sigmoid diverticulitis), a medial mobilization with a higher ligation of the sigmoidal branches was also the preferred approach whenever possible. For rectal or rectosigmoid cancers, a robotic total or partial mesorectal excision was performed, followed by distal division of the rectum with staplers as per surgeon preference. The next step included the complete intracorporeal division of the proximal mesocolon to the chosen transection point in the left/sigmoid colon. The chosen transection point was marked under white light with a clip or cautery (Fig. 2) followed by injection of 10 mg ICG dye as per protocol. During injection, the left-sided large bowel was observed using the fluorescence mode, and the previously chosen transection point was evaluated as perfusion became visible in the

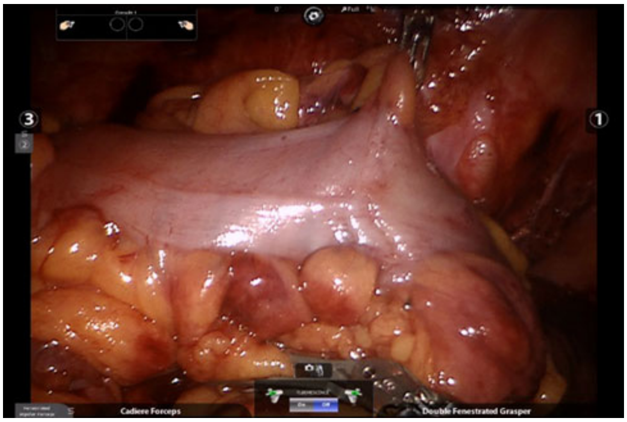

Fig. 2 Bowel perfusion in white light with change in transection location. Clip is placed at the planned transection line in white light

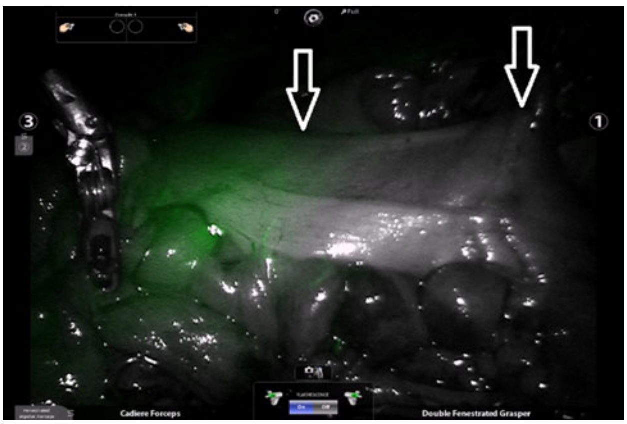

Fig. 3 Bowel perfusion fluorescence imaging with change in transection location. Transection line was moved more proximal in fluorescence light, as indicated by *arrows*

proximal bowel and was followed with the camera to the marked transection point. If, based on the surgeon's subjective assessment in fluorescence imaging mode by judging whether the transection location was showing bright fluorescence reflection, the transection point needed to be moved to a more proximal/distal location, the new location was also marked (Fig. 3). The bowel segment was exteriorized for removal of the specimen or placement of an anvil, and the transection line was re-evaluated under white light outside the abdominal cavity. If the transection line was changed under fluorescence mode the distance between the white line marking and fluorescence light marking was measured and recorded in centimeters. The distal stump was evaluated either during visualization of the proximal stump or prior to creation of the anastomosis. If needed, a second dose of ICG dye was given by the surgeon for either evaluation. The anastomosis was then performed in a standard stapled fashion or, in the case of a colo-anal anastomosis, by hand suture as per the surgeon's preference.

Demographic, perioperative, and postoperative data up to 30 days after surgery, as per protocol, was collected. Visualization information was recorded separately for the proximal and distal transection locations as well as the exterior assessment. In addition, the time of the ICG injections were recorded as well as the time for decision making. In case of exteriorization of the bowel, the transection location was again assessed by the surgeon and it was noted whether this 'open surgery assessment' corresponded subjectively with the intra-abdominal white light or fluorescence image location. The intra-abdominal part (the surgeon's view at the console) of the surgeries was recorded on video and the transection locations from both the white light and fluorescence imaging modes were reviewed by an independent reviewer board certified in colorectal surgery.

All data was prospectively collected, de-identified and centrally stored in an electronic database. Output was computed and statistically analyzed using SAS System version 9.2. (SAS Institute, Inc., Cary, NC USA). Patient characteristics and outcomes were summarized using means, standard deviations, and percentages for all patients, and were stratified by patients with benign versus malignant disease. Pair-wise comparisons for each outcome of interest were made using a χ^2 test. In the case of small numbers of patients, a Fisher's exact test was used. A p value of n$<$0.05 was considered statistically significant.

ICG

The ICG imaging agent is a sterile, water-soluble tricarbocyanine dye that serves as an optical contrast agent. Following intravenous injection, ICG is rapidly bound to plasma proteins with minimal leakage into the interstitium. It is removed from the blood by the liver with a half-life of 3–5 min and then excreted via the bile within 10–15 min with no known metabolites. It generates fluorescence at 830–845 nm wavelength when exposed to light in the NIR region, with a peak spectral absorption at 806 nm [19, 22–24]. ICG is manufactured by several companies worldwide and has been used clinically for the last 30 years with a high degree of safety with rare cases of anaphylaxis. It should be used with caution in patients with iodine allergy [25]. The manufacturers recommend a maximum daily dose of 2 mg/kg.

NIR fluorescence imaging system

The fluorescence-capable da Vinci Si high-definition (HD) vision system (Firefly) is incorporated into the latest Si Surgical System (Intuitive Surgical). The standard white-light visible imaging mode and the fluorescence mode can be readily switched as often as needed by the surgeon with a simple click of the camera pedal. In the NIR fluorescence mode, the device excites and images NIR fluorescence from the ICG contrast agent, but loses the white-light image [25]. This allows surgeons to view high-resolution NIR images, in the fluorescence mode, of blood flow in vessels and micro-vessels, tissue and organ perfusion in real-time. The fluorescence-capable illuminator provides lighting for the surgical field. The system displays the live video image on the three-dimensional-HD stereo viewer and the external screen. The camera control unit processes and displays the resulting angioscopic images as a fluorescent overlay on a black and white image.

This Firefly system has been used clinically for a variety of procedures to date [26–31].

Results

Forty patients (20 male/20 female) were enrolled in this study between October 2012 and May 2013. The mean age was 63.9 years and the mean body mass index (BMI) was 27.6 kg/m^2. The mean American Society of Anesthesiologists (ASA) classification score was 2.5. Thirty percent of the analyzed patients underwent surgery for benign disease and 70 % had a malignant lesion. Ninety percent of all patients suffered from comorbidities and 22.5 % had at least one previous surgery. Sixty-eight percent of patients with malignant status underwent neoadjuvant therapy.

Overall, three left colectomies (7.5 %), ten sigmoid resections (25 %), and 27 rectal resections (67.5 %) were carried out. A loop ileostomy was performed in 75 % of patients with malignant disease. The mean operative room time was 232 (±127) min, with significantly longer times for surgeries for malignant disease (278 min) versus benign procedures (128 min) [$p = 0.008$].

During the proximal visualization assessment, eight descending colons (20 %) and 32 sigmoid colons (80 %) were evaluated. The mean time between the white light and fluorescence decisions was 5.1 (±10.0) min. These parameters did not statistically differ between patients with benign and malignant disease ($p = 0.3071$). A second dose of ICG was given in 20 % (8/40) of all patients. However, only once was this dose given immediately after the first dose (4 min) for proximal evaluation. The other seven re-injections were performed with a median time delay of 39 min for the distal transection/stump evaluation. The location of the proximal transection was changed in one patient (1/12; 8.3 %) with a benign pathology and 15 patients (15/28; 53.6 %) with malignant disease ($p = 0.0122$). All changes of transection locations were performed to a more proximal direction, with a mean distance of 4 cm (±7.3 cm). In the exterior assessment performed in 38 patients, it was felt by the surgeon that the transection line marked in fluorescence mode (with or without change to the intra-abdominal white-light transection point) would have been chosen externally as well during evaluation of the distal colon with external white light and palpation. However, in 4 of the 16 cases where fluorescence imaging changed the location to a more proximal transection point, this was not appreciated in external white light. In other words, the fluorescence-marked transection point was more proximal than the surgeon would have chosen in external white light. In all four cases, the surgeons decided to divide the bowel at the transection point marked by fluorescence light. Detailed results regarding the proximal visualization results are listed in Table 1.

Table 1 Visualization results for the proximal transection location

Parameter	Patients with benign disease (n = 12)	Patients with malignant disease (n = 28)	All patients (n = 40)	p Value[a]
Bowel segment visualized [n (%)]				
Descending colon	2 (17)	6 (21)	8 (20)	
Sigmoid colon	10 (83)	22 (79)	32 (80)	1.000
Second dose needed [n (%)]	3 (25.0)	4 (15.4)	7 (17.5)	0.656
Time needed for fluorescence decision (min; mean ± SD)	3.3 ± 3.4	5.9 ± 11.8	5.1 ± 10.0	0.307
Location of transection changed [n (%)]	1 (8.3)	15 (53.6)	16 (40.0)	0.012
Estimated amount of change (cm; mean ± SD)	1.0 ± 0	4.2 ± 7.5	4.0 ± 7.3	n.a.
Estimated distance of transection from anal verge (cm; mean ± SD)	16.5 ± 8.7	21.7 ± 22.8	20.0 ± 19.1	0.361

[a] Comparison between patients with benign disease versus patients with malignant disease

During the distal visualization assessment, eight sigmoid colons (20 %) and 32 rectums (80 %) were evaluated for determining the transection location/distal stump. Seven patients (17.5 %) received a separate dose

Table 2 Video review results

Parameter	Patients with benign disease ($n = 10$)	Patients with malignant disease ($n = 25$)	All patients ($n = 35$)	p Value[a]
Agreement of reviewer with surgeon's white-light decision [n (%)]	10 (100)	19 (79.2)[b]	29 (85.3)[b]	0.291
Agreement of reviewer with surgeon's fluorescence-imaging decision [n (%)]	10 (100)	19 (76)	29 (82.9)	0.152
Agreement of reviewer with surgeon's overall decision, including white light and fluorescence imaging [n (%)]	10 (100)	14 (58.3)[b]	24 (70.6)[b]	0.015

[a] Comparison between patients with benign disease versus patients with malignant disease

[b] One patient (with malignant disease) video did not show white-light assessment clear enough for video review. Here the n was 24 for patients with malignant disease and 34 for all patients

of ICG for the distal evaluation, with a mean time delay of 39 min. The location of transection was changed once as a result of the distal assessment; it was moved distally by 2 cm in a patient with benign pathology undergoing a sigmoid resection. The estimated distance from the anal verge for the distal transection line was 6.3 cm (±3.0).

There were no intraoperative complications or any adverse events observed with the ICG injection or the fluorescence imaging.

Thirty-five of the surgical procedures were adequately captured by video. The independent video reviewer agreed with both the white light and the fluorescence imaging decisions in all resections for benign indications (100 %). Agreement during malignant cases was 79.2 % for the white-light decision and 76 % for the fluorescence-imaging decision. Overall agreement where the reviewer agreed with both assessments during malignant surgeries was 58.3 %, significantly lower than the agreement rate for benign cases of 100 % ($p = 0.0146$). Detailed results regarding the video review are listed in Table 2.

Overall duration of hospitalization was 6.6 days, with an inhospital postoperative complication rate of 10 %. There were two re-admissions (rate of 5 %) with the need for two re-operations for complications at the ileostomy site

Table 3 Perioperative and 30-day follow-up results

Parameter	Patients with benign disease ($n = 12$)	Patients with malignant disease ($n = 28$)	All patients ($n = 40$)	p Values[a]
Length of stay (days; mean ± SD)	5.1 ± 5.4	7.4 ± 7.7	6.6 ± 7.0	0.329
Post-operative complications prior to discharge [n (%)]				
Overall	1 (8.3)	3 (10.7)	4 (10)	1.000
Ileus	1 (8.3)	1 (3.6)		
Urinary retention		1 (3.6)		
Atrial fibrillation		1 (3.6)		
Complications discharge to 30 days [n (%)]				
Overall		3 (10.7)	3 (7.5)	0.541
Peristomal hernia		1 (3.6)		
Obstruction at stoma	0	1 (3.6)		
Death by suicide		1 (3.6)		
Re-admission [n (%)]	0	2 (7.1)	2 (5)	1.583
Re-operation [n (%)]	0	2 (7.1)	2 (5)	
Follow-up (days; mean ± SD)	23.5 ± 8.3	29.5 ± 9.9	27.6 ± 9.7	0.076
Anastomotic leaks [n (%)]	0	2 (7.1)[b]	2 (5)	1.000

[a] Comparison between patients with benign disease versus patients with malignant disease

[b] One leak presented at day 40

(obstruction and hernia, respectively). One patient who underwent an LAR of rectal cancer developed an anastomotic leak 15 days after the procedure. This patient had an extended left colectomy with proximal transverse colo-anal anastomosis. The extended left hemicolectomy was necessary to find a well-perfused segment of colon to bring to the anus. His leak was treated with transanal drainage and the ileostomy has been closed with no further complications. There was one incidence of a delayed leak in a patient who presented with persistent rectal pain at day 40 (outside the 30-day follow-up period per protocol). This patient had a combined right hemicolectomy with LAR. He underwent computed tomography-guided drainage of a pre-sacral abscess with no further intervention needed. Both patients with anastomotic leak had a change of transection location. The postoperative results are summarized in Table 3.

Discussion

Anastomotic leaks remain the most feared complications in colorectal surgery. Multiple factors can contribute to the risk of a leak, including gender, age, nutritional status, radiation status, location of anastomosis (left colon, rectal, and ultra-low rectal), and intraoperative complications [2, 5, 9, 18, 32]. However, one of the main factors is that adequate perfusion is absolutely necessary for anastomotic healing. Until recently, the evaluation of perfusion remained in the hands of the surgeon and was limited to white-light visualization, tissue coloration, bowel peristalsis and checking for bleeding at the edge of the bowel, and palpation of pulses. This information gives the surgeon a subjective impression of the adequacy of blood perfusion and these parameters have been shown to lack predictive accuracy [8, 18].

In recent years, new technologies have been developed that allow for imaging in a fluorescence mode, using injection of the fluorescence dye indocyanine green. Fluorescence imaging with indocyanine green or laser fluorescence angiography (LFA) has been progressively used in other fields of surgery in recent years, such as for the evaluation of reconstructive flaps [33], as well as in urological, foregut, and hepatobiliary surgery [26, 27, 34, 35]. Since the introduction of fluorescence imaging technology to the da Vinci Si System, this technology has been increasingly used by surgeons for the evaluation of tissue perfusion in partial nephrectomies, lymph-node mapping during oncologic resections, intraoperative cholangiography, and in other procedures [27, 36].

The first study to use fluorescence imaging for colorectal surgery was published by Kudszus et al. [18]. This retrospective study compared 201 patients with LFA to a control group. The authors reported an overall reduction of revision due to anastomotic leaks by 4 % in the LFA group (7.5 % LFA vs. 3.5 % control). The use of intraoperative LFA reduced the risk of leaks by 60 % in patients undergoing elective colorectal surgery, and by 64 % in patients above 70 years of age. In 13.9 % of patients, the use of LFA resulted in a change in the initially planned transection line. In this study, LFA was performed using a commercially available system (IC-View, Pulsion Medical System AG, Munich, Germany) with specially designed software (IC-Calc) that allows calculation of a perfusion index and to compare perfusion between different sites as well as plot curves. The authors concluded that intraoperative florescence imaging is very valuable and reduces the rate of severe complications in colorectal surgery.

NIR fluorescence laparoscopy following the intravenous injection of ICG provides a means of visualization of the microcirculation either immediately before or after anastomosis formation. In our study, intraoperative images were acquired before formation of the anastomosis with a bolus of ICG. Unfortunately, at present it remains a linear graded result that requires subjective interpretation as to the cutoff point between sufficient and insufficient perfusion. The evaluation of perfusion is a subjective qualitative impression of the surgeon. However, we felt that there was a very clear visible cutoff in fluorescence mode between not perfused and perfused bowel in the first seconds, with, admittedly, some washout of the cutoff line after 1–2 min (see Figs. 2, 3). Quantitative analysis of the fluorescence image would be desirable but is currently not available on the robotic or laparoscopic systems [22, 24].

The intensity of fluorescence is dependent on various conditions, such as distance between detector and subject as well as surrounding lighting conditions [22]. These conditions have to be controlled sufficiently. In intra-abdominal fluorescence evaluation there is only that much variation in distance due to the confined space. In addition the fluorescence lighting of the NIR camera is fixed. It may become more variable if the fluorescence imaging is used outside the abdomen, where lighting of the operating room and distance are much greater variables. We therefore believe that the most reproducible and reliable data is obtained intra-abdominally in the early phase of fluorescence visibility.

The ‘quenching effect’ is also important to consider. If the ICG concentration is low enough, the relationship between intensity and concentration will be kept in proportion [22]. However, if the concentration is beyond a certain level, the proportional relationship is lost, a phenomenon called quenching. This effect cannot be controlled and it is therefore better to keep a low-level concentration to avoid this problem. In our study, we used 10 mg of ICG. Only one patient had an immediate re-injection 4 min after the first injection for evaluation of the proximal transection line as the surgeon felt the first dose to be too low (this patient also had a change in transection line by 1.5 cm). In all other cases, the single dose of 10 mg was adequate and in contrary we believe that actually a lower initial dose could be used. The second injection was usually performed for the distal transection line or stump with a mean time between injections of 39 min Due to the short half-life in the vascular circulation, there were no issues with remaining background fluorescence being too high, in our experience.

So far only limited clinical data on the use of fluorescence imaging in minimally invasive colorectal surgery can be found in the literature. The first report describing the use of fluorescence imaging in robotic rectal surgery was a publication by Jafari et al. [19]. This group evaluated the use of indocyanine green with fluorescence imaging in a retrospective case control study. They compared LAR with and without fluorescence imaging to measure its impact on the assessment of bowel perfusion. The authors reported a change in the proximal transection point in 3 of 16 patients (19 %) and a reduced leak rate of 6 % when compared with 18 % for the control group. There were no intraoperative or anesthetic complications associated with the injection of ICG dye.

Sherwinter [23] evaluated the anastomosis of 20 patients undergoing LAR transanally with an endoscopic NIR imaging system (Pinpoint, Novadaq, Canada). After the anastomosis was formed, ICG green was injected and the NIR endoscopic camera was inserted transanally through an introducer. The anastomosis was then evaluated in fluorescence light and a fluorescence score recorded. They found an abnormal ICG angiogram in four patients. Two of these had a protective loop ileostomy and showed no signs of breakdown. The other two patients developed anastomotic leakage. The authors suggest that transanal ICG angiography is feasible and provides information on mucosal and anastomotic blood flow.

Our study was specifically designed to systematically assess the possible value of fluorescence imaging in evaluating bowel perfusion at the transection line and as such at the anastomosis during robotic left-sided colorectal resection in a multicentric, prospective design. Our results demonstrate that the application of this technology consumes very little time (mean of 5.1 min) in comparison to the overall operative time (232 min) The information obtained from fluorescence imaging was used to confirm that the transection location was well-perfused or resulted in a change of transection location in cases of hypoperfusion (16/40). A change in transection location mainly occurred in patients with malignant disease and was relatively high (40 %), which might be caused by the altered vascular approach that included a high ligation, often of the entire IMA. In this setting, the blood supply of the descending colon relies solely on the left-middle colic vessels and on the marginal artery of Drummond, which can be insufficient and is at risk of injury during splenic flexure mobilization. In addition, the transection lines may be chosen differently for benign disease (primarily sigmoid diverticulitis) with a more proximal transection line than for rectal resections.

In an attempt to provide an objective measure of the adequacy of the perfusion assessment, all surgeries were recorded, and a majority (88 %) were of adequate quality for an independent and blinded video review by a board-certified colorectal surgeon. While there was 100 % agreement for the transection locations in patients with benign disease, agreement during malignant cases was 79.2 % for the white-light decision and 76 % for the fluorescence-imaging decision. However, it may be challenging to revise a surgical decision by video only, particularly considering that the image quality is inferior when replayed in a lower resolution and only on two-dimensional image; there may be other, better objective measures that can be used in the future.

While both of the previous publications on fluorescence imaging for colorectal surgery reported a decrease in anastomotic leak rates, our study was not designed to compare anastomotic leak rates. Still, only 2 out of the 40 analyzed patients suffered from a leak, for an overall rate of 5 %, which matches the rate in the study by Jafari et al. [19]. One patient, who had a combined right hemicolectomy and LAR with change in transection line, presented with a small abscess around day 40 that was successfully drained by IR. The second leak was diagnosed at day 15 after LAR with extended left hemicolectomy and was managed with transanal drainage. Both patients were diagnosed with their leaks at a relatively late time, which suggests other factors than perfusion alone contributing to those minor leaks, such as tension and staple-line failure. Both underwent a revision of the transection location.

Conclusions

Overall, our results demonstrate that fluorescence imaging during colorectal procedures provides important additional information about bowel perfusion at the transection site during colorectal procedures, and can lead to a change of transection location. This may eventually help to better evaluate perfusion at the anastomosis and thus decrease leaks caused by hypoperfusion. However, our study was a preliminary study that confirmed feasibility of this technology and showed a frequent change of transection line. Whether this will eventually translate into decreased leak rates remains to be proven and will require larger prospective trials.

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