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ORIGINAL ARTICLE

Use of quantitative indocyanine green near-infrared fluorescence imaging in bariatric surgery: early results

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ABSTRACT

Introduction: Indocyanine green fluorescence angiography (ICG-FA) is commonly used in general surgery, but its use in bariatric surgery is still marginal. Moreover, post-operative leaks remain a dramatic complication after this surgery and the leak tests available have poor performance preventing them. The aim of the present paper is to assess the use and utility of a new innovative technology based on quantitative measures of fluorescence signal intensity.

Material and methods: From January 2022 to June 2022, 40 consecutive patients with a median age of 51 years and a preoperative median body mass index of 45.2 kg/m^2 underwent bariatric surgery with quantitative ICG fluorescence angiography in our center. Two different types of surgery, based on the multidisciplinary evaluation, were performed: laparoscopic sleeve gastrectomy (LSG) and one anastomosis gastric bypass (OAGB). For ICG visualization, quantitative laparoscopic ICG platform was used to identify the vascular supply.

Results: Thirteen patients underwent LSG and 27 patients underwent OAGB. ICG was performed in all patients with no adverse events. An adequate and satisfactory blood supply was assessed in each case. No case of post-operative leak was detected.

Conclusions: The quantitative ICG-FA seems to be a useful and promising tool for the prevention of complications in bariatric surgery but further studies are mandatory.

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Quantitative Indocyanine Green (ICG); laparoscopic sleeve gastrectomy (LSG); one anastomosis gastric bypass (OAGB); bariatric surgery; leak

Introduction

Since 1975, obesity has nearly tripled worldwide. It is estimated that in 2016, over 1.9 billion of adults (>18 years old) were overweight and of these more than 650 million were obese [1]. This rising prevalence represents a crucial health issue: the global economic impact of obesity was estimated ranging from 0.13% of Global Domestic Product (GDP) in Thailand to 2.8% in Italy up to 9.3% in the USA [2]. Nonoperative interventions with behavior modification, exercise and diet rarely achieve adequate and durable weight loss. The advent of minimally invasive techniques of bariatric surgery has led to significant and lasting weight loss associated with low complication rates [3]. Laparoscopic sleeve gastrectomy (LSG) and one anastomosis gastric bypass (OAGB) are two of the most common bariatric procedures performed worldwide. These are technically feasible, effective and rather safe elective operations. Among the risks, dehiscence and leak of staple line after LSG and of gastric pouch or gastro-jejunal anastomosis after OAGB are to be mentioned as the most severe complications after bariatric surgery. According to Baker et al. [4], leaks can be due to mechanical causes, usually appearing within two day after surgery (early), or ischemic causes, usually appearing five to six days post operatively (intermediate). In this frame, leaks lead to an increased length of post-operative hospital stay, a higher readmission percentage as well as higher morbidity and mortality rates resulting in increased costs for the public health sector. This aspect should be taken into account as obesity has been increasing and bariatric operations have been progressively more employed. The complications and their consequences, even if rare, cannot be ignored. For these reasons, to date, several intraoperative techniques for the detection of early leaks have been described and performed to assess the integrity of the staple line [5]. Among these, the methylene blue test has been widely used. However, this technique can only aid to detect the presence of the leak intraoperatively without providing any tissue characteristics.

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Moreover, intraoperative gastroscopy with air insufflation and hydropneumatic test has also been employed but without univocal results and with a worse cost effectiveness ratio; endoscopic testing requires availability of an endoscopist and is associated with increased procedure time and cost. These techniques have almost no impact on the late leak, basically due to tissue ischemia. Some authors [5] have recently implemented the use of intraluminal indocyanine green (ICG), through an orogastric tube, as an early leak test. This test had comparable sensitivity and specificity to intraoperative endoscopy without the negative aspects of the latter. However, it does not add any element of evaluation compared to the other techniques. Recent systematic analysis [3] suggests that around 79% of leaks will occur as late events, sometimes after postoperative day 10. Some surgeons have recently employed a new technology involving ICG fluorescence angiography (ICG-FA) to assess tissue perfusion and perform vascular mapping during laparoscopic bariatric surgery [6–9]. This technique may aid in improving the surgical technique to prevent ischemia-related leaks.

The common use of ICG-FA, however, highlights the need to standardize the qualitative visual effect of the distribution of the ICG. The use of a score could be a solution but it may still be affected by the surgeon's sense of confidence and by his or her subjective evaluation.

Following these lines, we described the use of intraoperative ICG-FA during LSG and OAGB, performed with an innovative platform from Medtronic, EleVision™ IR (Medtronic, Minneapolis, MN), that use a laser technology in conjunction with ICG for high-definition imaging and for the quantitative measurement of fluorescence signal intensity. The main aim of the present pilot study is to assess the utility of quantitative IGC during bariatric surgery in order to focus future research on the evaluation of the reliability of the quantitative IGC imaging as an innovative tool to reduce the postoperative leak rate.

Material and methods

Patients

This is a prospective observational study. Informed consent was obtained from all the participants. From January 2022 to June 2022, 40 consecutive patients underwent bariatric surgery with ICG-FA in our center based in Rome, Italy (San Giovanni Addolorata Hospital Complex). All patients were candidates for bariatric surgery according to the Italian Society for Obesity and Metabolic Surgery (SICOB) and the European Association for Endoscopic Surgery (EAES) guidelines [10]. Prior to surgery, all patients were screened by a multidisciplinary team consisting of an endocrinologist, a bariatric surgeon, a gastroenterologist, a nutritionist and a psychologist. Preoperative esophagogastroduodenoscopy with biopsy and abdominal ultrasound to evaluate the presence of gastroesophageal reflux disease, hiatal hernia, *Helicobacter pylori* and gallbladder stones disease was performed. The 40 patients enrolled in the present pilot study underwent two different types of surgery based on the multidisciplinary evaluation: LSG or OAGB. The latter was preferred in patients with BMI $>50\,kg/m^2$, patients with type 2 diabetes, or patients defined as 'sweet eaters'.

Surgical procedures

Surgeries and post-operative course were managed according to the Enhanced Recovery After Bariatric Surgery (ERABS) protocol [11]. All procedures were performed in French position (patient lying on the table with legs apart). The calibration tube size used was 36 Fr in diameter.

LSG was performed with a three-trocar approach. After freeing the great curvature of the stomach, the omentum, and any retro-omental adhesions with Ligasure™ (Medtronic, Minneapolis, MN), the stomach was stapled by using a 60 mm purple Tri-Staple™ cartridge (Covidien – Medtronic, Minneapolis, MN). Usually, five of these cartridges were used; except for the first couple of firing all remnant cartridges were reinforced. Specimen extraction was achieved from the median 12 mm port.

OAGB was performed with a four-trocar approach: an additional trocar was used in these cases for liver retraction. The stomach is dissected at the level of the *crow's foot* and staple-divided upwards keeping parallel to the lesser curvature under the guide of the orogastric tube with 60 mm cartridges until the angle of His is reached, thus creating a narrow, longitudinal gastric pouch. A side-to-side mechanical gastrojejunostomy with a 45 cartridge was performed on the anterior wall of the pouch, with a 200 cm long biliopancreatic limb in all patients. The enterotomies were closed with either a single-layer barbed suture or several 3-0 polydioxanone interrupted sutures tied with extracorporeal slip-knots.

Finally, after obtaining an intraoperative negative blue methylene test, a drain was placed in all procedures and the orogastric tube was removed. On the

first postoperative day, after a negative methylene blue leak test and clear liquid tolerance, the drain was removed in all cases. The patient was discharged on postoperative day 2. In this pilot study, a minimum follow-up of one month was considered in order to define the early results and assess the 30-day complication rate.

Indocyanine green fluorescence angiography

In all surgical procedures, after gastric tubulization in the LSG group, and both after gastric pouch and gastrojejunostomy creation in the OAGB group, 2.5 mg of ICG diluted with 20 cm^3 of sterile water were injected intravenously. For the quantitative ICG-FA, VisionSense™ VS3 Iridium (Medtronic, Minneapolis, MN), in EleVision™ IR Platform (Medtronic, Minneapolis, MN) was used to identify the vascular supply. This platform supports the simultaneous near infrared (NIR) and white light imaging as well as the ability to overlay NIR images onto white light images and shows blood flow superimposed on common laparoscopic view of tissue. Moreover, the system consists of a laser with an excitation wavelength of 805 nm that can be activated to detect the absolute and relative IR signal intensity (quantitative evaluation) of a selected area on the screen. The relative intensity is computed relative to a Base Point that usually was automatically set on the brightest area on screen. Surgeon can also choose a Base Point of interest on the screen known as good perfused tissue in each specific case. When using the VisionSense™ VS3 Iridium system, the screen displays three images, as shown in Figures 1 and 2. The exact order and type of image is determined by the selected profile. The possible images are: (a) IR (IR image showing fluorescence); (b) color fused (visible light image with an IR intensity pattern overlay); (c) green overlay (showing fused IR image in green); (d) visible (bright light image, showing visible image only). In all cases, a quantitative assessment was carried out using the *fusion mode* detecting signal intensity in the critical areas (i.e., proximal to the cardias on the left side in LSG and in the anastomosis area and at the level of the dissected *angulus* in OAGB).

Study design

Preoperative variables (gender, age, BMI), intraoperative variables (type of surgery, associated procedures, IGF-FA and methylene blue test outcome and operative time) and postoperative variables (complications according to Clavien-Dindo classification [12] and postoperative hospital stay), were recorded in an observational database. Continuous variables are expressed as mean and 95% confidence interval (CI)

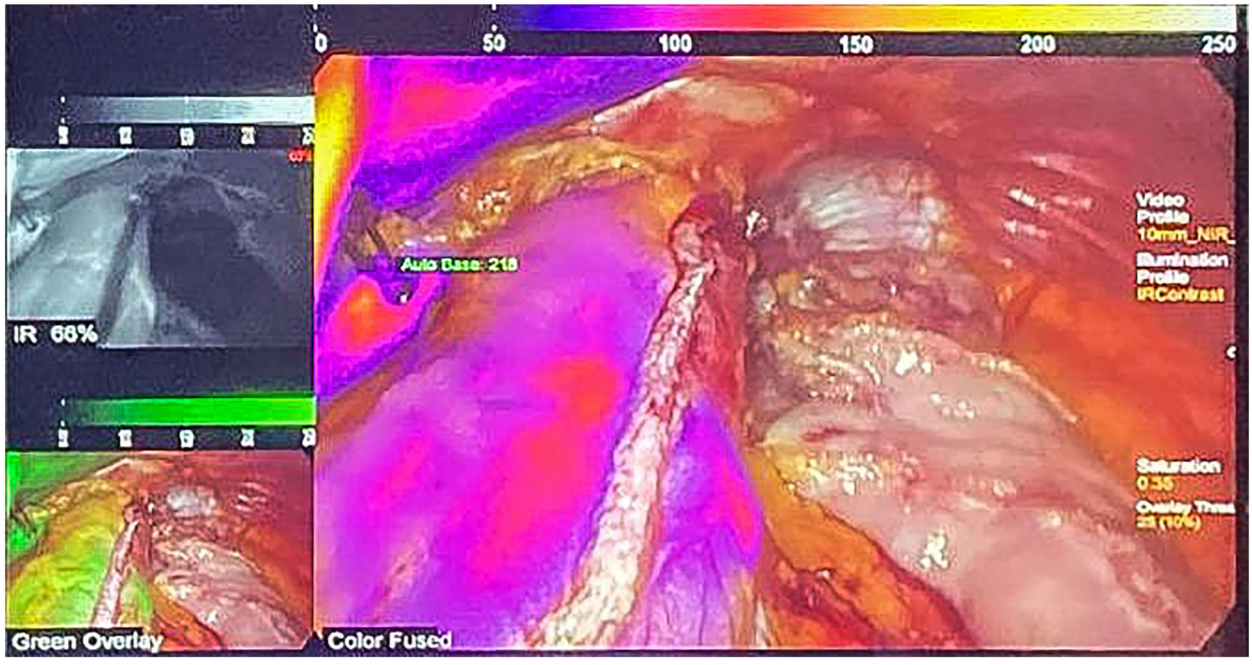

Figure 1. VisionSense™ VS3 screen showing three images during evaluation of the staple line in laparoscopic sleeve gastrectomy. Color-fused image profile showing, in the main figure, the visible light image with an IR intensity pattern overlay. The secondary pictures show the IR vision (top) and the ICG overlay (bottom).

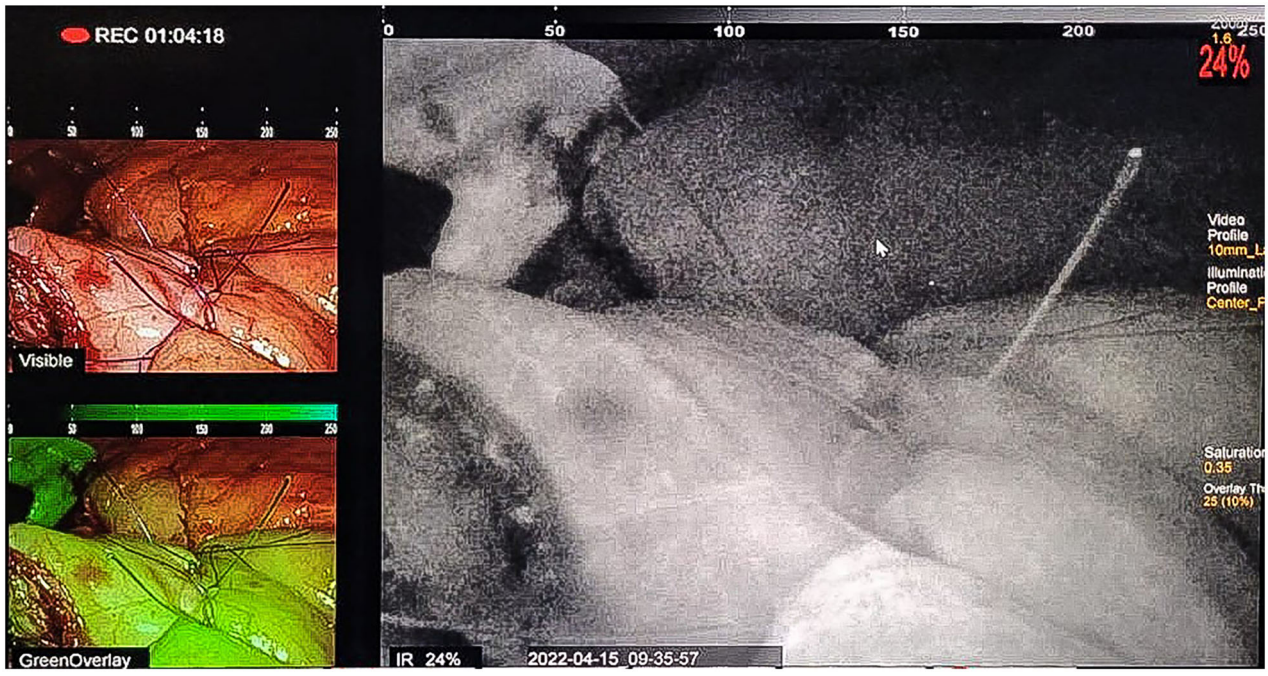

Figure 2. VisionSense™ VS3 screen showing three images after gastrojejunostomy during one anastomosis gastric bypass. IR image profile showing, in the main picture, the near infrared fluorescence pattern. The secondary pictures show the visible light vision (top) and the ICG overlay (bottom).

while categorical variables are expressed as frequencies and percentages.

Results

Tables 1 and 2 show patient characteristics and surgical details. Patients undergoing LSG had an average age of 37.2 years, average BMI of 47.7 kg/m^2 and 69% were women. Patients undergoing OAGB had an average age of 38 years, average BMI of 51.2 kg/m^2 and 67% were women.

Thirteen (32.5%) patients underwent LSG and 27 (67.5%) patients underwent OAGB. Six patients underwent associated procedures (15%): hiatoplasty in two cases (5%), cholecystectomy in three cases (7.5%), incisional hernia repair in one case (2.5%). ICG-FA was performed in all patients with no adverse events, and without any significant impact on operative time. In all patients, ICG-FA visualization was adequate and satisfactory: all staple line and gastric pouch were well perfused; there was no need to change surgical strategies in any case. Methylene blue test was also performed in all patients and was always negative. No conversion to open surgery occurred.

Postoperative complications were observed in one case (2.5%): anemization occurred in one OAGB patient without blush sign during intravenous enhanced abdominal CT scan and treated with blood transfusions (Clavien-Dindo grade II).

Table 1. Patient characteristics.

	Total, $n = 40$	LSG, $n = 13$ (30.8%)	OAGB, $n = 27$ (69.2%)
Age			
Mean ± SD	37.8 ± 15.1	37.2 ± 16.6	38 ± 14.8
95%CI	32.4–41.6	28.2–46.2	32.4–43.6
Gender			
Men:women	13:27	4:9	9:18
BMI			
Mean ± SD	45.2 ± 7.2	47.7 ± 9.8	51.2 ± 10.5
95%CI	[43–47.4]	[42.4–53]	[47.2–55.2]

No leaks were observed at seven and 30 days follow-up after discharge. Mean hospital stay was 2.25 days (95%CI 2.07–2.43 days).

Discussion

Leaks are the most common severe complications and the second cause of death after bariatric surgery. The alarming prevalence of obesity and the more frequent recourse to bariatric surgery, recognized as a safe treatment with generally low mortality rates [13,14] (from 0.3% to 2%; numbers comparable to other common procedures such as appendectomy and cholecystectomy) led to the necessity to focus the attention on the most common complications and on how to prevent them. Knowing the exact pathogenesis would reduce the risk of a leak occurring after bariatric surgery. The leak etiology is multifactorial; in most cases, it may be a combination of ischemic and

Table 2. Surgical details.

	Total, $n = 40$	LSG, $n = 13$ (30.8%)	OAGB, $n = 27$ (69.2%)
Associated procedures, *n* (%)	6 (15)	2 (15.4)	4 (14.8)
Hiatoplasty	2 (5)	1 (7.7)	1 (3.7)
Cholecystectomy	3 (7.5)	1 (7.7)	2 (7.4)
Incisional hernia repair	1 (2.5)	–	1 (3.7)
ICG-FA test			
Satisfactory	40 (100)	13 (100)	27 (100)
Not satisfactory	–	–	–
Methylene blue test			
Negative	40 (100)	13 (100)	27 (100)
Positive	–	–	–
Operative time, minutes			
Mean ± SD	98 ± 39	106 ± 58	98 ± 39
95%CI	[86–110]	[74–128]	[84–102]
Postoperative complication			
n (%) [Clavien Dindo grade]	1 (2.5) [II]	–	1 (3.7) [II]
Postoperative hospital stay, days			
Mean ± SD	2.25 ± 0.6	2.15 ± 0.4	2.30 ± 0.7
95%CI	[2.07–2.43]	[1.95–2.35]	[2.04–2.56]

mechanical factors that lead to a leak. Despite advancements in staple formation and improvements in surgical technique, leaks still occur, and ischemic factors contributing to leaks have not been formally addressed. Regarding LSG the presence of a 'critical area' at the level of the angle of His after gastroepiploic and short gastric vessels ligation is now well defined in the literature [4]. Different methods of intraoperative assessment of the leak have been described; however, with discordant results [5,15–18].

First of all, intraoperative tests do not help to identify ischemic areas or gastric tube/pouch blood supply [19–22]. Furthermore, the stress caused on the staple line by the test itself is a potential cause of leaks [23,24]. The recent introduction of the intravenous administration of ICG to evaluate real-time tissue perfusion in many surgical fields, including bariatric surgery, seems to be promising without, however, having achieved definitive results to date. The lack of a standardized quantitative fluorescence evaluation and of a clear and defined real-time image reconstruction are still the most debated limits [6–9].

Keeping in mind this evidence, the aim of this pilot study was to describe our experience about the intraoperative employment of quantitative ICG-FA and assess if this method can be a useful tool to reduce the ischemic leak rate. For this purpose, we have enrolled 40 patients undergoing bariatric surgery, 13 with LSG and 27 with OAGB. In all procedures, we employed quantitative ICG-FA by means of a new innovative system, VisionSense^{TM} Iridium. The latter uses an innovative laser technology in conjunction with ICG for high-definition imaging, providing real-time qualitative and quantitative measurement of infrared intensity, supporting surgical decision-making to optimize outcomes in real time. We believe that the introduction of quantitative technology is the first step in making the ICG evaluation objective. The technical characteristics of the quantitative ICG platform could suggest potential parameters in quantification of the fluorescence imaging signal that could help the surgeon in perfusion evaluation for the prediction of anastomotic leakage development. We also believe that the quantitative ICG technology can represent an innovative tool to overcome this difficulty associated with the different fluorescence distribution in different tissues. The ICG fluorescence intensity can be variable according to the vascular and anatomical characteristics of tissues/organs under investigation. In this specific case, there are evident differences between the fluorescence that can be seen in the stomach compared to the one in the small bowel which typically has a more widespread and intense distribution. The quantitative ICG technology, with his laser-mediated measurement, can overcome this obstacle represented by the subjective evaluation of different tissue enhancement. The surgeon can choose a Base Point of interest on specific tissues/organs in the screen, set on the brightest area of each one and thus an IR intensity relative to the specific organ. To date, EleVision^{TM} IR platform is the only system that is capable of real-time fluorescence measurements in both open and laparoscopic procedures, allowing surgeons to objectively analyze tissue perfusion by taking quantitative measurements in real time. Overall, in the literature, ICG during bariatric surgery are reported in a limited number of studies. For example, Ortega et al. [7] described the use of this technology during LSG in 86 patients to identify the variable blood supply patterns to the stomach and gastroesophageal junction. They concluded that ICG can be employed with satisfactory results to evaluate tissue

perfusion and vascular mapping before any dissection during LSG. Recently, Balla et al. [6] in a pilot study with 13 patients concluded that ICG during bariatric surgery is a safe, feasible and promising procedure, helping to reduce the ischemic leak rate, although they believe that standardization of the procedure and objective fluorescence quantification are still missing. Actually, the limit of most ICG platforms is to allow only a qualitative assessment which is a subjective evaluation of the fluorescence using a green scale imaging. At present, there are no studies concerning the quantitative ICG evaluation in bariatric surgery. This necessity has motivated the present study, in which a quantitative platform was evaluated. To the best of our knowledge, there are no studies with the Medtronic device concerning the gastrointestinal surgery field. Most of the studies on quantitative methods consist in post-processing assessment of the fluorescence intensity or artificial intelligence algorithm that could provide a sort of real-time overlapping intensity map. From our preliminary experience, we can speculate that the quantitative IGC fluorescence angiography can be a promising tool in bariatric surgery. In LSG, this technique can aid to evaluate the vascularization of the staple line (Figure 1) and thus to decide the site of manual stitch on the section line, if it is ischemic. Additionally, in the OAGB, the IGC is useful to assess the perfusion of the gastric pouch before the anastomosis is performed and to facilitate the eventual further resection if a portion of the pouch is badly perfused, in order to always achieve well-perfused tissue to perform gastrojejunostomy (Figure 2).

In the present study, we could outline the early results on the use of quantitative ICG in bariatric surgery. The univocal identification of the quantitative distribution of the molecule is ensured by Platform digital image restitution. Different color patterns on a continuous scale indicate the amount of ICG in each tissue area. Laser-based technology enables to detect the relative IR intensity score on the tissue of interest. This feature can allow to overcome the above-mentioned limit of the subjective evaluation of the vascularity linked with the qualitative ICG-FA imaging [6–9].

The present research is a pilot study and we are aware that we cannot give a solid conclusion at this time. The lack of relevant clinical data with the qualitative ICG measurement represents a starting point to investigate alternative and innovative ways to assess ICG tissue perfusion. To assess the effectiveness of this method, several studies with a large number of patients are mandatory with the aim of establishing an 'alert' cut-off parameter that should allow the prediction of anastomotic leakage and its statistically significant level. However, quantitative ICG-FA seems to be a useful and promising tool for the prevention of complications in bariatric surgery.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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