

# Role of Indocyanine Green on Visibility of Gastroesophageal Vascularity in Laparoscopic Sleeve Gastrectomy: An Experimental Study

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## ABSTRACT

**Background:** Obesity has evolved into a global epidemic, affecting millions of people worldwide and posing substantial challenges to public health. To date, sleeve gastrectomy has gained popularity due to its effectiveness in promoting weight loss, favorable impact on comorbidity, and its relatively lower rate of complications than other procedures. The visibility of the gastroesophageal junction (GEJ) vascularity is crucial and plays a critical role in the safety and the success of laparoscopic sleeve gastrectomy (LSG) including the prevention of postoperative leaks. This research aimed to explore the potential benefits of using indocyanine green (ICG) to improve the visibility of the GEJ vasculature during sleeve gastrectomy.

**Materials and methods:** This study investigates the impact of ICG administration, dose, and timing on fluorescence intensity (FI) as the quantitative measure of GEJ vascularity. Fourteen pigs were randomly divided into two groups low-dose (0.1 mg/kg) and high-dose (0.3 mg/kg). Fluorescence intensity was determined at 0, 30, 60, 90, 120, 150, and 180 seconds using FIJI software (v 2.0.0-rc-49/1.51) from images obtained by the Stryker 4K camera system with spy mode. Data were analyzed using a *t*-test and analysis of variance.

**Results:** The results showed a significant effect of ICG administration on FI ( $p < 0.05$ ) with a significant increase in FI after ICG administration. The interaction between ICG administration and dose was also significant ( $p < 0.05$ ). Both groups show a sharp increase in FI immediately after ICG administration. The high-dose group exhibits a steeper rise, reaching a higher peak between 0 and 60 seconds, while the low-dose group shows a less steep rise to a peak between 30 and 90 seconds. At 180 seconds, both groups maintain higher FI levels than their starting points.

**Conclusion:** This study demonstrates that ICG significantly enhances the visibility of GEJ vascularity, with the effect being dose-dependent and sustained over time. These findings support the use of ICG as a valuable method in LSG, improving the precision and safety of vascular supply to the GEJ during stomach handling and dissections.

**Keywords:** Gastroesophageal junction vascularity, Indocyanine green, Indocyanine green dose, Indocyanine green timing, Laparoscopic sleeve gastrectomy.

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## INTRODUCTION

Indocyanine green (ICG) has been used in various medical applications, including ophthalmology, liver clearance tests, and cardiac output monitoring. Recently, ICG has also found applications in colorectal, hepatobiliary, bariatric, gynecological, and most oncological surgeries.<sup>1,2</sup> In laparoscopic sleeve gastrectomy (LSG), ICG has been used for the assessment of gastric perfusion and the detection of leaks.<sup>3</sup> Top of form during vascular assessment, the ICG dye is administered intravenously to the patient shortly before or during the sleeve gastrectomy surgery. Once in the bloodstream, ICG binds to plasma proteins and emits near-infrared fluorescence, making it visible to a specialized imaging system at around an 800 nm wavelength.<sup>4</sup> During the operation, the surgeon uses a near-infrared camera to observe the ICG dye's fluorescence in the blood vessels supplying the stomach tissue. Indocyanine green in bariatric surgeries has emerged as a valuable tool to enhance the safety and precision of the surgical procedure. As technology and surgical techniques continue to evolve, the use of ICG and other intraoperative imaging methods is likely to play an increasingly significant role in enhancing the effectiveness of bariatric surgeries.

Obesity has evolved into a global epidemic, affecting millions of people worldwide and posing substantial challenges to public

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health. This chronic condition not only adversely affects physical health but also takes a toll on mental and emotional well-being, resulting in a diminished quality of life for those afflicted. As a result,

there has been a steady rise in the number of bariatric surgical procedures performed year after year.<sup>5</sup> For individuals experiencing severe obesity and who have struggled with conventional weight loss methods without success, bariatric surgery emerges as a life-changing solution due to its ability to induce significant and long-lasting weight loss.<sup>6-9</sup>

Bariatric surgery is not a one-size-fits-all solution, and the most suitable choice of surgery will differ based on various factors, including a patient's body mass index (BMI), medical history, age, and personal health objectives. Moreover, with ongoing research and advancements in surgical techniques, there is the potential for further refinements and enhancements in bariatric procedures as time progresses.

Laparoscopic sleeve gastrectomy involves the removal of a large portion of the stomach to create a smaller, banana-shaped sleeve. This restrictive procedure significantly reduces the stomach's capacity, leading to earlier satiety and reduced food intake, resulting in weight loss. To date, sleeve gastrectomy has gained popularity due to its effectiveness in promoting weight loss, favorable impact on comorbidity and its relatively lower rate of complications compared to other procedures.<sup>10-14</sup>

Studies have shown gastroesophageal junction (GEJ) being an area with poor perfusion when compared to other areas of the stomach and worse in obese patients since perfusion showed to be decreasing with increase in BMI at all areas of the stomach.<sup>15</sup> Furthermore, literature has shown the GEJ being the most area of leak in LSG and the cause of leak being ischemia following arterial blood supply injury and transection.<sup>16-19</sup> The injury is probably due to poor vascular visibility of this most distant area of the stomach during the mobilization and resection of the stomach. Even though leak as a complication occur in a small proportional (0-8%), it leads to increased burden with prolonged hospital stay (up to over 40 days), re-operations and even mortality of up to 0.4%.<sup>6,8,9,20-22</sup> The use of ICG fluorescence angiography holds promise in providing real-time feedback on tissue perfusion, enabling surgeons to make informed decisions during the operation. Despite the potential benefits in applications of ICG in various medical fields, minimal research has been conducted to investigate the specific role of ICG in improving visibility of GEJ vascularity during LSG. Numerous questions remain unanswered pertaining to the use of ICG on gastric vascular visibility, including the optimal timing after ICG administration, the required optimal dose, and the correlation between enhanced vascular visibility and patient outcomes. Additionally, Wityk et al.<sup>23</sup> reported lack of standardized qualitative assessment of fluorescence during ICG use. This research aimed to address this knowledge gap by exploring the potential benefits and limitations of ICG in enhancing the vascular visualization of specifically the GEJ. Top of form by doing so, the study seeks to contribute valuable insights to the field of bariatric surgery, with the goal of optimizing surgical approaches to enhance patient safety and postoperative recovery. The findings of this research provide a baseline for further studies in the field, potentially leading to more comprehensive investigations on how improved GEJ vascular visibility can influence patient outcomes. Ultimately, it may contribute to reducing postoperative complications and improving overall patient recovery and satisfaction.

## MATERIALS AND METHODS

### Study Design and Setting

This study employs a randomized controlled trial design to investigate the impact of several factors on the outcome of interest,

the GEJ vascular visibility. The factors under investigation include ICG administration, ICG duration, and ICG dose. By randomly assigning the pigs to different combinations of these factors, we examined both the individual effects of each factor and their combined effects on GEJ vascular visibility. This study spanned over a ten-month duration, August 2023–May 2024 and was carried out at the Animal Laboratory of World Laparoscopic Hospital, an educational institution specializing in minimally invasive surgery and endoscopic procedures in India. The study involved dividing the pigs into two groups: The low dose (0.1 mg/kg) ICG group and the high dose (0.3 mg/kg) ICG group. Each pig served as its control group, as we measured GEJ vascular visibility before ICG administration, and at various time points (30, 60, 90, 120, 150, and 180 seconds) after intravenous ICG administration. We included pigs weighing between 8 and 12 kg, as their abdomen corresponds to the size of the laparoscopic instruments used. These pigs were obtained from a single breeding farm to reduce genetic variability and ensure homogeneity in the study population.

To achieve the objective of this study, G\*Power was used to estimate the sample size. Based on the previous studies on the use of ICG, the baseline rate of tissue detection was set at 70%.<sup>25</sup> The input parameters were  $\alpha$ -error set at 0.05 and power  $(1 - \beta)$  at 0.95, two different groups (low and high doses) and measurements were taken before and after ICG administration. In a mixed-design analysis of variance (ANOVA) with within-between interaction using a priori power analysis, a total sample size of 10 pigs was determined, achieving an actual power of 0.97. Conservative recruitment of animals during wet laboratory skills practical sessions in August 2023 were done and a total of 14 pigs were included in this study.<sup>24</sup>

### Anesthesia and Preparation

On the day of the experiment, anesthesia was administered to the selected pigs by trained staff to ensure safe and comfortable handling during the experiment. The animals were positioned supine for laparoscopic examination.

### Subjects Randomization

An envelope with 14 folded papers marked LOW or HIGH in equal numbers was used to select the group for each subject. One of the laboratory staff picked one paper from the envelope, and the group was allocated to the subject to be examined.

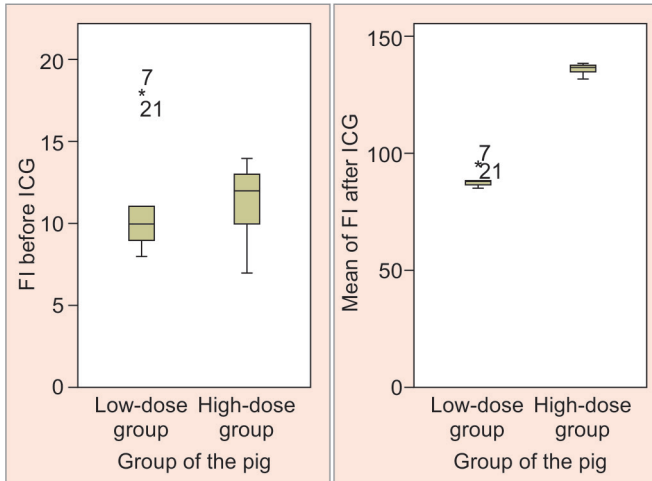
### Abdominal Access

A skin puncture on the midline, 2 cm below the umbilical, was made using a size 11 surgical blade. A Veress needle (10 cm size) is inserted, held like a dart in the right-hand perpendicular to the skin, which is pinched and elevated using the left hand, creating a 45° angle between the needle and abdominal wall. The Veress needle was inserted in the caudal direction. A two-click sound is heard as the needle pierces the fascia and peritoneum. The irrigation, aspiration, and drop-hanging tests were performed using a 5cc syringe filled with normal saline to confirm the intra-abdominal location of the Veress needle tip. The pneumoperitoneum was created by connecting the wall-mounted carbon dioxide tubing to the Veress needle at a flow rate of 5 L/min. The optimum pneumoperitoneum was checked by gently tapping the lumbar part of the abdomen to create a drum-like sound. The 10 mm cannula (without a trocar) was pressed on the puncture site to mark the required diameter, and using the size 11 surgical blade, the skin was cut to fit the mark. A puncture was performed using

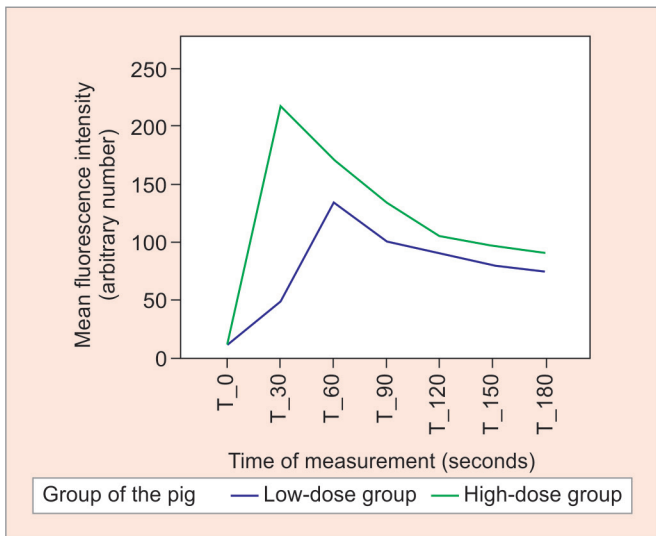


**Table 1:** Group characteristics and FI

Variable	Group	Mean	Std. deviation	N
Weight (kg)	Low dose	10.14	1.864	7
	High dose	10.71	1.254	7
FI before ICG (arbitrary number)	Low dose	11.00	3.266	7
	High dose	11.29	2.430	7
	Total	11.14	2.770	14
FI after ICG (mean) (arbitrary number)	Low dose	87.9524	3.28114	7
	High dose	135.9286	2.23577	7
	Total	111.9405	25.03934	14



**Figs 2A and B:** Fluorescence intensity: (A) FI before ICG administration, no difference; (B) FI after ICG administration, significance difference



**Fig. 3:** Fluorescence intensity over time. Both groups show a sharp increase in FI immediately after ICG administration. The high-dose group exhibits a steeper rise, a peak FI for the high-dose group occurs between 0 and 60 seconds, while the low-dose group shows a less steep rise to peak between 30 and 90 seconds

points, with the high-dose group showing a more pronounced and sustained increase compared to the low-dose group.

On assessment of the impact of time and dose on FI, the repeated measures ANOVA revealed a significant effect of time on FI [Wilks' Lambda:  $F(6, 7) = 427195.2, p < 0.05$ ], indicating that FI significantly changed over the measured time points. The between-subjects effect of the group was also significant [ $F(1, 12) = 748.3, p < 0.05$ ], suggesting a significant difference in overall FI between the low and high-dose groups. The interaction between time and dose further indicates that the pattern of change in FI over time was not uniform across the dose groups, suggesting a dose-dependent effect on the fluorescence response [ $F(6, 7) = 20371.4, p < 0.05$ ].

**DISCUSSION**

Laparoscopic sleeve gastrectomy is a widely performed bariatric surgery. Its restrictive nature significantly reduces the stomach's capacity, leading to earlier satiety and reduced food intake. Laparoscopic sleeve gastrectomy has gained popularity due to its effectiveness in promoting weight loss, its favorable impact on comorbidities, and its relatively lower rate of complications compared to other procedures.<sup>10-14,22</sup> However, like other surgeries, it is not without complications. The most common complication is postoperative GEJ leaks following ischemia due to arterial blood supply injury and transection.<sup>16-19</sup>

The visibility of GEJ vascularity is crucial to prevent injury and transection of the vascular supply to the GEJ and plays a critical role in the safety and success of LSG. In improving the technique of assessing GEJ vascularity, the use of ICG in LSG was evaluated. A quantitative measure of GEJ vascular visibility was used in this study to overcome the lack of standardization and non-reproducibility of qualitative methods used in previous studies.<sup>23,29,30</sup> This study showed that the FI for both low and high-dose groups had a statistically significant increase after ICG was injected and persistently remained higher throughout the 3 minutes of the experiment. This aligns with its known properties as a fluorescent dye used in many medical applications.<sup>1,2</sup> This improvement in visibility can facilitate safer and more precise dissection and tissue handling during LSG. Quantitative studies with ICG have shown the ability to predict anastomotic leaks in other procedures, including colonic anastomosis, by evaluating colonic perfusion and taking extra measures during the restoration of continuity to prevent the burden of anastomotic leaks.<sup>31,32</sup> With the findings of this study, there should be no doubt that the use of ICG to evaluate the visibility of GEJ vascularity will prevent leaks in the reconstructed gastric tube during LSG.

The study found a significant interaction between ICG dose and FI. This dose-dependent response was also reflected in the between-subjects effect of the groups, showing an overall higher FI in the high-dose group compared to the low-dose group. The temporal analysis revealed a faster and more intense response in the high-dose group. Over the measured time points, the FI remained elevated in both groups compared to their starting points, with the high-dose group maintaining a more pronounced and sustained increase. A "higher dose" used in this study of 0.3 mg/kg gave a more significant increase in FI and thus better visibility of GEJ vascularity. There is no consensus on the optimal dose for the use of ICG in the assessment of leaks. Generally, the typical dosage ranges from 0.1 to 0.2 mg/kg of body weight, with a maximum total dose of around 25 mg for an average adult patient (0.36 mg/kg in a 70 kg body weight).<sup>29,30,33-36</sup> It is essential to balance the benefits of higher doses with potential toxicity risks, underscoring the need



for optimizing dosing strategies in clinical practice. The 0.3 mg/kg used in this study was far below the reported toxicity of ICG in animals, which is 50–80 mg/kg.<sup>4,37</sup>

The timing of assessing tissue perfusion can vary depending on the tissue type and clinical context, highlighting the versatility of ICG in different surgical scenarios. In studying the biliary system, Dip et al.<sup>38</sup> found a split of opinion on the timing of IV ICG during laparoscopic cholecystectomy, ranging from 30 minutes, 60 minutes, and over 60 minutes. Boogerd et al.<sup>39</sup> on dosing and dosing time in studying fluorescence cholangiogram revealed that many studies administered ICG within one hour before imaging. When injected into the submucosa, ICG marks the site of injection, and its fluorescence decreases over days.<sup>40</sup> Studies have shown that the required duration for reading the results of ICG during its use in LSG is typically real-time or immediate, but they have not shown the exact time after ICG administration that gives optimal fluorescence. This study showed both groups exhibited a sharp increase in FI immediately after ICG administration. The high-dose group exhibited a steeper rise, reaching a higher peak compared to the low-dose group. The peak FI for the high-dose group occurred between 0 and 60 seconds, while the low-dose group showed a less steep rise to a peak between 30 and 90 seconds. Timing from 0 to 90 seconds gives an optimum FI when the dose of 0.1–0.3 mg/kg is administered, although up to 180 seconds the FI was still significantly high.

Several limitations of this study include factors such as BMI and the physiological state of the subjects, which were not controlled, as well as a small sample size. These limitations could influence the generalizability of the results.

## CONCLUSION

In conclusion, this study demonstrates that ICG significantly enhances the visibility of GEJ vascularity, with the effect being dose-dependent and sustained over time. These findings support the use of ICG as a valuable method in LSG, improving the precision and safety of vascular supply to the GEJ during stomach handling and dissections.

Future studies should include larger sample sizes and consider the impact of variables such as BMI and the physiological state of the subjects to provide more comprehensive insights. Additionally, investigating the long-term stability of FI and the possible impact of repeated ICG administrations could provide deeper insights into its utility and safety in clinical practice. Moreover, while this study was conducted on pigs, translating these findings to human patients is crucial. Human studies are necessary to confirm the safety and efficacy of ICG in enhancing vascular visibility during LSG.

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