Systematic Review and/or Meta-analysis

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Usefulness of fluorescence imaging with indocyanine green for evaluation of bowel perfusion in the urgency setting: a systematic review and meta-analysis

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Introduction: Fluorescence imaging with indocyanine green (ICG) has been extensively utilized to assess bowel perfusion in oncologic surgery. In the emergency setting, there are many situations in which bowel perfusion assessment is required. Large prospective studies or RCTs evaluating feasibility, safety and utility of ICG in the emergency setting are lacking. The primary aim is to assess the usefulness of ICG for evaluation of bowel perfusion in the emergency setting.

Materials and methods: The manuscript was drafted following the recommendations of Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (PRISMA). A systematic literature search was carried out through Pubmed, Scopus, and the ISI Web of Science. Assessment of included study using the methodological index for nonrandomized studies (MINORS) was calculated. The meta-analysis was carried out in line with recommendations from the Cochrane Collaboration and Meta-analysis of Observational Studies in Epidemiology guidelines, and the Mantel–Haenszel random effects model was used to calculate effect sizes.

Results: 10 093 papers were identified. Eighty-four were reviewed in full-text, and 78 were excluded: 64 were case reports; 10 were reviews without original data; 2 were letters to the editor; and 2 contained unextractable data. Finally, six studies[22-27] were available for quality assessment and quantitative synthesis. The probability of reoperation using ICG fluorescence angiography resulted similar to the traditional assessment of bowel perfusion with a RD was −0.04 (95% CI: −0.147 to 0.060). The results were statistically significant $P = 0.029$, although the heterogeneity was not negligible with a 59.9% of the I^2 index. No small study effect or publication bias were found.

Conclusions: This first metanalysis on the use of IGC fluorescence for ischemic bowel disease showed that this methodology is a safe and feasible tool in the assessment of bowel perfusion in the emergency setting. This topic should be further investigated in high-quality studies.

Keywords emergency and trauma surgery, indocyanine green fluorescence, meta-analysis, systematic review

Introduction

In the last decade the use of diagnostic intraoperative tools to assess the viability and function of intrabdominal organs has been widely implemented.

In particular, fluorescence imaging with indocyanine green (ICG) marker has been extensively utilized to assess bowel perfusion in oncologic surgery mainly to prevent complication due to anastomotic leak in colon-rectal surgery[1–5].

In the emergency setting, there are many situations in which bowel perfusion assessment is required to evaluate the need and the extent of resection and to prevent both short bowel syndrome or reoperation due to anastomotic leak or inadequate bowel resection at index surgery.

Particularly, bowel assessment is useful in all the conditionstied to acute mesenteric ischemia, which can be distinguished in two main categories: occlusive mesenteric ischemia (OMI) and nonocclusive mesenteric ischemia (NOMI). Primary etiology may vary from: mesenteric arterial embolism (accounting for 50% of cases); mesenteric arterial thrombosis, responsible

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of 15–25% of all occlusive ischemia; mesenteric venous thrombosis, accounting for 5–15% of all cases[6].

Acute bowel ischemia (ABO) has very low incidence, in fact ranges are between 0.09 and 0.2% of all admissions to emergency departments, nonetheless still remains a life-threatening disease and its morbidity and mortality rate still remain high with rates over 60% reported[7,8].

Ischemia is mainly due to the sudden or chronic absence of adequate tissue oxygenation, which is triggered either by vascular occlusion or nonocclusive causes.

Patient's outcomes depend on both timely recognition and treatment, in order to obtain either revascularization before ischemia progresses to intestinal gangrene or resection of ischemic segments of bowel[9,10].

Historically bowel perfusion has been diagnosed based largely on evaluation of clinical findings, computed tomography (CT) and or angiography imaging, and visual inspection, peristaltic movements, and mesenteric pulse assessment intraoperatively[11,12].

Classical strategies are not exempt from error and thus to reintervention due to complications such as further extension of ischemia or anastomotic leak. In the emergency setting, in which the patient may already present single or multiple organ disfunction, avoiding complications or reintervention could have a huge impact on prognosis[13,14].

Furthermore, with the widespread utilization of laparoscopy in the emergency setting and especially in ABO, in which setting is becoming the intervention of first choice, many authors cite the inability to adequately assess bowel perfusion has a limitation in laparoscopy employment due to reduced field of vision as a result of bowel distension, less haptic feed-back and bi-dimensional visualization[15,16].

For these reasons, there is a need to implement a diagnostic tool that could aid the surgeon in intraoperative decision regarding the extent of bowel resection and/or safety of anastomosis thus minimizing potential complications.

In literature large prospective studies or RCTs evaluating feasibility, safety and utility of ICG in the emergency setting are lacking. Currently available literature is constituted mainly of small retrospective studies therefore leaving huge void in high value scientific evidence regarding this field. Emergency surgeons have a strong need of a better knowledge that indicates which strategies, and in particular ICG fluorescence, could make the difference and impact patients prognosis in such a deadly and dangerous pathology.

Therefore, there is no clear standard on the evaluation of bowel viability during emergency surgery.

In vivo, ICG emits near-infrared fluorescence when it is excited by near-infrared light. The technique for observing ICG fluorescence with a near-infrared camera has been described as early as the 1970s and its safety and feasibility in many different settings such as hepatic function evaluation, biliary tree assessment during cholecystectomy or bowel perfusion in oncologic surgery have been widely demonstrated[17–20].

Fluorescence imaging with ICG has become one of the most popular imaging modes in surgery for the evaluation of bowel perfusion. The benefits of ICG are several. Firstly, ICG has a high contrast, that is, signal to noise ratio (SNR): this means that only the target, not background, is visible because separate wavelengths are used for illumination and recording. Moreover, ICG has a high sensitivity, because extremely small concentrations can often be made visible, and is cheap and easy to use tool.

HIGHLIGHT

- Systematic review and meta-analysis to investigate the use of indocyanine green in the emergency setting.

This study aims to completely evaluate the available literature regarding the use of ICG in the emergency setting and to perform a meta-analysis of the available studies.

The primary aim is to assess the usefulness of fluorescence imaging with ICG for evaluation of bowel perfusion in the emergency general surgery setting.

To the author's knowledge, the present study is the first meta-analysis evaluating this topic.

Materials and methods

The manuscript was drafted following the recommendations of Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (PRISMA, Supplemental Digital Content 1, http://links.lww.com/JS9/C610, Supplemental Digital Content 2, http://links.lww.com/JS9/C611) and AMSTAR (Assessing the methodological quality of systematic reviews) Guidelines (Supplemental Digital Content 3, http://links.lww.com/JS9/C612)[21,22].

The study's eligibility criteria were established utilizing the PICOS strategy: Patients, Intervention, Control, Outcome, Study. Regarding this study: (1) the participants were patients having ischemic bowel syndrome and requiring emergency surgery; (2) the intervention was evaluation of bowel perfusion with ICG; (3) the control arm was the change of strategy regarding extension of resection or no change; (4) the primary outcome was reoperation rate due to bowel ischemia; and (5) study evaluated for inclusion were prospective randomized controlled trials, if available, and nonrandomized prospective or retrospective studies.

Literature search strategy

No language, publication date, or states restrictions were used. A systematic literature search was done through Pubmed, Scopus, and the ISI Web of Science. The last research was performed on 1st July 2023. Search was kept very general and string utilized was: (green indocyanine AND bowel) OR (green indocyanine AND ischemia) OR (ICG AND bowel) or (ICG AND ischemia) OR (indocyanine green AND emergency) OR (indocyanine green AND urgency) OR (ICG AND emergency) OR (ICG AND urgency) OR (indocyanine green AND intestinal) OR (indocyanine green AND resection) OR (ICG AND intestinal) OR (ICG AND resection) OR (indocyanine green AND AMI) OR (indocyanine green AND acute mesenteric ischemia) OR (ICG and AMI) OR (ICG and acute mesenteric ischemia) OR (indocyanine green AND bowel obstruction) OR (ICG AND bowel obstruction). We used all related articles to enlarge the systematic search, and the references of included studies were examined.

Systematic review results were managed using CADIMA Free web tool software version 2.2.3 - Nov 2021.

Inclusion and exclusion criteria and study selection process

A PRISMA flowchart was plotted to report the study selection process and results from systematic review. Duplicate studies

were immediately excluded, remaining studies were screened according to the title and abstract in order to remove records not relevant for this study's aim. Subsequently eligibility was evaluated in the remaining full-text articles.

The following inclusion and exclusion criteria were used: (1) comparative, randomized or nonrandomized, design; (2) as intervention arm the utilization of ICG for the evaluation of bowel perfusion exclusively in the urgency and emergency setting; (3) reporting of reoperation rate due to further ischemic bowel complication; and (4) humans only clinical study.

Exclusion criteria were the following: (1) studies that did not report original data or reviews or meta- analyses; (2) studies with data reported in unextractable form; and (3) studies that did not report data about reoperation rate. Studies' selection was blindly and independently performed by two different authors. All papers considered eligible for the study were examined in full-text form, and all studies meeting all the inclusion criteria without the exclusion ones were selected for the analysis. Any possible disagreement was resolved after a collegial discussion between the reviewers and the senior author.

Data collection process

Data extraction was done by two reviewers and data was reported in a previously set excel sheet.

Information was extracted to define each study's characteristics: authors, affiliation and country, year of publication, type of design (randomized or nonrandomized), the technique of ICG, the setting in which it was used, the sample size of each arm, and the outcomes reported. All the potential disagreements were solved with a discussion between the reviewers and the last author.

Theory and calculation

Risk of bias in individual studies, summary measures, and synthesis of results

We carried out a qualitative assessment of included study using the methodological index for nonrandomized studies (MINORS). Categorical variables were reported as frequencies and percentages, while the continuous variables were described as means and SD.

The results were reported, for dichotomous variables, as risk difference (RD) and odds ratio (OR) with a 95% CI. The meta-analysis was carried out in line with recommendations from the Cochrane Collaboration and Meta-analysis of Observational Studies in Epidemiology Guidelines, and the Mantel–Haenszel random effects model was used to calculate effect sizes.

Risk of bias across studies and additional analyses

The risk of bias across included studies was tested, measuring both the 'between-study heterogeneity' and publication bias. The heterogeneity was measured by testing both I^2 and Cochran's Q statistics. The I^2 value reports the percentage of variation across the included studies related to heterogeneity rather than sampling error. The heterogeneity was interpreted as follows: If I^2 was <50% the risk of 'between-study' heterogeneity was considered low–moderate, and if I^2 was $\geq 50\%$, it was judged high. The Begg and the Egger test was used to exploring the presence of the publication bias, and a P-value <0.05 indicated a non-negligible 'small-study effect'. The statistical analysis was carried out using dedicated packages for STATA v14.

Results

Study selection and characteristics

The results of the systematic search of the literature following the PRISMA statement are reported in Figure 1. The search identified 10 093 papers: 3383 from the Medline/PubMed database, 2390 from the ISI Web of Science, and 4320 from Scopus. Two thousand four hundred twenty-six titles were left after de-duplication. Of these, 2342 were excluded from evaluating the title and abstract because they were not pertinent to our study field. Eighty-four were reviewed in full-text form, and of these, 78 were excluded because: 64 were case reports; 10 were reviews without original data; 2 were letters to the editor; and 2 contained unextractable data. Finally, six studies[23–28] were available for quality assessment and quantitative synthesis (Fig. 1). There was 100% agreement between the two reviewers. The characteristics of the studies selected are summarized in Table 1 and Supplementary Table 1 (Supplemental Digital Content 4, http://links.lww.com/JS9/C613). All the studies were published in the twenty-first century of which three in a Western country. The totality of studies included did not have a randomized design nor a propensity score matching analysis, all studies included were retrospective.

A total of 297 patients were used for final analysis: 101 (34.1%) in the ICG group, 196 (65.9%) patients were in the no ICG group. In Supplementary Table 1 (Supplemental Digital Content 4, http://links.lww.com/JS9/C613) is reported a description of the ICG technique utilized in the different studies. The quality of the studies despite their exiguity was reasonably good with a median of 12 (11–14) points.

Primary endpoint

The probability of reoperation using ICG fluorescence angiography resulted similar to the traditional assessment of bowel perfusion with a RD was – 0.04 (95% CI: – 0.147 to 0.060). The results were statistically significant $P = 0.029$, although the heterogeneity was not negligible with a 59.9% of the I^2 index, as shown in Forest plot graph (Fig. 2).

The data was also confirmed even when rerunning the analysis utilizing the OR. The results showed an OR of 0.690 (95% CI: 0.200–2.420) with an I^2 of 34.0% indicating a small heterogeneity in the results. The alternate analysis is shown in a different Forest plot (Fig. 3).

We eventually tested the presence of 'small study effects' without identifying any, both with the Begg' s test ($P = 0.602$) and Egger's test ($P = 0.582$).

Analysis regarding publication bias has been performed and is shown in Figure 3, the analysis showed once again the absence of both biases and heterogeneity.

Discussion

Fluorescence imaging with ICG has become a cornerstone of oncological surgery, and it is widely used to asses bowel perfusion to avoid anastomotic leak after curative surgery[29–32].

As of today, ICG fluorescence in the emergency setting has been used but seldomly studied, in fact current literature shows a lack of high-quality studies of randomized design. Thus, its utility in preventing a relaparotomy due to persistence of ischemic bowel is unknown.

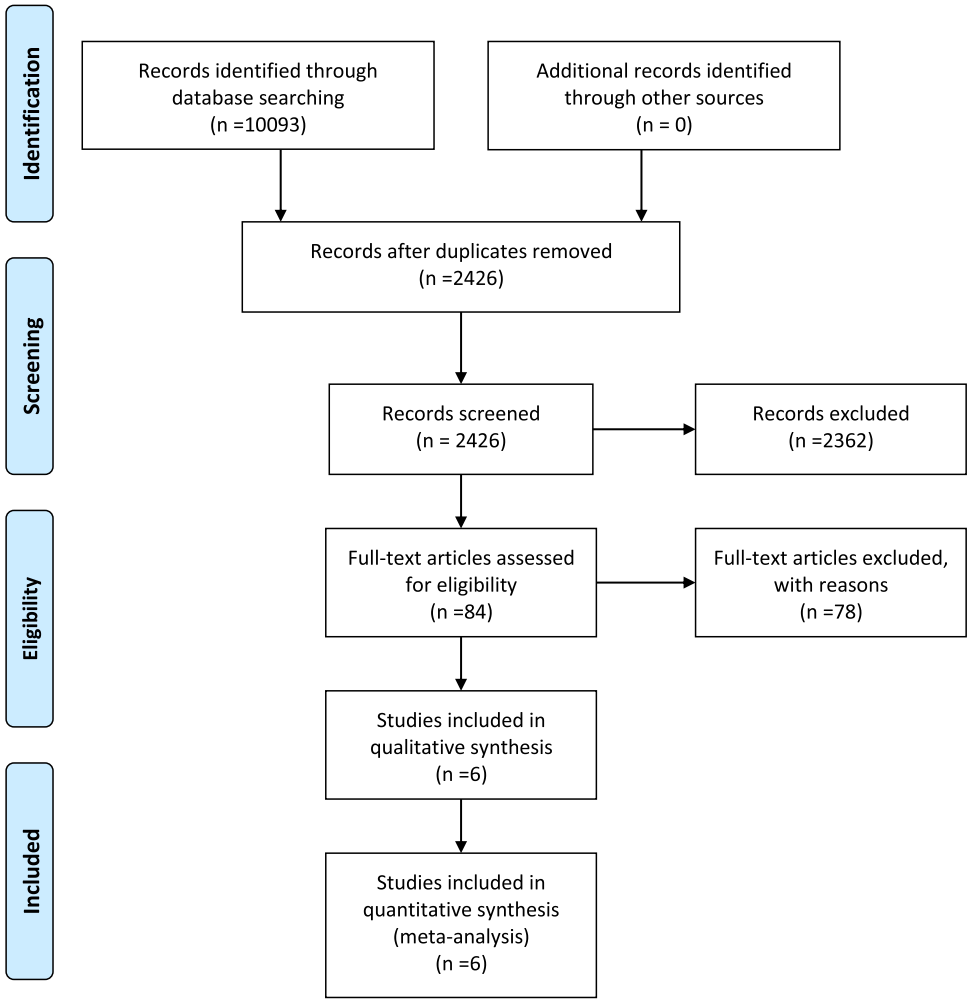

Figure 1. PRISMA flowchart of studies included in quantitative synthesis.

The present study aimed to make a summary of current evidence regarding the use of ICG fluorescence in assessing the vitality of bowel segments during surgery for intestinal ischemic disease.

To the authors' knowledge, this is the first metanalysis on such topic. During our literature search, we included six retrospective study to testify the lack of a large presence of available literature on this topic.

Table 1

Study characteristics of included papers.

Authors	Affiliation/Hospital	Year	Study design	Sample size		Outcomes reported	MINORS score
				ICG	No ICG		
Karampinis *et al.*[26]	University of Heidelberg	2018	Retrospective no PSM	7	9	Reoperation/mortality	11
Liot *et al.*[27]	University of Geneva	2018	Retrospective no PSM	15	25	Reoperation/mortality	13
Guerra *et al.*[23]	Pesaro Hospital Italy	2020	Retrospective no PSM	27	66	Reoperation rate/morbidity/LOS	10
Ishiyama *et al.*[24]	Kawasaki Saiwai Hospital, Japan	2022	Retrospective no PSM	18	36	Reoperation/anastomotic leakage	14
Joonsten *et al.*[25]	University of Amsterdam	2022	Retrospective case-series	18	38	Reoperation rate/30 d mortality	11
Shunjin *et al.*[28]	Department of Digestive Surgery, Kawaguchi, Japan	2022	Retrospective no PSM	16	22	Reoperation rate/ LOS/ post-operative morbidity	14
Total				101	196		12/24

ICG, indocyanine green; LOS, length of hospital stay; PSM, propensity score matching.

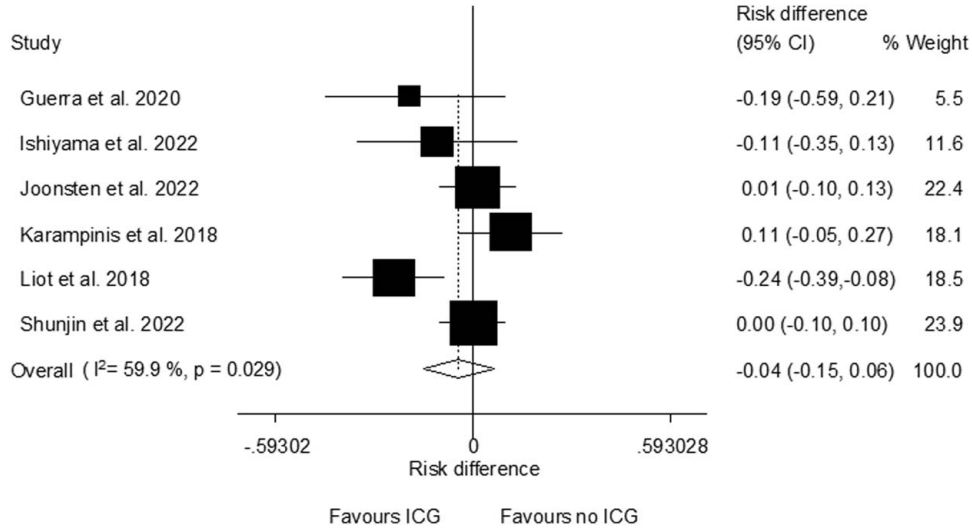

Figure 2. Forest plot with risk difference. ICG, indocyanine green.

Nonetheless, the studies included showed a fairly good quality with an overall mean MINORS score of 12/24.

When performing our analysis, we found that there is a slight trend towards ICG fluorescence as being a better tool for assessment of bowel perfusion than the use of visual inspection and mesenteric pulse assessment during laparotomy or laparoscopy, the risk difference was in fact – 0.04 (95% CI: – 0.147 to 0.060), thus not permitting a definitive conclusion in favor of the use of ICG fluorescence. However, this result was statistically significant ($P = 0.029$) but showed a high the heterogeneity, with a 59.9% I^2 value.

For this reason, we also performed the analysis using the OR. The data confirmed the trend in favor of the use of ICG fluorescence to avoid relaparotomy, 0.690 (95% CI: 0.200–2.420), in this case, heterogeneity was low but the result was not statistically significant ($I^2 = 34.0\%$; $P = 0.195$).

Both analyses showed nonetheless that ICG fluorescence has the potential of being an excellent tool in the emergency setting to aid the surgeon's decision and potentially to avoid severe complication that require relaparotomy and may put the patient's life in danger.

Of course, the available literature is probably insufficient to allow any definitive conclusions and as we previously stated there are no high-quality randomized controlled trials that might potentially give us an indication whether or not this methodology should routinely be applied in the specific setting of ischemic bowel disease.

Our study allows some conclusions: on the one hand, that ICG fluorescence is a tool that could be safely used in the assessment of bowel perfusion also in the emergency setting, on the other hand, that the efficacy and ability to aid the surgeon is still to be demonstrated with certainty and should be investigated by large high-quality studies.

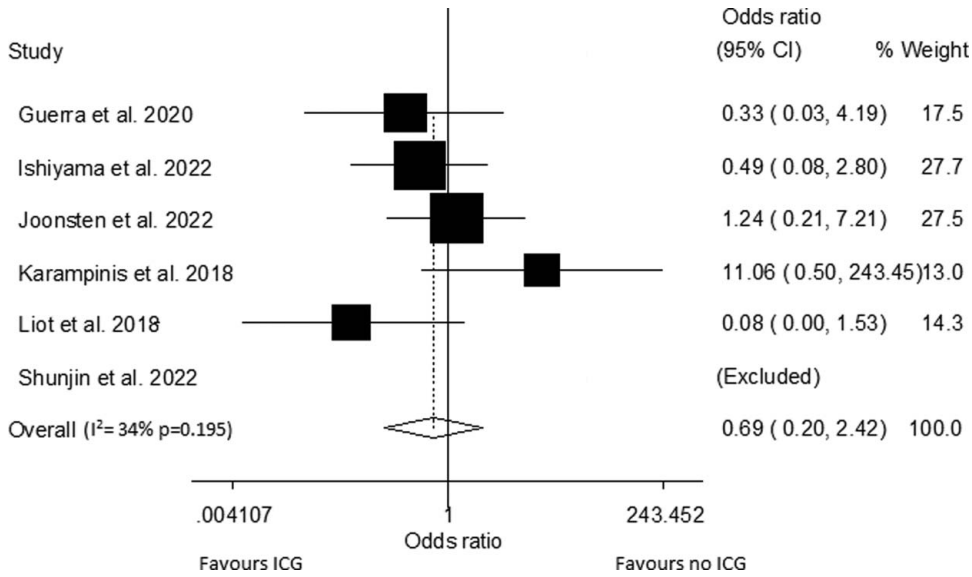

Figure 3. Forest plot with odds ratio. ICG, indocyanine green.

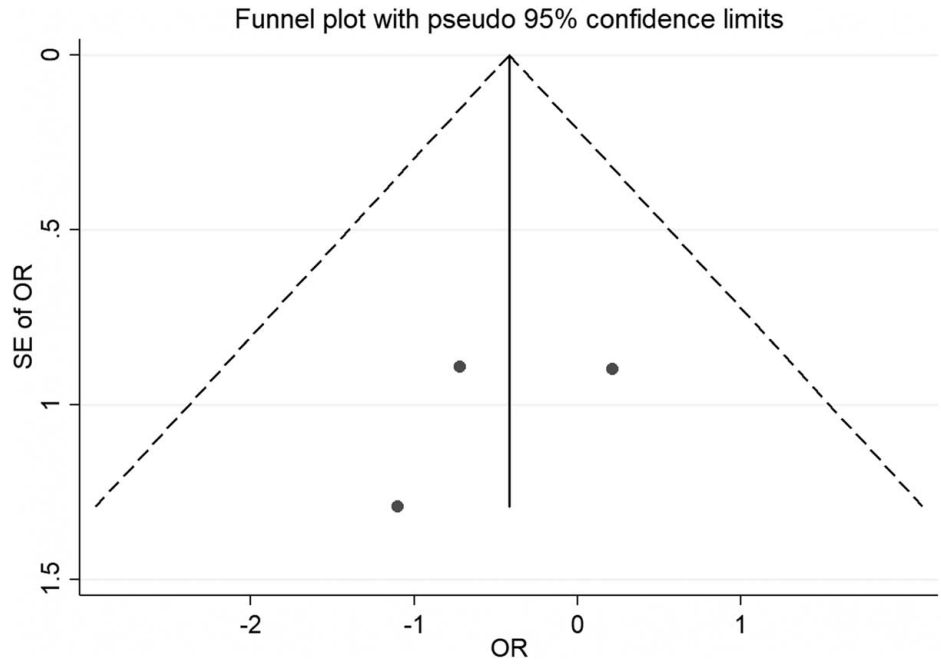

Figure 4. Funnel plot with odds ratio of included studies. OR, odd ratio.

Moreover, the analysis that we performed showed a trend in favoring the use of ICG fluorescence to avoid relaparotomy for the persistence of ischemic bowel or anastomotic leak when performing laparotomy or laparoscopy for ischemic bowel disease.

The present study should shed a light on this topic and potentially be a trampoline to allow the planning of a multicenter randomized controlled trial to investigate the actual usefulness of this methodology.

Limitations

The present study has some limitations, and its results must be interpreted with caution for several reasons. The main limitation is that all the included studies have a retrospective design, without randomization or PSM adjustment, this carries a risk of selection bias in favor of the ICG fluorescence group. This aspect is mitigated by the fact that publication bias and small study effect analysis showed a good balance in the effect of the studies present in current literature, as evident in the Funnel plot (Fig. 4) and explained by the Begg and Egger test, which were both non-significant. Moreover, the lack of literature on this topic has not allowed for the selection of a highly numerous sample, with a total of included patients of 297.

Conclusions

Despite its limitations this first metanalysis on the use of IGC fluorescence for ischemic bowel disease showed that this methodology is a safe and feasible tool in the assessment of bowel perfusion in the emergency setting and could potentially avoid relaparotomy for ischemic complications or anastomotic leak after index emergency surgery for bowel ischemia.

This topic should be further investigated in large cohort high-quality studies.

Ethical approval

No ethical approval necessary for this metanalysis.

Consent

No consent was needed for this systematic review.

Sources of funding

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Author contribution

R.R.: data collection, study design, analysis, and manuscript writing; C.V.: data analysis and manuscript writing; L.A. and F. C.: manuscript review and study concept; P.F.: data collection and manuscript review; M.S.: data interpretation and manuscript review; V.A.: data collection and manuscript review; G.L.B.: manuscript review and study concept; F.C.: study concept, study design, and manuscript review.

Conflicts of interest disclosure

The authors declare that they have no financial conflict of interest with regard to the content of this report.

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Guarantor

Fausto Catena and Roberta Rizzo.

Data availability statement

The authors confirm that the data supporting the findings of this study are available within the article and its Supplementary material. Raw data that supports the findings of this study are available from the corresponding author upon reasonable request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

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