

Original Article

The Role of Indocyanine Green Near-infrared Fluorescence in laparoscopic Cholecystectomy - A Systematic Review

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Introduction:

Laparoscopic cholecystectomy (LC) ranks among the most commonly conducted surgical procedures globally.^{1,2} With the extensive adoption of laparoscopic cholecystectomy (LC), the rate of iatrogenic bile duct injury (BDI) has significantly risen, with reported occurrences ranging from 0.2 to 1.5% in earlier research.³⁻⁵ Despite a decreasing trend, with the use of a critical view of safety (CVS) method in the dissection of the components of Calot's triangle, bile duct injuries (BDIs) continues to be a major

Abstract:

Near-infrared imaging with indocyanine green (ICG) has become more popular during laparoscopic cholecystectomy (LC) to delineate the biliary structures in order to minimise the bile duct injury (BDI). However, there is little evidence to show the role of this innovative technique in reducing bile duct injury compared to conventional white light (WL) imaging. This systematic review aimed to assess the capability of the near-infrared cholangiography with ICG (NIRC) to delineate biliary structures during LC. The literature search identified nineteen studies. Only 10 (2 RCTs, 2 prospective, and 6 retrospective) studies were included. Among the 3,631 patients included, 1,689 (46.50%) and 1,942 (53.50%) patients belonged to the NIRC and WL groups, respectively. The visualisation rate of biliary structures was significantly higher in the NIRC group than white light (WL) groups both before and after Calot's triangle dissection. Current evidence indicates that ICG NIRC is a favourable tool to widen the safety in laparoscopic cholecystectomy. When combined with white light (WL) imaging itrevealed to be superior to WL alone in delineating the extrahepatic biliary structures, thus reducing the risk of intraoperative BDI. Large-scale use of ICG NIRC is necessary to reduce iatrogenic BDI. Factors impacting the potency of the fluorescence signal and visibility of the biliary structures need to be evaluated to standardize this technique.

Keywords: Near-infrared fluorescence, Indocyanine green, Laparoscopic, Cholecystectomy, Bile duct injury

concern during LC. This complication can pose a serious risk to life and is among the leading causes of postoperative morbidity, linked to prolonged hospitalisation, higher healthcare expenses and the need for further interventions, or treatment. They are also a primary factor contributing to claims of malpractice within the field of surgery. The major risk factors of BDI are severe inflammatory processes e.g. acute inflammation causing acute cholecystitis (AC), dense inflammatory adhesion within the Calot's associated with chronic inflammation, and the

anatomical variation of the biliovascular structures.⁶ These factors also pose a risk for conversion to open surgery. To mitigate the risk of BDI, additional intraoperative imaging methods, including intraoperative ultrasound and cholangiography (IOC), have been implemented.⁷ Intraoperative cholangiography (IOC) plays a significant role when there are difficulties during dissection or concerns about the presence of stones in the main bile duct, but it has some disadvantages such as increasing the duration of surgery, necessitating mobile radiology equipment, trained personnel, risks associated with radiation, and additional cost. Routine IOC may assist in detecting a BDI during surgery, but it does not guarantee its prevention.⁸ Moreover, the necessity of injecting any contrast into the biliary tree during IOC could potentiate the risk of bile duct injury.

Specific strategies, comprehension of the regional anatomy, and enough visibility of the extrahepatic biliary systems are essential factors in fending off those injuries and making sure safe laparoscopic cholecystectomy (LC). Revised protocols for secure laparoscopic cholecystectomy (LC) awareness on minimizing the risk of bile duct injuries, while the use of indocyanine green (ICG) in near-infrared cholangiography (NIRC) is an emerging approach that could enhance the visibility of the extra-hepatic biliary structures.³⁻⁵ This technique allows for real-time biliary tree visualisation even before Calot's triangle is dissected. Ishizawa et al. initially demonstrated the role of ICG NIRC in 2009, injecting it directly into the bile duct during liver transplantation and administering it intravenously prior to open cholecystectomy.⁹ Given that the new laparoscopic systems now include a software feature that enables the gathering of images in near-infrared and the overlay of information over images taken in white light, this novel technique proved quite alluring. This allows the gathering of additional data without extending the operating time or altering the operating time sequence.¹⁰

ICG is an injectable drug that produces fluorescence imaging of biliary and vascular systems when triggered by near-infrared light (700–900 nm). ICG is exclusively metabolized by hepatic parenchymal cells and directly secreted into the bile. While the arterial system reaches its greatest concentration in 1-2 minutes after

injection, the bile reaches its maximal concentration between 30 minutes and 2 hours later.¹¹ ICG-assisted near-infrared imaging during LC is a relatively new technique.^{12,13} The biliary structures are fluorescently illuminated when exposed to near-infrared light, which may aid with anatomical identification and bile duct injury prevention. ICG has the advantages of being less invasive, requiring no cystic duct incision, and exposing the patient to no radiation. Additionally, while IOC is often carried out following the dissection of the CD, ICG may be able to detect the biliary tract prior to the dissection of Calot's triangle.

ICG-based near-infrared imaging is currently expanding to other surgical specialities. It is proposed that using near-infrared imaging with ICG in LC is both safe and feasible.¹⁴⁻¹⁶ Most recent published studies showed that NIRC using ICG during LC has significant potential to improve the visualisation of extrahepatic biliary structures thereby reducing the bile duct injury and conversion rate.^{17,18} However, these studies were mainly descriptive and did not compare the outcome between the NIRC and white light (WL) imaging. Therefore, the efficacy and impact of using NIRC during LC are still debatable in comparison to white light imaging alone. There is a high level of evidence supporting the large-scale use of NIRC. The main aim of this systematic review was to assess and compare the visualisation rate of extrahepatic biliary structures, bile duct injury rate, and conversion rate between NIRC and WL imaging in LC.

The primary question of this systematic review was whether the ICG-near-infrared cholangiography (ICG-NIRC) during LC can reduce bile duct injury by improving the visualisation rate of the extrahepatic biliary tree compared to white light (WL) imaging alone.

Methods:

Study design

Systematic review.

Study objective

To evaluate and compare the visualisation rate of extrahepatic biliary structures, bile duct injury rate, and conversion rate between NIRC and WL imaging in LC.

Study protocol

Up to January 2023, systematic electronic literature searches of EMBASE, PubMed, and

Cochrane Library databases were conducted using a predefined search strategy. The search terms were 'near-infrared fluorescence'/ 'indocyanine green' and 'laparoscopic cholecystectomy'. Inclusion criteria in this study were the studies that compared at least one of the following outcomes: visualisation rate of biliary structures, bile duct injury, and conversion to open surgery, between near-infrared cholangiography (NIRC) and white light (WL) imaging during laparoscopic/robotic cholecystectomy (LC/RC). Any study that did not compare any of the above outcomes between NIRC and WL groups was excluded from this review. Malignancies and studies without adequately described surgical procedures were excluded. Editorials, reviews, case reports, and case series were also excluded.

There were no language restrictions. The citations retrieval and studies inclusion were performed using EndNote software. The systematic review collected and analyzed the following data from the included studies: demographics, biliary structures visualisation rate, bile duct injury, and conversion rate in laparoscopic cholecystectomy while using NIRC and white light (WL) imaging.

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were followed and the OCEBM (Oxford Centre for Evidence-Based Medicine) 2011 recommendations were used to grade the level of the evidence of included studies.^{19,20} The Cochrane Collaboration's risk of bias tool was used to assess the risk of bias.²¹

The statistical analysis of the results was done by the Review Manager 5.4 (RevMan 5.4.1) software. The two-sample z-test and homogeneity testing were used to analyse the outcome measures. Mean difference (MD) for continuous outcome and odds ratio (OR) with 95% confidence interval (CI) for dichotomous outcomes were used to represent the results. The Cochrane Q statistic ($p < 0.10$ to indicate significant heterogeneity) and the I^2 statistic (values of 25, 50, and 75% representing low, medium, and high heterogeneity, respectively) were used to detect the heterogeneity of the included studies.^{22,23}

A fixed-effects model was applied for studies with no or low levels of heterogeneity; otherwise, a

random-effects model was used. For the pooling of continuous and dichotomous variable data, inverse variance and the Mantel-Haenszel (M-H) methods were utilized respectively. The result was considered as statistically significant when a two-sided p value was found less than 0.05. A visual funnel plot examination of the outcome was used for publication bias.

Results:

The PRISMA flow diagram (Fig. 1) illustrates the process of screening papers for selective inclusion in this systematic review. A total of 412 citations have been identified after the initial search method applied to the databases PubMed, Embase, and Cochrane. Nineteen papers were finally examined following removal of the duplicates and screening further titles and abstracts. A full-text review of the 19 papers was done and we did not include 9 studies for the reasons explained in Figure 1. A total, of 10 studies that met eligibility criteria were included in the meta-analysis which were published between the years 2017 and 2021 (Table-I).²⁴⁻³³ Among 10 studies, there were two RCTs (level of evidence 1b),^{27,29} two prospective studies (level of evidence 2b)^{25,30}, and six retrospective studies (level of evidence 3b).^{24,26,28,31-33} Two studies performed ICG-aided robotic cholecystectomy and compared conventional LC.^{26,31} A total of 3,631 patients were included in this study and 1,689 (46.50%) and 1,942 (53.50%) patients belonged to the NIRC and WL groups respectively. Out of 10 articles included, only 4 studies reported results on visualization of extrahepatic biliary structures,^{25,27,30,32} 4 studies reported bile duct injury^{26-28,33} and 7 studies reported conversion rates.^{24,26-29,31,33} Table-I summarises the characteristics of the included studies. Figures 2 and 3 show the individual component at risk of bias in all included studies in this systematic review.

Table-II summarises the visualization rate of extrahepatic biliary structures using NIRC and WL imaging in Laparoscopic Cholecystectomy. Only 4 studies reported on this outcome. However, in all of these studies, there was an improved visualization rate of CD, CBD, and CHD while using NIRC in comparison to WL imaging alone both before and after the dissection of Calot's triangle.

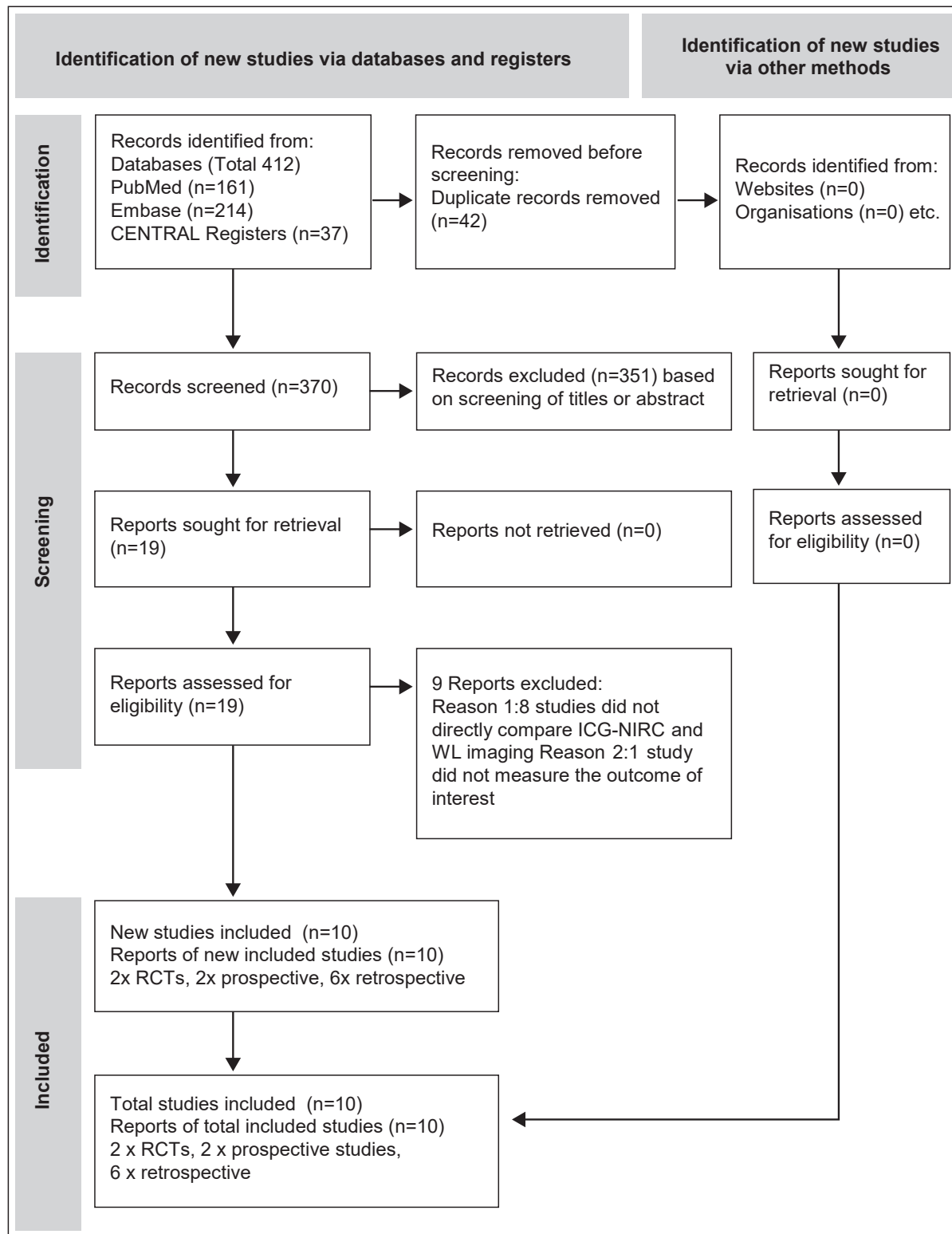


Figure-1: PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources

Table-I: Characteristics of studies included in the systematic review

Study name / First Outrhor	Study design, Level of evidence ^a	No of the case (NIRC/WL)	Bile duct injury, n (%) NIRC/WL	Conversion, n (%)
Ambe et al 2019 ²⁴	Retrospective	29	-	0(0%)
	3b	41		1(2.4%)
Ankersmit et al 2017 ²⁵	Prospective	18	-	-
	2b	18		
Broderick et al 2021 ²⁶	Retrospective	400	2(0.5%)	6(1.5%)
	3b	989	9(0.5%)	84(8.5%)
Dip et al 2019 ²⁷	RCT	321	0(0%)	1(0.31%)
	1a	318	2(0.62%)	96(1.88%)
Gangemi et al 2017 ²⁸	Retrospective	676	1(0.15%)	1(0.15%)
	3b	289	13(4.5%)	4(1.38%)
Koong et al 2021 ²⁹	RCT	30	-	2(6.25%)
	1a	33		3(8.35%)
Liu et al 2018 ³⁰	Prospective,	46	-	-
	2b	46		
Sharma et al 2018 ³¹	Retrospective	96	-	2(2.1%)
	3b	91		8(8.9%)
Wang et al 2020 ³²	Retrospective	34	-	-
	3b	36		
Yoshiya et al 2019 ³³	Retrospective	39	0(0%)	1(2.54%)
	3b	81	2(2.4%)	20(24.69%)

NIRC=Near infrared cholangiography; WL= White light imaging

Table-II: Visualization rate of extrahepatic biliary structures in NIRC and WL

Study name/ First author	No of case (NIRC/WL)	Before dissection of calot's triangle			After dissection of calot's triangle		
		CD (%) ICG/WL	CBD (%) ICG/WL	CHD (%) ICG/WL	CD (%) ICG/WL	CBD (%) ICG/WL	CHD (%) ICG/WL
Ankersmit et al 2017 ²⁵	18	30.7	15.3	-	72	38.8	-
	18	16.6	0	-	100	16.6	-
	321	66.6	49.4	28.9	96.6	75.7	52.3
Dip et al 2019 ²⁷	318	36.2	20.6	10.9	97.2	50	30.5
	46	32	52	44	84	76	68
Liu et al 2018 ³⁰	46	8	24	16	44	28	16
	34	91	53	79	-	-	-
Wang et al 2020 ³²	36	74	21	47	-	-	-

NIRC=Near infrared cholangiography; ICG=Indocyanine green imaging; WL=White light imaging; CD=Cystic duct; CBD=Common bile duct; CHD=Common hepatic duct

Other bias	+	+	+		+		+	+	+	
Selective reporting (reporting bias)	+	-	-	+	+	+			+	+
Incomplete outcome data (attrition bias)	+		+							
Blinding of outcome assessment (detection bias)	-			+		+				
Blinding of participants and personnel (performance bias)	-	-		-	-	-	-	-	-	-
Allocation concealment (selection bias)	-	-	-	+	-	+	-	-	-	-
Random sequence generation (selection bias)	-	-	-	+	-	+	-	-	-	-
	Ambe et al, 2019	Ankersmit et al, 2017	Broderick et al, 2021	Dip et al, 2019	Gangemi et al, 2017	Koong et al, 2021	Liu et al, 2018	Sharma et al, 2018	Wang et al, 2020	Yoshiya et al, 2019

Figure-2: Risk of bias Asummary of included studies

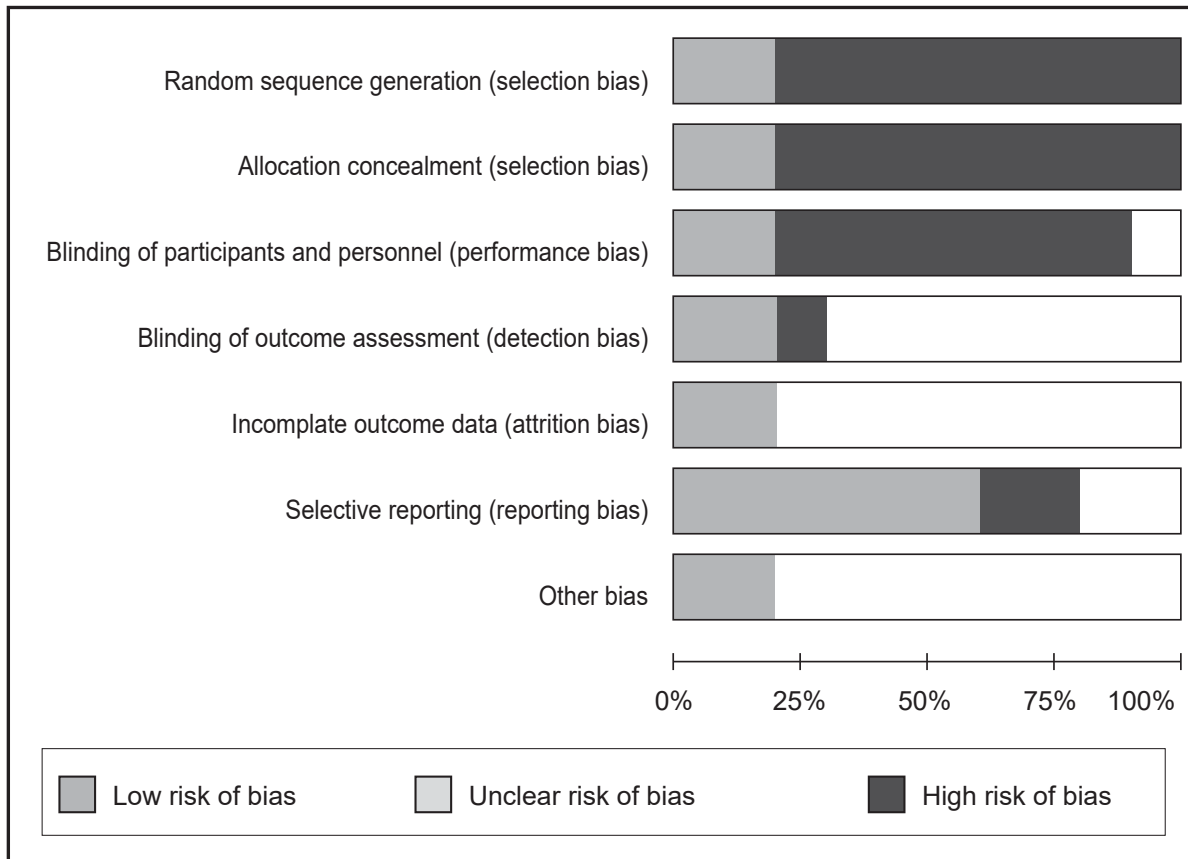


Figure-3: Risk of bias summary of included studies

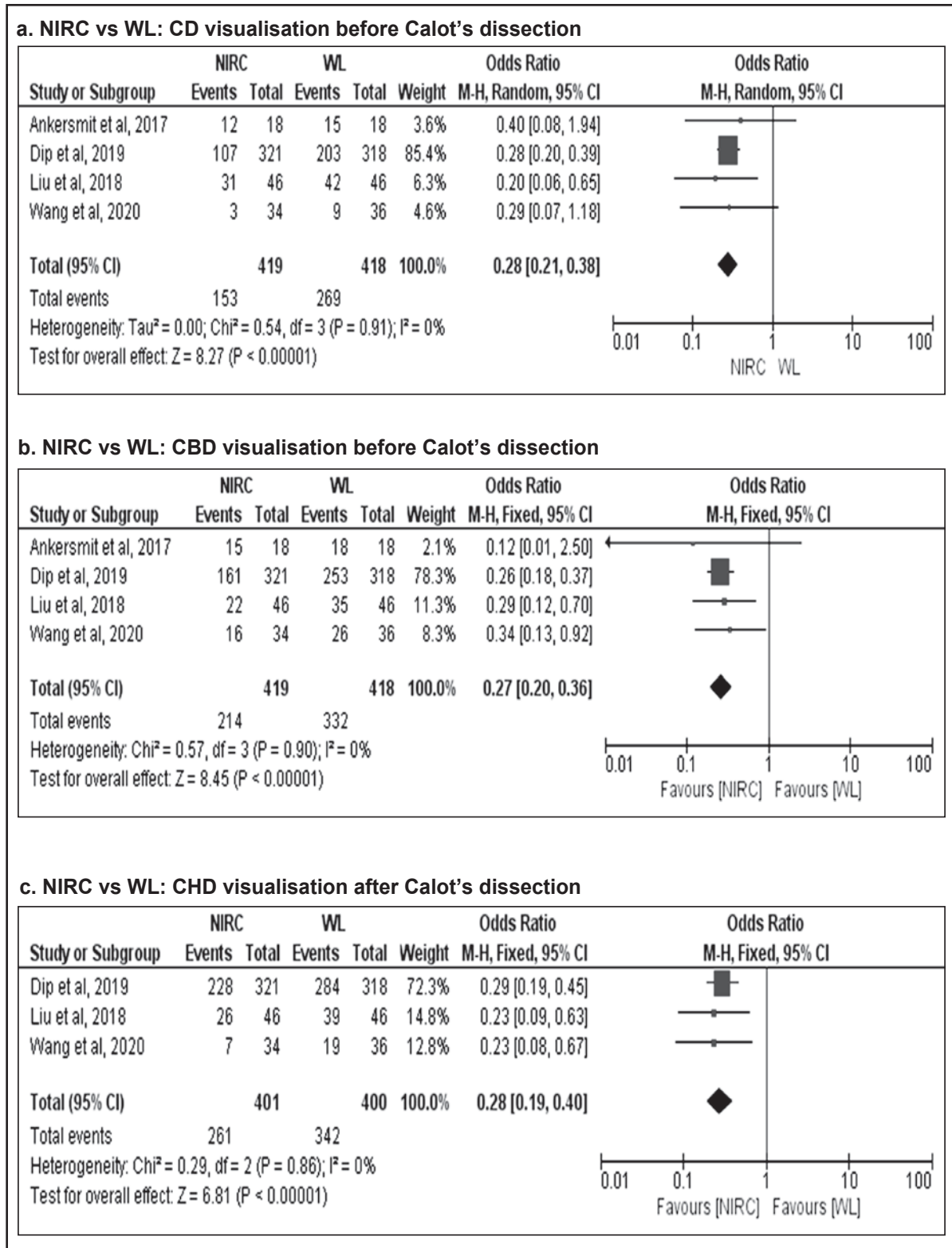


Figure-4: Visualisation of CD, CBD, and CHD before Calot's triangle dissection in NIRC and WL group

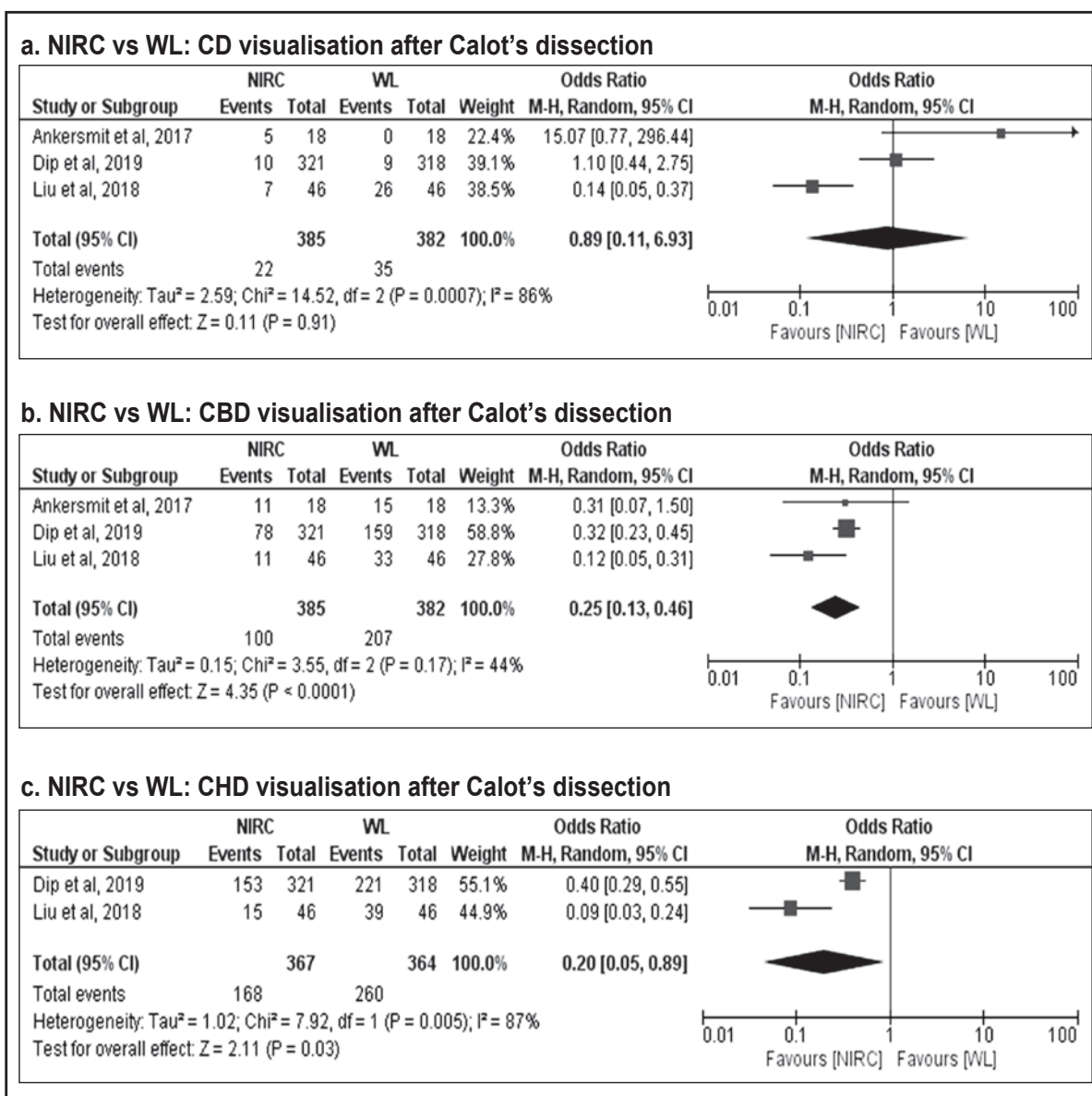


Figure-5: Visualisation of CD, CBD and CHD after Calot's triangle dissection in NIRC and WL group

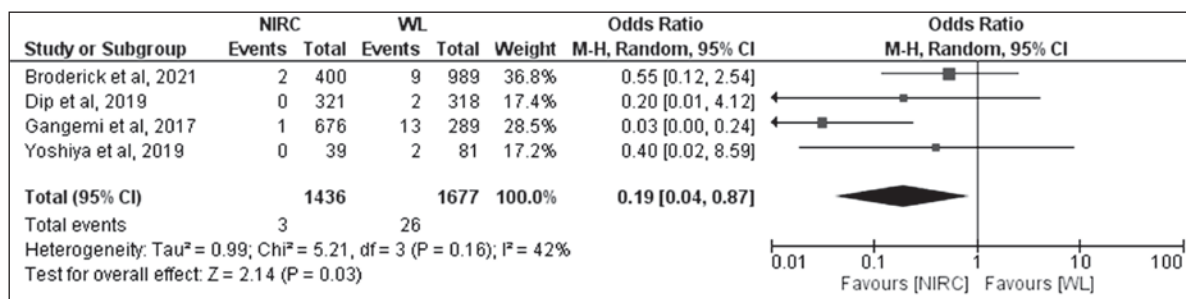


Figure-6: NIRC vs WL: Bile duct injury

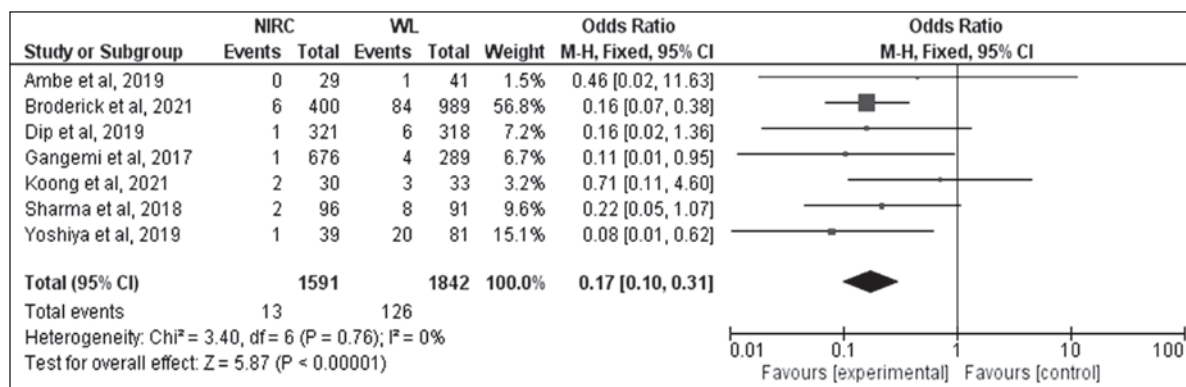


Figure-7: NIRC vs WL: Conversion rate

On the pooling of the data on this outcome, there was significantly higher visualization rate of CD (OR 0.28; 95% CI 0.21–0.38; $p < 0.00001$), CBD (OR 0.27; 95% CI 0.20–0.36; $p < 0.00001$) and CHD (OR 0.28; 95% CI 0.19–0.40; $p < 0.00001$) in NIRC group before dissection of Calot's triangle (Figure 4a-c) with no heterogeneity among the results of individual study ($p \geq 0.86$; $I^2 = 0\%$). There was also the same advantage in the visualisation of CBD and CHD in the NIRC group after the dissection of Calot's triangle (Figure 5a-c).

Only four studies (1436 patients in NIRC and 1677 patients in the WL group) reported bile duct injury while using NIRC and WL imaging during laparoscopic/robotic cholecystectomy.^{26-28,33} Out of 1436 patients only 3 patients (0.20%) had bile duct injury in the NIRC group. Among 1677 patients in the WL group 26 patients (1.55%) had bile duct injury which was significantly higher than the NIRC group. The meta-analysis showed a statistically significant advantage in favour of NIRC compared to the conventional WL group (OR 0.19; 95% CI 0.04–0.87; $p = 0.03$) (Figure 6). There was medium heterogeneity among the results of individual studies ($p = 0.16$; $I^2 = 42\%$).

Seven studies (1591 patients in NIRC and 1842 patients in the WL group) reported conversion rates while using NIRC and WL imaging during LC/RC.^{24,26-29,31,33} The conversion rate in the NIRC group is significantly lower (0.81%) in comparison to the WL group (6.8%). The meta-analysis showed a statistically significant higher conversion rate in WL groups than in the NIRC group (OR 0.17; 95% CI 0.10–0.31; $p < 0.00001$) (Figure-7) with no heterogeneity among the results of individual study ($p = 0.76$; $I^2 = 0\%$).

Heterogeneity

For the majority of outcomes, no or minimal heterogeneity was observed between studies. Low heterogeneity ($I^2 \leq 25\%$) was found in visualisation rate of CD, CBD, and CHD before Calot's dissection, bile duct injury, and conversion rate. "Nonetheless, assuming minimal heterogeneity for these outcomes could be misleading, as the I^2 statistic test has been shown to have a large bias when the number of studies is small."³⁴

Publication bias

Funnel plot examination on visualisation rate of CD, CBD, and CHD before and after Calot's dissection, bile duct injury, and conversion rate revealed a symmetrical plot, that indicates nobias for publication.

Discussion:

The burden of bile duct injury (BDI) during laparoscopic or robotic cholecystectomy to the patients and healthcare facilities is too critical to justify the widespread use of minimally invasive procedures worldwide. Despite adopting different techniques such as intraoperative ultrasound, and intraoperative cholangiography (IOC) to mitigate the bile duct injury during LC, the incidence of BDI remains higher and is considered a major concern during LC. The main reason for BDI in LC is the misidentification of biliary structures which may be caused by acute or chronic inflammatory biliary structures fusion in Calot's triangle or anatomical variation of the bilio-vascular structures. Additionally, these are risk factors for conversion to open surgery. By adopting the critical view of safety (CVS) method in dissecting the components of Calot's

triangle, the incidence of bile duct injuries (BDI) is decreasing. Indocyanine green (ICG) facilitated near-infrared cholangiography (NIRC) is a developing method that could enhance the visualization of extra hepatic biliary structures.⁵ This method offers real time visualization of the biliary tract prior to the dissection of Calot's triangle. Thus, it has great potential to help achieve CVS before ligation/clipping of any ductal structures in LC. Most recent published studies showed the significant potential of NIRC using ICG during LC to improve the visualisation of extrahepatic biliary tract thereby reducing the bile duct injury and conversion rate.^{17,18} However, these studies were mainly descriptive and did not compare the outcome between the NIRC and white light (WL) imaging directly. There is lacking a high level of evidence supporting the use of NIRC. The main aim of this systematic review was to evaluate and compare the visualisation rate of extrahepatic biliary structures, bile duct injury rate, and conversion rate between NIRC and WL. The primary question of this study was whether the ICG- near-infrared cholangiography during LC can reduce bile duct injury by improving the visualisation rate of the extrahepatic biliary tree in comparison to white light (WL) imaging.

In this study, we reported the largest accumulative analysis of studies that compared ICG-NIRC directly with the WL imaging during LC/RC. Out of 10 studies included in this systematic review, 4 studies are "high-quality" (RCTs and prospective) studies. Among 3,631 patients included in this study, 1,689 (46.50%) and 1,942 (53.50%) patients were in the NIRC and WL groups respectively. Taking all included studies into account, the results of the present meta-analysis revealed that ICG NIRC in LC/RC was associated with significantly higher visualisation rate of CD (OR 0.28; 95% CI 0.21–0.38; $p < 0.00001$), CBD (OR 0.27; 95% CI 0.20–0.36; $p < 0.00001$) and CHD (OR 0.28; 95% CI 0.19–0.40; $p < 0.00001$) before dissection of Calot's triangle when compared to WL imaging alone. The improved visualization of the biliary tree using ICG may give reassurance to the surgeon, ensuring that the CD, CBD, and CHD have been accurately recognized prior to the clipping of the CD and cystic artery.³⁵ This could be a potential solution for enhancing the safety of novice surgeons who are mastering the LC

technique. Furthermore, it has the potential to enhance the early cholecystectomy rates in acute cholecystitis (AC) and reduce the incidence of bile duct injury and the need for conversion in complicated cases. Broderick et al demonstrated that the overall BDI was reduced with the implementation of an ICG cholangiogram, indicating that enhanced visualisation of the biliary tree through ICG as a standard practice during LC may lower the incidence of iatrogenic bile duct injury.²⁶

In this study, the incidence of BDI was 0.20% in the ICG-NIRC group (ranging from 0 to 0.5%) compared to 1.55% in the non-ICG WL group, which varied between 0.5 and 4.5%, indicating a statistically significant advantage for the NIRC group. Studies with a small number of patients and elective procedures reported comparable rates of complications.^{24,29,32}

Overall, the conversion rate was 0.81% in the 1,591 patients in the ICG NIRC group and 6.8% in 1842 patients who underwent LC/RC with WL imaging alone. Since both BDI and conversion are low frequency complications of LC, the statistical significance between the ICG group and the non-ICG WL group increases with a larger patient cohort. In smaller groups, these issues may not arise naturally, or conversely, the existence of one or two distinct cases can considerably raise the incidence rate.

Limitations:

The present study had several limitations. First, factors influencing the fluorescence signal intensity and visibility of the extrahepatic biliary structures e.g. acute/chronic cholecystitis, obesity, BMI, dose, and timing of ICG administration were not considered. We included a limited number of the studies and most of the studies are low to medium-quality studies having significant risk of bias. Not every study evaluated each of the outcome measures, so cumulative results are less effective.

Conclusion:

Current evidence indicates that ICG NIRC is a promising tool to increase safety in laparoscopic cholecystectomy. Its use in combination with white light (WL) has been demonstrated to be superior to WL alone in identifying the extrahepatic biliary anatomy, thus lowering the risk of intraoperative BDI. This novel technique

may improve the early cholecystectomy rates in AC and reduce the BDI and conversion rate in complicated cases. Large-scale use of ICG NIRC is necessary to reduce iatrogenic BDI. Factors influencing the fluorescence signal intensity and visibility of the extrahepatic biliary structures need to be evaluated to standardise this technique.

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