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REVIEW ARTICLE

Safety and efficacy of biliary suprapapillary metal and plastic stents in malignant biliary obstruction: a systematic review and meta-analysis

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Abstract

Background and aims Biliary drainage is vital in managing malignant biliary obstruction (MBO). Suprapapillary stenting has emerged as a viable alternative to transpapillary stenting and is performed using inside plastic (iPS) or metal stents (iMS). This meta-analysis aims to evaluate the outcomes of suprapapillary stent placement for MBO.

Methods The Embase, PubMed, and Web of Science databases were systematically searched to include all studies published before September 31, 2023, that reported on the outcomes of suprapapillary stents placed for MBO. Using the random-effect model, the pooled, weight-adjusted event rate estimate for the clinical outcomes was calculated with 95% confidence intervals (CIs).

Results Twenty-eight studies were included, with a total of 1401 patients. The pooled clinical success rate was 98.9%. A subgroup analysis yielded non-significant differences between the iPS and iMS groups (99.3% vs. 98.6%, respectively; $P=0.44$). The pooled incidence rate of adverse events (AE) with suprapapillary stents was 9.5%. In a subgroup analysis, the incidence of AEs with iPS was 10.7% compared to 9% in the iMS group without a statistical difference ($P=0.32$). The most common adverse event was cholangitis (2.2%), followed by pancreatitis (1.1%), cholecystitis (0.5%), and bleeding (0.12%).

Conclusion When technically feasible, suprapapillary stenting for MBO is a viable endoscopic option with a high clinical success rate and acceptable adverse event rates. Both iPS and iMS exhibit similar efficacy.

Keywords Inside · Suprapapillary · Stent · MBO

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Malignant biliary obstruction (MBO) can manifest with significant clinical challenges due to its poor prognosis and the potential for a detrimental impact on patients' quality of life. It is characterized by the narrowing or blockage of the bile ducts, leading to jaundice, pruritus, fatigue, and sometimes cholangitis [1]. In recent years, there has been an increasing incidence of MBO, with estimates suggesting approximately 20% of subclinical jaundice cases attributed to malignant bile duct obstruction [2].

Whether the intent of intervention is palliative (in non-operable or surgically unfit cases) or as a bridge to resection (in specific scenarios, such as cholangitis, planned neoadjuvant therapies, and delayed surgical resection), biliary drainage plays a key role in the management of MBO. It is generally advised to drain at least 50% of the viable non-atrophic liver volume, often requiring more than one stent placement [3].

Stent selection is a critical consideration in managing MBO endoscopically. Optimal stenting provides prolonged and effective drainage with low risk of cholangitis, stent migration and stent occlusion. A variety of stent types and sizes are available with different features and various benefits and disadvantages [4]. In unresectable malignant hilar strictures, the American Society of Gastrointestinal Endoscopy (ASGE) 2021 guidelines suggested the use of metal stents (MS) in patients with short life expectancy (< 3 months), or when avoiding reintervention is desired, whereas plastic stent (PS) use was suggested when the diagnosis of the stricture is yet to be confirmed or in cases where the optimal drainage method is not determined yet [3].

While the transpapillary (across-the-papilla) stenting is viewed as the conventional intervention, suprapapillary (above-the-papilla) has emerged as a reasonable alternative method that can, at least theoretically, provide longer patency time and less reflux of bacteria since the stent is placed entirely within the biliary tree, which allows to maintain the physiological function of the sphincter of Oddi. It is worth noting that the current guidelines on MBO do not address suprapapillary versus transpapillary stent placement. A meta-analysis by Kovacs et al. included 12 studies and showed the superiority of suprapapillary stents in contrast to transpapillary stents in regard to patency time [5]. Notably, single stent placement is more likely in transpapillary stents, whereas suprapapillary stent cases usually require two or more stents in over 50% of instances [6, 7].

Similar to the transpapillary approach, in suprapapillary approach both plastic and metal stents are available. Inside plastic stents are modified by the manufacturer or the endoscopist to be equipped with a thread which traverses the major papilla to allow removal. For metal stents, in most cases, uncovered stents are more commonly used, and they come with various characteristics including size, material, shape, length and diameter. Fully or partially covered metal stents are also used in some cases.

In a recent randomized controlled trial, Kanno et al. showed no major differences in efficacy and safety between suprapapillary plastic and uncovered metal stents in the management of malignant hilar strictures, although the population size was relatively small ($N=87$) [8]. In this meta-analysis, we aim to comprehensively review the efficacy and safety of suprapapillary stents in the management of MBO with a focus on comparing outcomes betweeen plastic and metal stents. To the best of our knowledge, this is the first meta-analysis on this matter.

Methods

Search strategy and study eligibility

Two independent reviewers (S.A. and M.M) conducted a systematic search of studies published before September 30, 2023, reporting outcomes of suprapapillary biliary stents placed for MBO. We systematically searched the online MEDLINE, Embase and Scopus databases using key words in different combinations: (MBO or malignant biliary stricture or malignant bile duct obstruction or cholangiocarcinoma or gallbladder neoplasms) and (metal stent or plastic stent or endoprosthesis) and (intraductal or inside or suprapapillary). In addition, according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA), we screened the reference lists of the articles and corresponded with study investigators [9]. No language restrictions were applied, as long as study outcomes were reported in the text. A third reviewer (O.T.) resolved any disagreement.

Study inclusion and exclusion

We used the following criteria in this analysis: prospective or retrospective studies which evaluated patients with MBO (patient population) who underwent endoscopic retrograde biliary stent placement entirely above the sphincter of Oddi (intervention) where clinical safety and efficacy were reported (outcomes). Studies on single stent type (PS or MS) or comparison of those were included.

The study was excluded if: (1) it involved benign biliary strictures; (2) the location of the stents was completely or partially across the major papilla; (3) it was a case report, case series with less than 10 sample sizes, animal study, editorial, meta-analysis, or review article. Studies without relevant clinical data on adverse events (AEs) were excluded.

Data extraction and quality assessment

All relevant data were extracted according to predefined table independently by (S.A. and M.M.). The following parameters were extracted: first author, year of publication, country, study design, patient demographics, technical success, functional success, and outcomes of interest. Using the Newcastle–Ottawa Scale, the methodological quality of the included cohort studies was assessed independently by two investigators (SA and OT). In a case of discrepancy, a third independent individual (MM) was consulted.

Definitions of outcomes

The endpoint outcomes include stent patency period, stent occlusion, and overall AEs. The American Society for Gastrointestinal Endoscopy lexicon for grading of severity of procedural AEs with endoscopy was used to define major AEs [10]. Clinical success was defined as a reduction in total serum bilirubin level by more than 50% at 2–4 weeks. Recurrent biliary obstruction was considered in cases of stent migration, occlusion, or tumor ingrowth within the stent.

The primary goals of this study were to evaluate the clinical success and adverse event rates of suprapapillary (or inside) stents. The secondary goals were to compare the clinical success and adverse event rates between suprapapillary plastic stents (iPS) and metal stents (iMS) and to assess the patency period of both type of stents.

Data synthesis and statistical analysis

We used R, version 3.2.3 (R Project for Statistical Computing), with Meta and Metaprop packages for all analyses. Using the Freeman-Turkey Double Arcsine Transformation (FTT) method, the pooled, weight-adjusted event rate estimate for the clinical outcomes in each group was calculated using Metaprop package. Between-study heterogeneity was assessed using the Cochrane Q-statistic (I^2), which represents the percentage of total between-study variation that cannot be attributed solely to chance. Between-study heterogeneity was rated as low if $25\% < I^2 \leq 50\%$, moderate if $50\% < I^2 \leq 75\%$, and high if $I^2 > 75\%$. A leave-1-out meta-analysis was performed to assess the influence of the outcome by excluding each study and identifying influential studies that may contribute to heterogeneity. A subgroup analysis was performed based on the type of stent used (metal vs. plastic). Statistical tests were 2-sided and used a significance threshold of $P < 0.05$. The assessment of publication bias was investigated by evaluation of funnel plot asymmetry and sensitivity analysis.

Results

Literature search and study characteristics

A total of 1776 unique records were identified according to the above search strategy. Finally, 28 studies with a total of 1401 patients were included in the study. PRISMA flowchart illustrates our selection process as shown in Fig. 1. Table 1 shows the baseline characteristics of the included studies and their quality analysis. Most studies were from Asia, were retrospective and were from single centers. Among the included studies, 17 were of good, 9 were of fair, and 2 were of poor quality (Table 2). Table 3 shows a detailed description of stent types that were used. Most common location of stricture in the included studies was the biliary hilum. Additionally, more than 50% of cases required 2 or more stents.

Technical and clinical success

A total of 24 studies with 1004 patients showed a pooled clinical success rate of 98.9% (95% confidence interval (CI) 98.1–99.8; $I^2 = 46\%$). A subgroup analysis yielded non-significant difference between the iPS and iMS groups (99.3% [95% CI 98–100%] vs. 98.6% [95% CI 97.4–99.8%], respectively; $P = 0.44$) (Fig. 2). Technical success rate was high at 99.9% ([95% CI 99.2–100%], $I^2 = 0\%$).

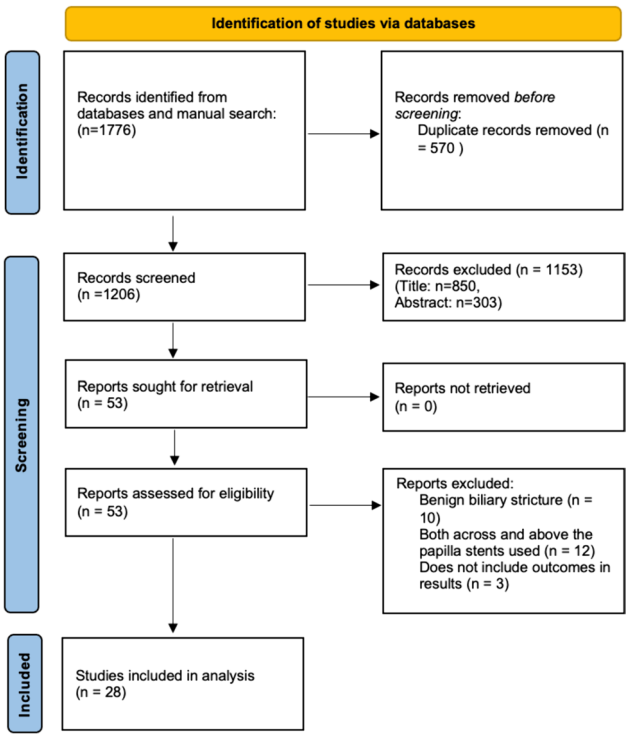

Fig. 1 PRISMA chart of included studies

Overall adverse events

Overall, a total of 28 studies (1401 patients) reported on the total number of AEs related to suprapapillary stents. The pooled incidence rate of AEs with suprapapillary stents was 9.5% (95% CI 8–11%; $I^2 = 75\%$) with substantial heterogeneity. In a subgroup analysis, the incidence of AEs with iPS was 10.7% [95% CI 9–12%] compared to 9% in iMS group [95% CI 8–12%] with no significant statistical difference ($P = 0.32$) (Fig. 3).

Individual adverse events

The most common adverse event was cholangitis (2.2%), followed by pancreatitis (1.1%), cholecystitis (0.5%), and bleeding (0.12%) Table 4.

(i) Cholangitis

Twenty-six studies reported the incidence rate of cholangitis. The pooled incidence of cholangitis was 2.2% ([95% CI 1.3–3.1%]; $I^2 = 69\%$). In a subgroup analysis

Table 1 Characteristics of included studies

First author and year	Country	Design	Centers	No. of patients	Age	Males	Stent type	Quality
Brijbassie et al. [11]	United States	Retrospective	Single	121	NR	NR	Metallic stent	Poor
Cosgrove et al. [12]	United States	Retrospective	Multiple	52	Mean: 65.98 (13.77)	32	Metallic stent	Fair
Douhara et al. [13]	Japan	Retrospective	Single	7	NR	NR	Metallic	Poor
Inatomi et al. [14]	Japan	Retrospective	Single	25	Mean: 67.5 ± 11.7	14	Both	Fair
Inoue et al. [15]	Japan	Retrospective	Multiple	40	Median: 74 (48–89)	17	Metallic stent	Good
Ishigaki et al. [16]	Japan	Retrospective	Multiple	40	Median: 74 (46–97)	20	Metallic stent	Good
Ishiwatari et al. [17]	Japan	Retrospective	Single	26	Median: 70 (55–86)	15	Plastic stent	Good
Kaneko et al. [18]	Japan	Retrospective	Single	27	Mean: 70.7 (39–88 years)	14	Plastic stent	Good
Kanno et al. [19]	Japan	Retrospective	Single	105	Mean: 79 ± 8	59	Both	Good
Kanno et al. [8]	Japan	Randomized Control Trial	Multiple	84	Mean: 78.1 ± 9.7	42	Both	Good
Kobayashi et al. [20]	Japan	Retrospective	Single	25	Median: 71.0 (57–84)	19	Metallic stent	Good
Kogure et al. [21]	Japan	Prospective	Multiple	81	Median: 73 (65–79)	41	Plastic stent	Fair
Koiwai et al. [22]	Japan	Retrospective	Single	25	Mean: 80.2 ± 8.7	12	Metallic stent	Fair
Koizumi et al. [23]	Japan	Retrospective	Single	77	NR	NR	Metallic stent	Fair
Kubota et al. [20]	Japan	Retrospective	Single	17	Mean: 67	10	Plastic stent	Good
Kurita et al. [24]	Japan	Retrospective	Single	94	Median: 53 (10–69)	57	Plastic stent	Fair
Kurita et al. [25]	Japan	Randomized controlled trial	Multiple	21	Median: 70.5 (61-90)	14	Plastic stent	Good
Mori et al. [26]	Japan	Retrospective	Single	51	Mean: 70 (25–84)	36	Metallic stent	Fair
Mukai et al. [27]	Japan	Randomized control trial	Multiple	30	Median: 75.5 (49–92)	14	Both	Good
Nam Cho et al. [28]	Japan and Korea	Randomized control trial	Multiple	37	Mean: (70.5 ± 12.9)	NA	Metallic stent	Good
Pedersen et al. [29]	Denmark	Randomized control trial	Single	17	Median: 75 (69–82)	9	Metallic stent	Fair
Shin et al. [30]	Korea	Retrospective	Single	44	Median: 74 (44–86)	23	Metallic stent	Good
Takada et al. [31]	Japan	Retrospective	Single	30	Median: 66 (57–84)	16	Metallic stent	Good
Taniguchi et al. [32]	Japan	Retrospective	Single	38	NR	NR	Metallic stent	Fair
Uchida et al. [33]	Japan	Prospective	Single	15	Mean: 76 (66–90)	6	Plastic stent	Good
Yamada et al. [34]	Japan	Retrospective	Single	38	Median: 71 (46–96)	13	Metallic stent	Good
Yan et al. [35]	China	Retrospective	Single	61	Mean: 68.8 ± 15.8	36	Plastic stent	Good
Yong Han et al. [36]	Korea	Retrospective	Multiple	51	Mean: 73.2 ± 9.5	28	Metallic stent	Good

NR not reported

there was no difference between iPS and iMS groups ($P = 0.69$).

(ii) Pancreatitis

The incidence of pancreatitis has been reported in 26 studies. The pooled incidence of pancreatitis after suprapapillary stent was 1.16% ([95% CI 0.44–1.87%]; $I^2 = 44\%$). In a subgroup analysis, the incidence of pancreatitis was significantly higher in the iPS group than in the iMS group (3.88% [95% CI 1.95–5.81%] vs. 0.73% [95% CI 0–1.50%]; $P < 0.01$).

(iii) Cholecystitis

Twenty-six studies reported the incidence of cholecystitis in the iPS and iMS groups. The overall incidence of cholecystitis was 0.55% [95% CI 0–1.15%]; $I^2 = 6\%$. There was no difference in subgroup analysis of iPS and iMS groups ($P = 0.69$).

(iv) Bleeding

Twenty-eight studies reported the incidence of bleeding. The overall bleeding incidence rate was 0.12% [95% CI 0–0.63%]; $I^2 = 0\%$. When iPS group was compared to iMS group, there was no significant difference ($P = 0.91$).

(v) Recurrent biliary obstruction and reintervention

The pooled incidence of RBO was 36.4% [95% CI 33.7–39.1%]. There was significant difference of RBO incidence between the iPS and iMS groups (45% [95% CI 40.2.9–49.7%] vs. 32.3% [95% CI 29.0–35.6%];

Table 2 Quality assessment of studies

First author and year	Selection				Comparability	Outcome			Quality
	Representativeness of the exposed cohort	Selection of the nonexposed cohort	Ascertainment of exposure	Demonstration that outcome of interest was not present at start of study	Comparability of cohorts based on the design or analysis	Assessment of outcome	Was follow-up long enough for outcomes to occur	Adequacy of follow up of cohorts	
Brijbassie et al. [11]	*		*		*				3
Cosgrove et al. [12]	*		*		*	*	*	*	6
Douhara et al. [13]	*		*			*			3
Inatomi et al. [14]	*		*		*	*	*	*	6
Inoue et al. [15]	*		*		**	*	*	*	7
Ishigaki et al. [16]	*		*		**	*	*	*	7
Ishiwatari et al. [17]	*		*		**	*	*	*	7
Kaneko et al. [18]	*		*		**	*	*	*	7
Kanno et al. [7]	*	*	*		**	*	*	*	8
Kanno et al. [8]	*	*	*		**	*	*	*	8
Kobayashi et al. [20]	*		*	*	**	*	*	*	7
Kogure et al. [21]	*		*		*	*	*	*	6
Koiwai et al. [22]	*		*		*	*	*	*	6
Koizumi et al. [23]	*		*		*	*	*	*	6
Kubota et al. [6]	*		*		**	*	*	*	7
Kurita et al. [24]	*		*		*	*	*	*	6
Kurita et al. [25]	*		*		**	*	*	*	7
Mori et al. [26]	*		*		*	*	*	*	6
Mukai et al. [27]	*		*		**	*	*	*	7
Nam Cho et al. [28]	*		*		**	*	*	*	7
Pedersen et al. [29]	*		*		*	*	*	*	6
Shin et al. [30]	*		*		**	*	*	*	7
Takada et al. [31]	*		*		**	*	*	*	7
Taniguchi et al. [32]	*		*			*	*	*	5
Uchida et al. [33]	*		*		**	*	*	*	8

Table 2 (continued)

First author and year	Selection				Comparability	Outcome			Quality
	Representativeness of the exposed cohort	Selection of the nonexposed cohort	Ascertainment of exposure	Demonstration that outcome of interest was not present at start of study	Comparability of cohorts based on the design or analysis	Assessment of outcome	Was follow-up long enough for outcomes to occur	Adequacy of follow up of cohorts	
Yamada et al. [34]	*		*		**	*	*	*	8
Yan et al. [35]	*		*		**	*	*	*	8
Yong Han et al.* [36]			*		**	*	*	*	8

$P < 0.01$). Seventeen studies reported the rate of re-intervention after suprapapillary stent placement with a pooled rate of 33.6% [95% CI 30.1–37.2%].

Patency time

A total of 25 studies reported the median patency time in days of the suprapapillary stents with a pooled median duration of 188.8 days [95% CI 106.1–260.9%]. There was no statistically significant difference between iPS and iMS (172.5 vs. 200.2 days; mean difference = 27.7 days; 95% CI [− 33.9, 89.4%], $P = 0.38$).

Assessment of publication bias and sensitivity analysis

A funnel plot of studies that reported on efficacy and safety of suprapapillary stents in MBO is presented in Fig. 4. The influence of a single study on the overall meta-analysis estimate was investigated by omitting one study at a time. The omission of any study resulted in no significant difference, indicating that our results were statistically reliable.

Discussion

To the best of our knowledge, this represents the first comprehensive meta-analysis of suprapapillary stents in MBO, discussing its efficacy and safety. Our meta-analysis showed a high clinical success rate of 98.9% for suprapapillary stenting and a pooled median stent patency of around 189 days. Due to the lack of removability of uncovered metal stents, and since re-interventions on occluded metal stents are often cumbersome, inside plastic stents have gained traction mostly in Asian countries due to the ease of exchangeability. Results from our analysis showed no difference of the clinical success between plastic and metal stents (99.3%vs. 98.6%, respectively) [12].

Our findings not only emphasize the efficacy of suprapapillary stents but also indicate their relative safety with an overall incidence of adverse events of 9.5%, which is consistent with Kanno et al.'s recent multicenter randomized trial [37]. Cholangitis was the most reported adverse event without difference between metal and plastic stents. Suprapapillary stenting allows for the preservation of an intact sphincter of Oddi, which acts as a physiological barrier to the reflux of bacteria and duodenal contents, potentially lowering the likelihood of developing cholangitis [38, 39]. However, not a minor proportion of cases underwent endoscopic sphincterotomy to facilitate suprapapillary stent placement, hence compromising the protective function of the sphincter of Oddi and lowering the risk reduction of cholangitis [40].

Pancreatitis is another important adverse event with higher rates in iPS compared to iMS. The existing literature indicates a higher occurrence of pancreatitis with transpapillary stents [41], possibly due to the compression of the pancreatic duct opening, leading to outflow obstruction [12]. This is also likely a key factor in the increased pancreatitis risk associated with iPS [42, 43]. Plastic stents are more prone to occlusion due to their smaller diameter and material properties, which can further exacerbate pancreatic duct obstruction and inflammation [43, 44]. Additionally, the relatively rigid nature of plastic stents may cause greater mechanical irritation to the pancreatic duct compared to more flexible metal stents. Rare complications associated with suprapapillary stenting included cholecystitis and bleeding, with no significant variation between plastic and metal subgroups. These rates were comparable to those observed with transpapillary stenting [45]. However, as bleeding has been often observed to stem from sphincterotomy [46], suprapapillary stenting decreases the need for

Table 3 Detailed characteristics of stent used in the studies

Study	Type of stent used	Model and manufacturer
Brijbassie et al. [11]	SEMS	GORE Viabil, W.L. Gore and Associates, Flagstaff
Cosgrove et al. [12]	UC-SEMS	ALIMAXX-B, Merit Medical, WallFlex, Boston Scientific, Zilver, Cook Endoscopy
Douhara et al. [13]	iPS	NR
Inatomi et al. [14]	Threaded iPS Conventional PS UC-MS	Flexima, Boston Scientific Double pigtail stents, Cook Medical Inc ZEOSTENT plus or JOSTENT SelfX, Zeon Medical Inc
Inoue et al. [15]	Long-stringed FCSEMS	Niti-S Kaffes, Taewoong Medical
Ishigaki et al. [16]	UC- MS	SIS Method: Niti-S large-cell D-type, LCD; Taewoong Corp SBS Method: WallFlex Biliary RX, Boston Scientific Corp
Ishiwatari et al. [17]	iPS	polyethylene PS (Inside Stent with Thread [IT], Gadelius Medical K.K
Kaneko et al. [8]	iPS	NA
Kanno et al. [7]	iPS MS	Three types: A. Flexima, Boston Scientific Japan K.K., Tokyo, Japan, B. Gadelius Medical. C. Quick Place V, Olympus SIS Method: Niti-S LCD type (Century Medical, Inc., Tokyo, Japan), BonaStent M-Hilar (Medico's Hirata Inc.,), Zilver 635 (Cook Japan Inc.), BileRush (Piolax Medical Devices, Inc.), ZeoStent V (Zeon Medical Inc.) SBS Method: Zilver 635 (Cook Japan Inc.), BileRush (Piolax Medical Devices, Inc.), ZeoStent V (Zeon Medical Inc.)
Kanno et al. [8]	iPS Uncovered SEMS	Inside Stent, from Through & Pass series, Gadelius Medical K.K. or Advanix J, Boston Scientific Japan K.K
Kobayashi et al. [20]	Conventional FC-SEMS iMS	Fr Amsterdam-type polyethylene stents or 8.5-Fr or 10-Fr Tannenbaum-type Teflon stents, Cook Medical Inc Amsterdam-type or Tannenbaum type fluorinated ethylene propylene endoprostheses with a nylon thread tied to the stent via a distal hole, Cook Medical Inc
Kogure et al. [21]	iPS	ThroughPass IS, Gadelius Medical K.K
Koiwai et al. [22]	iPS SEMS	ThroughPass IS, Gadelius Medical K.K., or Advanix J IS, Boston Scientific Zeo Stent V, Zeon Medical, or Niti-S Large Cell D-type Stent, Taewoong Medical
Koizumi et al. [23]	Modified PS	Flexima (Boston Scientific Japan. Cotton-Leung Sof-Flex Biliary Stent Cook. ThroughPass, Gadelius Medical
Kubota et al. [6]	iMS	Cook Medical Inc
Kurita et al. [24]	iPS	fluorinated-ethylene-propylene endoprosthesis, Olympus
Kurita et al. [25]	PS	Flexima, Boston Scientific
Mori et al. [26]	FCSEMS PS	Niti-S, Century Medical Inc., or Hanaro, Boston Scientific Japan Through and Pass, Gadelius Medical K. K
Nam Cho et al. [28]	FCSEMS	Niti-S ComVi, Taewoong Medical
Pedersen et al. [29]	MS	W.Cook, Europe
Shin et al. [30]	MS	NR
Takada et al. [31]	SEMS	NR
Taniguchi et al. [32]	FCMS	NR
Uchida et al. [33]	PS	Teflon Tannenbaum, Cook
Yamada et al. [34]	FCSEMS	HANAROSTENT Biliary (M.I.Tech), Evolution Biliary Controlled-Release Stent–Fully Covered (Cook Medical), Niti-S SUPREMO stent (TaeWoong Medical), EGIS biliary stent (SB-Kawasumi Laboratories Inc.), and BONASTENT M-Intraductal (Standard Sci Tech)
Yan et al. [35]	Conventional PS Suspended overlength PS	Straight PS Modified nasobiliary tube with multiple side holes, Boston Scientific Corporation
Yong Han et al. [36]	SEMS	NR

NR not reported, *iMS* inside metal stent, *PS* plastic stent, *MS* metal stent, *iPS* inside plastic stent, *SEMS* self-expandable metallic stent, *FCSEMS* fully covered self-expandable metal stent, *UC-MS* uncovered metal stent

this intervention, and could potentially reduce the incidence of this complication [14].

Our analysis showed RBO rate of 36.4%, mirroring evidence from previous literature [47]. The higher RBO incidence in iPS 45% versus 32.3% in iMS isn't surprising given the difference in stent caliber. The higher RBO incidence of iPS emphasizes the delicate balance between the advantages of iPS removability and the increased

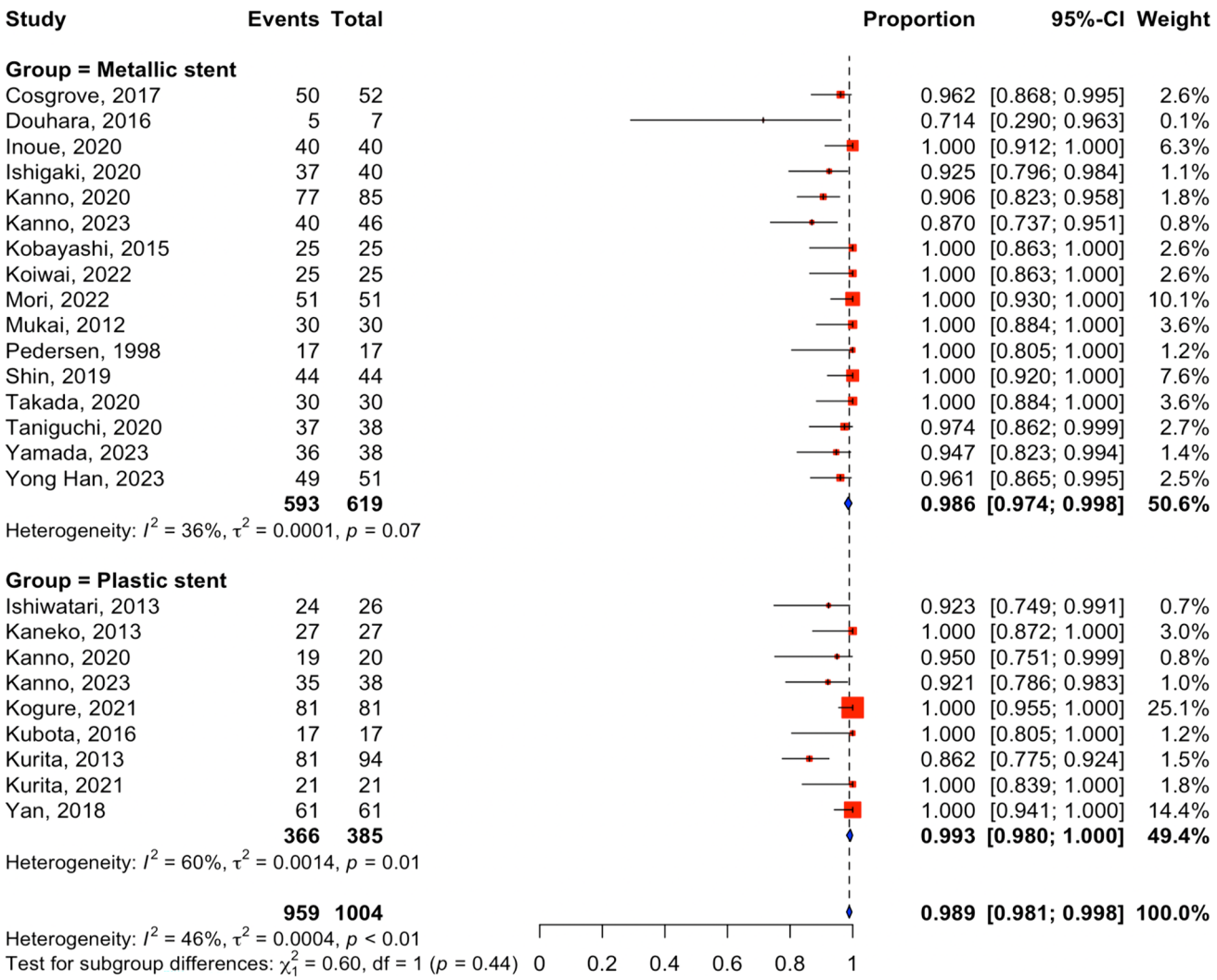

Fig. 2 Forest plot of clinical success rate

vulnerability to occlusion. In comparison, RBO was reported to be up to 27% in transpapillary stents [48]. Our analysis also revealed a pooled median patency duration of around 189 days with numerically, but not statistically significant, longer patency of the iMS than the iPS. Thus, in cases of limited life expectancy < 3–6 months, iMS likely represents a better option given the longer patency and lower rates of re-interventions. Additionally, previous metanalysis showed that suprapapillary biliary stents have longer patency times compared to transpapillary stents [5].

While traditionally the transpapillary approach has been used in malignant bile duct occlusion, emerging evidence has been in support of suprapapillary stenting [6, 12, 30]. A recent meta-analysis comparing suprapapillary to transpapillary stenting suggested better outcomes, longer patency time and fewer adverse events with the suprapapillary approach [5]. However, multiple factors limit the widespread utilization of the iPS due to lack of robust randomized data, lack of experience and lack of easy accessibility in the Western countries [49]. Most data on suprapapillary stents come from Eastern countries which may necessitate larger prospective studies that are generated in various patient populations in Western countries for the sake of generalizability of this approach. It is important to highlight the fact that our study isn't designed to compare the suprapapillary stenting to the standard transpapillary approach, albeit the comparable reported clinical success rates and low complication rates of the inside stenting.

A significant strength of our study is that it encompassed 28 studies involving a total of 1401 patients, making it the most comprehensive analysis that reports on the efficacy and safety of suprapapillary stents. However, our study also has certain limitations. Among the studies analyzed, only three are RCTs, with the remainder being retrospective. This distribution could introduce selection bias. Nevertheless, there was no significant publication bias based on the indicators

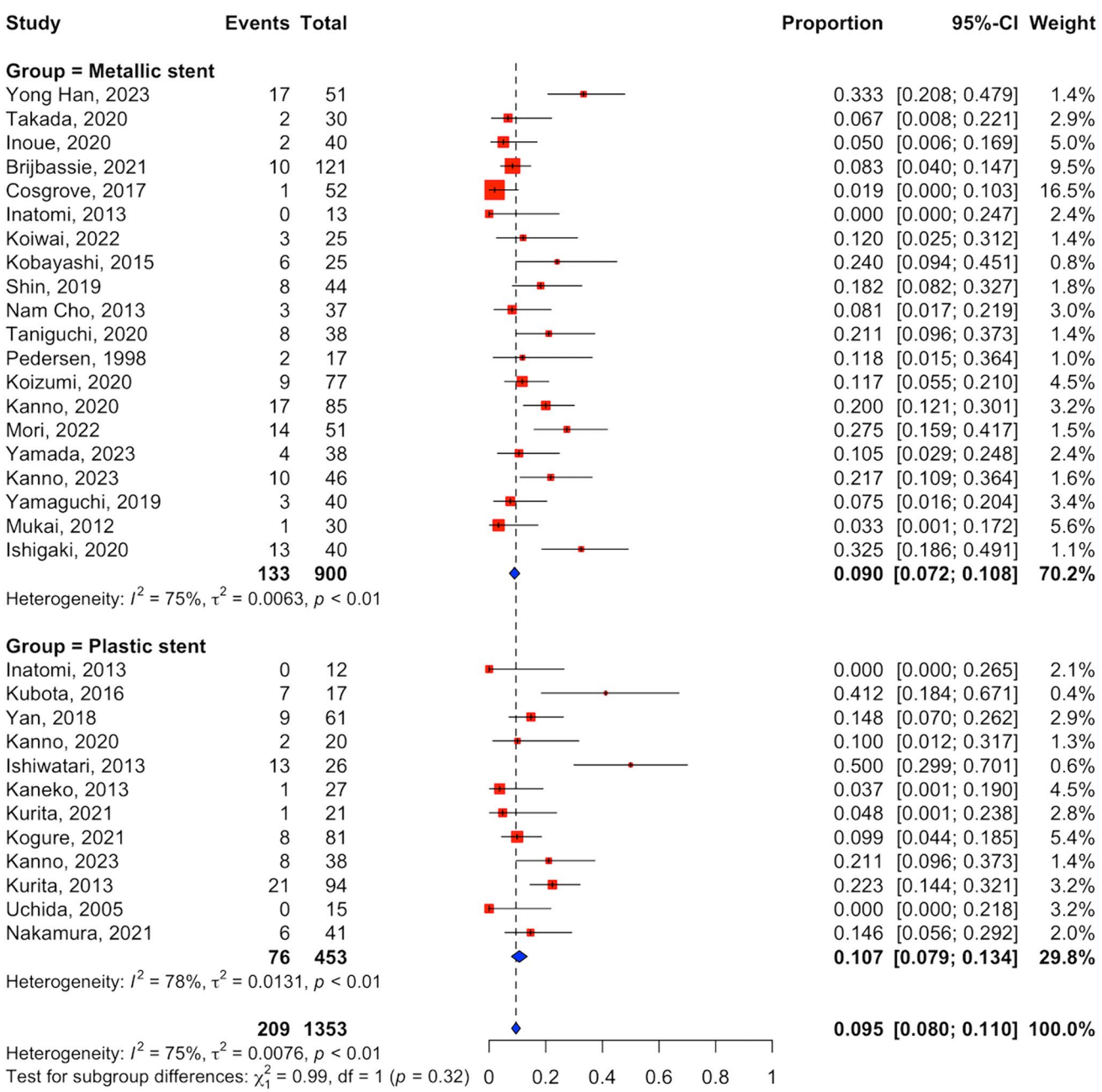

Fig. 3 Forest plot of overall adverse events

we employed. Additionally, only two of the studies in our analysis offered a direct comparison between plastic and metal stents. Other inherent limitations were the minor and major variations in study designs including procedural techniques, number of stents, stent models, inclusion, and exclusion criteria. Additionally, we were not able to conduct analysis for overall survival. In most studies, multiple stents are required in each case (whether PS or MS) including, for metal stents, stent-in-stent, side-by-side, or both. Lastly, suprapapillary stenting is primarily practiced and studied in Asia. The results of our meta-analysis aren't quite generalizable to the practice in the Western world.

In conclusion, suprapapillary stents have proven to be a viable effective option in managing biliary obstructions, demonstrating high clinical and technical success rates coupled with acceptable rate of adverse events. Both plastic and metal stents exhibit similarly high success rates, but the potential complications associated with each differ. Whether suprapapillary or transpapillary, when considering the type of stent to use, it remains most reasonable to take an individualized

Table 4 Summarized outcomes of suprapapillary stent

	Suprapapillary stent, %	iPS, % (95% CI)	iMS, % (95% CI)	iPS vs. iMS, *p*-value
Technical success	99.9 (99.2–100)	100 (99–100)	99.8 (98–100)	0.86
Clinical success	98.9 (98.1–99.8)	98.6 (97.4–99.8)	99.9 (99.2–100)	0.44
Overall adverse events	9.5 (8–11)	10.7 (9–12)	(8–12)	0.32
Cholangitis	2.2 (1.3–3.1)	2.5 (1–3.9)	2.1 (1–3.2)	0.69
Pancreatitis	1.16 (0.44–1.87)	3.88 (1.95–5.81)	0.73 (0–1.50)	< 0.01
Cholecystitis	0.55 (0–1.15)	0.39 (0–1.3)	0.64 (0–1.3)	0.69
Bleeding	0.12 (0–0.63)	0.1 (0–1)	0.1 (0–1)	0.91
Recurrent biliary obstruction	36.4 (33.7–39.1)	45 (40.2.9–49.7)	32.3 (29.0–35.6)	< 0.01
Patency time (days)	188.8	172.5	200.2	0.38

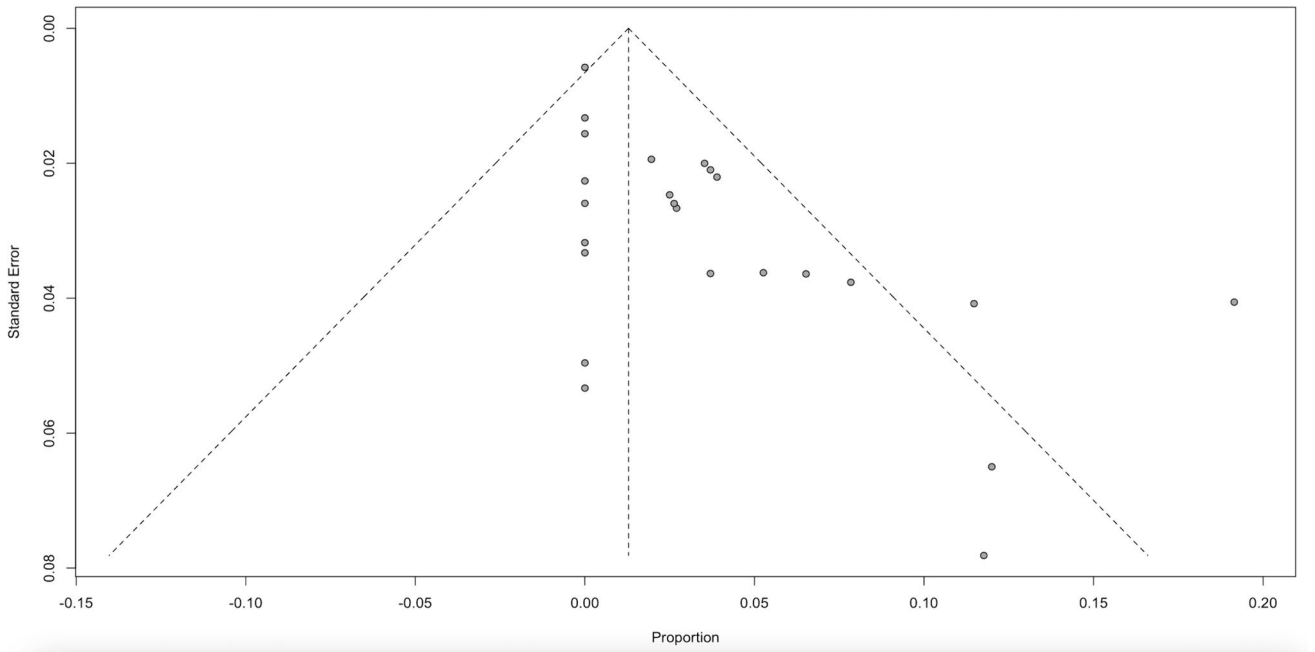

Fig. 4 Funnel plot

approach considering tumor location, respectability, patient values, life expectancy, and local expertise. Larger RCTs are needed to draw definitive comparisons between these two stent types and between suprapapillary and transpapillary stents.

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Declarations

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