

# Endoscopic metal stenting for malignant hilar biliary obstruction: an update meta-analysis of unilateral versus bilateral stenting

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## Abstract

**Introduction:** Malignant hilar biliary obstruction (MHBO) can arise in patients with malignant hilar hepatobiliary tumors or lymph nodules. Most MHBO patients are not suitable for surgical resection due to the advanced tumor stage. The only palliative treatment available is provided by endoscopic or percutaneous stenting.

**Aim:** To compare the efficacy of endoscopic unilateral versus bilateral metal stent insertion for treating MHBO.

**Material and methods:** A search of the PubMed, Embase, and Cochrane Library databases identified all relevant studies published until June 2020. The meta-analysis was undertaken using RevMan v5.3.

**Results:** We identified 154 studies initially, eight of which were used in our meta-analysis. The eight studies included 818 MHBO patients treated using either endoscopic unilateral ( $n = 396$ ) or bilateral ( $n = 422$ ) metal stenting. No significant differences were observed between the two groups in clinical success rate ( $OR = 2.64$ ;  $p = 0.18$ ), complication rate ( $OR = 0.63$ ;  $p = 0.46$ ), or OS ( $HR = 1.03$ ;  $p = 0.53$ ). The bilateral group had a lower stent dysfunction rate without significance ( $OR = 1.43$ ;  $p = 0.09$ ). Significantly longer stent patency was observed in the bilateral group ( $HR = 1.28$ ;  $p = 0.01$ ). Technical success rate was significantly higher in the unilateral group ( $OR = 0.26$ ;  $p = 0.04$ ). Funnel plot analysis indicated an absence of publication bias related to the selected study endpoints.

**Conclusions:** Our meta-analysis indicated that endoscopic unilateral stenting had a greater technical success rate for MHBO patients than bilateral stenting. However, the bilateral stenting could achieve longer stent patency.

**Key words:** stent, endoscopic, malignant hilar biliary obstruction, unilateral, bilateral.

## Introduction

Malignant hilar biliary obstruction (MHBO) can arise in patients with malignant hilar hepatobiliary tumors or lymph nodules [1–6]. Most MHBO patients are not suitable for surgical resection due to the advanced stage of the tumor [1–6]. The only palliative treatment available is provided by endoscopic or percutaneous stenting.

Metal stents have progressively taken the place of plastic stents, as they provide a higher clinical

success rate and better long-term stent patency as compared to plastic stents in those experiencing biliary obstruction [5, 7, 8]. Whether unilateral or bilateral stent insertion is optimal for MHBO treatment remains an open question [9–18]. Some researchers recommend unilateral stenting because they found that unilateral and bilateral stenting provided similar clinical efficacy for patients with MHBO [6, 8, 12]. However, other researchers have recommended bilateral stenting because they found that bilateral

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stenting provided lower re-intervention rates for patients with MHBO [9, 11, 13, 14].

Recently, Ashat *et al.* [9] performed a meta-analysis comparing unilateral and bilateral metal stenting for MHBO, finding the latter to have a lower rate of re-intervention. However, clinical efficacy might have been influenced by the stenting approach used (percutaneous or endoscopic). Aghaie Meybodi *et al.* [10] performed a meta-analysis assessing endoscopic unilateral and bilateral metal stent-mediated treatment of MHBO, and they found that endoscopic unilateral and bilateral metal stenting were equally safe and effective. However, they omitted several suitable studies from their meta-analysis [15, 17, 18].

## Aim

We therefore undertook the present meta-analysis to assess relative endoscopic unilateral versus bilateral metal stent insertion for the palliative treatment of MHBO.

## Material and methods

This meta-analysis was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement. PubMed, Embase, and the Cochrane Library databases were searched for relevant studies published up to June 2020.

### Search strategy and study design

The search strategy adopted used the following search query: (((((((cholangiocarcinoma [Title/Abstract]) OR (biliary obstruction [Title/Abstract])) OR (hilar obstruction [Title/Abstract])) OR (biliary malignancy [Title/Abstract])) OR (biliary tract neoplasia [Title/Abstract])) AND ((stent [Title/Abstract]) OR (SEMS [Title/Abstract]))) AND ((unilateral [Title/Abstract]) OR (unilobe [Title/Abstract]))) AND ((bilateral [Title/Abstract]) OR (bilobe [Title/Abstract])).

Inclusion criteria for these studies included: (a) studies comparing outcomes for unilateral and bilateral metal stent insertion for the treatment of MHBO; (b) stents placed via the endoscopic approach, and (c) studies in English.

Studies were excluded if they met any of the following criteria: (a) non-comparative studies; (b) case reports; (c) animal studies; or (d) reviews.

## Data extraction and quality assessment

Two investigators (X.M.W. and X.Q.H.) independently extracted data (authors, publication year, study design, baseline patient characteristics, and treatment information) from each study. Any discrepancies in the extracted data were resolved by the corresponding author.

The Cochrane Risk of Bias tool was used to evaluate randomized controlled trials (RCTs) [19]. Biases were assessed by evaluating the following items: selection, performance, detection, attrition, reporting, and other biases. All non-RCTs were evaluated using the 9-point Newcastle-Ottawa scale [20].

## Endpoints of the study

Analyzed endpoints included rates of technical success, clinical success, complications, stent dysfunction, stent patency, and overall survival (OS). Stent dysfunction rate was the primary endpoint.

## Definition of the endpoints

Successful stent insertion beyond the MHBO site, such that contrast media could pass easily through the stent, was used to define technical success, whereas clinical success was defined as a  $\geq 30\%$  decrease in total bilirubin within 2 weeks after stenting or a 50% decrease within 4 weeks [2, 3]. Stent dysfunction was defined by the occurrence of cholangitis or jaundice in affected patients. OS was the time from stent insertion to death.

## Statistical analysis

RevMan v5.3 was used for data analysis. Mantel-Haenszel analyses were used to determine pooled odds ratios (ORs) with 95% confidence intervals (CIs) for dichotomous variables. Overall survival was analyzed using hazard ratios (HRs) with corresponding 95% CIs. The  $\chi^2$  and  $I^2$  tests were employed to assess heterogeneity, with  $I^2 > 50\%$  being indicative of significant heterogeneity. Analysis proceeded via a random-effects model, while sensitivity and subgroup analyses were employed to assess sources of heterogeneity. Publication bias sources were assessed using funnel plots.

## Results

### Study characteristics

One hundred and fifty-four studies were retrieved by the initial search query. Eight of the

retrieved studies passed all relevant selection criteria, leading to their inclusion in our meta-analysis (Figure 1). Seven were non-RCTs [11–15, 17, 18] and one was an RCT [16]. Although the Mukai *et al.* study [14] was an RCT, it compared metal versus plastic stents, not unilateral versus bilateral stenting. The eight studies included 818 MHBO patients treated using either endoscopic unilateral ( $n = 396$ , Photo 1 A) or bilateral ( $n = 422$ , Photo 1 B) metal stenting.

Tables I and II show the details for these eight studies. Endoscopic stenting was performed using the side-by-side method in two studies [11, 17], using the stent-in-stent method in two studies [12, 14], and in a further four studies side-by-side and stent-in-stent approaches were both used or the technique used was not defined unequivocally [13, 15, 16, 18]. The 5 non-RCTs were evaluated as Newcastle-Ottawa scale 6-8. The risk of bias of the RCT is shown in Figure 2. This RCT had a high risk of blinding of participants and unclear risk of blinding of outcome assessment and other bias.

### Technical success

Technical success rates could be extracted from six of the studies [11–14, 16, 18]. No significant heterogeneity was detected ( $I^2 = 0\%$ ;  $p = 0.91$ , Figure 3 A).

A significantly higher technical success rate was found in the unilateral group (OR = 0.26; 95% CI: 0.07–0.93,  $p = 0.04$ ).

### Clinical success

Clinical success rates could be extracted from four of the studies [11, 16–18]. Statistically significant heterogeneity was observed ( $I^2 = 69\%$ ;  $p = 0.02$ , Figure 3 B). No difference in clinical successful rate was found between groups (OR = 2.64; 95% CI: 0.63–11.06,  $p = 0.18$ ). The significant heterogeneity disappeared ( $I^2 = 17\%$ ;  $p = 0.30$ ) when the Staub *et al.* study [18] was omitted. After removal, the clinical success rate in the bilateral group was significantly higher ( $p = 0.009$ ).

### Complications

Complication rates could be extracted from five of the studies [11, 12, 15, 16, 18]. Significant heterogeneity was detected ( $I^2 = 66\%$ ;  $p = 0.02$ , Figure 3 C). No significant difference in complication rates between these groups was found (OR = 0.63; 95% CI: 0.18–2.15,  $p = 0.46$ ). Sensitivity analysis demonstrated that heterogeneity disappeared after omitting the Naitoh *et al.* study [11] ( $I^2 = 48\%$ ). No differences were detected in complication rates after removing this study ( $p = 0.91$ ).

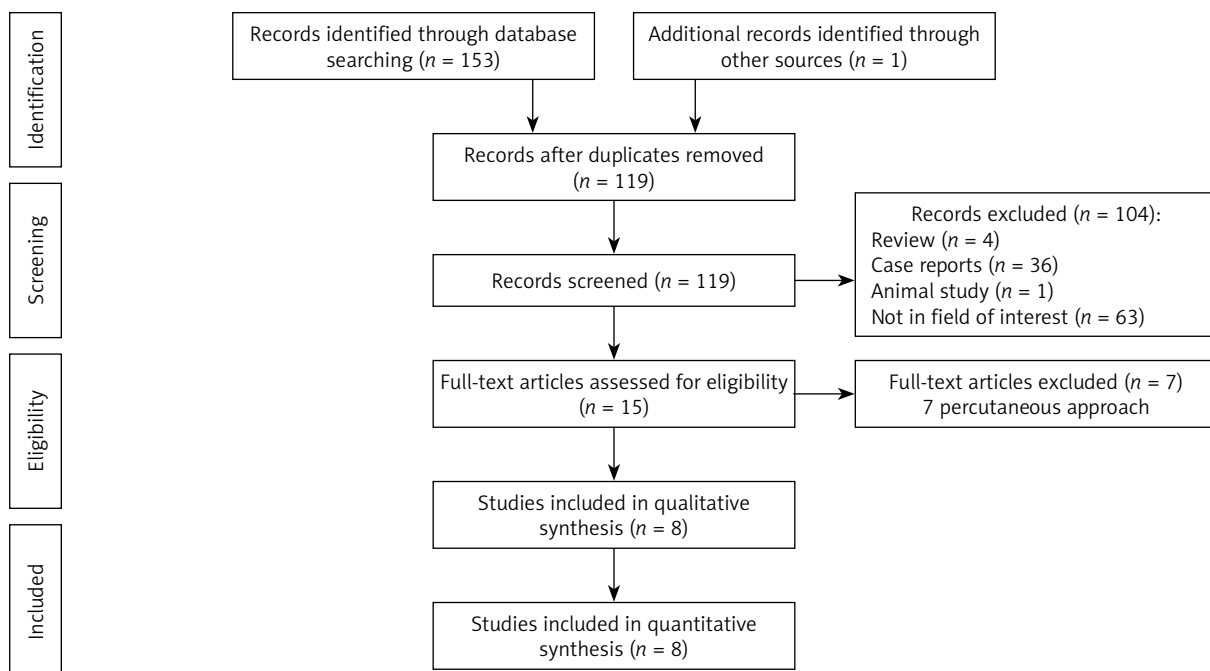
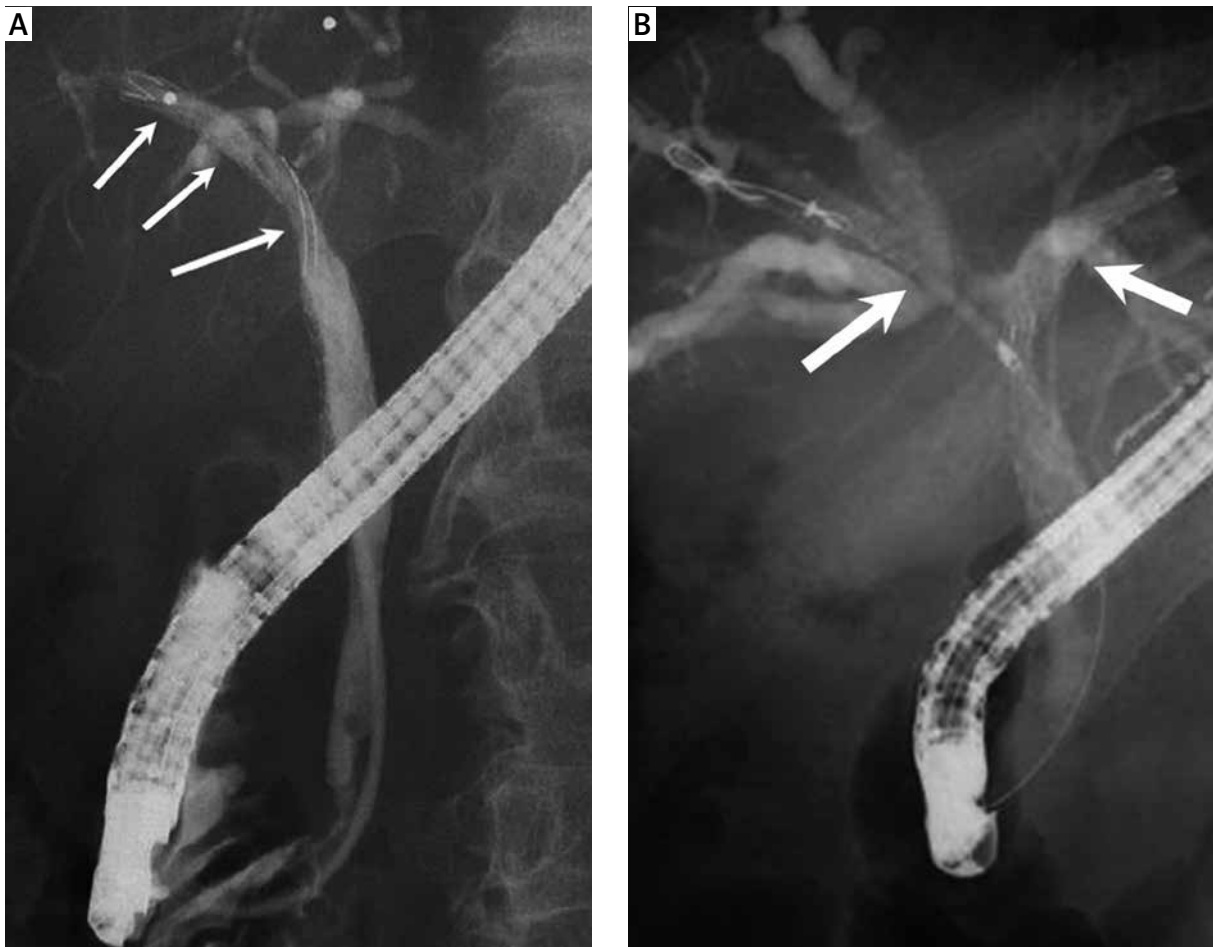


Figure 1. Flowchart detailing the separate stages of the meta-analysis



**Photo 1.** Images for (A) unilateral (arrows) and (B) bilateral (arrows) endoscopic stenting for MHBO

**Table I.** Characteristics of included studies

Study/year/country	Study design	Cancer types	Bismuth	Groups	Sample size	Age [years]	NOS
Naitoh/2009/Japan [11]	Retrospective	Multiple	I–IV	Unilateral	17	69	8
				Bilateral	29	70	
Iwano/2011/Japan [12]	Retrospective	Multiple	II–IV	Unilateral	65	71.6	8
				Bilateral	17	66.6	
Liberato/2012/Portugal [13]	Retrospective	Cholangiocarcinoma	II	Unilateral	35	–	6
				Bilateral	42	–	
Mukai /2013/Japan [14]	Non-RCT	Multiple	II–IV	Unilateral	14	–	6
				Bilateral	16	–	
Hatamaru/2017/Japan [15]	Retrospective	Multiple	II–IV	Unilateral	52	72.5	7
				Bilateral	27	74.4	
Lee/2017/Korea [16]	RCT	Multiple	II–IV	Unilateral	66	74.1	-
				Bilateral	67	73.5	
Xia/2020/China [17]	Retrospective	Multiple	II–IV	Unilateral	97	65.4	8
				Bilateral	87	65.5	
Staub/2020/Multicenter [18]	Retrospective	Cholangiocarcinoma	I–IV	Unilateral	50	73.1	7
				Bilateral	137	72.1	

NOS – Newcastle-Ottawa scale, RCT – randomized controlled trial.

**Table II.** Characteristics of treatments

Study	Deployments	Groups	TS	CS	SD	Patency [days]	OS [days]	Complications
Naitoh [11]	Side-by-side	Unilateral	17/17 (100%)	16/17 (94.1%)	10/17 (58.8%)	210	166	1/17 (5.9%)
		Bilateral	26/29 (89.7%)	25/26 (96.2%)	6/26 (23.1%)	488	205	11/26 (42.3%)
Iwano [12]	Stent-in-stent	Unilateral	60/63 (95.2%)	Not given	27/65 (41.5%)	133	125	7/65 (10.8%)
		Bilateral	17/19 (89.5%)	Not given	5/17 (29.4%)	125	126	2/17 (11.8%)
Liberato [13]	Both	Unilateral	35/35 (100%)	Not given	11/35 (31.4%)	168	Not given	Not given
		Bilateral	42/45 (93.3%)	Not given	5/42 (11.9%)	203	Not given	Not given
Mukai [14]	Stent-in-stent	Unilateral	Not given	Not given	4/14 (28.6%)	Not given	Not given	Not given
		Bilateral	Not given	Not given	8/16 (50%)	Not given	Not given	Not given
Hatamaru [15]	Not given	Unilateral	Not given	Not given	15/52 (28.8%)	Not given	Not given	8/52 (15.4%)
		Bilateral	Not given	Not given	9/27 (33.3%)	Not given	Not given	3/27 (11.1%)
Lee [16]	Both	Unilateral	66/66 (100%)	56/66 (84.8%)	38/66 (57.6%)	139	178	20/66 (30.3%)
		Bilateral	64/67 (95.5%)	61/64 (95.3%)	27/64 (42.2%)	252	270	12/64 (18.8%)
Xia [17]	Side-by-side	Unilateral	Not given	81/97 (83.5%)	42/97 (43.3%)	204	Not given	Not given
		Bilateral	Not given	86/87 (98.9%)	31/87 (35.6%)	288	Not given	Not given
Staub [18]	Not given	Unilateral	50/50 (100%)	Not given	21/50 (42%)	158	249	0/50 (0%)
		Bilateral	137/137 (100%)	Not given	60/137 (43.8%)	168	207	16/137 (11.7%)

TS – technical success, CS – clinical success, SD – stent dysfunction, OS – overall survival.

**Stent dysfunction and patency**

Stent dysfunction rates could be extracted from all eight studies. No statistically significant heterogeneity was detected ( $I^2 = 39\%$ ;  $p = 0.12$ , Figure 3 D). A lower stent dysfunction rate was observed in the

bilateral group, but the difference was non-significant (OR = 1.43; 95% CI: 0.95–2.17,  $p = 0.09$ ).

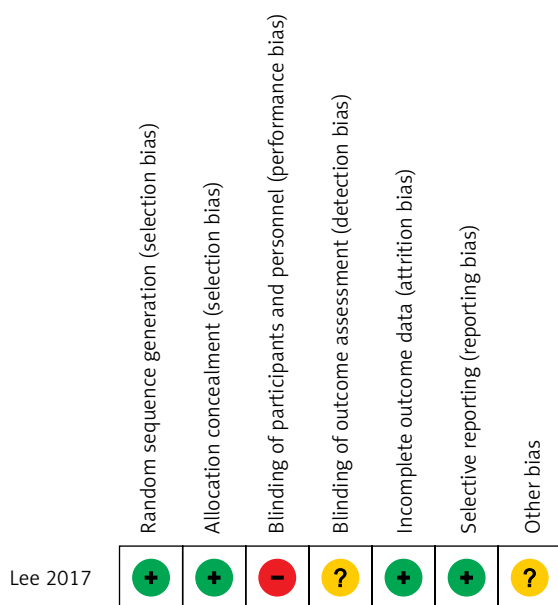
Stent patency could be extracted from six of the studies [11, 12, 16–18]. Statistically significant heterogeneity was detected ( $I^2 = 76\%$ ;  $p = 0.0007$ , Figure 3 E). Significantly longer stent patency was observed in the bilateral group (HR = 1.28; 95% CI: 1.05–1.56,  $p = 0.01$ ). Sensitivity analyses suggested that removing individual studies had no impact on the detected heterogeneity.

**OS**

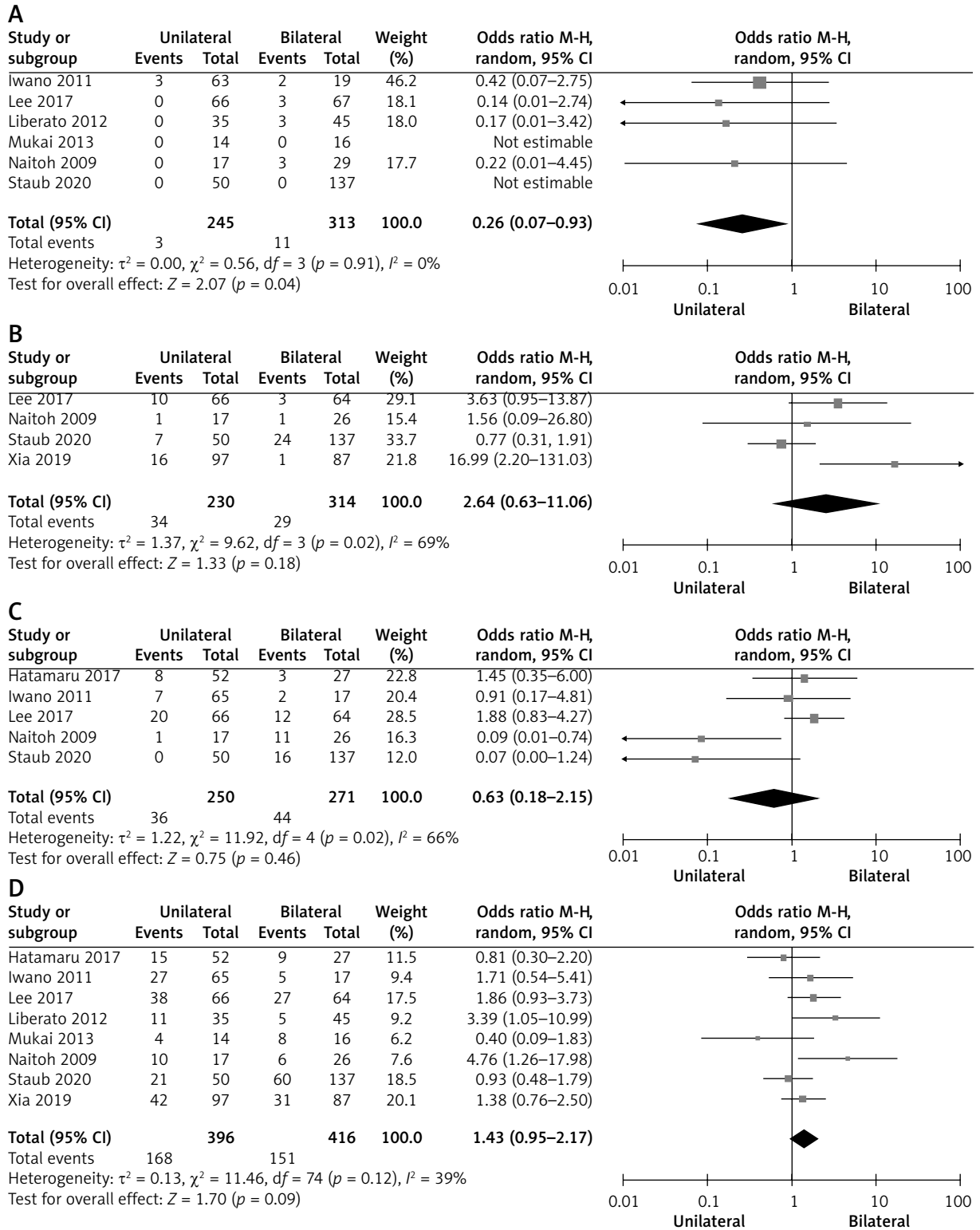
Overall patient survival could be extracted from four studies [11, 12, 16, 20]. Statistically significant heterogeneity was detected ( $I^2 = 85\%$ ;  $p = 0.0002$ , Figure 3 F). OS did not differ between groups (HR = 0.81; 95% CI: 0.42–1.56,  $p = 0.53$ ). Sensitivity analysis showed that heterogeneity disappeared after omitting the Staub *et al.* study [18] ( $I^2 = 35\%$ ). After its removal, OS did not differ between groups ( $p = 0.61$ ).

**Subgroup analysis**

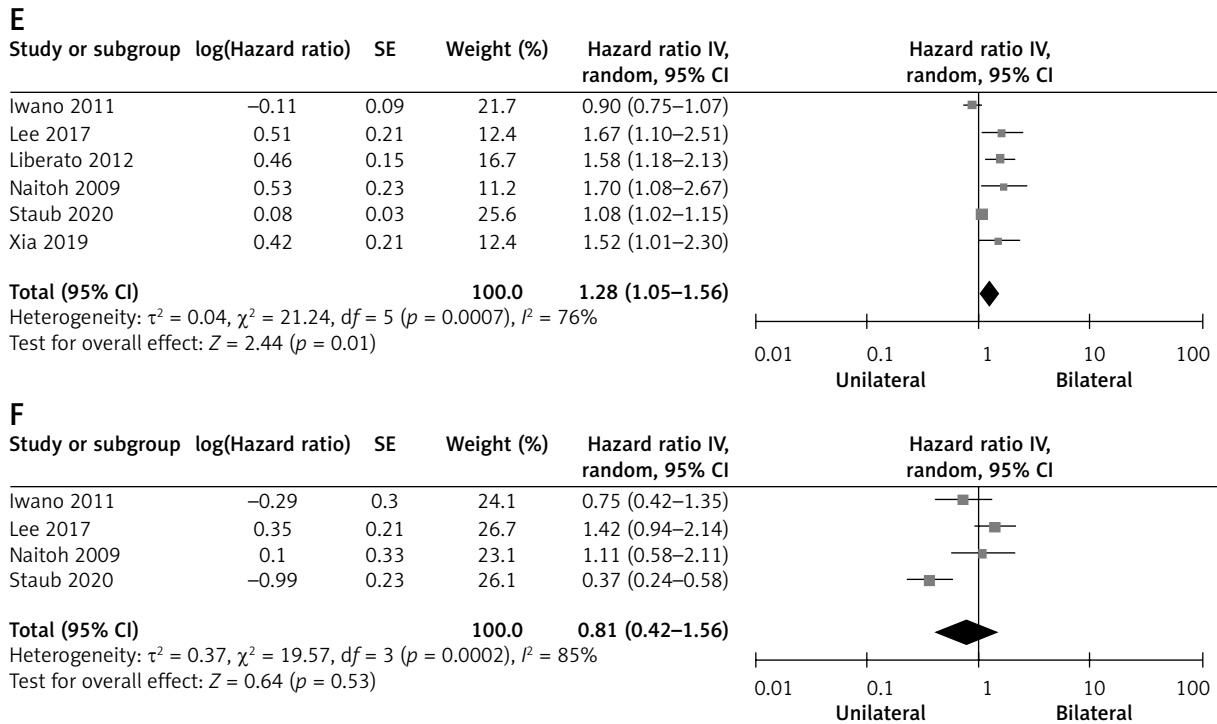
Table III shows the pooled stent dysfunction rates for different operative procedures (side-by-side, stent-in-stent, both or unclear) and different disease



**Figure 2.** Risk of bias of the included RCT



**Figure 3.** Forest plots detailing comparisons of technical success rates (A), clinical success rates (B), complication rates (C), stent dysfunction rates (D) between the unilateral and bilateral stenting groups



**Figure 3.** Cont. Forest plots detailing comparisons of stent patency duration (E), and overall survival (F) between the unilateral and bilateral stenting groups

**Table III.** Meta-analytic pooled stent dysfunction rates based on subgroup analysis

Parameter	Number of studies	OR (95% CI)	Favorable	Heterogeneity
Total	8	1.43 (0.95, 2.17), $p = 0.09$	–	$I^2 = 39\%$
Deployments				
Side-by-side	2	2.21 (0.68, 7.18), $p = 0.19$	–	$I^2 = 64\%$
Stent-in-stent	2	0.99 (0.22, 3.69), $p = 0.89$	–	$I^2 = 55\%$
Both or unclear	4	1.38 (0.79, 2.44), $p = 0.26$	–	$I^2 = 45\%$
Diseases				
Multiple	6	1.44 (0.89, 2.33), $p = 0.14$	–	$I^2 = 35\%$
Cholangiocarcinoma	2	1.61 (0.46, 5.66), $p = 0.46$	–	$I^2 = 72\%$

OR – odds ratio.

classifications (multiple or cholangiocarcinoma). All subgroups had equivalent stent dysfunction rates.

**Publication bias**

Funnel plot analysis suggested no publication bias relating to the selected study endpoints.

**Discussion**

In this meta-analysis, we compared relative clinical efficacy and long-term results of endoscopic

unilateral versus bilateral metal stent insertion used for palliative treatment of MHBO. We found a significantly higher technical success rate in the unilateral group. It is generally agreed that unilateral stenting is simpler than bilateral stenting. However, many studies of percutaneous stenting for patients with MHBO indicate similar technical success rates for both groups [6, 21–24]. Compared to the endoscopic approach, percutaneous stenting for MHBO is more straightforward, due to the very short distance from the puncture site to the obstructed site.

We found a similar initial clinical success rate for both unilateral and bilateral groups (OR = 2.64;  $p = 0.18$ ), although significant heterogeneity was present ( $I^2 = 69\%$ ;  $p = 0.02$ ). However, after correcting for heterogeneity, we found that bilateral stenting demonstrated greater clinical success. This is consistent with the recommendation made by the Asia-Pacific Working Group, that drainage volume should be > 50% of the entire liver [25]. Our result is different from previous studies of percutaneous stenting for MHBO, which indicated similar clinical success rates in the two groups [6, 21–24]. This finding may result from temporarily utilizing a post-percutaneous stenting biliary drainage catheter after percutaneous stenting [6, 21–24], as the catheter may help drain more bile. By contrast, a drainage catheter is not typically used after endoscopic stenting.

We did not find a difference in complication rates between the two groups. Future studies will need to assess complication rates in this context more rigorously.

Stent dysfunction is a key endpoint in biliary stenting. A previous meta-analysis found endoscopic unilateral and bilateral metal stenting techniques to be comparable in their efficacy and safety [10]. However, three suitable studies [15, 17, 18] had not been included. When we added these studies, we detected a higher stent dysfunction rate in the unilateral group without significance ( $p = 0.09$ ). Subgroup analyses also demonstrated comparable stent

dysfunction rates based on the different deployment approaches and cancer types. However, the pooled stent patency was significantly longer in the bilateral group ( $p = 0.01$ ). In this meta-analysis, many studies included many patients who underwent side-by-side bilateral stenting [11, 13, 16, 17]. This technique allows drainage to continue even when one stent becomes occluded. These results and findings might indicate that although bilateral stenting could not prevent stent dysfunction, it could prolong the time from stent insertion to dysfunction.

Bilateral stent patency may be influenced by several factors, including type of Bismuth, stent deployment approach (side-by-side versus stent-in-stent), or disease type. This is particularly important for stent deployment, since side-by-side stent insertion creates two drainage routes, allowing drainage to continue even when one stent becomes occluded or blocked. The stent-in-stent approach also requires a larger hilar mesh than the side-by-side deployment strategy, thereby potentially allowing for easier tumor ingrowth [26].

We observed similar overall survival in the two treatment groups, perhaps due to most patients in our meta-analysis being from studies where stenting was used as a post-operative anticancer treatment [16–18]. While such stenting may reduce jaundice in affected patients, it cannot affect the primary tumor directly. Additional anti-cancer treatment is needed to extend stent patency and patient survival significantly [27].

**Table IV.** Details of previous meta-analyses of unilateral vs. bilateral stenting for MHBO

Authors [references]	Number of included studies	Approaches	Type of stents	Bilateral techniques	Recommend	Reason
Hong <i>et al.</i> [28]	5	Endoscopic	Plastic, Metal	SBS, SIS	Unilateral	Simpler procedure
Sawas <i>et al.</i> [8]	7	Endoscopic	Plastic, Metal	SBS, SIS	Unilateral	Simpler procedure
Li <i>et al.</i> [29]	10	Endoscopic, Percutaneous	Plastic, Metal	SBS, SIS	Bilateral	Longer patency
Ashat <i>et al.</i> [9]	9	Endoscopic, Percutaneous	Metal	SBS, SIS	Bilateral	Lower re-intervention rate
Fu <i>et al.</i> [30]	7	Percutaneous	Metal	SBS, SIS	Unilateral	Simpler procedure
Chen <i>et al.</i> [31]	6	Endoscopic, Percutaneous	Metal	SBS	Bilateral	Lower re-intervention rate
Aghaie Meybodi <i>et al.</i> [10]	5	Endoscopic	Metal	SBS, SIS	Unilateral	Simpler procedure

SBS – side-by-side, SIS – stent-in-stent.



Table IV shows previous meta-analyses of unilateral vs. bilateral stenting for MHBO [8–10, 28–31]. From such work, it is clear that it remains controversial whether unilateral or bilateral stenting is the method of choice for patients with MHBO. Many factors, including stent types, stenting approaches, and bilateral stenting techniques, might influence the outcome of MHBO [8–10, 28–31]. In those previous meta-analyses of unilateral versus bilateral stenting for MHBO, some included both plastic and metal stents [8, 28, 29], and some included both percutaneous and endoscopic approaches [9, 29, 31]. Our present meta-analysis has some advantages over those previous meta-analyses: First, as we only included articles which used endoscopic metal stenting for MHBO, the risk of bias could be reduced. Second, the previous meta-analysis only pooled the stent dysfunction rates [9, 29–31]. However, our meta-analysis not only pooled the stent dysfunction rates, but also pooled the HR for stent patency. These results could evaluate the long-term outcomes in more detail. Third, subgroup analyses for the stent dysfunction rates were performed in this meta-analysis.

The limitations of our meta-analysis suggest several areas of potentially fruitful future research. First, most of the included studies were retrospective in nature, which may give rise to selection bias. Future RCTs will thus be needed to confirm or refute the findings outlined here. Secondly, the included studies used several different stent deployment techniques, principally stent-in-stent and side-by-side approaches, which can also bias the results. Thirdly, most of the included studies enrolled MHBO patients with a variety of cancers, which again can limit the wide applicability of the findings presented above.

## Conclusions

Our meta-analysis demonstrated that endoscopic unilateral stenting had a higher technical success rate for MHBO patients than bilateral stenting. However, bilateral stenting could achieve longer stent patency.

## Conflict of interest

The authors declare no conflict of interest.

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