Systematic Review and Meta-Analysis

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Stent insertion with high-intensity focused ultrasound ablation for malignant biliary obstruction

A protocol of systematic review and meta-analysis

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Abstract

Background: This meta-analysis was conducted in order to understand the clinical efficacy of stent insertion with high-intensity focused ultrasound (HIFU) ablation for the treatment of malignant biliary obstruction (MBO).

Methods: The Pubmed, Embase, and Cochrane Library databases were searched for all relevant studies published through July 2020. The meta-analysis was conducted using RevMan v5.3, with analyzed study endpoints including the rate of stent dysfunction, time to stent dysfunction, stent patency, complication rate, and overall survival (OS).

Results: In total, 35 potentially relevant studies were initially identified, of which 6 were ultimately included in the present meta-analysis. These 6 studies included 429 MBO patients that were treated either only via stenting (n = 221) or via stenting in combination with HIFU ablation (n = 208). Pooled stent dysfunction rates in the stent and stent with HIFU groups were 25.9% and 18.0%, respectively (OR: 1.59; 95% CI: 0.88, 2.84, $P = .12$). The average time to stent dysfunction was significantly longer in the stent with HIFU group relative to the stent group (MD: −3.15; 95% CI: −3.53, −2.77, $P < .0001$). Pooled complication rates in the stent and stent with HIFU groups were 17.1% and 19.6%, respectively (OR: 0.88; 95% CI: 0.49, 1.58, $P = .67$). Stent patency and OS were both significantly longer in the stent with HIFU group relative to the stent group ($P < .0001$ and.0001, respectively). Funnel plot analyses did not reveal any significant evidence of publication bias linked to the selected study endpoints.

Conclusions: This meta-analysis found that a combined stenting and HIFU ablation approach can achieve better stent patency and OS in MBO patients relative to stent insertion alone.

Abbreviations: CI = confidence intervals, HIFU = high-intensity focused ultrasound, HR = hazard ratios, MBO = malignant biliary obstruction, OR = odds ratio, OS = overall survival.

Keywords: biliary, high-intensity focused ultrasound ablation, malignant, stent

1. Introduction

Malignant biliary obstruction (MBO) typically occurs as a consequence of primary or metastatic tumors affecting the hepato-biliary-pancreatic system.[1–6] Metal stent insertion is the most common palliative intervention used to treat patients suffering from MBO.[1–6] However, stent dysfunction reportedly occurs in roughly half of patients within 6 months of stent insertion, primarily as a consequence of tumor growth.[7] The selection of appropriate post-stenting anti-cancer treatment strategies is thus essential in order to prevent stent dysfunction and prolong patient survival.[2]

MBO patients commonly undergo radiotherapy- or chemotherapy-based treatment regimens,[8,9] both of which are associated with substantial rates of treatment-related toxicity. Recently, high-intensity focused ultrasound (HIFU) ablation has been developed as an effective and non-toxic approach to cancer treatment.[10–17] In prior studies, HIFU ablation has been successfully used to prolong stent patency and survival in MBO patients.[11–15] However, these prior analyses were all retrospective and thus prone to selection bias. An appropriately conducted meta-analysis is thus essential to more fully understand the clinical value of HIFU ablation treatment in MBO patients that have undergone stent insertion.

The present meta-analysis was therefore performed to evaluate the clinical efficacy of stent insertion with HIFU ablation as an approach to treating MBO.

2. Materials and methods

The Institutional Review Board of The People's Hospital of Rugao approved this study. Pubmed, Embase, and Cochrane Library

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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databases were searched for relevant articles published through July 2020 based on the following search strategy: (((biliary [Title/Abstract]) OR (Cholangiocarcinoma [Title/Abstract])) AND (stent [Title/Abstract])) AND ((High-intensity Focused Ultrasound Ablation [Title/Abstract]) OR (HIFU [Title/Abstract])).

Study inclusion criteria were: (a) they compared clinical outcomes in MBO patients that had undergone stent insertion to those of MBO patients that had undergone stent insertion with HIFU ablation; and (b) they had at least one of the following outcomes: stent dysfunction rate, time to stent dysfunction, complication rate, clinical response rate of HIFU, and overall survival (OS).

All non-comparative studies, animal studies, case reports, and review articles were excluded from this study.

2.1. Data extraction

Two investigators independently extracted publication year, study design, authors, baseline patient characteristics, and treatment information from relevant studies. Discrepancies were resolved through discussion with the corresponding author.

2.2. Quality assessment

Randomized controlled trial (RCT) quality was assessed with the 8-point Jadad composite scale,[18] with the 9-point Newcastle-Ottawa scale was employed to gauge the quality of non-RCTs.[19] A high-quality study with low risk of bias was considered if the Jadad composite scale ≥5 or Newcastle-Ottawa scale ≥6

2.3. Endpoints and definitions

Analyzed study endpoints included stent dysfunction rate, time to stent dysfunction, stent patency, complication rate, clinical response rate of HIFU, and OS.

Stent dysfunction was defined as any condition resulting in the migration or re-obstruction of the stent. Time to stent dysfunction was the time between stent insertion and stent dysfunction. Stent

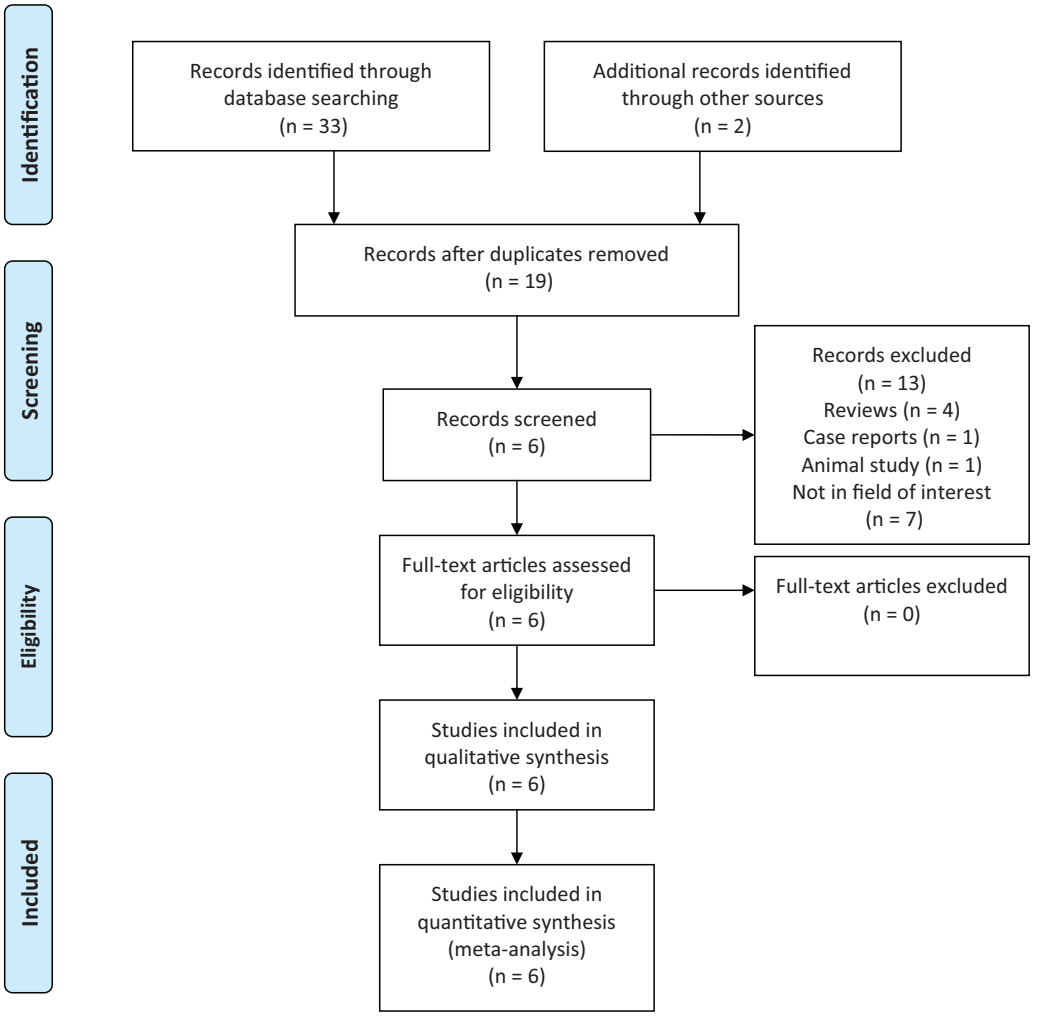

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Figure 1. Flowchart of this meta-analysis.

dysfunction was defined by the occurrence of re-obstruction or migration in affected patients. A positive clinical response to HIFU was one in which tumor necrosis or reduction was detected upon computed tomography (CT) assessment.[12] OS was the time between stent insertion and death.

2.4. Statistical analyses

RevMan v5.3 and Stata v12.0 were utilized for all statistical analyses. Pooled odds ratios (ORs) and 95% confidence intervals (CIs) for dichotomous variables were calculated via the Mantel-Haenszel appraoch, whereas pooled estimates of mean difference (MD) with 95% CIs were calculated the continuous variables. Hazard ratios (HRs) with 95% CIs were used to compare stent patency and OS between groups. Heterogeneity among included studies was gauged using X^2 tests and the I^2 statistic, with $I^2 > 50\%$ being indicative of significant heterogeneity. Fixed-effects models were utilized in the absence of any significant heterogeneity. Sources of potential heterogeneity were identified via sensitivity and subgroup analyses. Pooled clinical response rates were calculated using Stata v12.0. The potential for publication bias was analyzed with funnel plots.

3. Results

3.1. Study characteristics

We initially identified 35 potentially relevant studies, of which 6 were ultimately included in our meta-analysis (Fig. 1). All included studies were retrospective. These studies included 429 MBO patients that had either undergone stent insertion alone (n=221) or stent insertion and HIFU ablation (n=208).

Details regarding these 6 studies are compiled in Tables 1 and 2. All studies scored 6 to 8 points on the Newcastle-Ottawa scale and all of them could be evaluated as high-quality studie. These studies focused on patients with multiple types of cancer, pancreatic carcinoma, and hilar MBO in 2, 2, and 2 articles, respectively. The details of the treatment outcomes were shown in Table 3.

3.2. Stent dysfunction

Data associated with stent dysfunction rates were extracted from 4 of these 6 studies.[12–15] No significant heterogeneity was detected among these studies ($I^2=0\%$; $P=.93$, Fig. 2a, and the pooled stent dysfunction rates in the stent and stent with HIFU groups were 25.9% and 18.0%, respectively (OR: 1.59; 95% CI: 0.88, 2.84, $P=.12$).

3.3. Time to stent dysfunction

Data pertaining to time to stent dysfunction was extracted from 3 of these 6 studies.[10–12] No significant heterogeneity among these studies was detected ($I^2=0\%$; $P=.75$, Fig. 2b). The stent with HIFU group exhibited a significantly longer average time to stent dysfunction relative to the stent only group (MD: −3.34; 95% CI: −3.91, −2.77, $P<.0001$).

3.4. Patency

We extracted data relating to stent patency from 3 of these 6 studies.[12,14,15] We did not detect any significant heterogeneity among these studies ($I^2=0\%$; $P=.85$, Fig. 2c). We found that stent patency was significantly longer among patients that underwent stent insertion and HIFU ablation relative to patients that underwent stent insertion alone (HR: 2.19; 95% CI: 1.67, 2.87, $P<.0001$).

Table 1

Baseline data of the 6 studies.

Study	Year	Country	Design	Quality assessments	
				Jade score	Newcastle–Ottawa score
Cao[10]	2011	China	Retrospective	–	7
Cheng[11]	2014	China	Retrospective	–	6
Niu[12]	2016	China	Retrospective	–	8
Xia[13]	2017	China	Retrospective	–	8
Yang[14]	2019	China	Retrospective	–	8
Cao[15]	2020	China	Retrospective	–	8

Table 2

Characteristics of the patients.

Study	Stent type	Stent approach	Groups	Sample size	Age (y)	ECOG PS	Cancer types	Cancer stage	Post-stent chemotherapy
Cao[10]	Metal	Percutaneous	Stent	59	61	NG	Multiple	NG	None
			Stent+HIFU	63	63	NG			None
Cheng[11]	Metal	Percutaneous	Stent	15	NG	NG	Hilar obstruction	NG	None
			Stent+HIFU	17	NG	NG			None
Niu[12]	Metal	Percutaneous	Stent	27	63	0, 1, ≥2	Multiple	NG	None
			Stent+HIFU	24	64	0, 1, ≥2			None
Xia[13]	Metal	Percutaneous	Stent	42	63.6	2-3	Pancreatic carcinoma	II-IV	None
			Stent+HIFU	38	64.6	2-3			None
Yang[14]	Metal	Percutaneous	Stent	41	63.6	2-3	Pancreatic carcinoma	II-IV	12
			Stent+HIFU	34	65.2	2-3			10
Cao[15]	Metal	Percutaneous	Stent	37	63.2	2.6±0.5	Hilar obstruction	II-IV	None
			Stent+HIFU	32	66.5	2.6±0.5			None

ECOG PS = Eastern Cooperative Oncology Group performance status, HIFU = high-intensity focused ultrasound, NG = not given.

Table 3

Characteristics of the treatment outcomes.

Study	Groups	SD	TTSD	Patency	OS	Complications	Kinds of complications
Cao[10]	Stent	Not given	5.1 ± 1 mo	Not given	6.4 mo	16/59 (27.1%)	C, B
	Stent+HIFU	Not given	8.6 ± 2.4 mo	Not given	8.7 mo	17/63 (27.0%)	
Cheng[11]	Stent	Not given	4.5 ± 1.2 mo	Not given	Not given	Not given	–
	Stent+HIFU	Not given	7.9 ± 2.9 mo	Not given	Not given	Not given	
Niu[12]	Stent	8/27 (29.6%)	4.3 ± 0.6 mo	8.6 mo	5.1 mo	1/27 (3.7%)	C, P, B
	Stent+HIFU	4/24 (16.7%)	7.3 ± 1 mo	12.2 mo	7.9 mo	2/24 (8.3%)	
Xia[13]	Stent	9/42 (21.4%)	Not given	Not given	4.8 mo	Not given	–
	Stent+HIFU	6/38 (15.8%)	Not given	Not given	7.0 mo	Not given	
Yang[14]	Stent	13/41 (31.7%)	Not given	3.9 mo	4.5 mo	5/41 (12.2%)	C, P, B
	Stent+HIFU	7/34 (20.6%)	Not given	5.8 mo	7.0 mo	4/34 (11.8%)	
Cao[15]	Stent	8/37 (21.6%)	Not given	5.6 mo	5.9 mo	6/37 (16.2%)	C, Ch
	Stent+HIFU	6/32 (18.8%)	Not given	7.5 mo	8.2 mo	7/32 (21.9%)	

B = bleeding, C = cholangitis, Ch = cholecystitis, OS = overall survival, P = pancreatitis, SD = stent dysfunction, TTSD = time to stent dysfunction.

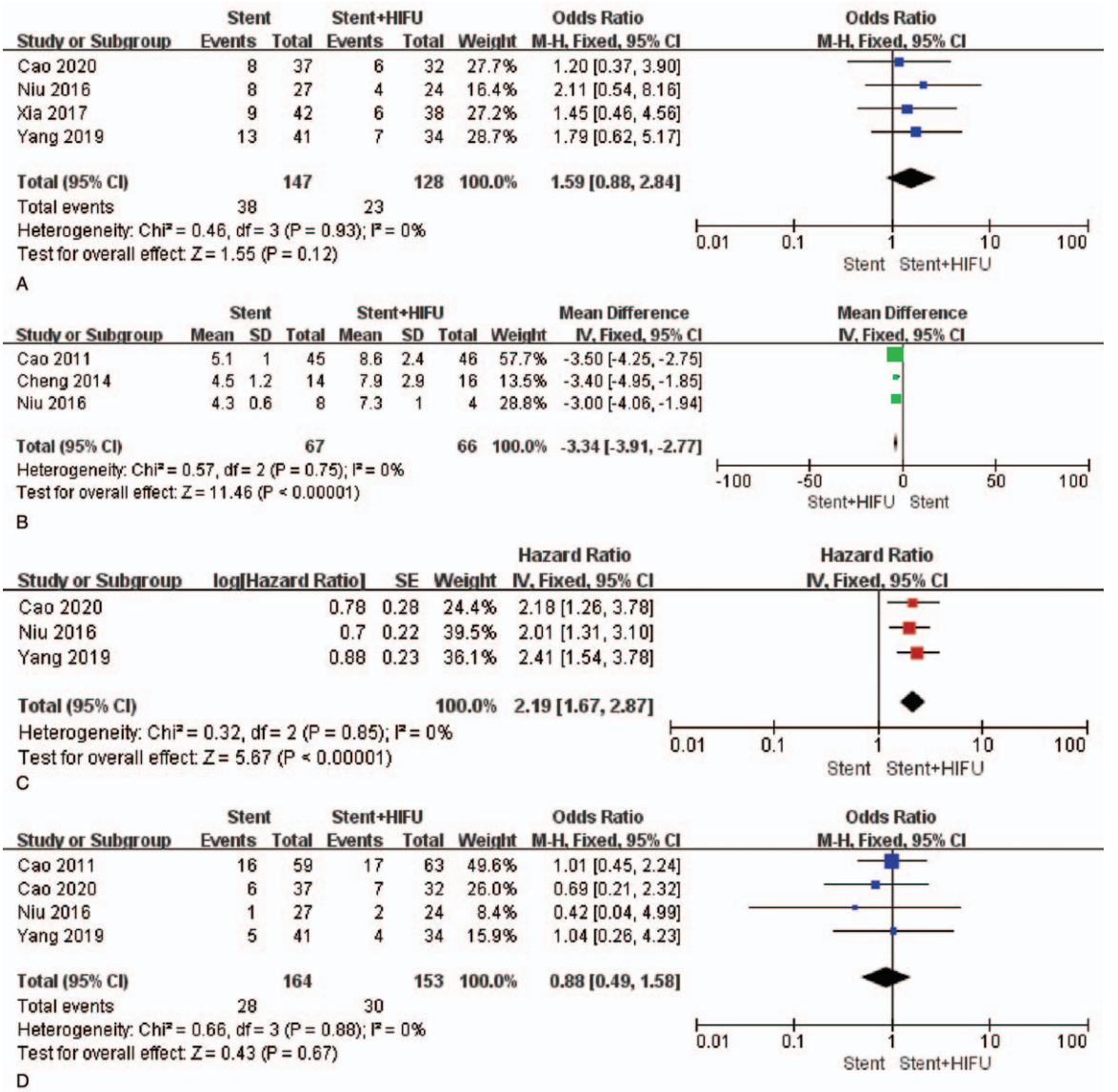

Figure 2. Forest plots of (A) stent dysfunction rates, (B) time to stent dysfunction, (C) stent patency, (D) complication rates, (E) clinical response rate, and (F) overall survival.

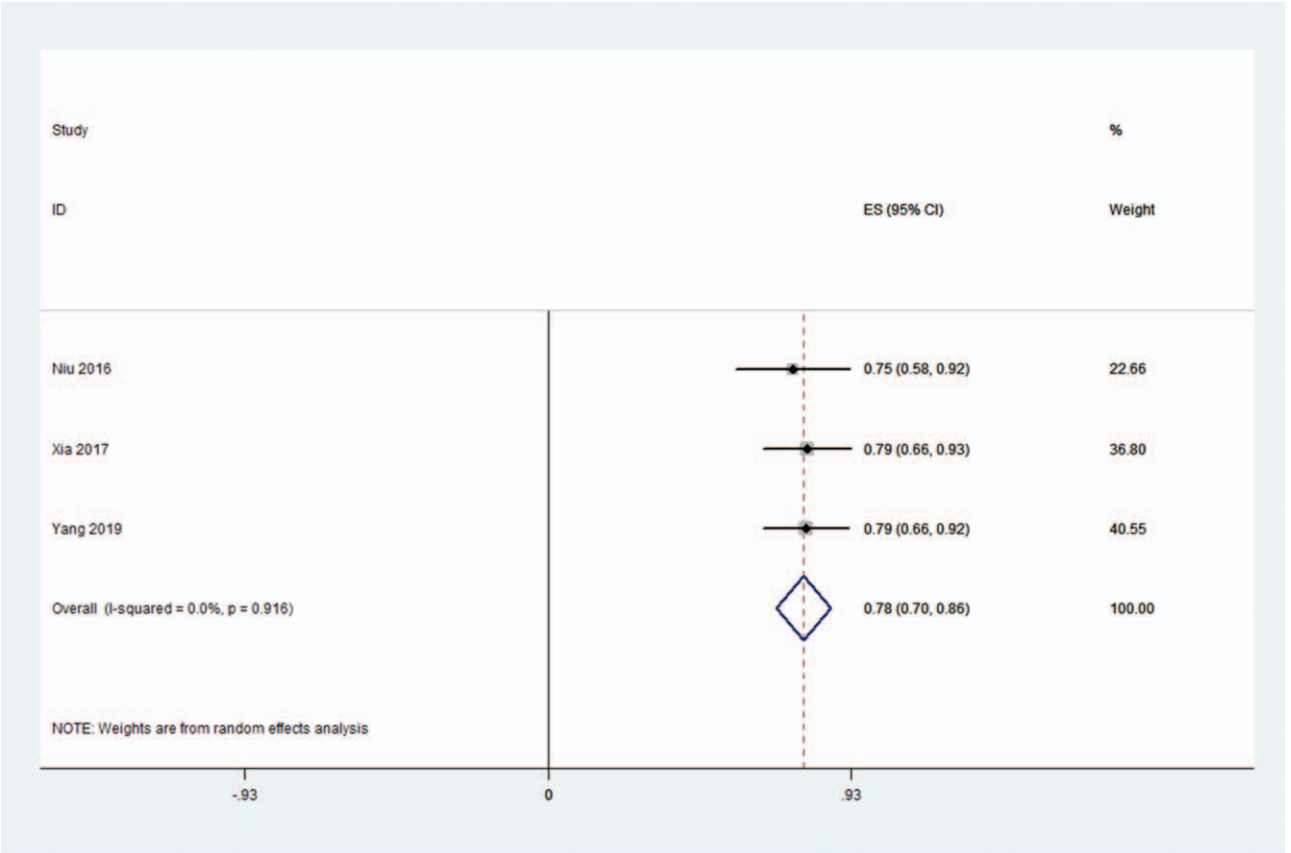

Figure 2. Continued.

3.5. Complications

We extracted data pertaining to complication rates from 4 of these 6 studies.[10,12,14,15] No significant heterogeneity was detected among these studies ($I^2 = 0\%$; $P = .88$, Fig. 2d). Pooled complication rates in the stent and stent with HIFU groups were 17.1% and 19.6%, respectively (OR: 0.88; 95% CI: 0.49, 1.58, $P = .67$).

3.6. Clinical response

We extracted data pertaining to clinical response rates from 3 of these 6 studies.[12–14] No significant heterogeneity was detected among these studies ($I^2 = 0\%$; $P = .916$, Fig. 2e). We found HIFU ablation to be associated with a 78% pooled clinical response rate.

3.7. Overall survival

We extracted data relating to patient OS from 5 of these 6 studies.[10,12–15] No significant heterogeneity was detected among included studies ($I^2 = 0\%$; $P = .88$, Fig. 2f). We found that OS was significantly longer among patients that underwent stent insertion and HIFU ablation relative to patients that underwent stent insertion alone (HR: 2.31; 95% CI: 1.99, 2.69, $P < .0001$).

3.8. Subgroup analyses

Two studies focused on the patients with multiple types of cancer.[10,12] Three endpoints could be pooled (Table 4). The pooled TTSD and OS were both significant longer in the stent

Table 4

Meta-analytic pooled results based on the studies regarding of multiple cancers.

	Number of studies	OR or HR (95% CI)	Heterogeneity	Favor
TTSD	2	−3.33 (−3.95, −2.72), $P<.00001$	$I^2=0\%$	Stent+HIFU
Complications	2	0.92 (0.43, 1.96), $P=.83$	$I^2=0\%$	–
Survival	2	2.23 (1.81, 2.75), $P<.00001$	$I^2=0\%$	Stent+HIFU

HIFU = high-intensity focused ultrasound, HR = hazard ratio, OR = odd ratio, TTSD = time to stent dysfunction.

insertion and HIFU ablation group ($P<.0001$ and .0001, respectively). Pooled complication rates in the stent and stent with HIFU groups were comparable ($P=.83$). No significant heterogeneity was detected among these studies (Table 4).

Two studies focused on the patients with pancreatic carcinoma.[13,14] Two endpoints could be pooled (Table 5). The pooled OS were significant longer in the stent insertion and HIFU ablation group ($P<.00001$). Pooled stent dysfunction rates in the stent and stent with HIFU groups were comparable ($P=.22$). No significant heterogeneity was detected among these studies (Table 5).

Two studies focused on the patients with hilar MBO.[11,15] However, no endpoint could be pooled. In Cheng et al.[11] study, only TTSD could be extracted. However, in Cao et al[15] study, TTSD was not reported, they reported the data of stent dysfunction, stent patency, OS, and complication.

3.9. Publication bias

No evidence of publication bias relating to selected study endpoints was detected in funnel plot analyses.

4. Discussion

Herein, we assessed the clinical efficacy of combined stent insertion and HIFU ablation in patients suffering from MBO. Biliary stents have previously been reported to be associated with a 50% cumulative 6-month re-obstruction rates,[20] with these rates being even higher in patients with hilar obstruction.[21] While some studies have found that covered stents that covered stents are associated with longer stent patency than uncovered stents in MBO patients,[22,23] these covered stents do not exhibit any advantageous anticancer activities. Covered stent insertion may also be associated with higher rates of cholecystitis and pancreatitis in treated patients.[22,23]

In the present study, we found that pooled stent dysfunction rates were comparable in MBO patients that underwent stenting with and without HIFU ablation ($P=.12$). However, patients that underwent HIFU ablation exhibited significantly longer average time to stent dysfunction and stent patency relative to patients that only underwent stent insertion ($P<.0001$ and .0001, respectively). Our results are consistent with findings from other studies regarding radioactive stent insertion in MBO patients.[8,24] This suggests that multiple anticancer treatments, including HIFU ablation and radiation therapy, cannot prevent tumor growth as not all patients were sensitive to these treatments. Nonetheless, HIFU ablation was able to inhibit tumor growth and to thereby prolong stent patency in treated patients.

No differences in complication rates were detected when comparing the 2 patient groups in the present meta-analysis, suggesting that HIFU ablation is not linked to any rise in complication rates. However, only 4 of the included studies provided data pertaining to complication rates, indicating that further clinical trials will be necessary to confirm these findings.

We found that pooled OS was significantly longer among patients that underwent stent insertion and HIFU ablation relative to patients that only underwent stent insertion. This is consistent with prior studies that have found that anticancer treatment can prolong survival in patients that have undergone stent insertion.[9] HIFU ablation has commonly been employed for the treatment of mass-like tumors,[16,17] using specialized equipment to focus ultrasound energy on a specific target within the body, thereby driving thermally-induced apoptosis and necrosis.[16] We additionally calculated the HIFU ablation to be associated with a 78% pooled clinical response rate. This finding, together with the OS-related results, suggests that HIFU ablation may be well-suited to the treatment of tumors affecting luminal sites.

The subgroup analyses were performed based on the different cancer types. Based on the patients with multiple cancers, the TTSD and OS were both favorable in the stent insertion and HIFU ablation group. When focusing on the patients with pancreatic carcinoma, the OS was also favorable in the stent insertion and HIFU ablation group. These results might indicate that different cancer types did not influence the long-term outcomes after stent insertion with HIFU ablation.

There are many limitations to this meta-analysis. For one, all studies included herein were retrospective, and as such, they are susceptible to selection bias. Future RCTs will therefore necessary in order to validate these findings. Furthermore, the included studies enrolled MBO patients with a range of different cancer types, potentially biasing the overall results. In addition, data pertaining to specific endpoints was absent in some of the included studies, potentially limiting the widespread applicability of these findings.

In summary, in this meta-analysis we found that MBO patients that underwent stent insertion and HIFU ablation exhibited

Table 5

Meta-analytic pooled results based on the studies regarding of pancreatic carcinoma.

	Number of studies	OR or HR (95% CI)	Heterogeneity	Favor
Stent dysfunction	2	1.63 (0.75, 3.54), $P=.22$	$I^2=0\%$	–
Survival	2	2.43 (1.85, 3.19), $P<.00001$	$I^2=0\%$	Stent+HIFU

HIFU = high-intensity focused ultrasound, HR = hazard ratio, OR = odd ratio.

significantly better stent patency and overall survival outcomes relative to MBO patients that only underwent stent insertion.

Author contributions

Conceptualization: Hong-Yan Deng.
Data curation: Hong Gu, Lei-Juan Zhu, Yuan-Shun Xu.
Formal analysis: Hong Gu.
Supervision: Yuan-Shun Xu.
Writing – original draft: Peng-Fei Cai.
Writing – review & editing: Yuan-Shun Xu.

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