Conventional and drug-eluting bead transarterial chemoembolization in patients with inoperable intrahepatic cholangiocarcinoma: a meta-analysis

Su-Rong Pan[1], Xue-Wen Wo[2], Hong-Fang Zhu[1], Feng-Fei Xia[3]

1 Department of Gastroenterology, Binzhou People's Hospital, Binzhou, China
2 Department of Neurology, Binzhou People's Hospital, Binzhou, China
3 Department of Interventional Vascular Surgery, Binzhou People's Hospital, Binzhou, China

KEY WORDS

conventional, drug-eluting beads, intrahepatic cholangiocarcinoma, transarterial chemoembolization

ABSTRACT

INTRODUCTION In patients with inoperable intrahepatic cholangiocarcinoma (ICC), both conventional transarterial chemoembolization (cTACE) and drug-eluting bead TACE (DEB-TACE) can be employed as therapeutic interventions. However, the relative advantages of these strategies remain to be clarified.

AIM This meta-analysis was performed to compare the safety and efficacy of DEB-TACE and cTACE in the treatment of ICC.

MATERIALS AND METHODS A comprehensive search of the Cochrane Library, PubMed, and Wanfang databases was conducted to identify publications that were pertinent to the present meta-analysis. The primary outcome of interest was the overall survival (OS) rate. Secondary outcomes were progression-free survival (PFS), disease control rate (DCR), objective response rate (ORR), and adverse event (AE) rate. Heterogeneity was evaluated using the I^2 statistic, while publication bias was assessed with the Egger test.

RESULTS A total of 6 articles involving 283 and 178 patients who received cTACE and DEB-TACE treatment, respectively, were included in this study. DEB-TACE was superior to cTACE in terms of DCR ($P = 0.004$), PFS ($P < 0.001$), and OS ($P = 0.004$), despite comparable pooled ORRs. No intergroup differences were observed with respect to AE occurrence. The ORR, DCR, and OS end points showed significant heterogeneity ($I^2 = 79\%$, $I^2 = 61\%$, and $I^2 = 95\%$, respectively). Additionally, the OS end point was subject to substantial publication bias (Egger test, $P = 0.002$).

CONCLUSIONS DEB-TACE was shown to be superior to cTACE with respect to efficacy, while the safety profile of these 2 interventions was similar. Consequently, DEB-TACE offers additional value in the management of inoperable ICC.

Correspondence to:
Feng-Fei Xia, MD,
Department of Interventional Vascular Surgery,
Binzhou People's Hospital,
515 Huanghe 7th Road,
256600 Binzhou, China,
phone: +86 0543 3282005,
email: xff510@126.com
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INTRODUCTION Intrahepatic cholangiocarcinoma (ICC) accounts for 10% to 15% of all primary liver cancers, and it is the second most commonly diagnosed primary liver cancer type.[1-3] While surgery can cure the disease, less than 30% of individuals with ICC are eligible for such treatment.[4] What is more, such patients are still at a risk of disease recurrence, resulting in 5-year overall survival (OS) and disease-free survival rates of approximately 55% and 41.7%, respectively.[5]

In individuals with inoperable ICC, locoregional therapies are the primary approach to prolonging survival and delaying progression of the disease.[6-8] Transarterial chemoembolization (TACE) is often employed as a locoregional approach for managing ICC or hepatocellular cancer (HCC).[8,9] It effectively disrupts blood supply of the tumor while also allowing for sustained local release of therapeutic agents. Conventional TACE (cTACE) and drug-eluting bead TACE (DEB-TACE) are 2 available techniques employed

TABLE 1 Modified Response Evaluation Criteria in Solid Tumors

Criterion	Definition
Complete response	Disappearance of any intratumoral arterial enhancement in all target lesions
Partial response	A decrease by at least 30% in the sum of diameters of viable (enhanced in the arterial phase) target lesions, with the baseline sum of the target lesions diameters serving as a reference
Stable disease	Not meeting the criteria of partial response or progressive disease
Disease progression	An increase by at least 20% in the sum of the diameters of viable (enhanced) target lesions, with the smallest sum of the viable (enhanced) target lesion diameters recorded since treatment initiation serving as a reference

in this therapeutic setting.[8,9] In cTACE, lipiodol serves as both the drug carrier and the embolic agent. Still, the utility of lipiodol is hampered by its highly fluid nature and poor amenability to sustained drug release.[6] DEB-TACE is an alternative approach that overcomes these limitations, as DEBs facilitate controlled, localized chemical release, thereby increasing the concentrations of drugs within tumors while limiting their systemic spread more effectively than in the case of cTACE.[6]

While DEB-TACE is used increasingly often to manage HCC,[9] its utility as a treatment for ICC has been explored to a limited extent. A systematic evaluation was performed to compare cTACE and DEB-TACE as treatment alternatives for ICC. The results showed that DEB-TACE was linked with a higher disease control rate (DCR) and superior tumor response outcomes, as compared with cTACE.[6] That review, however, was based on single-arm studies and was subject to a significant selection bias,[6] emphasizing the need for a meta-analysis focused on comparative studies.

AIM The current meta-analysis was designed to compare the relative safety and efficacy of cTACE and DEB-TACE as therapeutic approaches to inoperable ICC.

MATERIALS AND METHODS

Study selection The present meta-analysis followed the rules set by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) reporting guidelines and was registered at INPLASY.COM (registration No. INPLASY202460085).

A comprehensive search was undertaken to identify relevant papers published up until June 2024 in the PubMed, Cochrane Library, and Wanfang databases, using the following prespecified search terms: ((intrahepatic cholangiocarcinoma) OR (ICC)) AND ((transarterial chemoembolization) OR (TACE)) AND (conventional) AND ((drug-eluting beads) OR (DEB)).

The inclusion criteria comprised 4 domains: 1) type of intervention: cTACE and DEB-TACE; 2) population: patients with inoperable ICC; 3) study type: comparative analyses; and 4) language of publication: no limitations.

Case reports, reviews, letters, nonhuman studies, and single-arm studies were excluded from analysis.

Data extraction Two authors (SRP and XWW) independently chose eligible studies and extracted the relevant data, with a third author (FFX) serving as an arbiter in the case of any disagreements. Data collected from the included studies comprised the primary author name, year of publication, country of origin, study design, patient population, age distribution, sex ratio, tumor size, liver function test findings, number of tumors, and tumor stage. The collected outcome data included progression-free survival (PFS), OS, objective response rate (ORR), DCR, and adverse event (AE) occurrence.

Quality evaluation For randomized controlled trials (RCTs), quality evaluation was performed with the Cochrane risk-of-bias method. This involved assigning a low, high, or unclear bias risk to each of the following categories: performance, reporting, detection, selection, attrition, and other biases.

The Newcastle–Ottawa scale (NOS)[10] was used to assess observational studies, with 4, 3, and 2 points assigned to the selection, exposure, and comparability criteria, respectively. Studies with NOS scores of 7 or higher were considered to be of good quality.

End points The primary study end point was OS, while PFS, ORR, DCR, and AE incidence served as secondary end points. The analyzed AEs included elevated levels of aspartate aminotransferase (AST) or alanine aminotransferase (ALT), hyperbilirubinemia, and hypoalbuminemia. The patients who showed a complete or partial improvement in their condition were classified as having an objective response. Disease control encompassed both the patients with an objective response and those with stable disease. Evaluation of tumor responses was performed according to the modified Response Evaluation Criteria in Solid Tumors (**TABLE 1**). OS was measured from the time of TACE to death or loss to follow-up, while PFS was calculated from the time of TACE to primary and / or metastatic tumor progression.

Statistical analysis This meta-analysis was conducted using RevMan v5.3 (Cochrane Collaboration, Nordic Cochrane Centre, Copenhagen, Denmark) and Stata v12.0 (Stata Corporation, College Station, Texas, United States) software.

FIGURE 1
Meta-analysis flow chart

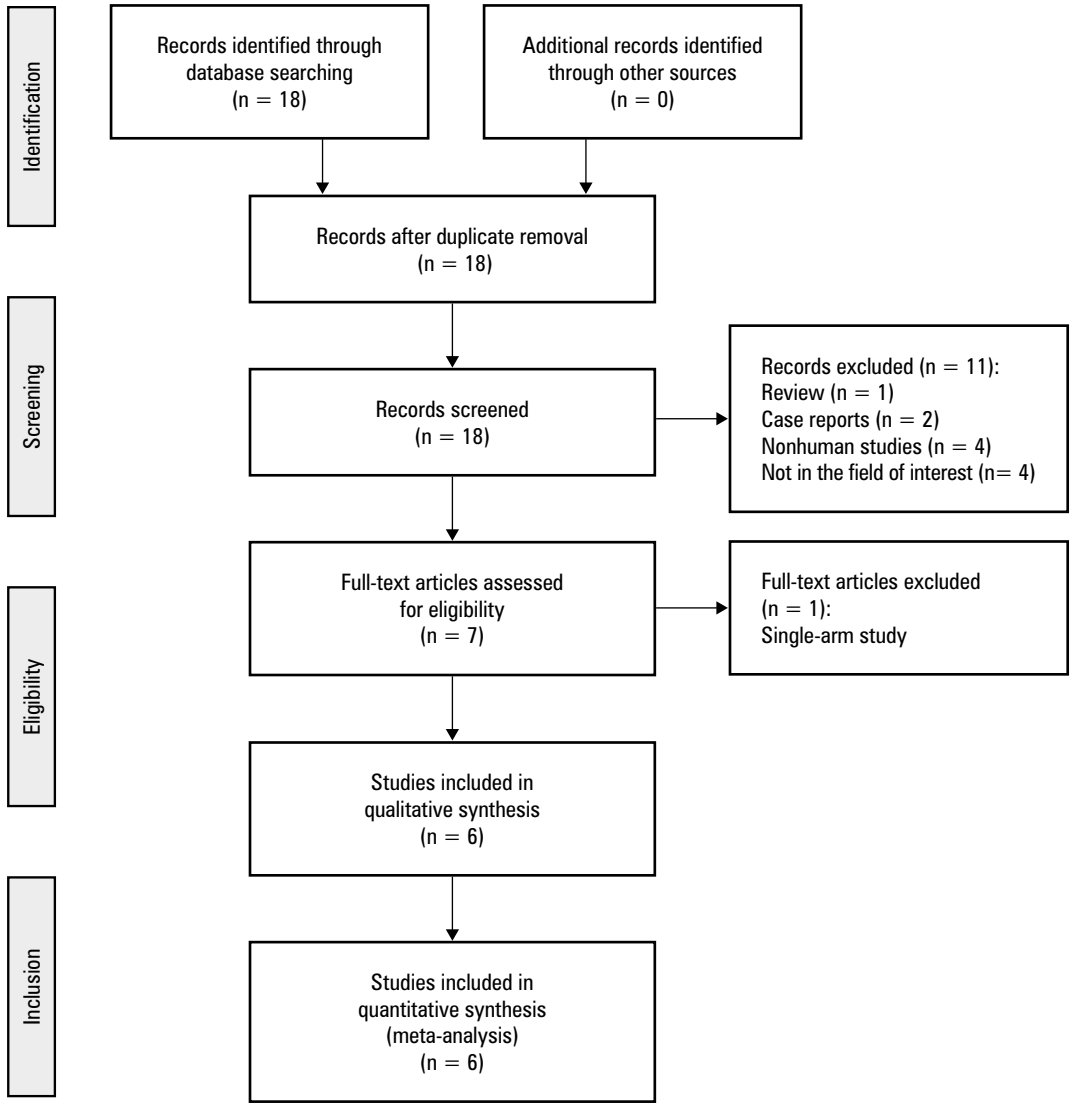

TABLE 2 General characteristics of the included studies

Study	Year	Country/area	Design	NOS
Hu et al[11]	2020	China	Retrospective	8
Hyder et al[12]	2013	United States	Retrospective	6
Kuhlmann et al[13]	2012	Germany	Retrospective	7
Sun et al[14]	2022	China	Retrospective	8
Wang et al[15]	2023	China	Randomized controlled trial	Not applicable
Zhang et al[16]	2024	China	Retrospective	8

Abbreviations: NOS, Newcastle–Ottawa scale

Dichotomous variables were analyzed using pooled odds ratios (ORs) and 95% CIs. Hazard ratios (HRs) were used when assessing pooled OS and PFS rates. Heterogeneity was evaluated with the *Q* test and I^2 statistic. In the case of significant heterogeneity (I^2 >50%), data were analyzed with random-effect models, otherwise, fixed-effect models were employed. Sensitivity analyses were performed using the leave-one-out technique. A significance level of *P* below 0.05 was used as the threshold. The risk of publication bias was assessed using the Egger test.

Ethics Approval of an ethics committee and written informed consent are not required for meta-analyses.

RESULTS **Study selection** A total of 18 studies were found to be potentially relevant during the initial database search. Of those, 6 studies met the inclusion criteria.[11-16] The study selection process is detailed in **FIGURE 1**.

Among the included studies, 5 were retrospective analyses and 1 was an RCT. General characteristics of all studies are presented in **TABLE 2**. Of the 5 retrospective studies, all exhibited NOS scores from 6 to 8. The RCT showed an uncertain risk of bias with respect to detection and performance (**FIGURE 2**).

The studies enrolled 283 and 178 patients in the DEB-TACE and cTACE groups, respectively. Patient characteristics are presented in **TABLE 3**, while the utilized chemical agents, OS data, and PFS data are detailed in **TABLE 4**.

Objective response rate Data on ORR were provided in 5 studies enrolling 155 and 167 patients in the DEB-TACE and cTACE groups, respectively.[11,13-15] In all studies, the ORR was

TABLE 3 Characteristics of patients included in the analyzed studies

Study	Groups	Patients, n	Age, y	Sex (M/F)	Mean tumor size, mm	Tumor location	Child–Pugh classes	TNM stages	Number of tumors
Hu et al[11]	cTACE	12	56.9	3/9	68	N/A	A–B	III–IV	≤3, 2 patients; >3, 10 patients
	DEB-TACE	13	55.9	7/6	68	N/A	A–B	III–IV	≤3, 7 patients; >3, 6 patients
Hyder et al[12]	cTACE	128	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	DEB-TACE	11	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Kuhlmann et al[13]	cTACE	10	62	8/2	N/A	N/A	N/A	N/A	N/A
	DEB-TACE	26	67	15/11	N/A	N/A	N/A	N/A	N/A
Sun et al[14]	cTACE	49	57.4	28/21	70	N/A	A–B	N/A	Single, 23 patients; multiple, 26 patients
	DEB-TACE	40	61.8	25/15	79	N/A	A–B	N/A	Single, 16 patients; multiple, 24 patients
Wang et al[15]	cTACE	20	N/A	11/9	N/A	N/A	A–B	III	N/A
	DEB-TACE	20	N/A	17/3	N/A	N/A	A–B	III	N/A
Zhang et al[16]	cTACE	64	56.9	46/18	84	Unilobar, 41 patients; bilobar, 23 patients	A–B	I–IV	≤4, 36 patients; >4, 28 patients
	DEB-TACE	68	58.1	42/26	99	Unilobar, 44 patients; bilobar, 24 patients	A–B	I–IV	≤4, 36 patients; >4, 32 patients

Abbreviations: cTACE, conventional TACE; DEB, drug-eluting bead; F, female; M, male; N/A, not available; TACE, transarterial chemoembolization; TNM, TNM Classification of Malignant Tumors

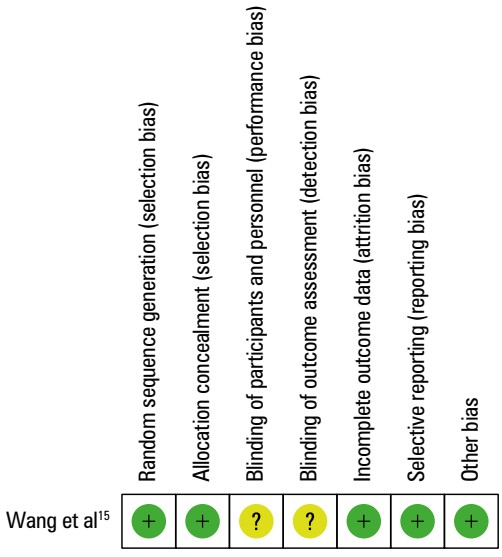

FIGURE 2 Quality assessment for the included randomized controlled trial.[15] The green circles represent low risk of bias, while the yellow circles represent uncertain risk of bias.

analyzed within 3 months of the treatment. In the DEB-TACE group, the ORR was higher than in the cTACE group (56.3% vs 26.5%; OR, 0.26; 95 CI%, 0.04–1.5; **FIGURE 3A**) but the difference was not significant. Substantial heterogeneity was observed (I^2 = 79%); however, it was reduced when the study by Zhang et al[16] was excluded from sensitivity analyses (I^2 = 14%). Despite exclusion of this study, no substantial disparity in ORR was noted between the groups (P = 0.05).

Disease control rate The DCR was reported in 3 studies[11,13-15] that enrolled 155 and 167 patients in the DEB-TACE and cTACE groups, respectively. In all these studies, the DCR was evaluated within 3 months of the treatment. The DEB-TACE group exhibited a higher DCR than the cTACE group (79.6% vs 50.3%; OR, 0.22; 95 CI%, 0.08–0.62; P = 0.004; **FIGURE 3B**). While significant heterogeneity was evident (I^2 = 61%), it disappeared once the study Zhang et al[16] was excluded from sensitivity analyses (I^2 = 0%). Even after exclusion of this study, DEB-TACE was associated with a higher DCR than cTACE (P = 0.008).

Progression-free survival A total of 4 studies provided data on PFS.[11,13-15] The patients treated with DEB-TACE presented longer PFS than those who underwent cTACE (HR, 1.66; 95% CI, 1.46–1.89; P <0.001; **FIGURE 3C**). There was no significant heterogeneity for this end point (I^2 = 0%).

Overall survival All studies reported on patient OS, with DEB-TACE treatment being associated with longer OS than cTACE (HR, 1.46; 95% CI, 1.13–1.89; P = 0.004; **FIGURE 3D**). Significant heterogeneity was detected (I^2 = 95%), but its source was not established through sensitivity testing.

Adverse events Pooled AE incidence rates are reported in **TABLE 5**. Both groups exhibited similar rates of elevated ALT and AST levels, hyperbilirubinemia, and hypoalbuminemia (P = 0.59, P = 0.56, P = 0.64, and P = 0.23, respectively).

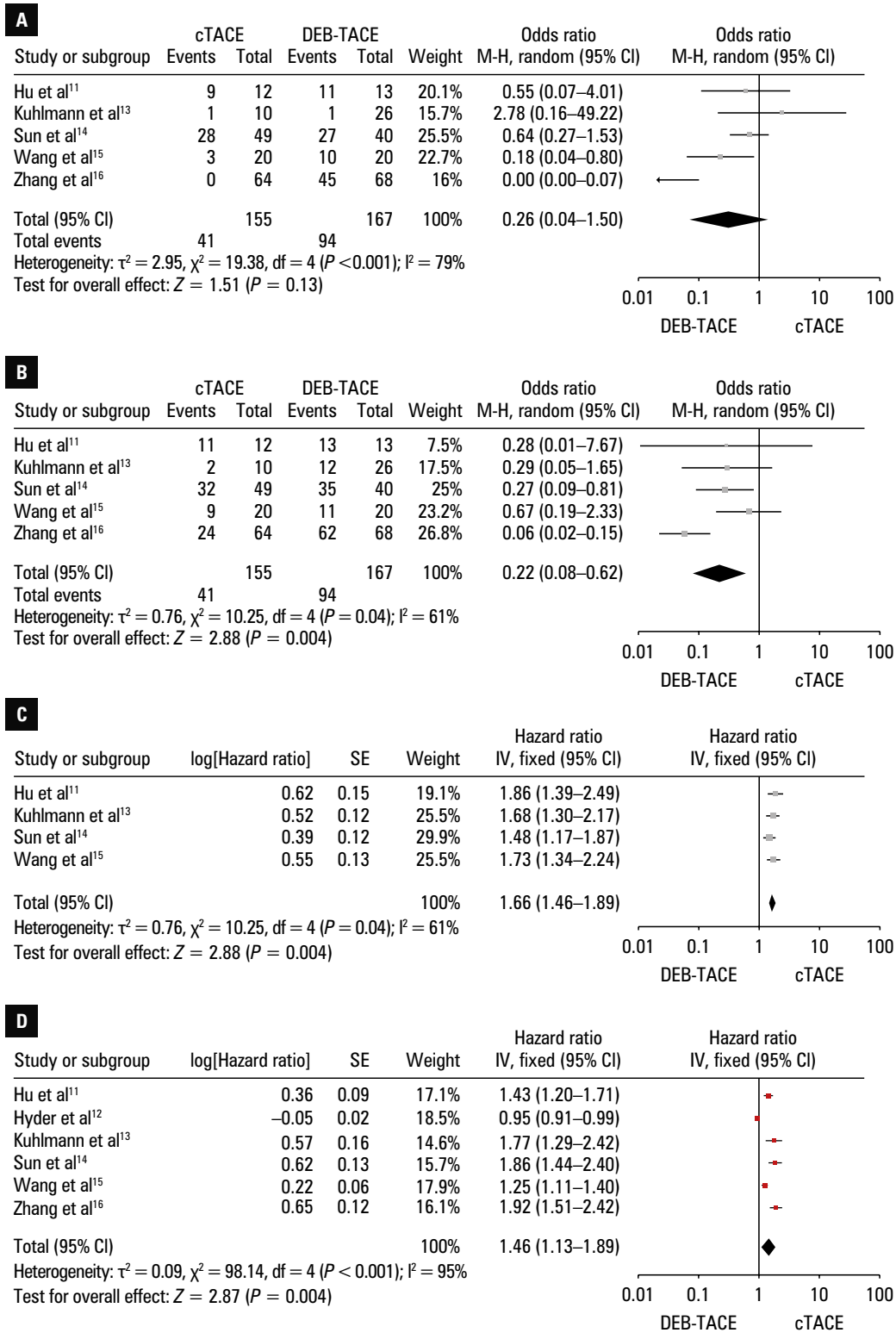

FIGURE 3 Pooled results for objective response rate (**A**), disease control rate (**B**), progression-free survival (**C**), and overall survival (**D**) in the conventional and drug-eluting bead transarterial chemoembolization groups
Abbreviations: df, degree of freedom; IV, instrumental variable; M-H, Mantel–Haenszel model; others, see **TABLE 3**

None of these AEs exhibited significant heterogeneity. However, heterogeneity testing could not be performed for the elevated AST end point owing to the 100% elevated AST rates in both groups in the study by Hu et al.[11]

Publication bias Publication bias was only found to be significant for the OS outcome (Egger test, $P = 0.002$).

DISCUSSION This meta-analysis explored the efficacy and safety of cTACE and DEB-TACE approaches for managing inoperable ICC based on patient therapeutic responses, AE occurrence, and survival rates. The results unequivocally showed that DEB-TACE is superior to cTACE in terms of tumor control and survival outcomes.

Therapeutic response is the most important aspect of tumor treatment. In the current

TABLE 4 Treatment characteristics

Study	Groups	Chemical agents	PFS, mo	OS, mo
Hu et al[11]	cTACE	Gemcitabine and cisplatin	10.3	14
	DEB-TACE	Gemcitabine and cisplatin	17	19.3
Hyder et al[12]	cTACE	Gemcitabine, doxorubicin, mitomycin, and cisplatin	N/A	13.4
	DEB-TACE	Doxorubicin and cisplatin	N/A	10.5
Kuhlmann et al[13]	cTACE	Mitomycin	1.8	5.7
	DEB-TACE	Irinotecan	3.9	11.7
Sun et al[14]	cTACE	Epirubicin	2	6
	DEB-TACE	Epirubicin	4	10
Wang et al[15]	cTACE	Irinotecan	3	9
	DEB-TACE	Irinotecan	8	19.5
Zhang et al[16]	cTACE	Pirarubicin	N/A	5
	DEB-TACE	Pirarubicin	N/A	12

Abbreviations: OS, overall survival; PFS, progression-free survival; others see **TABLE 3**

TABLE 5 Occurrence of adverse events

Adverse event	Studies, n	OR (95% CI)	*P* value	Heterogeneity	Favor
Increased ALT level	2[11,16]	1.21 (0.61–2.43)	0.59	$I^2 = 0\%$	–
Increased AST level	2[11,16]	1.24 (0.60–2.53)	0.56	Not applicable	–
Hyperbilirubinemia	3[11,15,16]	1.17 (0.61–2.25)	0.64	$I^2 = 0\%$	–
Hypoalbuminemia	2[11,16]	1.52 (0.77–3.02)	0.23	$I^2 = 7\%$	–

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; OR, odds ratio

meta-analysis, the DEB-TACE group exhibited a higher ORR than the *c*TACE group (56.3% vs 26.5%). However, the difference was not significant ($P = 0.13$), even after adjusting for heterogeneity ($P = 0.05$). This may be related to the fact that ORR was evaluated at different time points across studies. In some of them, ORR was assessed at 1 to 2 months post-treatment,[13-15] while it has been suggested that DEB-TACE requires at least 3 months to manifest its superior efficacy.[16] ICCs are characterized by poorer blood supply than HCCs, potentially contributing to worse overall clinical efficacy of TACE-based interventions in this patient population.

While no significant differences in pooled ORRs were noted in the present analysis, DEB-TACE outperformed *c*TACE in terms of DCR. There are several possible explanations for this result. For one, *c*TACE employs lipiodol as an embolic material. This agent is highly fluid, with limited embolization activity. In contrast, DEBs are nondegradable, flexible, and deformable. Their use as an embolic material can facilitate long-term embolization of tumor branches, triggering more extensive necrotic tumor cell death.[16] Additionally, relative to the short-acting nature of chemotherapeutic drugs delivered to the tumor during *c*TACE, utilization of DEBs can ensure persistent drug release.[16]

We showed that DEB-TACE was associated with superior OS and PFS outcomes, as compared with *c*TACE. This is in contrast with prior meta-analyses focusing on the efficacy of DEB-TACE in the management of HCC.[17,18] The higher OS and PFS rates observed in the individuals treated with DEB-TACE may be related to improved DCR in these patients. However, the OS end point was subject to significant heterogeneity, which may limit the reliability of our findings, emphasizing the need for additional, appropriately designed prospective RCTs to validate these results.

We found no discernible variations in the occurrence of AEs between the groups. As compared with the conventional approach, DEB-TACE entails the delivery of higher doses of chemotherapeutic drugs and results in higher local concentrations of these drugs in the target tumor, which may increase the risk of AE occurrence.[19] However, the ability of DEBs to mediate local drug release may be helpful in protecting against systemic toxicity.[20,21]

At present, radioactive stent insertion (RSI) is widely used for treating hilar cholangiocarcinomas.[22] The radioactive stent can both relieve jaundice and deliver brachytherapy to the tumor. However, ICC is a mass-like tumor; therefore, RSI is not a suitable treatment option.

The current meta-analysis has certain limitations. Firstly, most of the included studies were retrospective, which is associated with increased selection bias. Secondly, unbalanced patient numbers were evident for some of the studies, potentially leading to worsening of any selection bias. Lastly, treatment responses were assessed at different time points in the included studies, potentially leading to further bias.

CONCLUSIONS In summary, both chemoembolization strategies exhibited similar safety profiles. However, DEB-TACE outperformed *c*TACE in terms of therapeutic efficacy, highlighting the potential for broader application of DEB-TACE in the management of patients with inoperable ICC.

ARTICLE INFORMATION

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CONTRIBUTION STATEMENT F-FX conceived the concept of the study. S-RP and F-FX contributed to the design of the research. All authors were involved in data collection. X-WW and H-FZ analyzed the data. All authors edited and approved the final version of the manuscript.

AI STATEMENT Artificial intelligence was not used to write the article.

CONFLICT OF INTEREST None declared.

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