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Quantitative literature analysis on efficacy and safety of balloon-occluded transarterial chemoembolization for hepatocellular carcinoma

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Abstract

Aim To analyze the efficacy and safety of balloon-occluded transarterial chemoembolization (B-TACE) of hepatocellular carcinoma (HCC).

Methods We searched English databases, assessed the quality of the selected studies, analyzed the extracted data, tested heterogeneity of data, explored the resources of heterogeneity, and tested publication bias.

Results After inclusion and exclusion criterion, totally 7 studies included in our analysis. The numbers of complete response (CR) in B-TACE were significantly more than in Non B-TACE ($P = 0.003$). There were no significant difference in partial response (PR), stable disease (SD) and progressive disease (PD) between B-TACE and Non B-TACE. Moderate heterogeneity existed in CR and PR ($I^2 = 60\%$). Low heterogeneity existed in SD ($I^2 = 36\%$). Heterogeneity did not exist in PD ($I^2 = 0\%$). The numbers of treatment effect (TE) 4–1 in B-TACE were significantly more than in Non B-TACE, respectively ($P = 0.000007$, $P < 0.00001$). Heterogeneity did not exist in TE4 ($I^2 = 0\%$). Low heterogeneity existed in T3 - 1 ($I^2 = 48\%$). The numbers of post embolization syndrome(PES) in B-TACE were significantly more than in Non B-TACE, respectively($P = 0.000007$, $P < 0.00001$). There were no significant difference in adverse events (AEs) of grade 3 and 2 between B-TACE and Non B-TACE, respectively($P = 0.57$, 0.12). High heterogeneity existed in PES ($I^2 = 76\%$). Moderate heterogeneity existed in AEs of grade 2($I^2 = 57\%$). Heterogeneity did not exist in AEs of grade 3($I^2 = 0\%$).

Conclusion B-TACE was safe. It showed promising efficacy in achieving higher CR rates in short term compared to Non B-TACE.

Keywords Balloon-occluded transarterial chemoembolization, Hepatocellular carcinoma, Quantitative literature analysis

Introduction

TACE stands for transarterial chemoembolization, which is a procedure that involves injecting a mixture of chemotherapeutic drugs and iodized oil emulsion or drug-loaded microspheres through the tumor-feeding artery for embolization treatment [1]. Depending on the type of embolic agent used, it is mainly divided into conventional TACE (C-TACE) and drug-eluting bead TACE (D-TACE) [2]. C-TACE has become the first-line treatment for hepatocellular carcinoma(HCC) with intermediate stage based on The Barcelona Clinic Liver Cancer (BCLC) staging system [3]. Meanwhile, TACE is widely

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used in advanced HCC with vascular invasion or extrahepatic spread, especially popular in East Asia [4, 5].

However, hepatic arterial hemodynamics plays a crucial role in the treatment of HCC, especially during all type of TACE therapy. The hepatic arterial system includes two types of terminal hepatic arteries: one type accompanies the bile ducts as they penetrate the liver parenchyma, and the other is the"isolated artery"that penetrates the liver parenchyma directly without accompanying the bile ducts [6]. The presence of these two types of arteries may prevent the complete penetration of lipiodol emulsion or drug-loaded microspheres into the tumor, which could potentially lead to tumor recurrence and metastasis after repeated TACE treatment [7, 8].

With the advancement of interventional treatment equipment and concepts, Irie first reported balloon-occluded TACE (B-TACE) [9]. This method temporarily blocks the blood supply artery with a micro-balloon catheter, allowing the iodized oil emulsion to accumulate densely in the target tumor nodule, thereby improving the therapeutic effect based on the criteria of treatment effect (TE) on the target nodule established by The Japan Clinical Oncology Group (JCOG) [10, 11]. B-TACE has been widely used clinically in Japan, South Korea, and some European and American countries [12–14] and was proved better performance in tumor responses compared with C-TACE and D-TACE.

To date, large scale randomized controlled trials (RCT) are still lacking, and previous studies were almost retrospective. Based on these considerations, we aim to conduct a quantitative literature analysis, refers to meta-analysis, to evaluate the efficacy and safety of B-TACE for HCC.

Methods

Search strategy

We conducted a comprehensive literature search in database including PubMed, Cochrane Library and Excerpt Medica Database(EMBASE) up until September, 2024.

We used the following search terms with Medical Subject Headings (MeSH) and Title/Abstract and/or Keywords: “hepatocellular carcinoma” or “HCC”and “balloon-occluded transarterial chemoembolization”or “B-TACE”. All the data were available from published papers.

Inclusion and exclusion criterion

The studies were included with the following criterion: (1) the original research. (2) the participants in studies were human. (3) studies compared the efficacy and safety between B-TACE and non B-TACE. (4) tumor responses including complete response (CR), partial response (PR), stable disease (SD) and progressive disease (PD), post embolization syndrome (PES) and adverse events (AEs) were reported or could be calculated based on related data. (5) the language of studies were English.

The studies were excluded with the following criterion: (1) not clinical studies. (2) the data of studies were not tumor responses PES and adverse AEs. (3) data could not be extracted.

Data extraction and quality assessment

The titles and abstracts of potentially eligible studies were screened by two doctors independently. Then, another two doctors examined the full text to determine whether they could be included. One doctor extracted the data of included studies, including first author, country, publication year, study design, treatment, and patient number. One doctor assessed the qualities of included studies with the Newcastle–Ottawa scale [15].

Data analysis

We used software Review Manager 5.3 to analyze the data. The chi-square test and I^2 statistics were used to assess the heterogeneity [16, 17]. When a value of I^2 in section of [25%, 50%), [50%,75%) and ≥75%, it indicated low heterogeneity, moderate heterogeneity and significant heterogeneity, respectively. Subgroup and sensitivity analysis was performed to explore the sources of heterogeneity. Publication bias was evaluated using funnel plots [17]. For all analyses, $P < 0.05$ was considered statistical significance.

Results

Search strategy

After the search of databases, 36 of records were identified. 25 of records were remained after duplicating. 16 studies were assessed for eligibility, of which 9 studies were excluded with reasons. 7 studies had no control group, and 2 studies were unable to extracted data. Finally, a total of 7 articles were included in quantitative literature analysis [18–24] (Fig. 1).

Data extraction and quality assessment

We extracted data of included studies, containing first author, publication year, nation, study design, number of patients, therapeutic indicators of treatment and qualities of studies between B-TACE and Non B-TACE (Table 1). The scores of qualities of 7 included studies were all higher than 6, of which 1 was prospective study, and 6 were retrospective studies.

Data analysis

We compared the tumor responses including CR, PR, SD and PD in one month between B-TACE and Non B-TACE (Fig. 2). The number of CR in B-TACE was

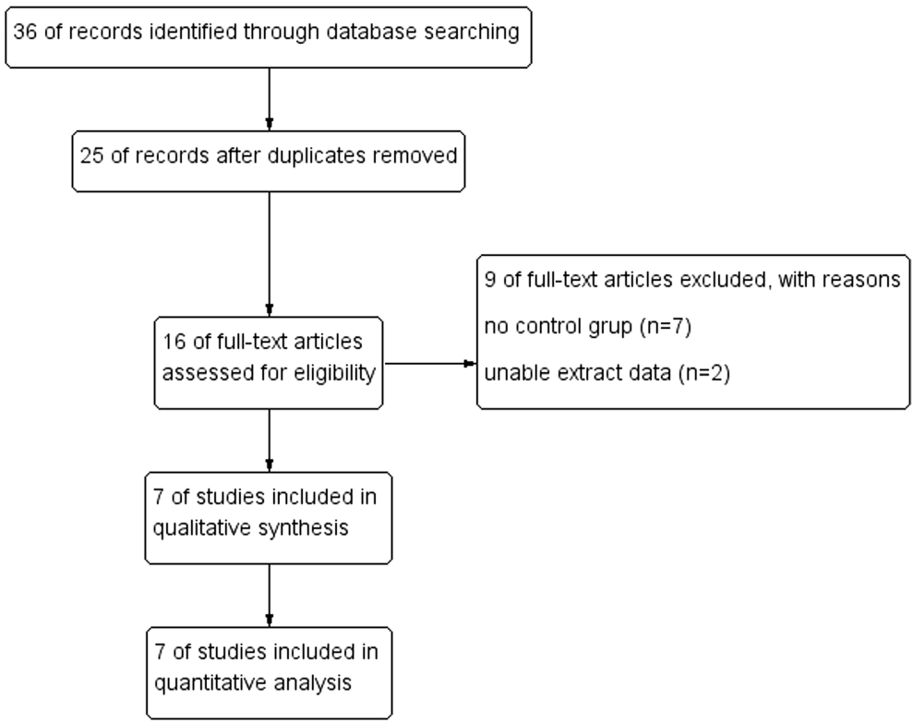

Fig. 1 Flow diagram

significantly more than in Non B-TACE ($P = 0.003$) (Fig. 2a). There were no significant difference in PR, SD and PD between B-TACE and Non B-TACE (Fig. 2b-d). Moderate heterogeneity existed in CR and PR ($I^2 = 60\%$). Low heterogeneity existed in SD ($I^2 = 36\%$). Heterogeneity did not exist in PD ($I^2 = 0\%$).

We compared the tumor responses including TE4,TE3 - 1 between B-TACE and Non B-TACE (Fig. 3). The numbers of TE4 (Fig. 3a) and TE3 - 1(Fig. 3b) in B-TACE were significantly more than in Non B-TACE, respectively ($P = 0.000007$, $P < 0.00001$). Heterogeneity did not exist in TE4 ($I^2 = 0\%$). Low heterogeneity existed in T3 - 1 ($I^2 = 48\%$).

We compared the PES and AEs between B-TACE and Non B-TACE (Fig. 4). The number of PES in B-TACE was significantly more than in Non B-TACE, respectively ($P = 0.000007$, $P < 0.00001$)(Fig. 4a). There was no significant difference in AEs of grade 3 and 2 between B-TACE and Non B-TACE (Fig. 4b,c), respectively ($P = 0.57$, 0.12). High heterogeneity existed in PES ($I^2 = 76\%$). Moderate heterogeneity existed in AEs of grade 2 ($I^2 = 57\%$). Heterogeneity did not exist in AEs of grade 3 ($I^2 = 0\%$).

In order to explore the sources of heterogeneity, we conducted the subgroup analysis. However, the sources of heterogeneity of CR and PR were not found. The numbers of selected studies about T3 - 1, PES and AEs were not enough to explore the sources of heterogeneity.

Figure 5 showed no publication bias was found.

Discussion

Our quantitative literature analysis, based on the procedure of meta-analysis, examined the efficacy and safety of B-TACE for HCC and yielded significant findings that underscored its potential advantages over Non B-TACE.

One of the key results of our analysis was that the CR rate in the B-TACE was significantly higher compared to the non B-TACE. This indicated that B-TACE enhanced the local control of tumors more effectively than traditional TACE, suggesting that the balloon occlusion technique allowed for better delivery and retention of chemotherapeutic agents within the tumor. The favorable CR rate was particularly important for patients with HCC, as achieving complete tumor ablation was associated with improved overall survival and reduced recurrence rates.

Despite the significant improvement in CR rate, our analysis did not reveal any notable differences in PR, SD, and PD rates between the two groups. Our results indicated that effectiveness of B-TACE in eliciting partial responses or controlling disease progression might be comparable to that of standard TACE. Consequently, while B-TACE presented an advantage in terms of

Table 1 Baseline characteristics of included studies

Study	Nation	Trail	Quality Score	Treatment	Patients Number	Sex (M/F)	MeanAge (Year)	Child Pugh (A/B/C)	ECOG PS (0/1/2)	BCLC Stage (A/B/C)	Virology (B/C/Other)	Cirrhosis Yes/No	AFP (mg/L) (≤ 400/> 400)	Tumor Number	Tumor Size (mm)	Indicators
Arai 2014	Japan	Retrospective	7	B-TACE	49	33/16	71.9	39/13/0	NA	16/33/0	1/41/7	NA	NA	NA	29	TE4,3,2,1,AEs
				C-TACE	48	39/14	69.9	37/11/0		37/11/0	4/36/8				24.5	
Ogawa 2016	Japan	Retrospective	7	B-TACE	33	19/14	74	24/7/2	NA	1/10/20	2/25/8	NA	NA	≥ 75	22	TE4,3,2,1
				C-TACE	28	20/8	74	7/1/20		0/7/19	0/18/10			≥ 53	24	
Irie 2016	Japan	Retrospective	7	B-TACE	28	22/6	72.5	17/11/0	NA	NA	5/17/6	NA	NA	36	39.2	TE4,3,2,1
				C-TACE	49	35/14	71.8	39/10/0			8/31/10			68	40.3	
Golfieri 2021	Italy	Prospective	8	B-TACE	91	75/16	68	67/24/0	NA	50/38/3	17/34/40	NA	NA	1.97	36	CR,PR,SD,PD,PES,AEs
				C-TACE	91	67/24	66	66/25/0		43/48/0	7/54/30			1.9	34	
Lucatelli 2021	Italy	Retrospective	7	B-TACE	22	19/3	65.9	15/7/0	NA	10/12	4/9/0	9/0	NA	35	NA	CR,PR,SD,PD
				D-TACE	127	112/15	68.6	79/48/0		84/43	22/66/0	39/0		191		
Rita 2021	Italy	Retrospective	7	B-TACE	91	75/16	68.59	67/24/0	NA	NA	NA	NA	NA	1.97	NA	CR,PR,SD,PD,PES,AEs
				C/D-TACE	91	80/11	67.62	72/17/2						2.08		
Chu 2023	Korea	Retrospective	7	B-TACE	32	23/9	64.9	28/4/0	31/1/0	NA	18/1/13	30/2	4/28	NA	NA	CR,PR,SD,PD
				C-TACE	32	22/10	65.2	25/7/0	30/2/0		18/0/14	29/3	7/25			

BCLC Barcelona Clinic Liver Cancer, *ECOG PS* Eastern Cooperative Oncology Group Performance Status, *TACE* Transarterial Chemoembolization, *B-TACE* Balloon-Occluded Transarterial Chemoembolization, *D-TACE* Drug-eluting bead Transarterial Chemoembolization, *C-TACE* Conventional Transarterial Chemoembolization, *TE* treatment effect, *CR* complete response, *PR* partial response, *SD* stable disease, *PD* progressive disease, *PES* post embolization syndrome, *AEs* adverse events, *NA* Not available

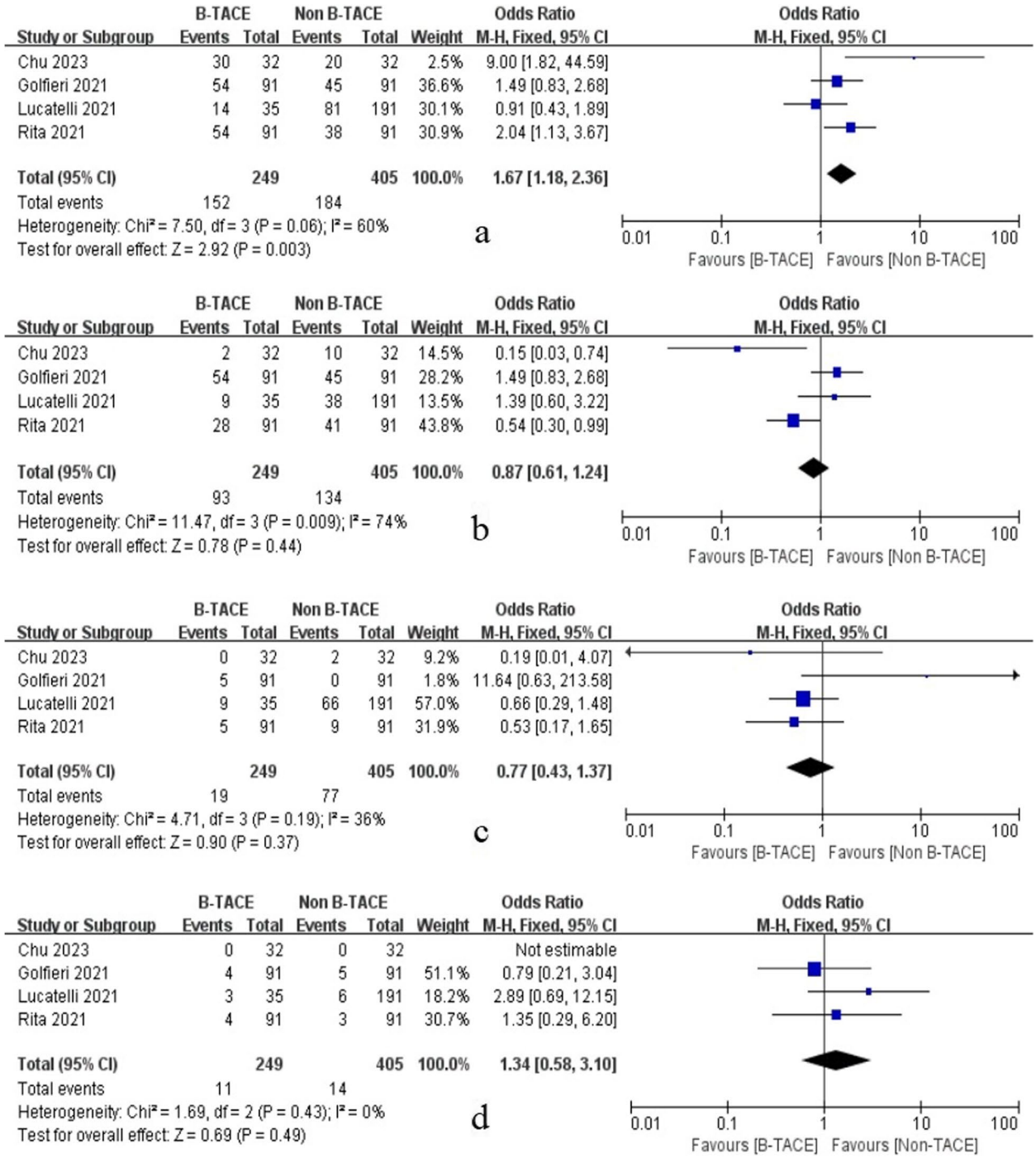

Fig. 2 **a** Complete response(CR) between B-TACE and Non B-TACE. **b** Partial response(PR) between B-TACE and Non B-TACE. **c** Stable disease(SD) between B-TACE and Non B-TACE. **d** Progressive disease(PD) between B-TACE and Non B-TACE

achieving CR, further researches were needed to explore its overall impact on disease stabilization and management. Moreover, our results demonstrated that the prevalence of treatment efficacy grades TE4 and TE3 - 1 in the B-TACE were significantly higher than in the Non B-TACE. These findings further supported the efficacy of B-TACE in inducing higher degrees of tumor necrosis [9]. Such results suggested that B-TACE might be especially effective for patients with more aggressive

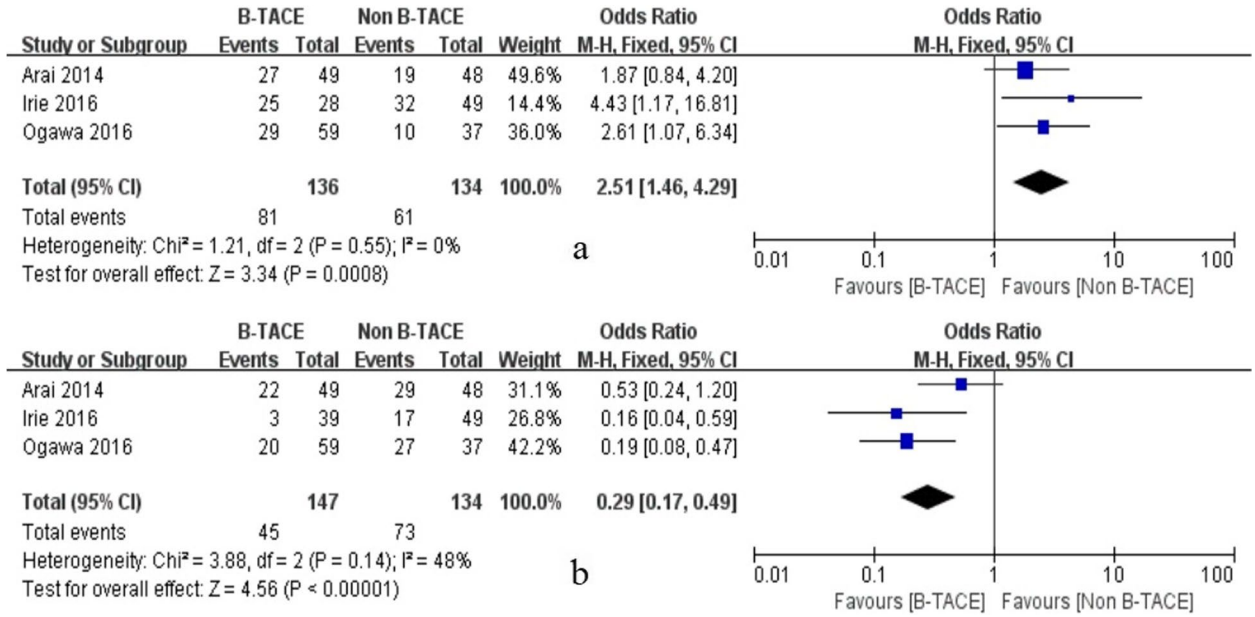

Fig. 3 **a** Treatment effect 4(TE4) between B-TACE and Non B-TACE. **b** Treatment effect 3–1(TE3 - 1) between B-TACE and Non B-TACE

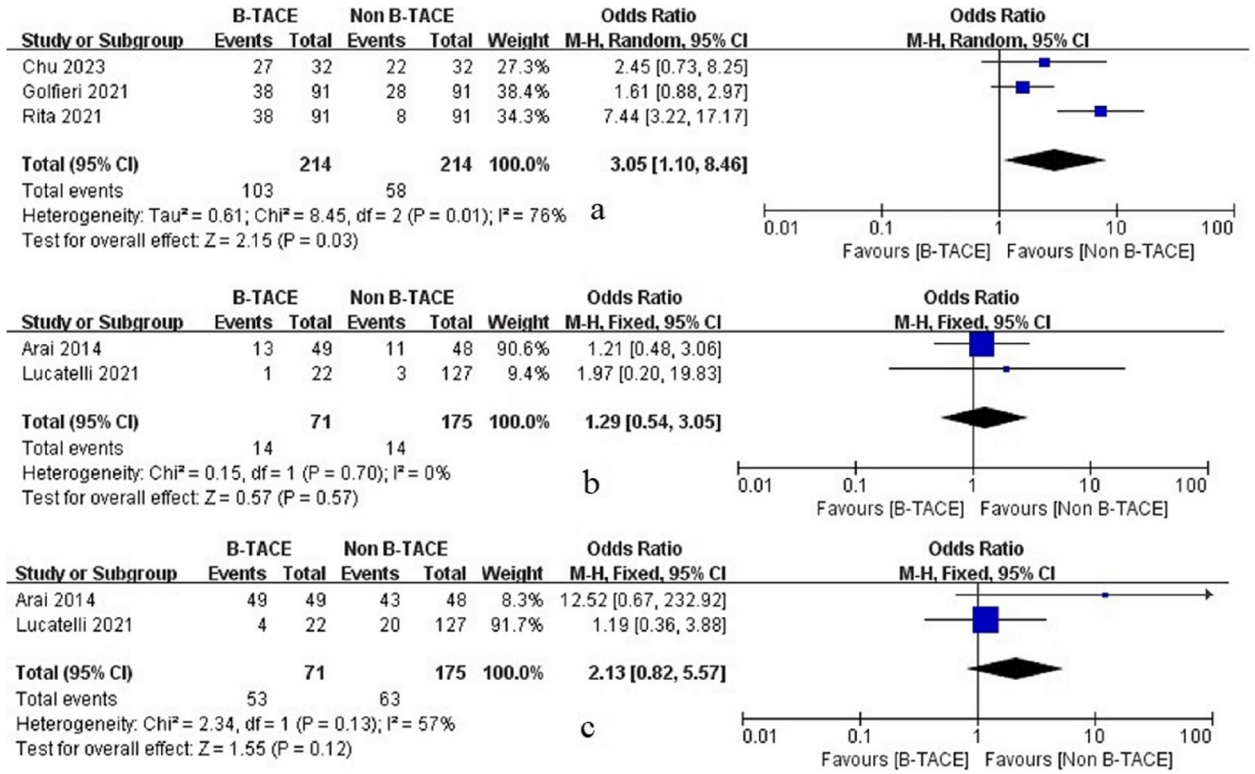

Fig. 4 **a** Post embolization syndrome(PES) between B-TACE and Non B-TACE. **b** Adverse events(AEs) of grade 3 between B-TACE and Non B-TACE. **c** Adverse events(AEs) of grade 2 between B-TACE and Non B-TACE

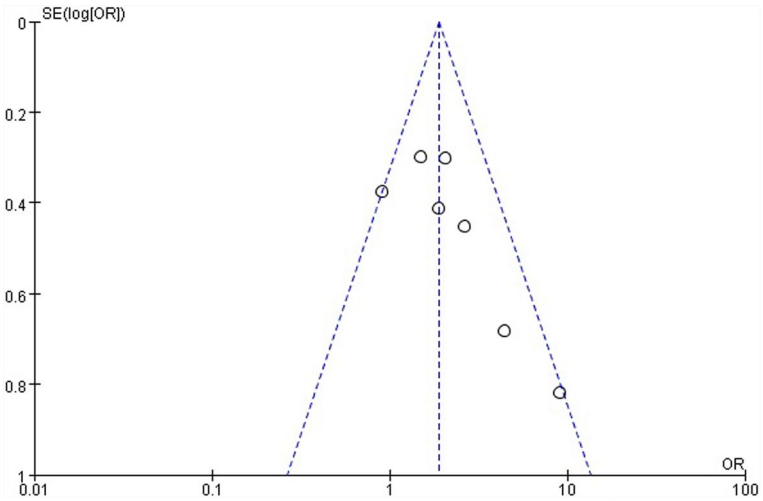

Fig. 5 Publication bias

tumor characteristics, allowing for tailored treatment approaches depending on individual disease profiles.

The other key results of our analysis was that the incidence of PES after B-TACE was higher than Non B-TACE, and no significant difference of AEs in grade 2,3 in two groups, suggesting that while B-TACE led to better tumor responses, it did not appear to increase the risk of significant complications compared to traditional methods. The ability to improve efficacy without compromising safety made B-TACE a compelling option for managing HCC. However, it remained essential for clinicians to monitor patients for any potential complications and ensured supportive measures were in place.

Due to the small number of studies, we were unable to further investigate the observed heterogeneity through subgroup analysis. There were some underlying reasons interpreting the heterogeneity in both tumor responses and PES. First, uneven tumor size might be the factor and influenced oncological response and PES. Larger lesions (30–50 mm) showed higher CR rate compared with small lesions (< 30 mm) [21, 24]. The desired effect of embolization accompanied with higher degrees of tumor necrosis, which led to high incidence of PES. Second, the level of superselective embolization might be another factor. B-TACE based on desired superselective technique induced embolic materials compact accumulated within the tumor and in the surrounding parenchyma, which called embolization segmentectomy [20, 25, 26], and also led to higher tumor responses and incidence of PES. Third, different chemotherapeutics mixed with iodized oil also influenced tumor responses. Shirono showed that epirubicin with B-TACE was more effective than miriplatin in prolonging time to progression (TTP), and achieving TE4 for HCC patients [27]. Additionally, Golfieri found that C-TACE and D-TACE based on balloon-occlude demonstrated similar tumor responses, with a slightly better CR rate for C-TACE with no statistical significance [23]. The equivalence in efficacy between C-TACE and D-TACE was demonstrated in previous studies [28, 29]. Consequently, under balloon occlusion, C-TACE and D-TACE were also almost equivalent. Fourth, the baseline characteristics including BCLC stage, virology, cirrhosis and AFP level in selected studies also could not be ignored as sources of heterogeneity in our analysis. Hatanaka found that the AFP level was significantly relevant to the tumor response [30]. However, many other researches did not conduct subgroup analysis or variables analysis to verify the efficiency of B-TACE based on various baseline characteristics of patients.

Future researches should focus on conducting prospective, multicenter clinical trials, including various baseline characteristics (BCLC stage, virology and cirrhosis, etc.), longer follow-up periods, to verify the efficacy and safety of B-TACE. Besides, owing to lack of standardized procedure of B-TACE, we should pay attention to optimal technical aspects of B-TACE procedures (balloon size, occlusion time, etc.). Furthermore, we should attach importance to exploring the possibility of B-TACE in combination with other treatment modalities, such as ablation therapy, targeted therapy, and immunotherapy, and its role in different subtypes of HCC and at different clinical stages.

Our study has some limitations. First, since our analysis was almost based on retrospective studies, there might be selection bias and an inability to explore the sources of heterogeneity. Secondly, the limited sample size of the studies we analyzed affected the generalizability of the outcomes. Third, we should not ignore the potential

publication bias, even if our results showed no significant publication bias.

In conclusion, B-TACE showed promising efficacy in achieving higher CR rate in short term with a comparable safety profile to traditional TACE.

Abbreviations

B-TACE	Balloon-Occluded Transarterial Chemoembolization
HCC	Hepatocellular carcinoma
CR	Complete response
PR	Partial response
SD	Stable disease
PD	Progressive disease
TE	Treatment effect
PES	Post embolization syndrome
AEs	Adverse events
BCLC	Barcelona Clinic Liver Cancer
JCOG	The Japan Clinical Oncology Group
RCTs	Randomized controlled trials
MeSH	Medical Subject Headings
TTP	Time to progression

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Authors' contributions
Wei fan sui wrote the main manuscript text and prepared all figures and tables. All authors reviewed the manuscript.
All authors reviewed the manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
All authors consented to publication.

Competing interests
The authors declare no competing interests.

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