Review Article

Efficacy and features of balloon-occluded transarterial chemoembolization for hepatocellular carcinoma: a narrative review

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Background and Objective: Systemic therapy for hepatocellular carcinoma (HCC) is recommended in transarterial chemoembolization (TACE)-refractory and unsuitable cases. In Japan, TACE is broadly classified into conventional TACE (C-TACE), balloon occluded TACE (B-TACE), and drug-eluting beads TACE. However, the type of TACE recommended for TACE-refractory or unsuitable cases has not been elucidated, and a targeted approach for individual cases and appropriate TACE selection is important. B-TACE is considered a valuable therapeutic option in the management of HCC. The technique involves the precise placement of a microcatheter with a balloon into the target hepatic artery, followed by selective occlusion of the hepatic artery, including tumor-feeding vessels, using the balloon. By leveraging the hemodynamic changes resulting from arterial occlusion, B-TACE enables effective accumulation of chemotherapeutic agents within the tumor. Incorporating B-TACE into the treatment strategy for HCC is of utmost importance. Therefore, this article provides an overview of the technique.

Methods: A comprehensive review of all available literature in the English language through December 1, 2023 utilizing PubMed was conducted.

Key Content and Findings: In the intermediate stage, TACE and systemic therapy play complementary roles, and it is important to select a treatment strategy that considers tumor status and hepatic reserve. However, no study has investigated the various types of TACE in the treatment of such patients. Currently, TACE in Japan is broadly classified into C-TACE, B-TACE, and drug-eluting beads TACE (DEB-TACE). This article outlines the evolution of B-TACE for HCC. We identified retrospective and prospective studies evaluating B-TACE. In this review, we evaluate data on B-TACE for HCC.

Conclusions: In the era of systemic therapy, B-TACE may play a complementary and synergy effect role.

Keywords: Hepatocellular carcinoma (HCC); balloon occluded transarterial chemoembolization (B-TACE); conventional transarterial chemoembolization (C-TACE); hemodynamic

Received: 06 December 2023; Accepted: 31 March 2024; Published online: 20 June 2024.

doi: 10.21037/tgh-23-117

View this article at: https://dx.doi.org/10.21037/tgh-23-117

Introduction

Background

Hepatocellular carcinoma (HCC) accounts for >90% of primary liver tumors and is the leading cause of cancer death worldwide (1). In cases of large tumor size or advanced HCC, hepatectomy is considered as the only curative treatment. However, even after radical hepatectomy, the recurrence rate for HCC is high, with postoperative recurrence in 50% and 80% of patients at 2 and 5 years, respectively (2,3). Furthermore, intrahepatic recurrence is inevitable, even with local ablation (4,5). There are two

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Table 1 Narrative review search methodology

Items	Specification
Date of search	December 1, 2023
Databases and other sources searched	PubMed
Search terms	All terms were placed in the context of B-TACE, HCC
Timeframe	All published articles up to December 1, 2023
Inclusion criteria	Articles that included B-TACE and HCC
Selection process	The study selection was performed and reviewed by T.I. References of articles were further reviewed to identify possible sources

B-TACE, balloon-occluded transarterial chemoembolization; HCC, hepatocellular carcinoma.

types of HCC recurrence: intrahepatic metastasis (IM), which is self-explanatory, and multicentric carcinogenesis (MC), in which a completely different clone of HCC arises due to a preexisting liver injury caused by the hepatitis virus or other factors. Intrahepatic recurrence accounts for >90% of the recurrent forms, and treatment is important for intrahepatic recurrent lesions.

To prevent recurrence, Togo *et al.* described the possibility of background liver treatment for prevention of MC and hepatic infusion for IM, with the use of both transarterial chemoembolization (TACE) and transarterial chemoinfusion (TACI) expected in the systemic therapy era (6).

In recent years, systemic drug therapy using molecular-targeted drugs and immune checkpoint inhibitors has made remarkable progress, with proven efficacy and safety in managing HCC. The development of systemic drug therapy has changed the indications for conventional local therapy, with the indications for interventional radiology (IVR) becoming much stricter in particular. Here, we review the evolution of B-TACE, which has been performed mainly in Japan, and the role of IVR in the pharmacotherapy era. The author presents this article in accordance with the Narrative Review reporting checklist (available at https://tgh.amegroups.com/article/view/10.21037/tgh-23-117/rc).

Methods

A comprehensive review of all available literature in the English language through December 1, 2023 utilizing PubMed was conducted. Our search was limited to HCC and B-TACE. *Table 1* includes further methodology details of how our search was conducted.

Transition of TACE indications

The Barcelona Clinic Liver Cancer (BCLC) staging system, which was established based on consensus at the European Association for the Study of the Liver (EASL) meeting held in Barcelona in 2000, is widely used worldwide as a staging and treatment algorithm for HCC (7). Initially, in the BCLC staging system, TACE was considered the standard treatment for intermediate and advanced stage HCC without portal invasion. However, in the 2022 revision, the intermediate stage is divided into three groups: those meeting the extended Milan criteria, those with clear tumor hyperstaining, preserved portal vein blood flow, and suitable tumor artery selection, and those with diffuse spread or widespread infiltration in both lobes. TACE is recommended for patients with clear tumor hyperstaining, preserved portal vein blood flow, and feasible tumor artery selection (8).

Advancement in TACE procedure

TACE is a therapeutic approach that was initially reported in the 1980s by Yamada *et al.* and has undergone development and improvements since then (9). In the early 2000s, the survival benefits of TACE were demonstrated in two randomized controlled trials (10,11). In Japan, the conventional TACE (C-TACE) technique has been developed, which involves the ultra-selective catheterization of tumor-feeding vessels, injection of a mixture of cytotoxic anticancer drugs and Lipiodol, and subsequent embolization of the tumor vasculature using gelatin sponge or other embolic drugs to induce blood flow obstruction and necrosis of tumor cells.

However, the use of this treatment posed a risk of

impairing liver reserve function since it also causes a certain degree of reduced blood flow to healthy liver cells.

In 2014, microspheres (beads), which are spherical embolization materials, were approved in Japan for TACE, as opposed to C-TACE. TACE using drug-eluting beads (DEB-TACE) impregnated with anticancer drugs has also been accepted as a new therapeutic strategy. The notable feature of this method is the use of 100–500 μm microspherical embolization material instead of the 1–2 mm embolization materials used in C-TACE. DEB-TACE has shown short-term results that anticancer drugs remain in high concentrations in tumors and do not flow into peripheral blood, so they have few systemic side effects caused by anticancer drugs and are highly effective in treatment (12).

Since 2008, Irie *et al.* have reported the use of a microballoon catheter in TACE to prevent the migration or leakage of embolic materials, addressing the challenges associated with conventional TACE. In 2011, the microballoon catheter was introduced in Japan, leading to the evolution of B-TACE (13).

What is B-TACE?

B-TACE technique

First, the hepatic artery is selectively occluded with a micro balloon catheter, and a lipiodol emulsion is injected while reducing the arterial pressure. As a result, the viscosity of the solution and the smaller pressure gradient between the arterial and portal veins cause early stagnation of arterial blood flow in the normal liver parenchyma.

However, tumor vessels have low vascular resistance and relatively preserved blood flow, limiting the influx of lipiodol into the normal liver parenchyma and increasing lipiodol accumulation in the tumor.

Even when the hepatic artery is occluded, peripheral blood flow is maintained through anastomotic branches, the peribiliary plexus, and isolated arteries. Therefore, achieving a good occlusion effect is indicated by a balloon-occluded arterial stump pressure (BOASP) of <64 mmHg. A lower BOASP is considered to facilitate the injection of more lipiodol and embolic material into and around the tumor (13).

The balloon also prevents the backflow of the anticancer drug and embolization material, reducing the risk of leakage outside the target node. Additionally, the balloon allows pressure to be applied to the occluded distal area during the infusion, enhancing the therapeutic effect by pressurizing lipiodol and embolization material into the tumor (14). *In vivo* study, a better embolization profile of oncological intra-arterial interventions performed with balloon micro-catheter regardless of the embolic agent employed (15).

Based on these factors, it is expected that balloon occlusion will primarily offer the benefit of drug accumulation through hemodynamic modifications (13). B-TACE is also expected to reduce the number of selected vessels, enabling efficient drug delivery thanks to the pressure gradient. However, the treatment efficacy is greatly influenced by the positioning of the balloon and the injection pressure of the lipiodol emulsion. Matsumoto *et al.* compared BOASP between two groups: the group in which a microballoon catheter was selected up to the lobar hepatic artery ("non-targeted" group) and the group in which it was selected up to the subsegmental or segmental hepatic artery ("selective" group). Based on their report stating that the BOASP in the "non-targeted" group is significantly greater than that in the "selective" group, it is considered important to select the microballoon catheter to the subsegmental or segmental hepatic artery region during the B-TACE procedure (16).

While the outcomes and indications for B-TACE are not fully elucidated, considerations regarding its indications have been made based on factors such as tumor size, number, and location. B-TACE is expected to be effective in patients for whom selectively inserting microcatheters is challenging or in cases where adequate results were not achieved with C-TACE (16,17).

Analyses of the hemodynamic usefulness of B-TACE

Sugimoto *et al.* reported that contrast-enhanced ultrasound can predict the accumulation of lipiodol emulsion and determine its therapeutic effect (18). Kakuta *et al.* observed that balloon occlusion at the third branch enhances the stump pressure more effectively than at the first branch (19).

Based on stump pressure data, non-selective B-TACE which is defined as the selecting lobar hepatic artery should not be performed. Additionally, the presence of anastomosis and a communicating arcade in A1, A4, and A8 suggests the possibility that B-TACE may be rather inefficient in these areas (16).

However, the local recurrence rate shows a significant difference depending on whether the computed tomography (CT) value immediately after B-TACE is above average. It is crucial to obtain sufficient CT values to reduce local recurrence. Ishikawa *et al.* reported that multivariate analysis

Table 2 Summary of studies of therapeutic effect of balloon-occluded transarterial chemoembolization for hepatocellular carcinoma

Reference	Procedure	No. of patients	Therapeutic effect
Arai *et al.* (25)	B-TACE	49	TE4: 55.1%, TE3: 38.8%, TE2: 4.1%, TE1: 2.0%
	C-TACE	48	TE4: 39.6%, TE3: 33.3%, TE2: 25.0%, TE1: 2.1%
Ogawa *et al.* (26)	B-TACE	33	TE4: 49.2%
	C-TACE	28	TE4: 27.0%
Kim *et al.* (27)	B-TACE	60	CR: 75.0%, PR: 25.0%
	C-TACE	46	CR: 73.0%, PR: 27.0%
Golfieri *et al.* (28)	B-TACE	91	CR: 59.3%, PR: 30.8%, SD: 5.5%, PD: 4.4%
	C-TACE	91	CR: 49.5%, PR: 45.1%, SD: 0.0%, PD: 5.7%
Irie *et al.* (29)	B-TACE	28	TE4: 89.3%, TE3: 10.7%, TE2: 0.0%, TE1: 0.0%
	C-TACE	49	TE4: 65.3%, TE3: 20.4%, TE2: 6.1%, TE1: 8.2%
Maruyama *et al.* (30)	B-TACE	50	LE ratio: 4.48±2.08 (1.8–9.91)
	C-TACE	50	LE ratio: 3.42±1.57 (1.32–7.35)

Data are presented as mean ± standard deviation (range). B-TACE, balloon-occluded transarterial chemoembolization; C-TACE, conventional transarterial chemoembolization; TE, treatment effect; CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease; LE ratio, the lipiodol emulsion concentration ratio of hepatocellular carcinoma to embolized liver parenchyma.

showed that only the CT value (>373.55 Hounsfield unit) immediately after B-TACE with MPT [hazard ratio (HR) 0.11; 95% confidence interval (CI): 0.01–0.98; P=0.048] was the significantly correlated with local recurrence (20). While B-TACE is expected to be effective, digital subtraction angiography alone may not determine its effectiveness in all patients. If the pixel value decreases under occlusion, B-TACE may not necessarily be effective. Therefore, it is important to measure the pixel values using cone-beam CT before and after intraoperative balloon occlusion to differentiate between these cases (21,22).

Additionally, Yoshimatsu *et al.* reported a poor treatment effect when the tumor occupied the central area and when computed tomographic hepatic angiography (CTHA) with balloon occlusion showed insufficient staining (23). Asayama *et al.* reported a poor treatment effect when CTHA with balloon occlusion was performed with coronal staining, no coronal staining, or reduced perfusion defects compared to normal CTHA (24). They also found that CTHA with reduced perfusion defects was less effective than CTHA without coronal staining, CTHA with coronal staining, or CTHA with normal staining.

As mentioned earlier, various methods have shown potential in predicting the therapeutic effect of B-TACE. When performing B-TACE, it is of utmost importance to incorporate intraoperative image diagnosis, including not only digital subtraction angiography but also contrast-enhanced ultrasound, cone-beam CT, or CTHA.

The efficacy of B-TACE and its comparison with C-TACE

Ishikawa *et al.* reported a local recurrence rate of 11.1% at 6 months and 26.2% at 12 months for HCC treated with B-TACE, with the CT value immediately following B-TACE being a significant factor in local recurrence (20). *Table 2* presents the efficacy of B-TACE, demonstrating its superior antitumor effect on target nodules compared to C-TACE. Arai *et al.* compared B-TACE and C-TACE in patients with single-lesion HCC and found that the B-TACE group received a significantly higher dose of miriplatin, resulting in a significantly better antitumor effect (25). Additionally, Ogawa *et al.* reported a significantly higher percentage of treatment effect 4 (TE4) with B-TACE, indicating a better antitumor effect (26).

These consistent findings highlight that B-TACE allows for greater intratumoral injection of miriplatin and lipiodol, leading to a more favorable therapeutic outcome in target nodules compared to C-TACE. Factors associated with treatment efficacy, including the appearance of new lesions and enlargement of target nodules, include the number of tumors (HR 4.44, 95% CI: 1.26–15.7, P=0.02) and α-fetoprotein (AFP) levels (HR 11.40, 95% CI: 2.75–46.9,

P=0.001). However, Minami *et al.* reported no benefit of B-TACE in the treatment of uncountable multiple HCC, with 9 out of 10 patients experiencing progressive disease (31). Further investigation is needed to validate these findings in future studies.

Kawamura *et al.* achieved TE4 in nodules with irregular ring enhancement and emphasized its usefulness for classically hyper-vascularized tumors (32). Kim *et al.* reported a high response rate with cisplatin-based B-TACE, even in C-TACE-refractory, multiple, and BCLC-C patients (27). Propensity score matching analysis revealed that B-TACE had a higher initial complete response (CR) rate than C-TACE in treating single HCC larger than 30 mm, with a significantly higher initial CR rate after one session of treatment (33).

In some cases, a double platinum therapy combining miriplatin and cisplatin has shown favorable outcomes (34). Shirono *et al.* compared the use of anthracycline-based drugs in B-TACE and found higher TE4 achievement rates with epirubicin-B-TACE compared to miriplatin-B-TACE (35). Lucatelli *et al.* observed higher response rates at 1 month and 3–6 months with CR rates of 44.8% and 52.9%, respectively, and partial response (PR) rates of 55% and 23.5%, respectively (36).

The evaluation also considered tumor size, and Golfieri *et al.* compared B-TACE and C-TACE to assess the size range in which the two techniques provided higher rates of CR and objective response (OR) in a single session. In intermediate-sized HCCs (30–50 mm), B-TACE showed a significant superiority in achieving a CR (72.3% *vs.* 54.1%, respectively; P=0.047) (17).

Adverse effect and prospect of B-TACE

B-TACE is a treatment method in which anticancer drugs or embolic agents are pressure-injected while occluding with microballoons. Its aim is to minimize damage to normal liver parenchyma caused by reflux, by preventing the backflow of drugs (37). In Japan, miriplatin, known for its minimal vascular damage, is primarily used as the anticancer drug. Miriplatin has been found to cause less vascular injury compared to other anticancer drugs and restricts drug influx into normal liver tissue through hemodynamic changes (25,26). Considering these factors, it is predicted that B-TACE has fewer complications or is equivalent to C-TACE in terms of safety. B-TACE is safe and effective, achieving higher CR rates than non-B-TACE. Hence, patients undergoing B-TACE had a significantly lower retreatment rate within the first 6 months but higher post-embolization syndrome rates (28).

Several studies have shown that the occurrence of complications does not significantly differ between B-TACE and C-TACE, suggesting their equivalent safety profiles. However, no clinical symptoms of grade 3 or higher severity were observed, and serum ALT levels returned to baseline within 1 month in all patients. Nevertheless, there have been reports of a significant increase in ALT immediately after treatment.

Depending on the case, favorable outcomes can be expected, such as B-TACE being safer than non-B-TACE methods like C-TACE and DEB-TACE, with a higher CR rate and a longer local recurrence-free (LRF) period. Considering these factors, B-TACE is anticipated to continue being performed consistently.

Regarding anthracycline B-TACE, while the response rate is increasing, there have been limited studies comparing miriplatin and anthracyclines in terms of safety, and further investigation is necessary. Anthracyclines, including epirubicin, are generally considered to cause significantly induce more vascular damage compared to miriplatin (29,38). There is also a risk of drug and embolic substances entering the vascular plexus around the bile ducts, which is not addressed by selective C-TACE. If this is confirmed in future studies, it would suggest the need for a safer treatment strategy.

TACE has previously predominated in the intermediate stage; however, with the development of pharmacotherapy, the indications for TACE have narrowed. Propensity matching study recently revealed that in HCCs of 30–50 mm, B-TACE should be preferred to cTACE, whereas in smaller nodules (<30 mm), cTACE can suffice in achieving a good CR rate (17,30). The statistically significant lower re-treatment rate of the B-TACE cohort after a single procedure reduced the risk of complications due to multiple TACE, which could worsen the patient prognosis (30).

In comparing B-TACE, C-TACE, and DEB-TACE, the LRF periods of nodules with complete necrosis (TE4) obtained the longest with B-TACE, suggesting that B-TACE should be used to achieve a radical cure in patients with HCC (39). Hence, B-TACE showed a trend of better oncological response over DEM-TACE with and longer TTR with a similar adverse events rate, in patients presenting with larger tumors (40). In a comparison of the safety between B-TACE and DEB-TACE, Lucatelli *et al.* reported no significant difference in adverse effects compared to DEB-TACE (40) (*Table 3*). However, they

Table 3 Summary of adverse effect balloon-occluded transarterial chemoembolization for hepatocellular carcinoma

Reference	Procedure	No. of patients	Adverse effect
Arai *et al.* (25)	B-TACE	49	Elevation of ALT grade 3: 14.3%, P<0.05
	C-TACE	48	Elevation of ALT grade 3: 8.3%
Kim *et al.* (27)	B-TACE	60	Post-embolization syndrome major: 6.7%, minor: 83.3%, NS
	C-TACE	46	Post-embolization syndrome major: 1.7%, minor: 78.3%
Lucattelli *et al.* (40)	B-TACE	22	All adverse events grade 3: 4.5%, NS
	DEB-TACE	127	All adverse events grade 3: 2.4%

B-TACE, balloon-occluded transarterial chemoembolization; C-TACE, conventional transarterial chemoembolization; DEB-TACE, drug-eluting beads transarterial chemoembolization; ALT, alanine aminotransferase; NS, not significant.

observed a high antitumor effect in large HCCs treated with DEB-TACE.

Furthermore, as a multidisciplinary treatment with ablation therapy, B-TACE contributes to safe and extensive local control (41).

Conclusions

The evolution of B-TACE and its current indications are reviewed. TACE has previously predominated in the intermediate stage; however, with the development of systemic therapy, the indications for TACE have narrowed. Furthermore, it is important to consider the synergistic combination of systemic therapy and B-TACE to maximize the therapeutic effect. In the era of systemic therapy, B-TACE may play a complementary role and synergy effect role.

Acknowledgments

I would like to thank Editage (www.editage.com) for English language editing.
Funding: None.

Footnote

Reporting Checklist: The author has completed the Narrative Review reporting checklist. Available at https://tgh.amegroups.com/article/view/10.21037/tgh-23-117/rc

Peer Review File: Available at https://tgh.amegroups.com/article/view/10.21037/tgh-23-117/prf

Conflicts of Interest: The author has completed the ICMJE uniform disclosure form (available at https://tgh.amegroups.com/article/view/10.21037/tgh-23-117/coif). The author has no conflicts of interest to declare.

Ethical Statement: The author is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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doi: 10.21037/tgh-23-117
Cite this article as: Ishikawa T. Efficacy and features of balloon-occluded transarterial chemoembolization for hepatocellular carcinoma: a narrative review. Transl Gastroenterol Hepatol 2024;9:48.