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Original Article

Comparative outcomes of DEB-TACE and conventional TACE in Hepatocellular Carcinoma: Current evidence and future perspectives

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Abstract

One of the three main cancer types linked to mortality, hepatocellular carcinoma (HCC) is the sixth most widespread form of cancer and frequently arises in individuals with underlying liver cirrhosis. Given that 3–5% of cirrhotic patients develop HCC annually, routine monitoring through ultrasound is essential. The staging system for Barcelona Clinic Liver Cancer (BCLC) is frequently used to help choose the best course of treatment. Definitive treatments like liver resection or Patients with early-stage illness are typically candidates for transplantation., while transarterial chemoembolization (TACE) is commonly employed as the primary therapy for individuals with intermediate-stage HCC. TACE includes three main approaches: Drug-eluting bead TACE (DEB-TACE), conventional TACE (c-TACE), and degradable starch microsphere TACE (DSM-TACE). c-TACE employs a chemotherapeutic mixture based on lipiodol, which is followed by embolization. DEB-TACE enables more controlled drug release and limits systemic toxicity, while DSM-TACE provides temporary embolization and remains under investigation. Technique selection depends on tumor burden, liver function, and treatment intent. Comparative studies between c-TACE and DEB-TACE have yielded mixed results. Some randomized trials and meta-analyses report no significant differences in survival or tumor response, though DEB-TACE may offer safety advantages in patients with portal vein thrombosis or compromised liver function. Early clinical trials in China showed that DEB-TACE had favorable pharmacokinetics, low toxicity, and promising tumor responses. Common complications, including post-embolization syndrome, were reported at similar rates across both methods. While neither method has shown consistent superiority, DEB-TACE may provide slight clinical benefits in select subgroups.

Keywords: DEB-TACE; Conventional TACE; Hepatocellular Carcinoma

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Introduction

Hepatocellular carcinoma (HCC) is the world's third leading cause of cancer mortality and a significant cause of death among individuals with cirrhosis. In cirrhosis patients, yearly incidence of HCC ranges from 3% to 5%, making regular screening essential for early tumor detection within this group at high risk. Ultrasound (US) remains the preferred method for surveillance owing to its affordability, non-invasive nature, and reasonable sensitivity typically between 60% and 80% when performed by skilled operators. Over time, numerous staging systems for HCC have emerged to direct treatment strategies, typically integrating key elements like tumor burden, hepatic functional reserve, patient performance status, and suitable treatment modalities. Among these, the Barcelona Clinic Liver Cancer (BCLC) system is the most widely recognized and utilized globally. It categorizes patients based on disease progression and helps match them with the most suitable treatments. Treatment selection relies on several considerations, including tumor size and spread, hepatic function, and overall patient condition. Curative and non-curative treatment modalities may involve liver transplantation and surgical removal, local ablative procedures, transarterial chemoembolization (TACE), and systemic therapies. Management should always involve a multidisciplinary team to ensure optimal decision-making. Patients with adequate liver function are generally suitable candidates for liver resection, especially those with a single, less than 2-cm tumor. and no signs of portal hypertension when cirrhosis and portal hypertension are present in patients with early-stage HCC (BCLC stage 0 or A), liver transplantation is typically regarded as the best choice for treatment. Before liver transplantation, loco regional therapies such as microwave ablation (MWA) and radiofrequency ablation (RFA) are commonly used for individuals who are ineligible for surgical intervention. They can also serve as a bridge method. Transarterial procedures including transarterial radioembolization (TARE) and transarterial chemotherapy (TACE) are widely used as conventional treatments for patients with intermediate-stage HCC. For patients with unrespectable tumors, stereotactic body radiation treatment (SBRT) provides an additional choice, providing targeted tumor destruction via the introduction of high-precision, high-dose radiation. In advanced HCC cases characterized by portal vein involvement or distant metastasis, systemic treatment with sorafenib, an oral multikinase inhibitor, has demonstrated a survival benefit. [1]

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For intermediate-stage HCC (BCLC-B), TACE is the recommended first-line treatment, according to AASLD and EASL guidelines, which adheres to the BCLC staging method, demonstrating its standing as a proven and successful treatment. This stage characterizes patients (Child-Pugh A/B) with maintained liver function and ECOG performance status 0, and large or multinodular tumors confined to the liver. Evidence indicates TACE improves survival in appropriately selected patients with sufficient hepatic reserve. Furthermore, TACE can be utilized in cases of early-stage HCC (BCLC-0/A) when surgical resection or ablation is unsuitable, or as a bridging therapy prior to liver transplantation. [3]

Different TACE Types

1. Conventional TACE (c-TACE)

The frequently employed c-TACE technique involves introducing a chemotherapeutic drug into the artery supplying blood to the tumour directly in the form of an oil-in-water (OWE) or water-in-oil (WOE) emulsion, then administering an embolic material to interrupt the blood flow. While c-TACE has been extensively used and has demonstrated efficacy in managing unresectable HCC, its limitations include inconsistent drug

distribution and variable patient response. Recent findings from a randomized controlled trial indicated that although c-TACE may result in greater liver injury, its localized therapeutic impact is less than that of DEB-TACE. Nonetheless, six randomized controlled trials were meta-analyzed, and the results showed no discernible difference between the two methods. [4]

Research indicates that WOE has more potent embolic effects than OWE. When enough WOE accumulates, the tumor's drainage pathways may Permit the amount of the iodized oil to enter the portal veins. It can also reach the portal circulation through the plexus around the tumor. Due to its high viscosity, near the tumor, Iodized oil may temporarily obstruct blood flow through the portal, even reversed flow into the tumor Furthermore, iodized oil is capable of migrating through arterial pathways to nearby hepatic branches or even extrahepatic arteries, aiding in the identification and treatment of concealed tumor-feeding vessels. This approach may also inhibit the formation of collateral vasculature following TACE. Gelatin sponge particles can successfully embolize the hepatic artery and the portal vein in the area surrounding the tumor when they are administered after the iodized oil. This technique leads to ischemic necrosis not only in the highly vascularized areas of the tumor but also in the surrounding regions, including parts of the tumor receiving blood by way of the hepatic artery and portal vein. As a result, it can also cause shrinkage of nearby healthy liver tissue. However, this highlights a potential risk of c-TACE damaging normal liver parenchyma, emphasizing the importance of precise, selective catheterization to limit hepatic toxicity. Additionally, minimizing the volume of iodized oil used is crucial; the recommended maximum is 15 mL in Western countries and 10 mL in Japan.Technically, chemoembolization is most effective when performed with a high degree of selectivity. Delivering the chemotherapy drug in a selective or super-selective manner, along with embolic particles, permits a targeted dosage to enter the tumor while reducing exposure throughout the body. These embolic agents trap the drug inside the tumor and produce a hypoxic environment by obstructing the tumor's blood supply, which can enhance the cytotoxic effect of the chemotherapy. [5]

One significant benefit of c-TACE is that lipidol, being naturally radiopaque, can be easily visualized on post-treatment CT scans, enabling confirmation of the embolized region. Its radiopacity also allows clinicians to monitor its dispersion in real time during the procedure, helping to assess its distribution within the tumor's feeding vessels. Before administering Lipidol via the hepatic artery, conducting an angiographic assessment is crucial to identify any arteriovenous shunting within the liver. Lipiodol has the ability to pass via the veins and sinusoids of the liver, possibly arriving at the peripheral pulmonary arteries. Although low volumes typically pose minimal concern, larger quantities may cause pulmonary oil embolism symptoms. The threat is increased if there is a shunt between the hepatic vein and the tumor-feeding artery, which could cause an unrecognized pulmonary or systemic embolization during the procedure. During the procedure, Lipidol serves as a vehicle for transporting chemotherapy agents directly to the tumor while also contributing to the blockage of the tumor's microvasculature. To achieve temporary embolization, gelatin sponge particles might be added if the targeted vessel is still patent following the typical dosage. These absorbable agents permit the restoration of blood flow within one to two weeks. [5]

2. Drug eluting bead transarterial chemoembolization (DEB-TACE)

Introduced by **Hong et al.** in 2006 [6], DEB-TACE is a modified form of c-TACE that uses drug-loaded beads or microspheres to both administer chemotherapy and block the blood supply to the tumor. These microspheres act as embolic carriers that can attach to chemotherapeutic agents like Idarubicin, Irinotecan, Epirubicin, and Doxorubicin through ionic bonding, The negative charge of microsphere functional groups enables binding with positively charged drug compounds.

Several types of drug-eluting beads (DEBs) are available, each designed to be compatible with specific chemotherapy drugs, which may lead to differences in treatment outcomes. According to studies, choosing beads that fall within particular size ranges and reducing the drug dosage may improve the treatment's effectiveness and safety. The technique begins by loading DEBs with a specific chemotherapeutic drug, usually 50–75 mg of either doxorubicin or Epirubicin per vial. This usually requires 30 to 60 minutes. It is important

to adhere to Instructions for use from the manufacturer (IFU) specific to each DEB type during preparation. In recent years, bead size has received increased attention. A higher risk of hepatobiliary complications is linked to smaller beads, especially those smaller than 100 microns, if feeder channel catheterization is not performed with great precision and selectivity. A growing trend involves using a combination of bead sizes to optimize both deep tissue penetration from smaller beads and the strong embolic effect of larger ones. Currently, four permanent DEBs are authorized for clinical use in DEB-TACE: DC Bead®, HepaSphere®, Embozene TANDEM®, and LifePearl®. Each type offers unique properties and benefits, giving physicians several choices depending on the clinical scenario. [7]

- **DC Beads**

The hydrophilic, biocompatible, and precisely calibrated DC (BTG International, London, UK) are hydrogel microspheres that cannot be reabsorbed. These beads are frequently infused with irinotecan or doxorubicin, two chemotherapy medications. They have a high drug-loading efficiency of approximately 99%, and regardless of their sizeTheir maximum drug capacity per milliliter of hydrated beads is roughly 45 mg.

- **DC Bead LUMI**

Non-resorbable, biocompatible hydrogel microspheres designed to be radiopaque are called DC Bead LUMITM (BTG International, London, UK). Cone-beam computed tomography, fluoroscopy, and CT scans can all clearly visualise them because to this property. There are several sizes available, 100-300 µm, 300-500 µm, and 70-150 µm.

- **HepaSphere**

HepaSphere microspheres (Merit Medical, Rockland, MA, USA) are biocompatible, non-resorbable beads that can expand and be loaded with chemotherapy drugs. In aqueous environments, they absorb surrounding fluids, resulting in considerable swelling while retaining their softness and flexibility. This adaptability enables them to pass through most microcatheters and conform to the shape of blood vessel walls. HepaSphere beads possess a distinctive capacity to reduce their volume by up to 80% from the original size. The dry material is categorized into distinct particle size fractions: 30-60 µm, 50-100 µm, 100-150 µm, and 150-200 µm. The most often utilized medication with these beads is doxorubicin, however other chemotherapeutic drugs like oxaliplatin, irinotecan, and epirubicin been used.

- **TANDEM microspheres**

Polymethacrylate hydrogel beads known as embozene TANDEM microspheres are non-resorbable (CeloNova Biosciences/Boston Scientific, Marlborough, MA, USA). These beads are capable of being loaded with various chemotherapy agents, These include doxorubicin-HCl, idarubicin-HCl, epirubicin-HCl, and irinotecan-HCl, with peak loading capacities reaching 50 mg/mL. Unlike many other drug-eluting beads, Embozene TANDEM microspheres are designed to retain their original size after loading, ensuring consistent and predictable performance.

Embolization technique

Once the appropriate drug-eluting beads (DEBs) are selected and prepared, the clinician must carry out extremely specific catheterization with a microcatheter in the tumor's supply direction. Proper placement is verified using either cone-beam CT (CBCT) or angiography. The DEBs are then combined with agent of contrast to improve visualization and prepared for administration. To avoid the syringe's beads from sediment, the contents should be regularly agitated or kept suspended utilizing a stopcock with three ways. The beads are infused slowly in steady pulses, matching the rhythm of natural arterial flow, and delivered through the microcatheter into the tumor’s blood supply. Continuous fluoroscopic monitoring is essential throughout the procedure to observe for any particle reflux. The injection proceeds until blood flow significantly slows, typically measured by a 10-beat pause in cardiac pulsation. [7]

Once blood flow stagnation is detected, the injection should be halted, regardless of how much bead volume has been used. Since TACE works through both chemotherapeutic and ischemic mechanisms, the primary aim is to achieve full tumor de-vascularization. This can sometimes be accomplished with a minimal number of beads, though additional treatment sessions may be necessary if complete de-vascularization is not achieved—so long as the total Doxorubicin dose remains below 150 mg. DEB-TACE offers better control over drug

administration than conventional TACE techniques, lowering systemic exposure while maintaining the tumor site's concentration high. Additionally, the microspheres release the drug gradually over time and conform closely to the vessel walls, enhancing their embolic effectiveness. The advantages of DEB-TACE have been extensively studied and demonstrated in both laboratory and animal models over time. Nevertheless, when comparing DEB-TACE to c-TACE or other treatment approaches, several clinical trials haven't found any statistically significant differences in important outcomes, like rate of survival or treatment responses. [8]

Outcomes of c-TACE and DEB-TACE

Post-embolization syndrome, the most widely reported adverse event, occurred in the c-TACE and DEB-TACE groups at same rates. However, findings from **Schindler et al.** [9] indicated that DEB-TACE may be more frequently linked with adverse effects in patients who have HCC and PVTT, particularly when liver function tests are abnormal. These differing outcomes are likely due to multiple contributing factors. Notably, **Schindler et al.'s** study was retrospective, while the research conducted by **Zhou et al.** [10] was a prospective randomized controlled trial, generally considered a higher level of evidence. Nevertheless, despite the randomized design, patient characteristics in Zhou et al.'s study were still not fully balanced, which may have influenced the results.

Results from earlier studies of DEB-TACE and lipidol-based c-TACE in patients with intermediate-stage HCC have shown a slight variability. The latest meta-analysis, encompassing seven studies, determined that the two treatment approaches produce similar outcomes. Although tumor response did not significantly differ, DEB-TACE was associated with improved patient safety outcomes. [9]

Early phase I/II clinical trials of DEB-TACE performed in China focused on the pharmacokinetics of doxorubicin, its maximum tolerated dose, safety characteristics, and effectiveness in tumor response. In the phase I portion, doxorubicin doses ranged from 25 mg to 150 mg across five cohorts of three patients each (totaling 15 patients). In phase II, a fixed dose of 150 mg was used. Adverse events related to treatment were observed in 11.4% of patients, with no dose-limiting toxicity reported at the highest administered dose. There were no treatment-related fatalities, and the average peak plasma concentration of doxorubicin remained low at 49.4 ± 23.7 ng/mL. Following two sessions of TACE therapy, according to RECIST criteria, the rates of partial and complete response were 50% and 0%, respectively, while the modified RECIST showed rates of 63.3% for partial response and 6.7% for complete response one month following the second session. Additional phase II studies involving DC-Beads for unresectable HCC mostly in intermediate BCLC stages—have shown overall response rates ranging from 59.6% to 81.8%. The reported survival rates at one and two years varied between 65–92.5% and 55–88.9%, respectively, while major procedure-related complications were observed in about 3.2% of patients. [11]

Comparative efficacy analysis of c-TACE and DEB-TACE for HCC yielded inconsistent findings in a meta-analysis. The evaluation included three randomized controlled trials along with two case-control investigations. The most extensive trial, conducted by Lammer, found no notable difference in overall disease control between the two treatment methods. However, subgroup analysis revealed that Individuals with more progressed stages of the disease such as those with Child-Pugh B classification, bi-lobar tumor involvement, or recurrent HCC (accounting for 67% of the study population) had notably improved overall survival and disease control when treated with DEB-TACE in comparison with c-TACE. [12]

Similarly, another analysis by **Facciorusso et al.** [12] identified no meaningful differences in either efficacy or safety between DEB-TACE and c-TACE, although a modest, non-significant trend appeared to favour DEB-TACE. The same meta-analysis also concluded that neither treatment demonstrated clear superiority regarding overall survival or safety. These results suggest that DEB-TACE provides comparable, if not slightly improved, outcomes relative to c-TACE. It may also offer greater clinical advantages for individuals with more advanced HCC and represent a safer choice for those at higher risk.

Safety, efficacy, survival outcomes and future perspectives of TACE techniques

As an illustration, **Brown et al.** [13] performed a randomized clinical trial at one tertiary care institution, including 101 individuals diagnosed with HCC. The study participants were randomly

divided into two groups: 50 patients received DEB-TACE, while 51 patients underwent TAE using microspheres. The main objective of this study was to evaluate tumor response using RECIST 1.0 criteria, with the first evaluation conducted 2 to 3 weeks after treatment and follow-up assessments every three months thereafter. Reviewers assessing the outcomes were blinded to the treatment assignments. The findings revealed comparable rates of adverse events between the two groups, showing no meaningful variation in tumor response according to RECIST criteria. In a similar vein, A meta-analysis conducted by **Wang et al.** [(4)] assessed the effectiveness of c-TACE versus DEB-TACE and found that both treatments delivered comparable therapeutic benefits, with no apparent increase in the incidence of serious complications. However, other meta-analyses have reported differing outcomes, indicating that DEB-TACE may provide improved results, especially concerning overall survival (OS). Overall, despite some recent studies challenging its benefits, DEB-TACE remains a reliable, safe, and effective therapeutic approach for managing liver tumors .[(11)]

In a prospective randomized study, TACE was used as a bridging therapy for 61 patients with BCLC stage B HCC, **Vogl et al.** [14] revealed that DSM-TACE resulted in a notably improved tumor response compared to c-TACE at the one-month follow-up. These findings align with the outcomes observed in our subgroup analysis, which also indicated that DSM-TACE outperformed c-TACE. Although the advantage of DEB-TACE and DSM-TACE over c-TACE appears modest, these outcomes are supported by a pilot study conducted by **Schicho et al.** [(15)] which explored how different TACE modalities affect vascular endothelial growth factor's (VEGF) driven neo-angiogenic response.

The observed response is attributed to ischemia and subsequent reperfusion caused by TACE, which reduces its efficacy since VEGF plays a crucial part in promoting tumor progression through angiogenesis, metastasis, and cancer cell migration. In their research, **Schicho et al.** [(15)] found that c-TACE triggered a significantly higher VEGF response compared to DEB-TACE and DSM-TACE. They proposed that lipiodol, lacking a consistent particle size, creates a prolonged but fluctuating hypoxic environment followed by repeated reperfusion. This contrasts with the consistent occlusion seen with DEB or the temporary blockage achieved with DSM. These findings may help explain our results and suggest that DEB-TACE or DSM-TACE could be preferable as an initial treatment strategy in cases of VEGF overexpression.

Conclusion:

TACE remains a key therapeutic approach for individuals with intermediate-stage HCC who are unsuitable for curative therapeutic options. c-TACE and DEB-TACE exhibit similar efficacy in tumor control, progression-free survival and overall survival across diverse patient cohorts. However, DEB-TACE offers specific pharmacokinetic advantages, including sustained and controlled drug release, lower systemic drug exposure, and improved safety particularly in individuals with impaired liver function or extensive tumor burden. According to recent research, DEB-TACE could be more efficient than c-TACE. in limiting tumor progression related to angiogenesis, likely due to its more controlled and localized embolization. However, variability in study methodologies, types of embolic materials used, and evaluation criteria has made it challenging to draw firm conclusions. To better identify the most effective TACE approach, future large, standardized clinical trials with clearly defined outcomes are needed. Moving forward, incorporating factors such as tumor characteristics, liver function, and predictors of treatment response will be crucial for tailoring transarterial therapies and enhancing outcomes in hepatocellular carcinoma management.

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