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Clinical evaluation of oxaliplatin-loaded drug-eluting callispheres beads transarterial chemoembolization for unresectable or recurrent esophageal carcinoma

Yonghua Bi[1], Jianzhuang Ren[1] and Xinwei Han[1*]

Abstract

Background A majority of esophageal carcinoma patients are diagnosed at an advanced stage and are no longer suitable for surgical resection. Drug-eluting beads transarterial chemoembolization (DEB-TACE) with oxaliplatin-loaded CalliSpheres beads (CB) have been used for advanced hepatocellular carcinoma and lung cancer, but they have not been reported for the treatment of unresectable or recurrent esophageal carcinoma.

Methods DEB-TACE was performed on 22 patients with unresectable or recurrent esophageal carcinoma between March 2019 and May 2022. The clinical outcomes, complications, and efficacy were retrospectively recorded and analyzed.

Results A total of 39 sessions of DEB-TACE were performed in 22 patients, with a technical success rate of 92.3% and clinical success rate of 65.0%. No severe complications such as procedure-related death, esophageal rupture or paraplegia were observed. Complete response, partial response, and stable disease were observed in 14.3% (2/14), 42.9% (6/14), and 21.4% (3/14) of patients 6 months after DEB-TACE, respectively. The objective response rates were 62.5%, 42.9% and 57.1% respectively at 1-, 3-, and 6-month after DEB-TACE. Subsequent interventional treatments were administered to 12 patients, including DEB-TACE for hepatic metastasis in 3 (13.6%), esophageal stenting in 5 (22.7%), and airway stent placement in 5 (22.7%). Two patients were lost to follow up. A total of 9 patients died due to tumor progression ($n=5$), pneumatic infection ($n=1$), and tumor-related massive esophageal hemorrhage ($n=3$). The median overall survivals were 13.9 months and 26.5 months from the first session of DEB-TACE and the diagnosis of esophageal carcinoma, respectively.

Conclusions DEB-TACE with oxaliplatin-loaded CB is suggested as a safe and effective treatment of unresectable or recurrent esophageal carcinoma, and more studies are required to confirm its efficacy and safety.

Keywords Esophageal carcinoma, Drug-eluting beads transarterial chemoembolization (DEB-TACE), Oxaliplatin, CalliSpheres beads (CB), Transarterial chemoembolization (TACE)

*Correspondence:
Xinwei Han
dreamweaver08@126.com
[1]Department of Interventional Radiology, The First Affiliated Hospital of Zhengzhou University, No.1, East Jian She Road, Zhengzhou 450052, China

Background

A majority of patients with advanced esophageal carcinoma are no longer suitable for vital radical resection [1]. Moreover, therapeutic effect is limited in some patients due to the insensitivity to chemotherapy and radiotherapy [2]. Most of patients with advanced esophageal carcinoma die within one year after diagnosis [3], with a poor prognosis and a low survival rate [4].

Drug-eluting beads transarterial chemoembolization (DEB-TACE) is an effective local interventional treatment wherein chemotherapeutic drugs are slowly released after direct embolization of tumor feeding arteries. Compared with conventional transarterial chemoembolization (TACE) and intravenous chemotherapy, DEB-TACE can slow control release of chemotherapeutic drugs in tumor tissues to reduce the drug toxicity. Pirarubicin or doxorubicin-eluting CalliSpheres beads (CB) have been used for many kinds of malignant tumors [5–8], and oxaliplatin-loaded CB have been used for advanced hepatocellular carcinoma [9]. Currently, DEB-TACE with oxaliplatin-loaded CB has not been reported for the treatment of unresectable or recurrent esophageal carcinoma, although artery infusion chemotherapy has been used for esophageal carcinoma to improve the killing effect of carcinoma and the survival rate after surgery [10]. In this current study, the safety and clinical efficacy of DEB-TACE in the treatment of esophageal carcinoma were retrospectively studied and evaluated.

Methods

Patients' selection

The chest computed tomography (CT) scanning and/or esophagography was administered to assess the tumor size, location and metastases before DEB-TACE procedure (Figs. 1A, 3C and 4A). We retrospectively collected and reviewed the clinical data of patients with unresectable or recurrent esophageal carcinoma treated by DEB-TACE with oxaliplatin-loaded CB between March 2019

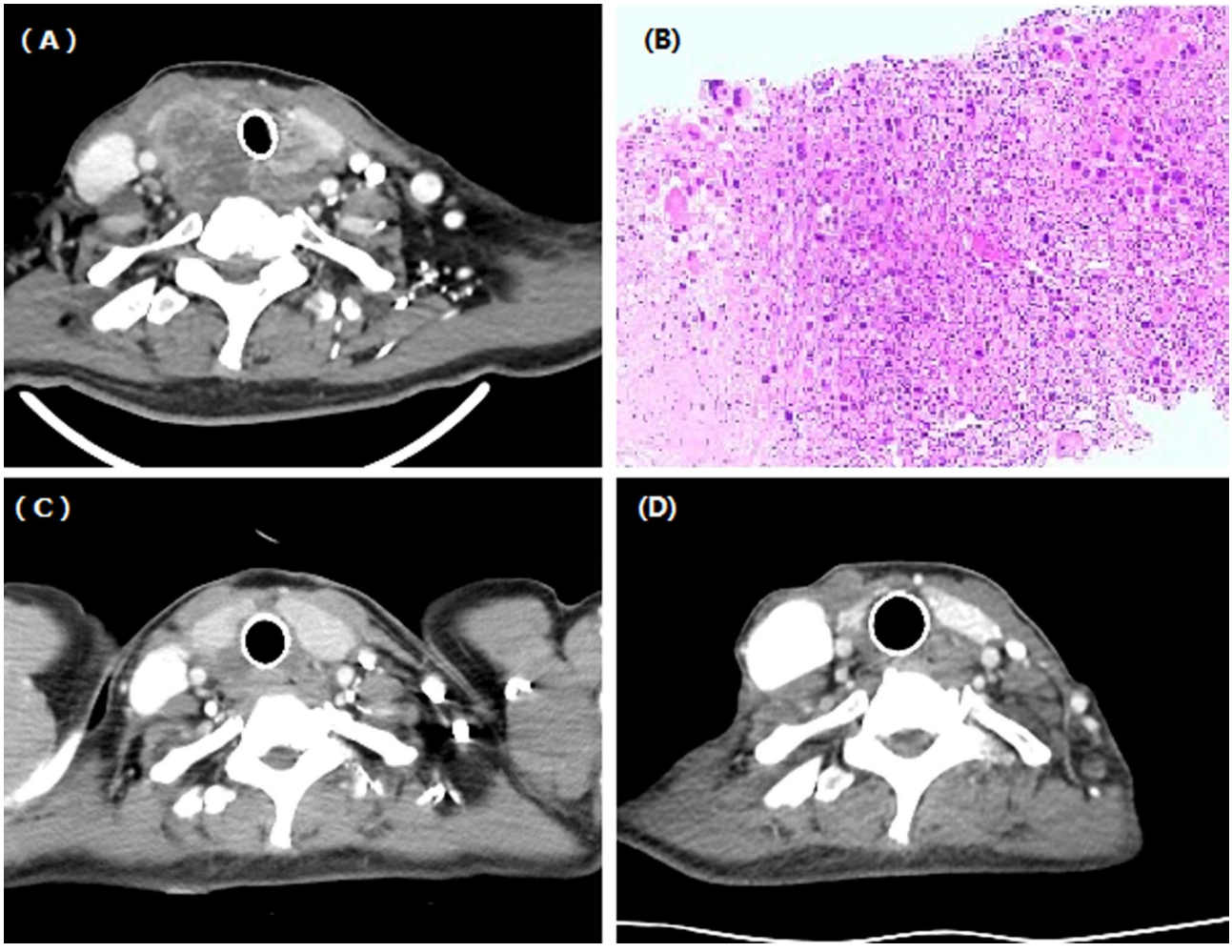

Fig. 1 Images of a 50-year-old female with esophageal cancer in upper esophagus and cervical metastasis. (**A**) Esophageal cancer invaded the trachea and caused airway stenosis, and an airway stent was inserted. (**B**) The pathology of the right neck tumor indicated a squamous cell carcinoma. (**C**) After 2.4 months, chest CT scan revealed a shrunk mass in the upper esophagus. (**D**) The tumor disappeared 13.3 months after first session of DEB-TACE

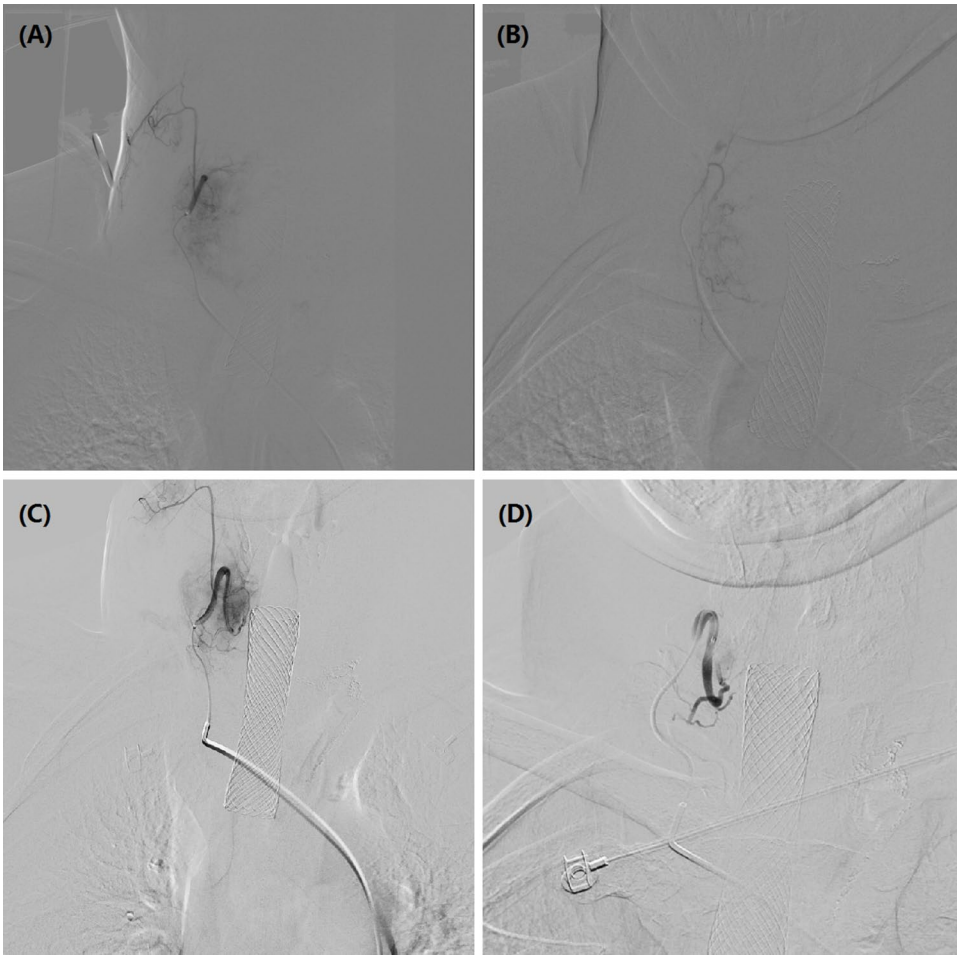

Fig. 2 DEB-TACE procedure. (**A**-**B**) A tumor staining was noted in the cervical esophagus and two tumor-feeding arteries were derived from the right external carotid artery. (**C**-**D**) A second session of DEB-TACE was performed after 2 months; the right trunk carotid artery was super-selectively catheterized by a microcatheter and embolized using oxaliplatin-loaded CB

and May 2022. This study was approved by the Medical Ethics Committee of our hospital. Informed consent of DEB-TACE procedure had been obtained from all patients before procedure.

Indications and exclusion criteria

Inclusion criteria: Esophageal carcinoma confirmed by endoscopy, histopathology or medical imaging (Figs. 1B and 3AB); Tumor recurrence after surgical resection confirmed by medical imaging; Tumor progression after failed radiochemotherapy; age older than 18 years; Ineligible or refused radiochemotherapy.

Exclusion criteria: combined with other kinds of life-threatening diseases but without standard treatment; ECOG > 2; Leukocytes < 3.0×10^9/L; Platelet count < 40×10^9/L; Sever insufficiency of renal or liver function; Pregnant woman or breast feeding; Patients' life expectancy < 3 months.

DEB-TACE procedure

All DEB-TACE procedures were performed under fluoroscopic guidance. After local anesthesia, the right femoral artery was punctured and the feeding artery of tumor mass was catheterized by using a 5 F-Cobra catheter (Terumo, Japan). Albumin-bound paclitaxel (100–200 mg), or fluorouracil (500–1000 mg), or raltitrexed (4 mg) were diluted in 100–200 ml solution and slowly infused via the catheter. Oxaliplatin (50–100 mg) was loaded by CB (Jiangsu Hengrui Medicine Co. Ltd., Jiangsu, China) for about 20–30 min, and then injected into the tumor-feeding arteries for embolization (Fig. 2AB; Fig. 3DE; Fig. 4D). Polyvinyl alcohol particles (Merit, American) or gelatinum sponge particles were used if one ampoule of CB is insufficient. The DEB-TACE was performed once more if no completed response was achieved (Fig. 2CD).

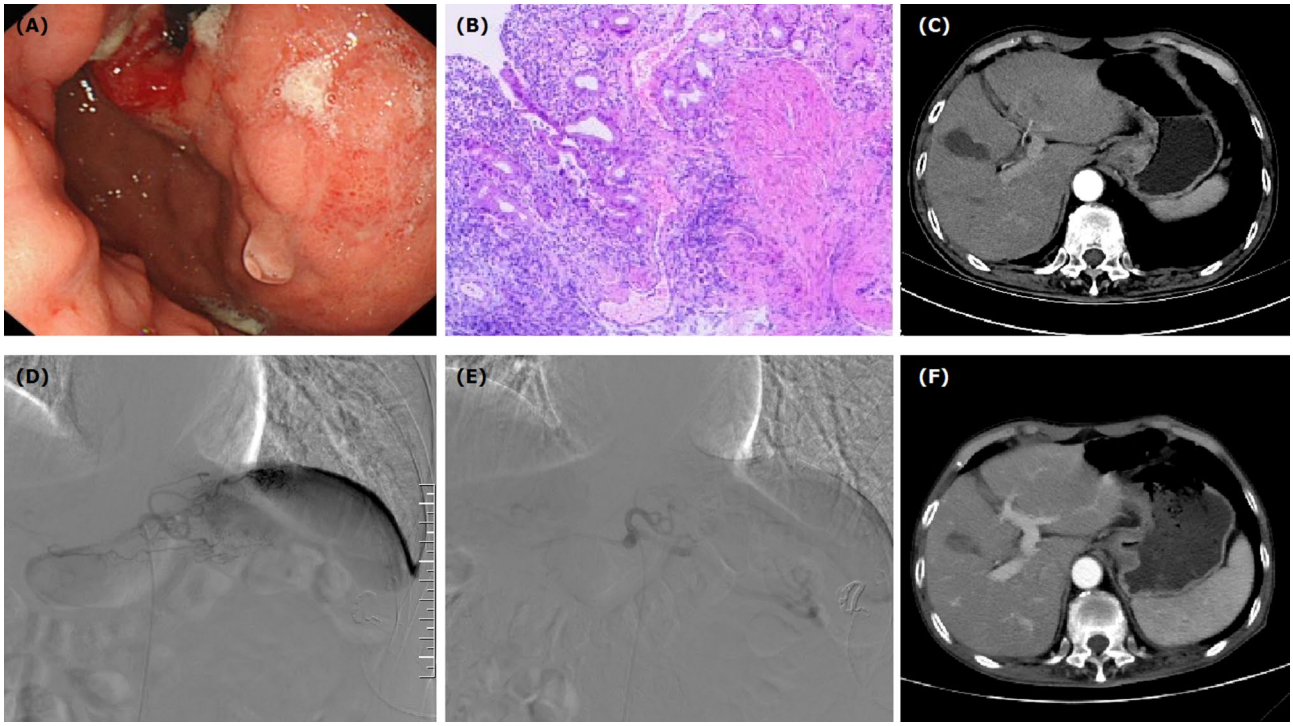

Fig. 3 Images of a 67-year-old male with esophageal cancer in esophageal cardiac junction. (**A**) Endoscopic examination was performed and a tumor was observed. (**B**) He was diagnosed with esophageal adenocarcinoma via endoscopic biopsy. (**C**) Chest CT scan shows a thickened tumor mass in cardia of stomach. (**D**) The left gastric artery is the tumor-feeding artery. (**E**) The tumor staining disappeared after DEB-TACE with CB loading with 100 mg of oxaliplatin. (**F**) CT scan shows a thin tumor mass 4 weeks after DEB-TACE

Clinical efficacy evaluation

The chest CT and/or esophagography were performed about 1–2 months thereafter during follow up period (Fig. 1CD; Figs. 3F and 4EF). Tumor diameter and length of esophageal carcinoma were recorded and clinical efficacy was evaluated according to new guidelines for evaluating the efficacy of treatment of solid tumors [11]. Technical success was defined as a complete disappearance of tumor staining and its feeding artery but without serious adverse events, such as death, massive esophageal bleeding, esophageal perforation, and so on. Objective response rate was defined as the sum of cases with complete response and partial response. Disease control rate was defined as the sum of cases with complete response, partial response, or stable disease.

Adverse reactions assessment

Routine laboratory tests were performed before and after the procedure, including routine blood tests, coagulation function, renal function and liver function. Adverse drug reactions and procedure-related complications were recorded and evaluated based on National Cancer Institute Common Terminology Criteria for Adverse Events (version 4.0).

Follow up and definition

Follow-up was finished via phone interviews or in-person interviews at the clinic with the last date on 12 December 2022. Technical success was defined as a successful finding and complete embolization of tumor staining and its tumor-feeding arteries with no serious complications during the perioperative period. Clinical success was defined as partial response and completed response in patients with technical success during follow up.

Statistical analysis

All quantitative data are presented as mean±standard deviation and other data are expressed as the count (%) or median (Interquartile range (IQR)). The Kaplan-Meier method was used for calculation of overall survival and progression-free survival (PFS) by GraphPad Prism 5 software (GraphPad Software, Inc., SanDiego, CA). A P value<0.05 is considered to indicate statistical significance.

Results

Patient characteristics

A total of 22 patients were enrolled, including 19 male and 3 female with a mean age of 63.7±10.7 years (range, 42–81 years). Except for 4 patients without histopathology, the remained 10 patients had adenocarcinoma (45.5%) and 8 patients had squamous cell carcinoma

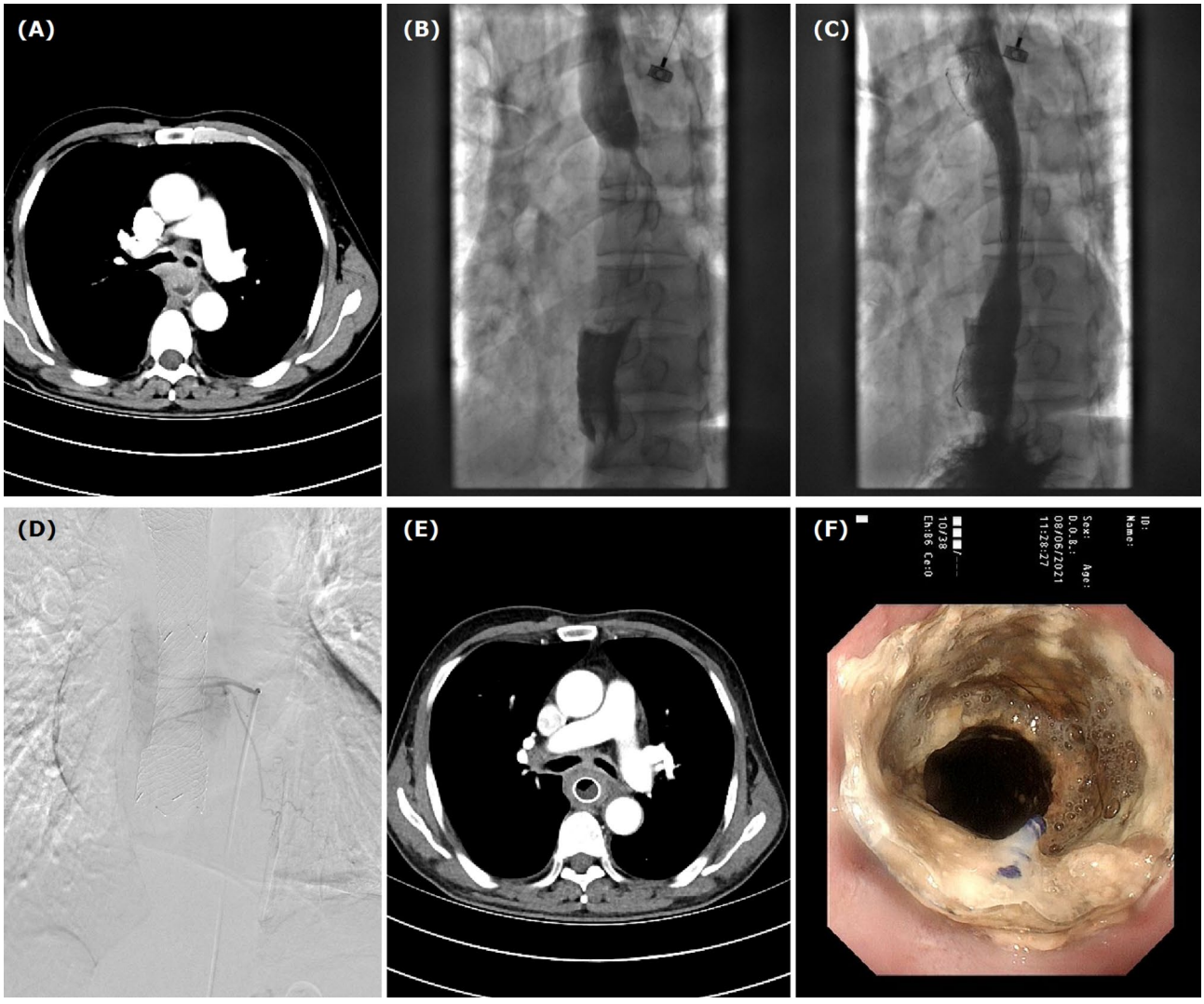

Fig. 4 Images of a 65-year-old male with esophageal cancer in middle and lower esophagus. (**A**) Chest CT scan shows an obvious thickening and apparently enhanced mass with invasion into tracheal wall. (**B**-**C**) Severe stenosis was seen in the middle and lower segments of the esophagus, and an 18*120 mm esophageal stent was inserted. (**D**) The proper esophageal artery is super-selectively catheterized and embolized using oxaliplatin loading-CB. (**E**) Chest CT scan shows that the lesion has significantly reduced and the arterial phase enhancement is not apparent after 6 weeks. (**E**) Endoscopic examination was performed after about 7 months

(36.4%). Six patients had a history of previous esophagectomy and tumor recurrence after surgical resection confirmed by medical imaging; seven patients had tumor progression after failed chemoradiotherapy, and the remaining nine patients were ineligible or refused radiochemotherapy. According to the clinical stages of the American Joint Cancer Commission (AJCC) [12], 1, 6, and 9 cases were categorized as T3, T4a, and T4b, respectively. Tumor mass was observed in the upper and middle segments, middle and lower segments, and esophageal cardiac junction in 9, 4, and 9 cases, respectively (Table 1). Hypertension, diabetes mellitus, and old cerebral infarction were found in 6, 2, and 2 cases, respectively. Moreover, 12 patients received previous treatments, including 8 cases who received systematic chemotherapy and 4 cases who received chemotherapy combined with radiotherapy. Six patients received targeted therapy and/or immunotherapy.

DEB-TACE procedure and complications

A total of 39 sessions of DEB-TACE was performed on a mean of 1.9±1.6 sessions (range, 1–7 sessions). Of which, 36 sessions were successfully performed and the technical success rate was 92.3%. A total of 50 tumor-feeding arteries were embolized, including the bronchial arteries (n=6), the internal mammary arteries (n=5), the proper esophageal arteries (n=4), the right gastroepiploic arteries (n=5), the left gastric arteries (n=21) and other tumor-feeding arteries (n=9). A microcatheter was used for superselective catheterization in 31 procedures

Table 1 Patient and cancer characteristics

Characteristics	Values
Sex, male, n (%)	19 (86.4%)
Mean age, years	63.7 ± 10.7
History of previous treatments, n (%)	
Systematic chemotherapy	8 (36.4%)
Chemotherapy + radiotherapy	4 (18.2%)
Surgical resection	6 (27.3%)
Median course of disease, months	8.5 (2.0, 15.0)
Esophageal carcinoma diagnosis	
Adenocarcinoma/Squamous cell carcinoma	10 (45.5%)/8 (36.4%)
Local/distant metastases	13 (59.1%)/4 (18.2%)
Comorbidities, n (%)	
Hypertension	6 (27.3%)
Diabetes mellitus	2 (9.1%)
Old cerebral infarction	2 (9.1%)
Main symptoms and signs, n (%)	
Dysphagia	13 (59.1%)
Choking cough	4 (18.2%)
Gastrointestinal hemorrhage	2 (9.1%)
Others	3 (13.6%)
Location of carcinoma, n (%)	
Upper and middle segments	9 (40.9%)
Middle and lower segments	4 (18.2%)
Esophageal cardiac junction	9 (40.9%)

Table 2 Clinical outcomes of DEB-TACE with oxaliplatin-loaded CB

Variables	Value
Median operation time, min	89.0 (75.0, 110.0)
Median inpatient duration, days	10.5 (8.3, 15.5)
Mean session of DEB-TACE	1.9 ± 1.6
Total session of DEB-TACE	39
Mean cost,×10^4 ¥	7.1 ± 2.0
Technical success rate	92.3%
Clinical success rate	65.0%
The embolized arteries	
The bronchial arteries	6 (15.4%)
The proper esophageal arteries	4 (10.3%)
The internal mammary arteries	5 (12.8%)
The left gastric arteries	21 (53.8%)
The right gastroepiploic arteries	5 (12.8%)
Others tumor-feeding arteries	9 (23.1%)
Complications	
Chest pain	5 (22.7%)
Nausea or vomiting	5 (22.7%)
Subsequent interventional treatments	
TACE for hepatic metastasis	3 (13.6%)
Esophagus stenting	5 (22.7%)
Airway stenting	5 (22.7%)
^{125}I seeds implantation	1 (4.5%)

Table 3 Local tumor response and follow up

Response, *n* (%)	1 month	3 months	6 months
Complete response	0 (0.0%)	0 (0.0%)	2 (14.3%)
Partial response	10 (62.5%)	6 (42.9%)	6 (42.9%)
Stable disease	6 (37.5%)	6 (42.9%)	3 (21.4%)
Progressive disease	0 (0.0%)	2 (14.3%)	3 (21.4%)
Objective response rate	10 (62.5%)	6 (42.9%)	8 (57.1%)
Disease control rate	16 (100.0%)	12 (85.7%)	11 (78.6%)

(79.5%) to prevent drug reflux and ectopic embolization. Subsequent interventional treatments were administered to 12 patients, including DEB-TACE for hepatic metastasis in 3 (13.6%) patients and esophageal/airway stenting in 5 (22.7%) patients (Fig. 4BC).

Treatment-related complications were noted in 8 patients during and after the procedure, including chest pain in 5 patients and nausea or vomiting in 5 patients. All symptom of postembolic syndrome was mild and symptom relief about 1–3 days after treatment. No serious complications were observed, such as procedure-related death, esophageal rupture or paraplegia (Table 2).

Evaluation of the clinical efficacy

As shown in Tables 3, 6 and 10 cases exhibited partial response and stable disease 1 month after the first session of DEB-TACE. Complete response, partial response, and stable disease were noted in 14.3% (2/14), 42.9% (6/14), and 21.4% (3/14) of patients 6 months after DEB-TACE, respectively. The objective response rates were 62.5%, 42.9% and 57.1% respectively at 1-, 3-, and 6-months after DEB-TACE. The disease control rates were 100.0%, 85.7% and 78.6%, respectively at 1-, 3-, and 6-months after DEB-TACE.

Follow-up outcomes

During follow-up, 2 patients were lost to follow up, with a follow up rate of 90.9%. Among the remained 20 patients, 2 patients achieved complete response and 11 patients showed partial response, thus the clinical success rate of DEB-TACE was 65.0%. Nine patients died due to tumor progression ($n=5$), pneumatic infection ($n=1$), and tumor-related massive esophageal hemorrhage ($n=3$). The median overall survivals were 13.9 months and 26.5 months after the first DEB-TACE session and diagnosis of esophageal carcinoma, respectively. The 3-, 6- and 12-month overall survival rates were 90.0%, 85.0 and 65.0%, respectively. The median progression-free survival was 8.8 months after the first DEB-TACE session.

Discussion

Surgical radical resection is the first choice of treatment for resectable esophageal carcinoma. Unfortunately, the vast majority of patients with esophageal cancer do not go to the hospital until the onset of significant dysphagia,

often being diagnosed late stage and losing the chance of radical surgical resection. The prognosis of surgical radical resection is still poor and the survival rate ranges from 15 to 20% due to the recurrence of residual carcinoma and tumor metastasis. Nowadays, neoadjuvant chemotherapy and/or radiotherapy has been attempted to improve the survival time and local control rate [13]. For the systematic chemotherapy, fluorouracil plus cisplatin is the first-line chemotherapy regimen, and oxaliplatin based regimen (epirubicin + oxaliplatin + 5-Fu) is also effective for advanced esophageal carcinoma [14]. However, the incidence of postoperative complications may increase, such as esophageal fistula and esophageal tracheal fistula, which is a main concern for both doctors and patients.

DEB-TACE is an effective local interventional treatment with low adverse reaction due to slow release of chemotherapeutic drugs and embolization of tumor-feeding arteries, and has been used clinically for many kinds of cancer, such as hepatocellular carcinoma [8, 15] and refractory lung cancer [5, 6, 16–18]. DEB-TACE could theoretically improve antitumor efficacy and reduce the toxicity of chemotherapeutic drugs if compared with conventional TACE and intravenous chemotherapy. Currently, few studies have been reported except for one case report [19] and one study with doxorubicin-eluting CB for advanced esophageal carcinoma [20]. To our knowledge, DEB-TACE with oxaliplatin-loaded CB has not been reported for the treatment of unresectable or recurrent esophageal carcinoma.

In the present study, 22 patients with unresectable or recurrent esophageal carcinoma were treated with DEB-TACE; there were 2 (14.3%) cases of complete response, 6 (42.9%) cases of partial response, and 3 (21.4%) cases of stable disease 6 months after treatment. The objective response rates were 62.5%, 42.9% and 57.1% respectively at 1-, 3-, and 6-months after DEB-TACE. Our result seem better than previous report with doxorubicin-eluting CB for advanced esophageal carcinoma [20], in which, the objective response rates were 42.9%, 28.6% and 20.0% respectively at 1-, 3-, and 6-months after DEB-TACE. In the previous study [20], the median overall survival was 9.4 months, and the 3-, 6- and 12-month overall survival rates were 75.5%, 55.0 and 13.8%, respectively. In this current study, the median overall survival was 13.9 months and the 3-, 6- and 12-month overall survival rates were 90.0%, 85.0 and 65.0%, respectively. It's indicating that oxaliplatin-loaded CB shows a better survival outcome than doxorubicin-eluting CB for advanced esophageal carcinoma.

Unlike TACE or DEB-TACE treatment for advanced hepatocellular carcinoma, the key to TACE or DEB-TACE treatment for advanced esophageal carcinoma is to find all accurate tumor-feeding arteries, considering that the tumor-supplying arteries are more variable and complex. The feeding artery of esophageal carcinoma is closely related to the tumor location, which is conducive to the operator to find the correct tumor-feeding artery. For patients with carotid esophageal carcinoma, inferior thyroid artery is often the supply artery of tumor mass; the proper esophageal artery and bronchial artery should be found out for patients with thoracic esophageal carcinoma. Besides, the left gastric artery and right gastroepiploic artery is the main tumor-feeding artery supply vessel for tumor located in esophageal cardiac junction. In our study, 50 tumor-feeding arteries were embolized, including the bronchial arteries ($n=6$), the internal mammary arteries ($n=5$), the proper esophageal arteries ($n=4$), the right gastroepiploic arteries ($n=5$), the left gastric arteries ($n=21$) and other tumor-feeding arteries ($n=9$). A microcatheter was used for superselective catheterization in 31 procedures to prevent drug reflux and ectopic embolization.

Regarding safety, no serious complications were observed in this study, which is similar to previous reports [6, 20, 21]. Unlike solid malignancies (e.g., hepatocellular carcinoma, lung cancer), if malignant tumors of cavity organs (e.g., esophageal, gastric, and colorectal cancer), are treated with TACE or DEB-TACE, researchers often worry about the risk of perforation and rupture of cavity organs. Based on our clinical experience, the choice of an appropriate embolization endpoint is crucial. The disappearance of tumor staining was considered the embolization endpoint and additional embolization of the main tumor-feeding artery to complete stasis of blood flow is not recommended.

Previous studies have shown that DEB-TACE with doxorubicin-loaded beads seems safe for gastric cancer and colorectal cancer [6, 21]. It's reported that DEB-TACE with doxorubicin-loaded beads was conducted in 21 patients with with unresectable or recurrent esophageal carcinoma, and no serious complications were observed, including procedure-related deaths, massive bleeding, and esophageal perforation [20]. No serious complications were observed in this preliminary study, which seems to confirm that DEB-TACE with oxaliplatin-loaded beads is also safe in the treatment of esophageal carcinoma.

Subsequent interventional treatments are other factors that may be able to influence patient survival and prognosis, such as esophagus stenting, airway stenting and radioactive ^{125}I seeds implantation. Patients with advanced esophageal cancer often have severe dysphagia due to esophageal stricture, and the placement of esophageal stent to improve the nutritional status of patients is beneficial to patient survival. It's also important to treat life-threatening complications caused by esophageal cancer, such as severe airway stricture, and airway stenting

can avoid death as much as possible. In this study, airway stent implantation was performed in 5 patients with severe airway stricture. Additionally, TACE and ^{125}I seeds implantation of esophageal cancer metastases (such as hepatic metastasis) may also prolong patient survival.

There were some limitations. This is a single-center retrospective study, and selection bias may be present. As a cavity organ that is not easy to measure, there is no standard for the efficacy evaluation of esophageal cancer, and our response evaluation by RECIST 1.1 may not be accurate enough. The sample size was small and only 22 patients were enrolled in this study. There was no control group and lack of comparison with chemotherapy, TACE or radiotherapy is a major shortcoming, it is unknown whether this treatment has advantages in terms of cost and efficacy. Thus, further multicentre, prospective studies with large sample size and comparison are required to validate the true efficacy and safety of DEB-TACE for esophageal carcinoma.

Conclusions

DEB-TACE with oxaliplatin-loaded CB may be a safe and effective treatment of unresectable or recurrent esophageal carcinoma. However, more studies are required to confirm its efficacy and safety.

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Author contributions
Bi YH, Ren JZ and Han XW made substantial contributions to conception and design, acquisition of data, and analysis; Bi YH took part in drafting the manuscript or revising it; Bi YH, Ren JZ and Han XW agreed to submit to the current journal; Bi YH, Ren JZ and Han XW gave final approval for the version to be published; and agreed to be accountable for all aspects of the work.

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Not applicable.

Data availability
The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding authors.

Declarations

Ethics approval and consent to participate
This study was approved by the Ethics Committee Board of Zhengzhou University First Affiliated Hospital. All informed consents were obtained from the patients.

Consent for publication
Written informed consent was obtained from all patients enrolled in the investigation. The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki and the guidelines of the regional ethical committees of Zhengzhou University First Affiliated Hospital.

Competing interests
The authors declare no competing interests.

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