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Complications of Transcatheter Hepatic Arterial Chemoembolization (TACE) in Chinese Hepatocellular Carcinoma Patients Running Title: TACE-associated Mortality in China

LI Yong, BI Tao, ZHANG Bing-yuan, FENG Yu-jie, HAO Cui-ping, ZHAO Wei[△](Second Department of General Surgery, Department of Respiratory Medicine, The Affiliated Medical College Hospital,
Qingdao University, Qingdao, Shandong, 266003, China)

ABSTRACT Objective: To discuss the complications related to TACE in Chinese patients so as to increase the clinical effect and to gain more experience. **Methods:** We retrieved articles from January 1994 to September 2008 in Chinese Medical Current Content (CBM) and National Knowledge Infrastructure (CNKI). Meta-analysis was performed on the results of homogeneous studies. All calculations for the current meta-analysis were performed using REVIEW MANAGER 4.2. **Results:** There were 150 reported cases of deaths after TACE, among which hepatic failure, upper gastrointestinal bleeding and ruptured liver cancer with hemorrhage occurred in 84% of cases, and 78.7% survived less than one month after operation. **Conclusion:** The primary etiology of death following TACE is acute liver failure, upper gastrointestinal bleeding and ruptured liver cancer with hemorrhage. The majority of peri-procedure fatalities are less than 30 days following TACE.

Key words: Transcatheter hepatic arterial chemoembolization; Hepatocellular carcinoma; Death; Etiology

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Introduction

In Asia, especially Southeast Asia is the high risk region of liver cancer [1,2]. In China, most patients with liver cancer also get hepatitis or liver cirrhosis at different levels [3,4]. So many patients are poor in liver function without the tolerance to receive liver operation. Transcatheter arterial chemoembolization (TACE) is a technique which can not only increase the drug concentration of local tissue of the tumor but also decrease the side effect all over the body. It is the primary therapy in treating liver cancer patients who cannot receive operation [5]. TACE is commonly used for palliation of unresectable tumors as well as an adjunct to surgical resection, bridging therapy before transplantation, and in conjunction with other ablative therapies in a multimodality approach. Many articles take positive attitude to TACE [5-7]. It gives the patients the opportunity of second excision so that life time can be prolonged and life quality can be increased. If there is complication due to mistakes or improper action after operation, this technique will increase the death rate of the patients [8]. In China, there are many reports that some doctors lack of the information about this technique. Combined with our own experience, we searched and studied the articles and the pertinent literature in recent 14 years in China, tried to discuss the cause of death by transcatheter hepatic arterial chemoembolization in Chinese patients so as to increase the clinical effect

and to gain more experience.

1 Materials and Methods

1.1 Strategy

We searched, without language restrictions, from January 1994 to September 2008 in Chinese Medical Current Content (CBM) and National Knowledge Infrastructure (CNKI) using the search strategy ('transcatheter hepatic arterial chemoembolization' or 'TACE' or 'TACE complication' or 'TACE death' and 'in China').

1.2 Criteria for inclusion

Acceptable publications complied with the following criteria: (1) Hepatocellular Carcinoma (HCC) patients were confirmed cytologically or pathologically or diagnosed by Computed tomography (CT); (2) trials were described as randomized clinical trials (RCTs) or nonrandomized controlled clinical trials (CCTs); (3) the published data of primary interest were survival and tumor response for the calculation of the odds ratio (OR) at a 95% confidence interval (CI).

1.3 Exclusion criteria

The following exclusive selection criteria were set: (1) non-randomized studies; (2) No clinical data were collected for primary or secondary outcomes (e.g. overall survival rate, tumor recurrence and treatment response) and (3) None of the intervention procedure of TACE was applied.

1.4 Data extraction

We independently selected the trials and performed the data extraction. Discrepancies were resolved by discussion. Information lacking in the original publications was supplemented through correspondence with the original principal investigator. Finally, the

Author introduction: LI Yong, male, Current Master Student,

E-mail: liyong4231@126.com

△ Corresponding Author: ZHAO Wei, male,

E-mail: tiankong4231@126.com

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following information was extracted from each included trial: (1) the characteristics of methods (the randomization procedure, concealment of allocation, blinding procedure, withdrawal and reasons, and protection against contamination); (2) the number of patients allocated, and patient characteristics (clinical stage, Child-Pugh score); (3) the interventional measures used (anticancer drugs, embolic agents, TACE course); (4) outcomes such as complication, death rate.

1.5 Statistical methods

The meta-analysis was carried out by Review Manager software. Pooled OR was calculated using the DerSimonian and Laird method (random-effected model) to control the potential heterogeneity of trials^[9]. The results were reported as pooled OR and 95% C-I. The quantitative heterogeneity between trials was evaluated by the DLQ statistic^[9]. In addition, a funnel plot was used to test a potential publication bias. All calculations for the current meta-analysis were performed using REVIEW MANAGER 4.2 (Cochrane Collaboration, Oxford, UK). This article follows the QUORUM and the Cochrane Collaboration guidelines data extraction.

2 Results

2.1 Selection of trials

A total of 84 trials were identified for possible inclusion in the review. After carefully reading titles and abstracts, 40 trials were excluded because of duplication, without detailed data or because the objective did not satisfy the inclusion criteria. A total of 44 trials were retrieved for further assessment by reading more. Of these, 11 trials were excluded because they had an inadequate control-arm. 3 trials were excluded because they repeatedly appear. Ultimately, 30 trials (2925 patients) followed our inclusion criteria. Descriptive information was collected and quality was assessed (Fig. 1).

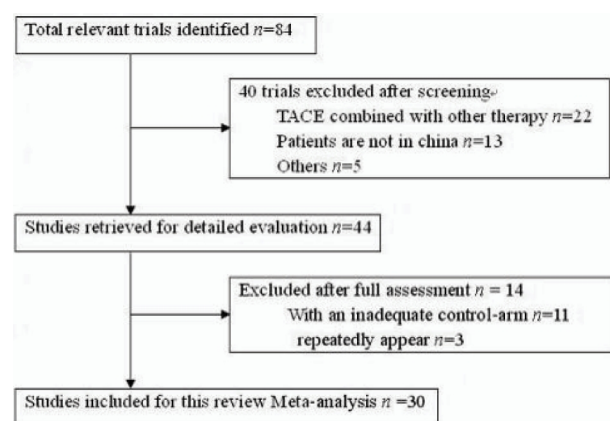


Fig.1 Database search and study selection. 'TACE' or 'TACE complication' or 'TACE death' and 'in China'

2.2 Causes of Death

In the 30 articles, 150 cases (0.51%) out of 2925 patients with TACE are reported death, among which liver function failure 71 cases (47.3%), upper gastrointestinal bleeding 43 cases (28.7%),

liver cancer collapse bleeding 12 cases (8.0%), lung embolism 6 cases (4.0%), acute renal failure 4 cases (2.7%), paraplegia 3 cases (2.0%), acute respiratory failure 2 cases (1.3%), septicemia 2 cases (1.3%), gastroduodenal ulcer 1 case (0.67%), cardiac death 3 cases (2.0%), hepatophyma 1 case (0.67%), disseminated intravascular coagulation 1 case (0.67%), acute pancreatitis 1 case (0.67%). For cases of both liver and renal failure, they are counted by the eternal cause of death. (Figure 2,3,4)

2.3 Classified by reason

Those cases with liver function failure are all with liver cirrhosis at different levels, some with combined phlebocarcinoma (10 cases), hypertension and diabetes (9 cases) and liver and kidney syndrome (7 cases), before operation, liver function are mostly Child B-C level (98.7%), after TACE liver function are all Child B-C level (100%). In 30 cases of death of UGB, esophagus fundus varicosity bleeding 22 cases (73.3%), stomach duodenal mucosa bleeding 8 cases (26.7%). Liver cancer collapse bleeding cases are all huge hepatoma, with different levels of liver cirrhosis, pathological vicinity liver surface 7 cases (7/12,58.3%), situated on the edge of liver 5 cases (5/12,41.7%). 5 cases (5/6,83.3%) out of 6 are exposed in high dangerous factors, among those, 2 (2/6,33.3%) are accompanied with diabetes, 2 cases (2/6,33.3%) with hypertension, 1 (1/6,16.7%) with arrhythmia. 1 case (1/3,33.3%) with CA-D history died from myocardial infarction out of 3 cardiac death. There is one case in each type of cardiac death and heart function failure (2/3, 66.7%) without heart dysfunction.

2.4 Death time

Divide the post-surgery period into 3 sections at the point of less than 1 month, 1 to 2 months and more than 2 months. 118 cases of death (118/150,78.7%) happened within 1 month after the surgery, including 48 cases of liver failure (48/71,67.6%), 37 patients died of hemorrhage in upper digestive tract (37/43,86%), 9 patients died of hemorrhage lead by rupture of hepatoma (10/12, 83.3%), 1 case of septicaemia (1/2, 50%), death caused by lung embolism, acute kidney failure, paraplegia, acute respiratory failure, gastrointestinal ulcer, cardiac diseases, hepatophyma, disseminated intravascular coagulation and acute pancreatitis all occurred in this section of time period. 23 cases (23/150,15.3%) happened between 1 to 2 months after the surgery, among which there were 18 cases of liver failure (18/71,25.4%), 3 cases of upper gastrointestinal hemorrhage (3/43,7.0%), 1 case of hemorrhage lead by rupture of hepatoma (1/12,8.3%), 1 case of septicaemia (1/2, 50%). 9 cases (9/150,6.0%) occurred after 2 months of the surgery, including 5 cases of liver failure (5/71,7.0%), 3 cases of upper gastrointestinal hemorrhage (3/43,7.0%) and 1 case of hemorrhage lead by rupture of hepatoma (1/12,8.3%).

2.5 Method of intervention

Seldinger method was adapted to all the patients^[10]. The tube entered common hepatic artery and proper hepatic artery through

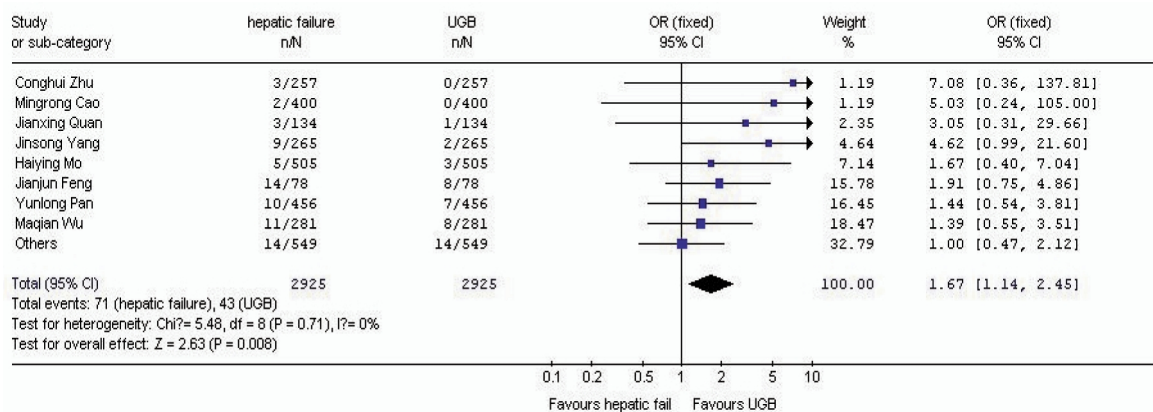


Fig.2 Forest plots for the results of meta-analysis for death from hepatic failure and UGB

Review: Complications of TACE in Chinese hepatocellular carcinoma patients

Comparison: 01 Deaths from Complications of TACE in China

Outcome: 02 Deaths from rupture of HCC versus Deaths from lung embolism

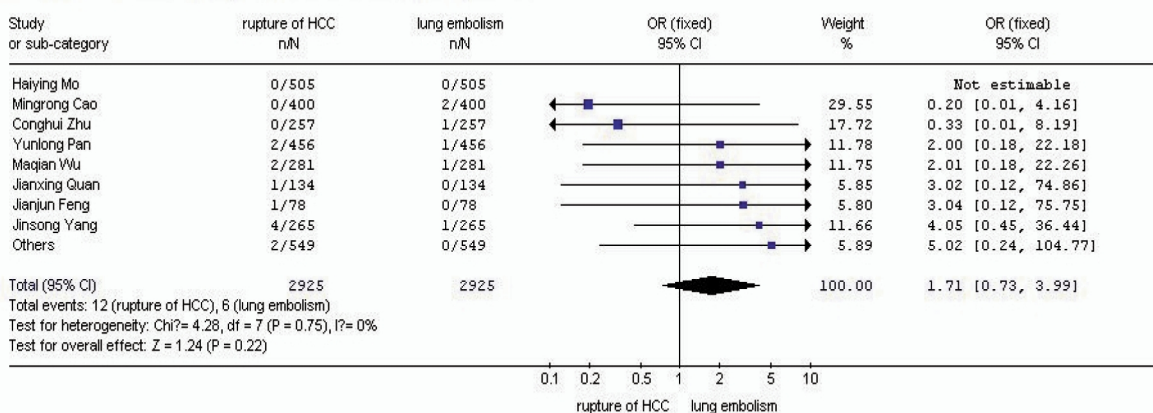


Fig.3 Forest plots for the results of meta-analysis for death from rupture of HCC and lung embolism

Review: Complications of TACE in Chinese hepatocellular carcinoma patients

Comparison: 01 Deaths from Complications of TACE in China

Outcome: 03 Deaths from renal failure versus Deaths from other reasons

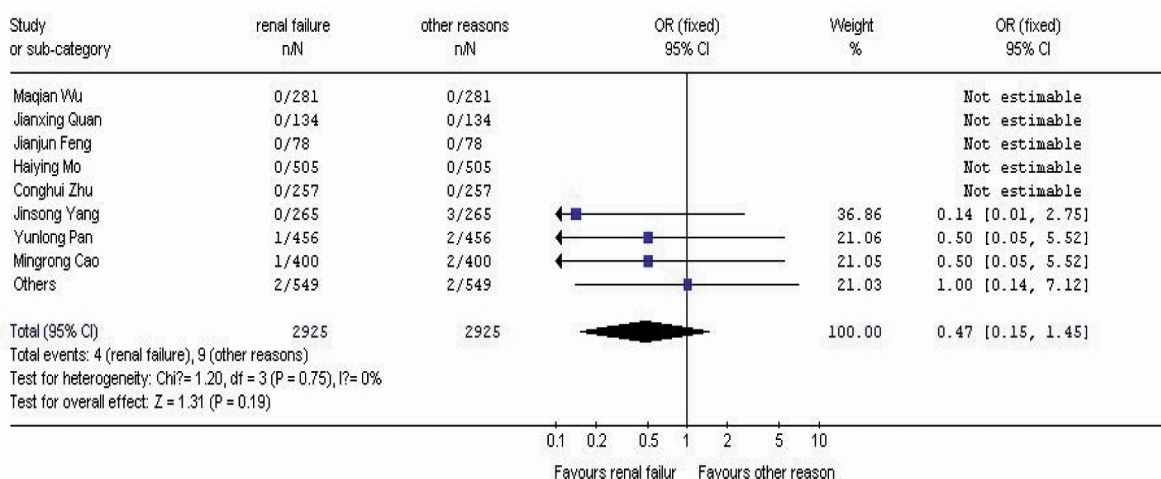


Fig.4 Forest plots for the results of meta-analysis for death from renal failure and other reasons

percutaneous femoral artery puncture. According to the result of digital subtraction angiography (DSA), insert the tube into the core of feeding artery or artery branches by ultraselection. 2 to 3 drugs for chemotherapy selected from mitomycin (8 mg-20 mg), adriamycin (20 mg-60 mg), pharmorubicin (20 mg-60 mg), fluorouracil (500 mg-1000 mg), carboplatin (200 mg-300 mg), and

cis-platinum (50 mg-100 mg) were injected with iodized oil. Proper amount of gel sponge was used as embolism in some patients.

3 Discussion

TACE is based on the facts that liver is supported by both veins and arteries, and tumor is supported by hepatic artery [6]. Af-

ter percutaneous femoral artery puncture guided by X ray, tip of the tube was inserted into the proper hepatic artery or left/right hepatic artery according to the position of the tumor. Injected chemoembolization blocked the blood supply from the hepatic artery to the tumor, so as to keep high content of chemotherapeutics and biological activity, and suppress growth of the tumor. This is a treatment of cancer by way of killing the tumor cell.

As a best non-surgical option of treatment against hepatoma, TACE is applauded for its curative effect, minimum injury and repeatability [7]. Most patients experienced embolism syndrome and light liver damage including fever, pain in the liver area, sickness, vomiting and jaundice [11]. They can recover soon after proper treatment. However, some patients died of severe complications. Some studies showed that TACE might not be able to remove hepatoma, and cases of death related to the treatment exist (4.1%-9.4%) and often happen within 20 days after the surgery. 78.7% cases of death happen within 1 month after TACE, which is respondent to former fact. It is highly recommended to be prepared for vital complications with sufficient knowledge and information, provide prevention and treat patients properly so as to improve the curative effect of TACE and lower the death rate.

The fact that the most common death-causing complication after TACE is liver failure might because that most hepatoma cases in China is primary hepatoma with different degree of liver cirrhosis [12]. Not only can embolism such as chemotherapeutics and iodized oil interfere with metabolism of tumor and deoxygenating the tumor, but also influence normal tissue around the tumor. The influence depends on liver function and times of TACE, on the other hand, hepatic artery that was blocked. The lower the liver function is, the closer the embolism is to the core, it is more likely for the liver failure to happen, which means shorter life span. Moreover, for patients with diabetes mellitus, hypertension and coronary artery diseases, the mass cellular necrosis right after the TACE may cause massive release of bio-active materials which might aggravate the complications, worsen overall condition, and finally, liver failure [13]. It's also worth noticing that phlebocarcinoma in portal vein, especially in main portal vein, is also risky. Because it might block the blood flowing to the liver after TACE, which might lead to massive hepatonecrosis and at last kill the patient by liver failure [14].

Upper gastrointestinal bleeding is the other reason that causes post-TACE-operative death. There are researches shows that 78.3% of bleeding of the patients in TACE operation are caused by varicose vein bleeding of esoph-fundus of stomach which is showed the most normal reason of upper gastrointestinal bleeding according to this research [15]. This was mainly due to the TACE liver cancer patients have different degrees of liver cirrhosis and esophageal varices, on the one hand, after TACE the reactive swelling of the liver could add more original portal hypertension, on the other hand, drug into Gastroduodenal artery caused hiccup,

severe vomiting, which caused variceal bleeding, and the many chemotherapy bolt tournament, the more side effects of drugs that caused the degree of hardening of the liver further, and the formation of portal hypertension gastropathy, thereby increasing the risk of bleeding of the varicose vein [16]. Another factor is the incidence of gastroduodenal mucosal bleeding, which is caused by that the gastroduodenal artery embolization increase the gastric mucosal ischemia. At the same time, combined with the damage of chemotherapy drug on the gastroduodenal mucosa, the risk of acute gastroduodenal mucosal bleeding lesions and drug-related reflux [17] after TACE increased.

Liver cancer bleeding is caused by liquefied tumor necrosis after TACE and swelling involved in the use of excessive dose of iodized oil, the injection pressure and speed too fast, especially near the surface of the liver and liver at the edge of the large occurrence of liver cancer causes the higher probability, in addition to the literature there are frequent reports of severe vomiting caused by intra-abdominal pressure is too high can also cause liver cancer on the surface rupture [18].

Pulmonary embolism (PE) after TACE is a very high mortality rate of complications, the rapid progress of the disease, at home and abroad reported that the incidence rate of 0.05%-4% [19,20], coincides with the group, research shows that diabetes, high blood pressure, coronary heart disease, obesity, varicose veins of lower extremity, such as occurred after TACE is a risk factor for pulmonary embolism [21,22], that at this stage, TACE after acute PE is a large number of oil and chemotherapy embolization common result of: Iodized oil into the hepatic artery, a certain dose of iodized oil will move through the liver - or fistula traffic branch vein into the liver [23], the inferior vena cava to reach pulmonary circulation, pulmonary embolism larger branches and pulmonary capillary bed. The delayed for PE oil particles in the lungs by fatty embolization esterase have caused decomposition, but some recent studies have revealed that the primary liver cancer after TACE pulmonary embolism, not merely a matter of iodine Obstruction caused by oil, it is possible Lp-based block, thrombosis, thrombosis and even chemotherapy drugs such as common components of different pathogens [24].

A commonly seen mortality factor, acute renal failure is reported to come up with liver failure to increase mortality risk, which may be related to liver-kidney syndrome brought by liver cirrhosis [25]. Under the double embolization of large hepatocellular carcinoma TACE with iodized oil and gelatin sponge, death of ischemic tumor results in large emission of tissue protein from kidney and then acute tubular necrosis died. Besides, toxicity of some chemical therapeutic medicine to kidney is one of factors for acute renal failure after operation [26]. There are also some reports must be pay highly attention to that injury of renal glomerulus cells caused by overdose of contrast medium lead to acute renal failure to death [27,28].

It is rare that other complications cause patient mortality after TACE operation. Less reported interiorly, paraplegia in literature is caused by inapt operation in TACE that brings about regurgitation of embolic agent or accidental injury of spinal cord by wrong embolization of the 10th to 11th right intercostals arteries and subcostal arteries^[29]. Respiratory failure is caused by pulmonary embolism or lung metastas from hepatocarcinoma in patients before pulmonary embolism intervention. Blood poisoning and liver abscess are commonly caused by large liqueficiently necrotic tumor. Based on this condition, batteries of intestine reflux to liver or brought in on intervention operation grow and reproduce abscess in the necrosis of cancer. The infection is out of control and quickly leads to blood poisoning^[30]. Cardiac complication is commonly seen among the older that used to have history of coronary disease and arrhythmia etc^[31]. And a pharmacological research showed that Adriamycin-antitumor-drug can come into the cells of cardiac muscle and lead to degeneration of the cells and hyperplasia of Atrial muscle fiber as well as injury and retardance of AV (Atrial and Ventricular) nerves, some severer can hurt heart badly and improve rate of cardiac toxicity^[32]. This is also one of reason present heart failure without cardiac disease in statistics. There is also a case that Hyperkalemia caused sudden cardiac death in melanoma to liver metastasis after TACE operation. It may be considered a large number of tumor cells related to necrosis. A variety of reasons may cause disseminated intravascular coagulation, like hepatocirrhosis, influence of liver cancer tissue on platelets' quality and coagulation system activated by chemotherapy and embolization^[33]. These symptoms further damage the function of liver and weakened its ability to regulate blood coagulation system. Based on cancer illness, gastroduodenal ulcer perforate is caused by TACE being stressful factor as well as aggravation of gastroduodenal mucosal ischemia. Acute pancreatitis may be caused by stress in the body after TACE, but we can't exclude gastroduodenal artery embolism caused by ectopic^[34].

To sum up, TACE is an effective and safe non-surgical method for liver cancer patients who lost opportunities for surgery or radical resection to bring hope. However, we should make it clear that TACE itself is also a double-edged sword, which can cause severe and fatal complications. Some people have already proved that for patients with unresectable primary liver cancer, TACE cannot extend the survival time^[35] at the expense of liver tumors in exchange for narrow tumor. Guided by the principles of evidence-based medicine we will strictly control over their indications and contraindications and make perfect and reasonable treatment plan as well as strengthen prevention and timely and correct treatment of symptomatic to reduce the danger in and off surgery better play its role in the anti-tumor.

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中国肝细胞癌患者 TACE 术后死亡原因分析

李 勇 毕 涛 张炳远 冯玉杰 郝翠萍 赵 伟[△]

(1 青岛大学医学院附属医院普外二科 山东 青岛 266003; 2 青岛大学医学院附属医院呼吸科 山东 青岛 266003)

摘要 目的:通过探讨中国肝细胞癌患者肝动脉化疗栓塞术(TACE)术后并发症及死亡原因,来提高临床治疗效果,并积累治疗经验。**方法:**通过联合检索 CBM 及 CNKI 上从 1994 年 1 月到 2008 年 9 月的关于中国肝细胞癌患者行 TACE 术后出现并发症的相关文章,分析总结肝细胞癌患者 TACE 术后死亡的原因及特点。**结果:**中国肝细胞癌患者 TACE 术后并发症较为危重,致死率较高,死亡原因有 84%是肝功能衰竭、上消化道出血及肝癌破裂出血,且死亡病例发生在术后 1 月内的占 78.7%,因此大多是早期死亡。**结论:**中国肝细胞癌患者 TACE 术后死亡原因主要是肝功能衰竭、上消化道出血及肝癌破裂出血,且术后死亡常为早期死亡,因此 TACE 术后严重并发症可直接影响患者的预后情况,我们需要提高对 TACE 术选择时机的重视程度,规范介入治疗手段和流程,尽量避免和减少严重并发症的发生。

关键词:肝动脉化疗栓塞术;肝细胞癌;死亡原因

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作者简介:李勇,男,硕士研究生,肝胆血管外科,

E-mail:liyong4231@126.com

[△]通讯作者:赵伟,男,E-mail: tiankong4231@126.com

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