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ORIGINAL ARTICLE

Transarterial chemoembolization vs. bland embolization in hepatocellular carcinoma: real-world outcomes

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Abstract

Background: *Transarterial chemoembolization (TACE) is the most frequently used treatment for intermediate-stage hepatocellular carcinoma (HCC); however, evidence supporting its superiority over bland transarterial embolization (TAE) is limited.* **Objective:** *To compare the effectiveness and liver-related complications of TACE and TAE using propensity score matching (PSM).* **Method:** *We retrospectively analyzed patients with HCC treated with first-line TACE or TAE at two referral centers between 2019 and 2021. Overall survival (OS) was the primary outcome. Predictors of OS were evaluated using a Cox proportional hazards model after PSM adjustment.* **Results:** *A total of 114 patients were included (73 TACE, 41 TAE). Most patients had advanced chronic liver disease, and 72.8% were Child-Pugh A. After a median follow-up of 17.9 months and PSM adjustment, no significant difference in OS was observed between TACE and TAE (HR 1.19; 95% CI 0.64–1.96; p = 0.69). On multivariate analysis, only the Child-Pugh score was independently associated with OS. Liver-related complications were comparable between groups (OR TACE vs. TAE 3.7; 95% CI 0.90–14.62; p = 0.06).* **Conclusions:** *After PSM, TACE and TAE show similar long-term survival and liver-related complication rates in patients with HCC.*

Keywords: *Chemoembolization. Hepatocellular carcinoma. Propensity score.*

Quimioembolización transarterial vs. embolización blanda en carcinoma hepatocelular: resultados en el mundo real

Resumen

Antecedentes: *Aunque la quimioembolización transarterial (TACE) es el tratamiento más utilizado en el carcinoma hepatocelular (CHC) en estadio intermedio, existe evidencia limitada que demuestre su superioridad frente a la embolización transarterial blanda (TAE).* **Objetivo:** *Comparar la efectividad y las complicaciones hepáticas de TACE y TAE.* **Método:** *Se analizó retrospectivamente una cohorte de pacientes con CHC tratados con TACE o TAE como primera línea. El desenlace primario fue la supervivencia global (SG). Se empleó un modelo de riesgos proporcionales de Cox tras ajuste mediante emparejamiento por puntaje de propensión (PSM).* **Resultados:** *Se incluyeron 114 pacientes (73 TACE, 41 TAE). Todos presentaban hepatopatía crónica, con Child-Pugh A en el 72.8%. La mediana de seguimiento fue de 17.9 meses. Tras el ajuste por PSM, no se observaron diferencias significativas en la SG entre ambos procedimientos (HR 1.19; IC 95%: 0.64–1.96;*

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p = 0.69). En el análisis multivariante, solo la puntuación Child-Pugh se asoció de forma independiente con la SG. Las complicaciones hepáticas fueron similares entre grupos (OR TACE vs. TAE: 3.7; IC 95%: 0.90–14.62; p = 0.06). **Conclusiones:** *Tras el ajuste por PSM, TACE y TAE muestran resultados comparables en supervivencia y complicaciones hepáticas en pacientes con CHC.*

Palabras clave: *Quimioembolización. Carcinoma hepatocelular. Puntaje de propensión.*

Introduction

Hepatocellular carcinoma (HCC) remains the most prevalent primary liver malignancy worldwide and continues to pose a significant global health burden due to its dismal prognosis[1,2].

The treatment of HCC is usually a clinical challenge due to the complexity of its management and the concurrent diagnosis of chronic liver disease[2]. For patients with HCC who meet transplantation criteria, the preferred curative options are liver transplant or resection, with reported 5-year survival rates of 75-80%[2,3]. However, many patients receive their diagnosis at an advanced stage, precluding surgical or ablative options and leading to systemic therapies[4]. Although there is no standard treatment for unresectable HCC, patients presenting with an intermediate HCC, classified as Barcelona Clinic of Liver Cancer (BCLC) stage B, are considered good candidates for trans-arterial embolization techniques[5].

One of the hallmarks of HCC is tumoral neoangiogenesis which confers its classic pattern of arterial hypervascular enhancement and venous washout on dynamic imaging[3]. Since these tumors receive most of their blood supply through the hepatic artery, intra-arterial therapies represent the mainstay of treatment for such patients[6]. Among the available therapies, transarterial embolization (TAE) and transarterial chemoembolization (TACE) are the two main locoregional treatment options[3]. Both procedures lead to tumor ischemia and inhibition of tumor growth through tumor blood flow shutdown[7]. TACE involves a dual process of intra-arterial chemotherapy infusion combined with embolization[6,7], aimed at selectively targeting the tumor while minimizing damage to healthy liver tissue[6]. In contrast, TAE aims to achieve the occlusion of tumor-feeding vessels without the addition of chemotherapeutic agents[5,7]. Both TACE and TAE induce tumor necrosis at rates in the range of 16-60%[8,9]. Although TACE is the most common procedure for the treatment of intermediate-stage HCC[3], scarce data from observational studies and randomized clinical trials (RCT) have demonstrated any superiority of this approach over TAE[9-16]. Therefore, the most effective transcatheter embolization strategy for unresectable HCC is still uncertain, as confirmed by recent meta-analyses[17-20]. In this study, we sought to compare the effectiveness and liver-related complications of these two procedures in a real-world setting using a propensity score matching (PSM) analysis.

Methods

Patient selection

Patients with HCC diagnosed by histology or by non-invasive criteria at imaging based on European Association for the Study of the Liver guidelines, with a BCLC stage A or B, considered not resectable, not candidates for liver transplantation, and not amenable to ablation were retrospectively identified from electronic clinical records. We included all patients who underwent TACE or TAE as primary treatment for HCC, as indicated by a multidisciplinary tumor board (MTB) in two referral centers from January 2018 to December 2021. Patients were required to have a Child-Pugh score A or B and a performance status Eastern Cooperative Oncology Group (ECOG) 0 or 1. Patients who had one of these procedures as a bridge to liver transplantation were also selected. We excluded patients with any prior trans-arterial or local procedure. Any additional TAE/TACE or systemic therapy was recommended to some patients depending on tumor response and liver function, after discussion in the MTB.

Clinical characteristics were collected from medical electronic records. Patients were followed up with post-operative imaging (liver magnetic resonance imaging or computed tomography scan) every 4-6 months or clinically indicated to assess tumor response. The primary outcome was overall survival (OS). The safety outcome was the frequency of hepatic decompensation, defined by an increase of at least one point in the Child-Pugh score 1 month after the

procedure. Per local protocols, patients with hepatic decompensation were not allowed to receive any further endovascular intervention.

Trans-arterial procedures

Patients were treated with trans-arterial therapy following standard local protocols. TACE using epirubicin was the standard of care for trans-arterial treatment in two hospitals, whereas TAE using lipiodol was the standard of care for patients in other.

In the case of TACE, 20 mg of epirubicin were either loaded on 100 μm drug-eluting beads (100 μm; Embozene Tandem® microspheres, Celonova Biosciences, Ulm, Germany), or manually emulsified with 5-10 mL of ethiodized oil (Lipiodol® Ultra Fluide, Guerbet, France) as previously described[16]. In lipiodol TACE, drug administration was immediately followed by embolization using biocompatible, hydrophilic, non-absorbable, and acrylic polymer microspheres impregnated with porcine gelatin (Embosphere Merit Medical Systems, UT, USA) under fluoroscopic control.

In the case of TAE, 10-15 mL of pure ethiodized oil (Lipiodol® Ultra Fluide, Guerbet, was injected through the catheter as selective as possible. This procedure was followed by embolization with Embospherel® microspheres of 300-500 um (Merit Medical Systems, UT, USA) until complete stasis of the arterial flow.

Statistical analysis

Descriptive categorical variables are presented as frequencies and percentages, or as means ± standard deviations in case of continuous variables. Categorical variables were compared through the Chi-square test, or Fisher test when indicated. Comparisons among baseline characteristics were performed before and after the PSM.

Since TAE and TACE procedures were not randomly assigned in the studied population, a PSM was used to reduce the influence of potential confounding variables between both groups. Patients were matched to receive one of these therapies based on a propensity score estimated by a multivariable logistic regression model, in which the TACE procedure was the dependent variable and the following baseline characteristics were used as covariates: Child-Pugh score, sex, and ECOG performance status. The PSM was performed using a 1:1 matching without replacement (Greedy-matching algorithm).

The primary outcome was OS as measured from the date of first TACE/TAE until death according to the National Registry System. The association between endovascular therapies (TAE or TACE) and OS was examined using a Kaplan-Meier survival curve. The log-rank test was used to compare the distributions of OS among therapies after adjustment using a PSM (1:1 greedy nearest-neighbor matching). An univariate Cox proportional-hazard regression model was used to determine the hazard ratio (HR) and its corresponding 95% confidence interval (CI) for the association between OS and the endovascular treatment received. The model was also adjusted for ECOG, Child-Pugh score, and age as covariates. The odds ratio (OR) and its 95% CI was used to measure the association between liver decompensation and the trans-arterial procedure. $p < 0.05$ was considered statistically significant. All the analyses were performed using the Statistical Analysis System (SAS)® software version 9.3 (SAS Institute Inc. Cary, NC, USA). The STROBE Guidelines were followed in reporting this observational study. The Institutional Review Board approved this protocol (R023-SABI-0337).

Results

General characteristics

During the study period, a total of 114 patients underwent TAE (n = 41; 35.9%) or TACE (n = 73; 64.1%). Clinical characteristics of the studied population before and after PSM are summarized in table 1. Most patients were male (n = 74, 64.9%), with a mean age of 68.5 ± 8.7 years, good performance status (ECOG 0-1: n = 102; 89.5%), and a BCLC stage of B (n = 87, 76.3%). All patients had chronic liver disease and 42.5% (n = 31) of them had clinical signs of portal hypertension. Most patients had metabolic-associated fatty liver disease as underlying hepatic disease (n = 72, 63.2%). After PSM, 76 patients were included in the analysis.

Efficacy and safety outcomes

After a median follow-up of 17.9 months, a total of 72 patients died (63.2%). Median OS for the whole population was 19.9 months (95% CI: 15.8-26.2 months). The probability of survival at 3 years was 32%. As depicted in figure 1, there was no significant difference between the probability of OS between patients who received TAE or TACE as endovascular treatment for

Table 1. General characteristics of the studied population before and after the propensity score matching

Variable	Before PSM		p	After PSM		p
	Trans-arterial procedure			Trans-arterial procedure		
	TAE, n = 41 (35.9)	TACE, n = 73 (64.1)		TAE, n = 38 (50)	TACE, n = 38 (50)	
Sex, n (%)			0.03 (χ^2 = 8.95)			0.99 (χ^2 = 0.12)
Male	32 (43.2)	42 (56.8)		29 (50)	29 (50)	
Female	9 (22.5)	31 (77.5)		9 (50)	9 (50)	
Age, n (%)			0.19 (χ^2 = 6.125)			0.17 (χ^2 = 6.42)
< 55 years	0	11 (100)		0	4 (100)	
55-70 years	19 (41.3)	27 (58.7)		16 (59.3)	11 (40.7)	
> 70 years	22 (38.6)	35 (61.4)		22 (28.2)	23 (71.8)	
ECOG (%)			0.001 (χ^2 = 16.27)			0.04 (χ^2 = 8.31)
0	28 (58.3)	20 (41.7)		26 (78.8)	7 (21.2)	
1	13 (19.7)	53 (80.3)		12 (27.9)	31 (72.1)	
Underlying liver disease, n (%)			0.44 (χ^2 = 5.85)			0.45 (χ^2 = 5.77)
Alcoholic liver disease	5 (23.8)	16 (76.2)		5 (38.5)	8 (61.4)	
MAFLD	28 (38.9)	44 (61.1)		27 (51.9)	25 (48.1)	
Autoimmune hepatitis	1 (50)	1 (50)		1 (100)	0	
Chronic HBV	2 (28.6)	5 (71.4)		2 (50)	2 (50)	
Chronic HCV	3 (75)	1 (25)		2 (100)	0	
Other	2 (28.6)	5 (71.4)		1 (25)	3 (75)	
Child-Pugh score, n (%)			0.11 (χ^2 = 7.54)			0.99 (χ^2 = 0.12)
A	33 (39.8)	50 (60.2)		31 (50)	31 (50)	
B	7 (23.2)	23 (76.7)		7 (50)	7 (50)	
C	1 (100)	0		0	0	
Barcelona clinic liver cancer stage, n (%)			0.55 (χ^2 = 2.11)			0.99 (χ2 = 0.12)
A	11 (40.7)	16 (59.3)		10 (50)	28 (50)	
B	30 (34.5)	57 (65.5)		10 (50)	28 (50)	
Alpha-fetoprotein, n (%)			0.66 (χ^2 = 1.59)			0.77 (χ^2 = 1.13)
> 400 ng/dL	35 (36.8)	60 (63.2)		32 (50.8)	31 (49.2)	
< 400 ng/dL	6 (31.6)	13 (68.4)		6 (46.2)	7 (53.8)	
TAE/TACE as a bridge for liver transplantation (%)	1 (10)	9 (90)	0.09 (χ^2 = 6.49)	1 (33)	2 (66)	0.56 (χ^2 = 2.06)

PSM: propensity score matching; TAE: trans-arterial embolization; TACE: trans-arterial chemoembolization; ECOG: Eastern Cooperative Group; MAFLD: metabolic associated fatty liver disease; HBV: hepatitis B virus; HCV: hepatitis C virus.

HCC (HR: 1.19; 95% CI: 0.64-1.96 p = 0.69). Table 2 shows the results of the multivariate analysis for OS. After adjusting for potential confounders, only the Child-Pugh score (B vs. A) was associated with poor OS (median OS 15.5 vs. 23.3 months, respectively).

Hepatic decompensation occurred in 9 (23.7%) and 3 (7.9%) patients who underwent TACE and TAE, respectively (OR TACE vs. TAE: 3.7; 95% CI: 0.90-14.62; p = 0.06). Among patients with hepatic decompensation, the most frequent event was grade I hepatic encephalopathy (n = 5), followed by worsening ascites (n = 4) and transient hyperbilirubinemia (n = 3). Similarly, infectious complications were numerically more common after TACE compared with TAE, although the difference was not statistically significant (13.2 vs. 5.3%; OR: 2.27; 95% CI, 0.49–15.01; p = 0.23). Infectious complications included nosocomial pneumonia (n = 5), urinary tract infection (n = 3), and spontaneous bacterial peritonitis (n = 2). Other uncommon adverse events included hepatorenal syndrome in one patient treated with TACE and variceal bleeding in one patient from each treatment group.

Discussion

The findings of our study showed comparable OS and liver-related complications among patients receiving TAE or TACE for unresectable HCC. RCTs and observational studies comparing conventional TACE and TAE have shown conflicting results in determining

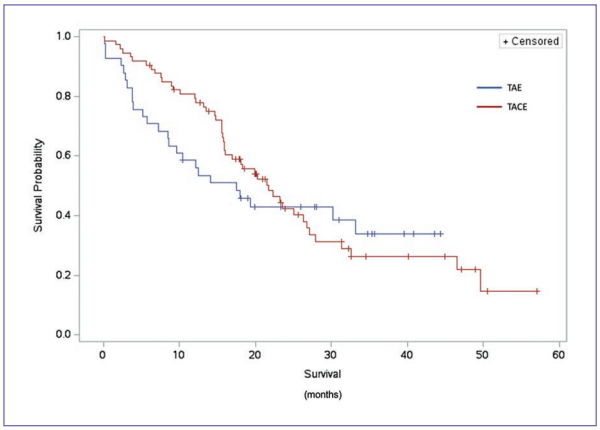

Figure 1. Overall survival for patients receiving trans-arterial chemoembolization or trans-arterial embolization according to the Kaplan-Meier method.

Table 2. Multivariate analysis for overall survival after propensity score matching analysis

Variable	Hazard ratio (95% CI)	p
Sex (female vs. male)	0.98 (0.50-1.92)	0.95
ECOG performance status (0 vs. 1)	0.52 (0.18-1.55)	0.235
Child-Pugh score (A vs. B)	0.32 (0.15-0.66)	0.002*
Type of treatment (TACE vs. TAE)	1.68 (0.84-3.33)	0.138

CI: confidence interval; ECOG: Eastern Cooperative Group; TAE: trans-arterial embolization; TACE: trans-arterial chemoembolization.

the superiority of one technique over the other[10-16]. For instance, one RCT comparing TACE, TAE, and best supportive care (BSC) was prematurely closed due to the superiority of TACE over BSC, and it was not powered enough to determine the efficacy of TACE over TAE[11]. On the other hand, another RCT concluded that the addition of cisplatin did not enhance the therapeutic effect of TAE for the treatment of patients with unresectable HCC[16]. Similarly, a recent trial also failed to show the superiority of TACE (using doxorubicin-eluting microspheres) over bland embolization[14].

Although the heterogeneity of the included patients in each trial can explain the aforementioned differences among studies, our results are in line with the null effect of chemotherapy when added to selective arterial embolization. Indeed, four recent reviews and meta-analyses found no conclusive evidence to support TAE or TACE for these patients[17-20]. Some authors have argued that available trials comparing bland embolization to TACE are inconclusive since they include populations that do not match the profile of patients for whom TACE would be recommended[5]. Besides, the selection criteria for these endovascular techniques are broad, from bridge or downstaging to liver transplantation to patients unsuitable for surgery. In contrast, our population was composed only by patients with a BCLC stage of A and B, for whom a MTB indicated TACE or TAE based on clinical judgment and current guidelines[5]. Hence, our results can adequately compare both procedures in a cohort of patients with a clear indication for the intravascular procedure, excluding subjects with vascular invasion, extrahepatic disease, or diffuse or extensive liver involvement.

Although the relatively small sample size of this analysis can affect the precision of our findings, and the retrospective design can arise some concerns regarding selection and informative bias, we were able to provide a fair comparison between both intra-arterial procedures in a cohort of patients from a "real-world" scenario, which frequently differs from the setting of a RCT. Indeed, previous studies have indicated that selection criteria of HCC patients for intra-arterial procedures are usually broader in real clinical practice in comparison to those criteria suggested by clinical guidelines[21].

Although other cohort studies have reported similar results to ours regarding the inconclusive superiority of one of the intra-arterial procedures over the another[13], the selection of a PSM in this research enhances the comparability between both comparison arms. Given these contradictory results and the absence of superiority of one technique over the other, many authors coincide that the effects of embolic therapies derive mainly from tumor ischemia produced by occlusion of the arterial vessels and that the addition of chemotherapy has little effect on tumor control[3].

It has also been argued that TACE may incite more liver damage than bland embolization especially when conducted in a non-selective manner. Common side effects of liver embolization include fever, pain, and transient elevation of aminotransferases and bilirubin levels. More serious complications can also be present such as hepatic and kidney failure, sepsis, and death. Although our findings showed a higher percentage of patients with liver decompensation after TACE versus TAE, these differences were not statistically significant. Of note, all intra-arterial procedures were performed by well-trained interventional radiologists who prefer

ultra-selective embolization in all cases when feasible, which lower the probability of side effects. Besides, the assessment of hepatic decompensation was performed 1 month after the procedure, and previous studies have confirmed that hepatic impairment is usually transient and self-limited[22].

The decision to use OS as a primary endpoint responds to the interobserver variation during the evaluation of response after TAE/TACE, which makes less reproductible the assessment of progression[23]. Besides, in real-world studies, OS is a more appropriate endpoint since it is less prone to information bias. In addition, some authors have argued against the use of progression-free survival as a valid surrogate efficacy outcome in patients with HCC due to its vulnerability to interpretation bias and low correlation with OS[24].

Of note, the 3-year OS rate in this cohort was inferior to the reported by recent series (33 vs. 55 to 66%)[3], probably due to low access to medical therapies after TAE/TACE failure.

In conclusion, our findings demonstrated comparable long-term outcomes and liver-related complications in patients treated with TAE or TACE for HCC.

In the absence of new RCTs comparing these two strategies, our results are useful to challenge the routine use of chemotherapy-eluting beads or lipiodol chemoembolization for the treatment of patients with BCLC-A or BCLC-B HCC.

Conclusion

In this real-world retrospective analysis, TACE and TAE showed comparable efficacy after propensity score matching.

Authors' contributions

C. Umaña and A. Ramos-Esquivel: conceptualization. All authors: data curation, formal analysis, investigation, methodology, and project administration. A. Ramos-Esquivel: supervision. All authors: writing-review and editing.

Clarification note

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of humans and animals. The authors declare that the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the World Medical Association and the Declaration of Helsinki. The procedures were authorized by the Institutional Ethics Committee.

Confidentiality, informed consent, and ethical approval. The authors have followed their institution's confidentiality protocols, obtained informed consent from all patients, and secured approval from the Ethics Committee. SAGER guidelines have been followed as applicable to the nature of the study.

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing or creation of the content of this manuscript.

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