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Trans-Arterial Chemoembolization for the Treatment of Hepatocellular Carcinoma: A Single Tertiary Care Institute Experience

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ABSTRACT

Introduction: Trans-arterial chemoembolization (TACE) is a mainstay therapeutic option indicated in early-stage non-resectable hepatocellular carcinoma (HCC) and has been shown to be associated with survival improvements. This study aimed to evaluate the radiological and clinical response of those who underwent TACE.

Aims & Objectives: We aimed to evaluate the radiological and clinical response in patients who underwent Trans-arterial chemoembolization.

Place and Duration of Study: This study was conducted in the Vascular Interventional Radiology Department, Dow Institute of Radiology, Dow University of Health Sciences, Ojha Campus Karachi for a period of 18 months between January 2021 and June 2022.

Material & Methods: HCC patients (n=181) who underwent TACE as their primary treatment at Dow Hospital Ojha Campus Karachi between January 1st, 2021, and June 30th, 2022 were included. Inclusion criteria followed the Barcelona Clinic Liver Cancer (BCLC) and Child-Pugh staging systems. Tumor response was evaluated using "modified Response Evaluation Criteria in Solid Tumors (mRECIST)", and patients were categorized into complete response (CR) or partial response (PR) groups. The study compared background, clinico-laboratory, and radiological features between these groups, including HCC sizes and CT scan findings before and after TACE. The retrieved data was entered and analyzed using SPSS version.21.

Results: Of the total 118 patients, 51.70% showed CR to the TACE, while PR was noted in 48.30%. Age, sex, viral hepatitis, and co-morbids showed no intergroup differences. However, Child-Pugh stage and BCLC were significantly associated with tumor response. Similarly, laboratory parameters revealed significant mean differences between the two groups ($p<0.001$), except international normalized ratio and alanine transaminase. Those who had achieved CR had a mean number of tumor less than that of PR. Similarly, tumor size significantly decreased post-TACE ($p<0.0001$). Moreover, arterial-phase enhancement and portal venous and delayed phases washout tumors before TACE were reported in 76.30%. Over half of the patients had no residual tumor tissue after TACE. Tumors with arterial-phase enhancement and portal venous and delayed phases washout were highly susceptible to TACE.Furthermore, Child-Pugh classA had a greater estimated mean survival than class B ($p<0.001$).

Conclusion: Over half of the patients showed complete response to the TACE. BCLC staging (B), Child-Pugh (stage A), and small tumors had a favourable effect on the radiological and clinical response in the early-stages of HCC. Tumors with an arterial-phase enhancement and portal venous and delayed phases washout were more susceptible to TACE.

Keywords: Hepatocellular carcinoma; Trans-Arterial Chemo-embolization; Chronic liver disease; TACE; radiological response

INTRODUCTION

Hepatocellular carcinoma (HCC) is a serious and a major global health issue with about 500,000 new cases identified yearly, making it the most prevalent and the 5th most frequent primary liver cancer[1,2]. It represents between 70%-90% of all cases of primary liver cancer[3]. In Asian countries, the prevalence ranges between 0.3% and 1.6%[4]. Chronic viral hepatitis or cirrhosis, environmental contaminants, secondary viral infections such as hepatitis B(HBV) and C (HCV) and alcoholic or fatty liver conditions, lifestyle aspects including smoking, alcohol intake, and dietary habits, metabolic conditions like diabetes and high body mass index, and genetic and hereditary issues are the most common causes[3,5]. Despite diagnostic, and therapeutic advancements, HCC continues to pose significant diagnostic and treatment limitations[5,6].

"The Barcelona Clinic Liver Cancer (BCLC) staging system" considers tumor characteristics, performance status and liver function for evidence-based treatment selections[7]. Hepatic resection, radio-frequency ablation (RFA) and liver transplantation are recommended for early stage HCC BCLC (stage A). Nevertheless, due to specific situations, these modalities cannot always be utilized for all HCC patients. Loco-regional treatment (LRT) is a bridging technique for patients on the transplant queue[8,9]. Trans-arterial chemo embolization (TACE) is a therapeutic approach that involves the selective delivery of chemotherapeutic agents and embolic materials directly into the tumor-feeding arteries, leading to the dual effect of tumor necrosis and arterial occlusion. It is the most frequently used treatment in patients with BCLC stage B, which includes multi-nodular tumors with Child-Pugh (A or B) stage and good performance status and is not susceptible to resection. Arterial neoangiogenesis is the hallmark of HCC or hepatoma. These aggressive liver tumors rely heavily on the development of an extensive blood supply to sustain their rapid growth and progression. TACE blocks tumor blood flow, inhibits tumor growth and produces significant findings in terms of tumor response, which is about 50%[9,10]. This means that about half of the patients treated with TACE experience a significant reduction in tumor size or stabilization of the disease, leading to improved clinical outcomes. These findings highlight the considerable impact of TACE in managing HCC and its potential as a curative or palliative treatment modality.

The radiological and clinical response of TACE in the treatment of HCC has been a subject of significant interest and research. Assessing tumor response to TACE is crucial for determining treatment efficacy and future therapy.[11] To assess response to LRT, a "modified response evaluation criterion in solid tumours (mRECIST) are a set of published rules used to assess tumor burden in order to provide an objective assessment of response to therapy with targeted agents for hepatocellular carcinoma (HCC). It considers the extent of viable contrast-enhancing regions within the tumor[9,10,12]. Although there is a validated relationship between HCC enhancement patterns and image results, these findings are closely associated with tumor differentiation, which plays a crucial role in understanding the aggressiveness and prognosis of HCC[11,13,14]However there is a data scarcity of this region and the therapy outcomes remain diverse. Considering this, the present study is conducted to determine the radiological and clinical response of HCC patients who underwent TACE.

MATERIAL AND METHODS

This retrospective cross-sectional study analysed HCC patients from January 1st, 2021, to June 30th, 2022, at the Department of Radiology, Dow Hospital Ojha Campus, Karachi. The study protocol was agreed by the Dow University of Health Sciences Ethical Review Committee vide number IRB-2790/DUMS/EXEMPTiON/2023/31 dated 19th Nov 2022.

All patients who have undergone TACE for multicentre HCC during the study were included, without calculating formal sample size. 118 patients completed this study.The criteria for inclusion were diagnosed case of chronic liver disease (CLD) with unresectable multi-centric HCC (those with partial portal vein thrombosis and those with multi-centric HCC not amenable to percutaneous ablation).Exclusion criteria included diagnosed CLD with complete portal vein thrombosis, Child-Pugh stage C , local or distant metastases, and received prior treatment from another institute, or loss of follow-up during treatment.

Background characteristics such as age and sex, clinical and laboratory characteristics, including viral hepatitis, co-morbids, Child-Pugh stage, BCLC, total albumin and bilirubin, alanine aminotransferase (ALT), alpha-fetoprotein (AFP), INR, and tumor characteristics such as number of tumors, appearance, size, and location were recorded.

TACE Technique:

Prior to the TACE procedure, written informed consent was obtained. Once the aseptic measures were taken, a local anaesthesia was administered and the common right femoral artery was punctured. A 6Fr vascular sheath was then placed, and the celiac and superior mesenteric arteries were surveyed angiographically. The next step was to perform a common hepatic angiography to determine the tumor's blood supply. After that, a microcatheter was cautiously and selectively inserted into the artery that was feeding the tumor. Doxorubicin 50mg, the chemotherapy agent mixed with lipiodol was injected. Additional embolisation was performed with PVA particles (100–350 microns). The interventional radiologist determined the correct amount of the chemotherapeutic and embolic agents based on the several factors like size and number of tumors, the tumor arterial blood supply, the degree of liver impairment, and renal function. For those who had

adequate hepatic function reserve (Child-Pugh A or Child-Pugh B < 8) and a residual viable tumor, repeat TACE treatments were planned at 6 to 8weeks intervals after the initial treatment. However, those patients who showed no evidence of residual viable disease (i.e., with CR according to mRECIST), imaging follow-up was recommended every 2 to 3 months.

Radiological Characteristics:

The pre- and post-TACE triphasic abdominal CT scans were performed, and tumor characteristics were recorded as reported by experienced radiologists. The HCC attenuation in each phase was classified as arterially enhancing with washout in porto-venous and delayed phases tumor and heterogeneously enhancing with washout in portal venous and delayed phases. The pattern of enhancement is classified as residual tumor enhancement or no residual tumor enhancement. Tumor size was compared pre- and post TACE.

Post TACE Tumor Response:

Patients were evaluated at 6weeks of post TACE period by contrast CT scan of abdomen with triphasic protocol and then followed up every 2 to 3months, depended on individual tumor response until they reached the endpoints, which included death or survival. The tumor response was measured based on the modified RECIST (mRECIST) standards[12] with two categories of response: complete response (CR) and partial response (PR) obtained at first follow-up visit.

Statistical Analysis:

The retrieved data was analysed SPSS version 21. Quantitative variables were presented as mean and standard deviation, medians and interquartile ranges, or both. Numbers and percentages were used for categorical variables. The Chi square test or Fisher exact was used to determine the association between categorical variables, and numerical data differences were calculated using the student independent t test. A paired sample t-test was used to see the pre- and post-mean differences. Survival analysis was done using the Kaplan-Meier curve. Statistical significance was set at 5% with a 95% confidence interval. p value≤ 0.05 was considered significant,

RESULTS

The details of the study patients (n=118) are summarised in Table-1. The mean age of the study patients was 49.42±10.74 years [median (IQR) 50.00 (16.25)]. Nearly two-thirds of the study participants were male. Viral hepatitis caused by HCV was observed in 81 (68.64%) patients and HBV in 37 (31.36%) patients. Those who had coexisting illnesses were 53 (44.92), where hypertension was documented in 41 (34.75%), and diabetes mellitus in 38 (32.10%). Majority patients were grouped into Child-Pugh stage A, whereas 75.42% of the patients were in stage B based on "The Barcelona Clinic Liver Cancer (BCLC) staging system." All patients had multiple tumors. The HCC diameter was 3.99±0.90 cm, with 83 (70.30%) having a tumor size >3 cm. Tumors were located in more than half of the patients in right lobe of the liver. On the other hand, one-fourth of the patients had portal vein tumor thrombus.

The study patients were divided into two tumor response categories. Of the total 118 patients, 51.70% showed complete response to TACE, while 48.3% had partial response (PR). Patient background, laboratory, and tumor characteristics, as well as the outcome of both tumor response categories, are presented abridged in Table-1. Age, sex, viral hepatitis infection, and co-morbid conditions showed no intergroup differences. Child-Pugh stage and BCLC were significantly associated with tumor response. Laboratory parameters including total bilirubin, albumin, and AFP showed a significant mean inter group differences ($p<0.001$). Those who responded completely had a mean tumor (3.00±1.00 vs.5.00±1.00 $p<0.001$) compared to the partial responders. Those with smaller (≤3cm) tumor sizes had a higher rate of complete response than those with larger (>3cm) ones did not [(26(42.60%) vs. 9(15.80%)], and the association was statistically significant ($P<=0.001$). Patients were followed, and at the endpoint, no mortality was noted in those who responded completely.

Tumor size was assessed using a CT scan of the abdomen with a triphasic protocol, and the results were compared pre- and post-6-weeks TACE as shown in Fig-1. A paired sample t-test was run to ascertain whether there was a statistically significant mean difference before and after TACE. There was a significant mean difference in tumor size (3.27±0.90 vs. 3.99±1.02, $p<0.0001$). The paired mean difference was 0.72 (95% CI [0.62-0.82]). Arterially enhancing with washout in portovenous and delayed phases tumor appearance before TACE was documented in 90 (76.30%), followed by heterogeneously enhancing with washout in portal venous and delayed phases in 28 (23.70%). Post-TACE, no residual enhancement was documented in more than half of the patients. A high proportion of patients showed no residual enhancement of tumor in arterial phase, as given in Fig-2 and Fig-3.

The average duration of patient survival was 12.55 months (95% confidence interval: 11.90–13.19), with a median survival of 14.00 months (95% confidence interval: 12.36–15.64). Tumor response yielded no statistics because all cases were censored in CR. The computed mean [(12.68, 95% 11.99-13.37 vs. 11.63, 95% 10.42-12.83)] duration for the absence of PPVT was greater compared to the presence (p=0.414). Overall, the estimated mean duration for tumor size ≤3 was greater than that for tumour size >3 (12.42 Vs.12.22) but the difference was statistically nonsignificant (p=0.138). Likewise, BCLC (stage B) had an estimated mean survival time greater than that of BCLC C, and the difference was statistically nonsignificant (p=0.414). On the contrary, Child-Pugh score A had an estimated mean survival time greater than that of score B, and the difference was statistically significant (p<0.001) as shown in Fig-4.

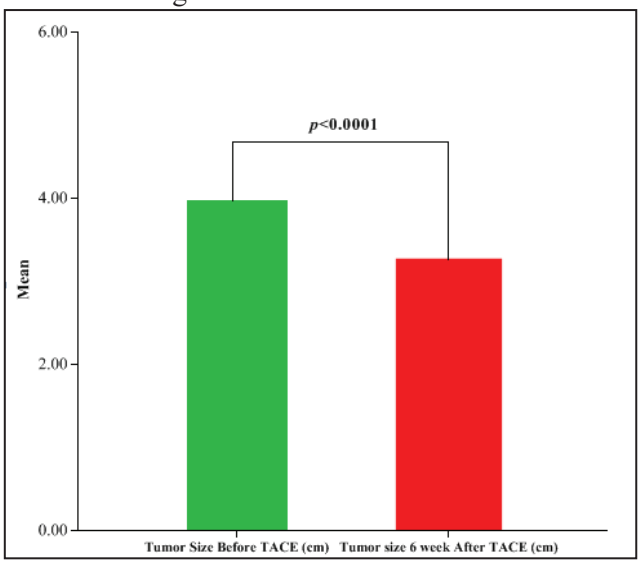

Fig-1: Tumor size before and 6 weeks after TACE

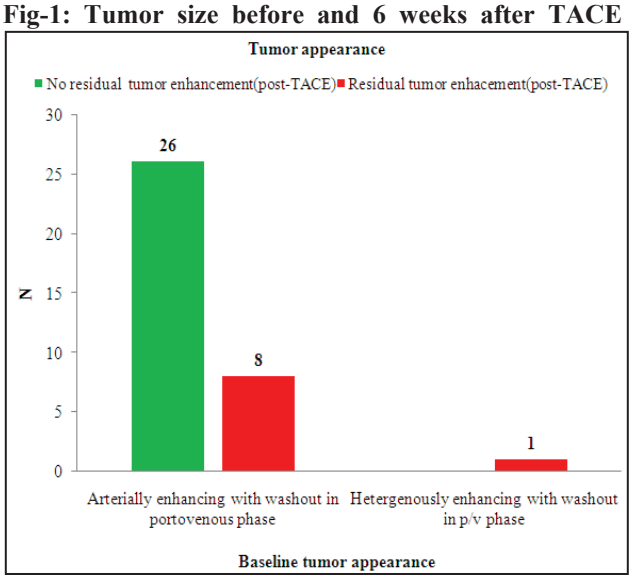

Fig-2: Tumor appearance before and 6 weeks after TACE.

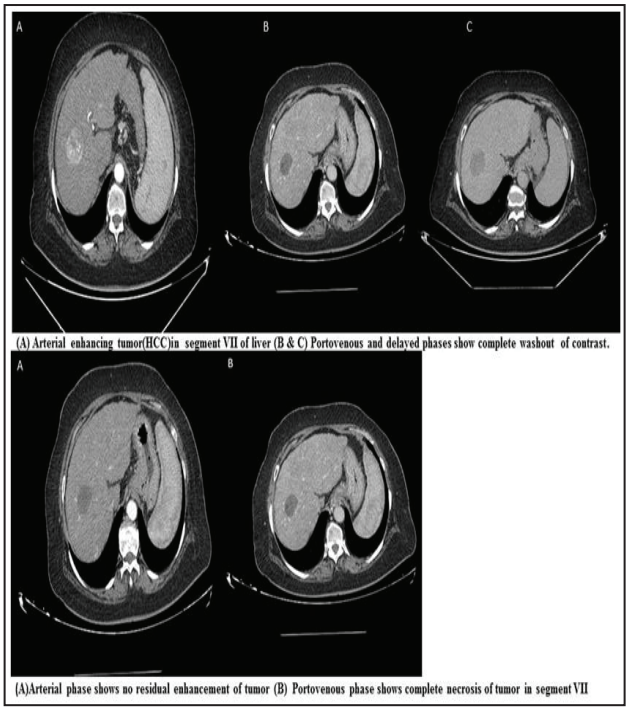

Fig-3: The pre-TACE CT scan of the patient's abdomen with contrast (Triphasic protocol), followed by a post-TACE CT with contrast, revealing a remarkable complete response of the HCC.

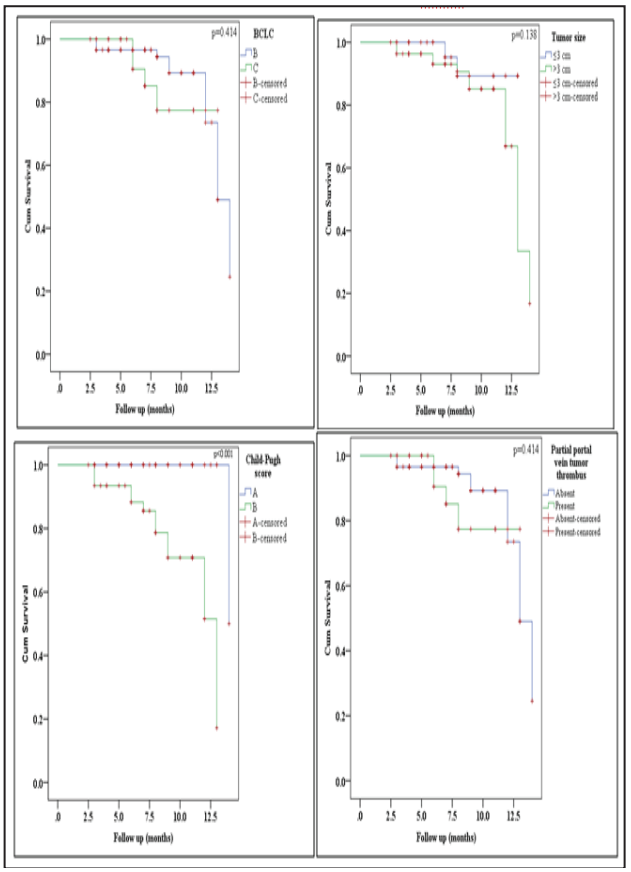

Fig-4: Overall survival comparing (a) partial portal vein thrombosis (b) Tumor size (c) BCLC (d) child-Pugh score

Characteristics		Total	Tumor Response		P-value
			CR N=61	PR N=57	
Age(years)	Mean± SD	49.4± 10.7	48.2± 11.9	50.7± 9.2	0.201
Sex, n (%)	Female	42 (35.6)	17 (27.9)	25 (43.9)	0.070
	Male	76 (64.4)	44 (72.2)	32 (56.2)	
Viral hepatitis, n (%)	HBV	37 (31.4)	19 (31.2)	18 (31.6)	0.960
	HCV	81 (68.7)	42 (68.9)	39 (68.4)	
Presence of Comorbid, n (%)	No	65 (55.1)	34 (57.7)	31 (54.4)	0.883
	Yes	53 (44.9)	27 (44.3)	26 (45.6)	
Diabetes mellitus, n (%)	No	80 (67.8)	42 (68.9)	38 (66.7)	0.800
	Yes	38 (32.2)	19 (31.2)	19 (33.3)	
Hypertension, n (%)	No	77 (65.3)	40 (65.6)	37 (64.9)	0.940
	Yes	41 (34.6)	21 (34.4)	20 (35.1)	
Child-Pugh score, n (%)	A	72 (61.02)	53 (86.89)	19 (33.33)	<0.001
	B	46 (38.9)	08 (13.1)	38 (66.7)	
BCLC staging	B	89 (75.4)	54 (88.5)	35 (61.4)	0.001
	C	29 (24.6)	07 (11.5)	22 (38.6)	
Total bilirubin (mg/dl)	-	1.86± 0.29	1.76± 0.28	1.96± 0.27	<0.001
Albumin (g/dl)	-	3.56± 0.26	3.67± 0.23	3.45± 0.25	<0.001
International normalised ratio (INR)	-	1.23± 0.14	1.22± 0.13	1.24± 0.15	0.300
Alpha-fetoprotein (ng/mL)	-	1588.9 ± 1315.0	1170.1 ± 1009.6	2037.2 ± 1458.3	<0.001
Alaninetransamina(ALT) U/L	-	53.4± 5.9	53.52± 6.00	53.33± 6.01	0.863
Number of Tumor	-	4.19± 1.39	3.00± 1.00	5.00± 1.00	<0.001
Tumor location in liver	Both lobe	39 (33.1)	05 (8.2)	34 (59.7)	<0.001
	Left lobe	15 (12.7)	12 (19.7)	03 (5.3)	
	Right lobe	64 (54.3)	44 (72.2)	20 (35.1)	
PPVT	No	89 (75.4)	54 (88.5)	35 (61.4)	0.001
	Yes	29 (24.6)	7 (11.5)	22 (38.6)	
Tumor size	≤3	35 (29.7)	26 (42.6)	9 (15.8)	0.001
	>3	83 (70.3)	35 (57.4)	48 (84.2)	
Outcome	Alive	102 (86.4)	61 (100.0)	41 (71.9)	<0.001
	Expire	16 (13.6)	0	16 (28.1)	

Table-1: Background, biochemical, tumor related characteristics and intergroup differences.

DISCUSSION

TACE is the preferred loco-regional treatment for intermediate-stage HCC, according to the clinical guidelines. Multimodal therapies based on TACE have been shown to be more efficient than conservative management. To evaluate the efficacy, it is crucial to perform post-TACE radiological response analysis, utilizing the modified RECIST principle, which recommends one-dimensional evaluation of the longest remaining tumor dimension and the RECIST numerical criteria of response[12,15]. The measurement of residual viable tumor tissue after TACE to determine personal responses is a proxy indication of the survival rate.

Our findings revealed that a CR was achieved in 51.70% of patients. A study conducted by Lee, S. W., et al[9] reported radiological CR in 60% of the study patients. A similar study in Italy with a single HCC undertaking TACE reported a 64% CR rate and 26% PR[16].The variation could be attributed to the tumour size, inclusion criteria, selectivity of technique, and expertise of the treating consultant. Most clinico-laboratory variables had no effect on the CR. However, a smaller Child-Pugh grade was found to have significant impact on TACE response in the study. This association has been shown frequently in studies[10,17,18], and it may be associated to the aggressive therapy regimen that patients with a better functional liver status were able to tolerate as compared to that utilised in the wake of advanced disease.Patient with larger tumors (≥3 cm) had a significantly higher percentage of CR compared to those with smaller tumors (<3 cm) (42.60% vs 57.40%).TACE is the treatment of choice for large tumors and neoadjuvant chemoembolization to reduce the size of the tumor for liver transplant or resection[19]. Previous studies suggest that small tumors are more likely to achieve CR, unlike our study findings[16,20]. The plausible explanation for these differences, where larger tumors had a higher percentage of CR, could be attributed to differences in the patient population, tumor characteristics, or therapy protocols. It is also possible that the sample size or methodology of the earlier studies was not robust enough to detect the effect of tumor size on TACE response.

In our study, those with no partial portal vein tumor thrombus (PVTT) had a high radiological complete response. TACE paired with radiation has demonstrated greater efficacy in patients with HCC and PVTT by maintaining portal blood flow, preventing the loss of liver function, and preventing intra-vascular tumour progression[19]. The presence of PVTT poses a therapeutic challenge, and its

presence may compromise the candidature for TACE due to the risk of liver function deterioration and hepatic infarction. However, selective, or super-selective TACE procedures can still be performed safely in some cases.

To further understand what factors, influence HCC responsiveness, the study divided HCC lesions into two groups based on radiological appearance and found that 76.30% of tumors were arterially enhancing with washout in the porto-venous and delayed phases, while 23.70% were heterogeneously enhancing with washout in the portal venous and delayed phases. More than half of the patients had no residual enhancement after TACE. In arterial phase, a large number of patients had no residual tumor enhancement as found by Zhang Wie et al[10], found that lesions with strong arterial phase enhancement had a higher probability of near-complete necrosis compared to those with mild to moderate enhancement (37%).Considering enhancement and margin factors may help determine TACE outcomes, and examining both variables before treatment may be beneficial.The findings imply that the application of enhancement and margin factors may aid in determining the probability of TACE outcome, and henceforth it may be beneficial to examine both variables concurrently before subjecting patients to surgical procedures.

The absence of PPVT and tumor size ≤3 had a longer mean duration than the presence and larger size. BCLC (B) had a greater estimated mean survival time than BCLC (C), while Child-Pugh score A had a greater estimated mean survival time than score B, with a significant difference. CR had no statistics for tumor response, but TACE-induced radiological tumor response predicted overall survival, and no mortality was observed in those who achieved CR. The study's findings are consistent with those of other studies regarding smaller tumors, Child-Pugh score, and BCLC staging on cumulative survival[9,16,20]. TACE is an effective therapy for unresectable HCC, including BCLC-C and Child-Pugh-B stages, and can improve survival and responsiveness without affecting liver function[19,21]. The study has limitations such as a retrospective design, selection and reporting biases, small sample size, grouping of radiological response into two categories only, and lack of characterization of tumor margin shape. Prospective studies with more cases and covariates are needed to improve the findings.

CONCLUSION

Based on this study's findings, it can be concluded that over 50% of the patients achieved a complete response to TACE. Factors such as BCLC B stage, Child-Pugh class A, and small tumor size positively influenced the response to TACE during the early stages of HCC. Additionally, tumors exhibiting arterial enhancement and washout in the porto-venous and delayed phases were found to be more susceptible to TACE treatment. The use of CT imaging could aid in refining the criteria for selecting TACE as a treatment option, thereby enhancing overall outcomes and patient survival. It is important to consider an individual's risk profile, co-morbid conditions, and potential benefits when deciding to pursue TACE as a therapeutic approach, with the goal of improving survival rates while minimizing adverse events.

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