

Conventional Transarterial Chemoembolisation vs Drug-Eluting Beads in Patients with BCLC Intermediate Stage of Hepatocellular Carcinoma; a short term follow up study

Ahmed Mohamed Rozeka Abuelatta^{1*}, Amr Farouk Ibrahim², Mohamed Elsayed Gadelmola³, Reda Hasan Tabashy⁴

¹Radiologist, National Cancer Institute, Cairo University

²Assistant Professor of Radiodiagnosis, National Cancer Institute, Cairo University

³Lecturer of Medical Oncology, National Cancer Institute, Cairo University

⁴ Professor of Radiodiagnosis, National Cancer Institute, Cairo University

*ahmedrozeka88@gmail.com

Abstract

Background: Hepatocellular carcinoma (HCC) is the 3rd leading etiology of cancer-related mortality worldwide and the 6th most prevalent tumor overall.

Aim: To evaluate the comparative effectiveness of conventional transarterial chemoembolization (TACE) and drug-eluting beads TACE (DEB-TACE) in treating unresectable liver carcinoma.

Patients and methods: This prospective investigation involved 75 cases with unresectable hepatocellular carcinoma managed with conventional Transarterial Chemoembolization (TACE) in Group I (n=42) or Drug-Eluting Bead Transarterial Chemoembolization (DEB-TACE) in Group II (n=33) at the National Cancer Institute in Cairo from 2019 to 2023.

Results: Both groups showed comparable clinical parameters. Group I's tumor load ranged from 2.1 to 8.3 cm (mean: 4.18 cm, SD: 1.93) and AFP levels from 304.4 to 1760.3 (mean: 1157.75, SD: 344.8), while Group II had a tumor load from 2 to 9.1 cm (mean: 4.48 cm, SD: 2.04) and AFP levels from 118.3 to 2582.6 (mean: 1280, SD: 573), with no significant distinctions (P=0.5169 and P=0.2552, correspondingly). Treatment responses were also similar, with both groups showing nearly identical distributions of complete, partial, stable, and progressive disease (P=0.998). However, regarding adverse effects, nausea and abdominal pain were significantly more frequent (P=0.0126 and P=0.0282, correspondingly), while vomiting rates remained comparable between the groups.

Conclusion: Both procedures, cTACE and DEB-TACE, are efficient in the management of intermediate stage hepatocellular carcinoma with no statistically significant superiority of DEB-TACE. Fewer complications are noticeable with cTACE in comparison with DEB-TACE.

Key words: HCC, TACA, DEB-TACE.

INTRODUCTION

Hepatocellular carcinoma (HCC) is the 3rd leading etiology of cancer-related mortality worldwide and the 6th most prevalent tumor overall (1). The Barcelona Clinic Liver Cancer (BCLC) system has been utilized in most major trials of HCC interventions and is able to include new treatment choices. It specifies an appropriate therapy for every tumor stage in guideline format (2). Treatment recommendations in Europe and the US both state that for these cases, local-regional therapies such as transarterial chemoembolization (TACE) are frequently the only available course of treatment (3). TACE is also utilized in clinical practice to treat early-stage HCC, as a bridge to liver transplantation, and in circumstances when curative treatment is contraindicated (4). TACE is the combination of intra-arterial injection of a chemotherapeutic medication (like doxorubicin) with feeding artery embolization, resulting in an ischemia and cytotoxic impact (5). When evaluating the cancer response to systemic treatment, the Response Evaluation Criteria in Solid Tumors (RECIST) technique has gained widespread acceptance (6). The shortcomings of Response Evaluation Criteria in Solid Tumors in evaluating the cancer response following intra-arterial treatment led to the creation of a

more appropriate method (7). The goal of this investigation was to assess the comparative effectiveness of conventional transarterial chemoembolization (TACE) and drug-eluting beads TACE (DEB-TACE) in treating unresectable liver carcinoma.

Patients and methods

This prospective investigation, permitted by the institutional ethical committee with informed consent from every participant, evaluated 75 cases with unresectable hepatocellular carcinoma treated with conventional TACE (Transarterial Chemoembolization) in Group I (n=42) or DEB-TACE (Drug-Eluting Bead Transarterial Chemoembolization) in Group II (n=33) at the National Cancer Institute in Cairo from 2019 to 2023. Patient ages varied from forty-nine to eighty-one years (mean: 59.5, SD: 5.78). Data on demographics, treatment, outcomes, and imaging (CT/MRI) were collected to assess tumor quantity, location, size, and stage at the first embolization.

Inclusion criteria: All cases included in the investigation were ineligible for operative or local ablative therapies according to BCLC guidelines. They had intermediate-stage hepatocellular carcinoma, characterized by large, multinodular, or bilobar tumors, with liver function classified as CHILD A or B.

Exclusion criteria: Cases classified as CHILD C, those with elevated serum total bilirubin concentrations (> three milligrams per deciliter), low serum albumin concentrations (< 2.0 milligrams per deciliter), renal failure (serum creatinine > 2 milligrams per deciliter), or cardiovascular and respiratory failure. Additionally, cases with poor performance status, nutritional impairment, ascites, or encephalopathy have been excluded from the study.

METHODS

Cases had comprehensive clinical evaluations, involving radiological investigations such as ultrasound and Doppler assessment of the portal vein and vascular invasion, along with dynamic contrast studies (CT/MRI). Laboratory tests were also conducted, including liver function tests (SGPT, SGOT, albumin, bilirubin), coagulation profiles (PC, INR, PT, PTT), alpha-fetoprotein (AFP), complete blood counts, and kidney function tests. A multidisciplinary team of hepatic surgeons, interventional radiologists, and oncologists determined the management protocol. **The technique of drug-eluting beads—TACE:** For cases with bilobar lesions, treatment focused on controlling the lobe with the higher tumor burden, with the second lobe treated later. Before the procedure, cases received antiemetic and H2 blocker infusions (Zofran and Zantac). A 6F sheath was inserted into the right femoral artery under sterile conditions, followed by angiography with a 5F catheter to map the hepatic arteries and tumor feeders. A 2.7F microcatheter was used for selective angiography to target the tumor's feeding artery. Hepasphere 40-60 U loaded with doxorubicin was injected until vessel stasis was achieved. **The technique of conventional TACE** is similar to the steps done in DEB-TACE till reaching the tumor feeding vessel. The chemoembolizing material used was an oil-doxorubicin emulsion. The oil-doxorubicin emulsion has been created by mixing 5-10 milliliters of iodized oil (Lipiodol) with 10-20 milliliters of doxorubicin 25 milligrams. Following the oil-doxorubicin emulsion injection, the tumor-feeding artery was always embolized with gelfoam. **Follow up after TACE:** Following the operation, cases have been observed for 4-6 hours to ensure proper hydration and manage any symptoms, like nausea, pain, and vomiting. Local tumor response has been evaluated four to six weeks following the first TACE session using dynamic contrast imaging (triphasic CT or dynamic MRI) and the modified response evaluation criteria in solid tumors (mRECIST). The longest dimension of the viable tumor was measured before and after treatment. In multicentric cancers, for cases with up to three focal lesions, the total cancer lengths have been estimated, but for cases with more than three cancers, the sum of the three largest lesions has been estimated. The percentage change in tumor length before and after treatment was compared, with progressive response defined by an increase in length and regressive response by a decrease in length.

Statistical Analysis

Data sorting and analysis were performed utilizing the Statistical Package for Social Sciences (SPSS) version 21. Qualitative data have been described with percentages and numbers, while quantitative data have been presented as means and standard deviations (SD). Parametric tests, such as the independent sample t-test, have been utilized for normally distributed data to compare means. For categorical variables, the Chi-square test was applied, and when inappropriate, it was replaced by the Monte Carlo exact test. Correlations between variables were assessed using Pearson and Spearman correlation coefficients. Survival analysis was conducted using Kaplan-Meier survival curves. A significance level of P-value less than 0.05 has been considered.

RESULTS

Table (1): Distinction of age between the study groups.

	Group I Number=42			Group II Number=33			T	P
	Mean ± SD	Min.	Max.	Mean ± SD	Min.	Max.		
Age	59.5 ± 5.78	49	81	59.45 ± 6.23	49	81	0.0323	0.974

t: independent sample t-test

Table 1 showed that the seventy-five cases have been involved in this investigation; the age ranged from forty-nine to eighty-one (mean: 59.5, SD: 5.78). In group I, the age varied from forty-nine to eighty-one years (mean: 59.5, SD: 5.78). In group II, the age varied from forty-nine years to eighty-one years (mean: 59.45 years). SD: 6.23).

Table (2): Liver function and tumor characteristics of all cases

	N=75	
Child	N	%
A	55	73.3
B	20	26.6
Enhancement		
Homogenous	44	58.7
Heterogenous	31	41.3
Infiltrative		
Yes	10	13.3
No	65	86.7

Table 2 showed that the study included 75 cases, with 55 (73.3%) classified as Child-Pugh A and 20 (26.6%) classified as Child-Pugh B. Tumor enhancement characteristics revealed that 44 cases (58.7%) exhibited homogenous enhancement, while 31 cases (41.3%) had heterogeneous enhancement. Regarding infiltrative features, 10 cases (13.3%) showed infiltrative characteristics, while 65 cases (86.7%) did not demonstrate such features.

Table (3): Comparing the tumor load and tumor marker between both groups.

	Group I Number=42				Group II Number=33				P
	Mean ± SD	Min.	Max.		Mean ± SD	Min.	Max.		
mRECIST target-lesions	4.18 ± 1.932	2.1	8.3		4.48 ± 2.04	2.0	9.1		0.5169

AFP	1157.75	±	344.8	304.4	1760.3	1280.2	±	573.0	118.3	2582.6	0.2552
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Table 3 showed that, in Group I, the tumor load ranged from 2.1 to 8.3 cm (mean: 4.18, SD: 1.93), while in Group II, it ranged from 2 to 9.1 cm (mean: 4.48, SD: 2.04). The independent sample t-test demonstrated a statistically insignificant distinction among both groups (P-value: 0.5169). Regarding AFP levels, Group I had values ranging from 304.4 to 1760.3 (mean: 1157.75, SD: 344.8), and Group II had values ranging from 118.3 to 2582.6 (mean: 1280, SD: 573), with statistically insignificant distinction among the groups (P-value: 0.2552).

Table (4): Comparing the overall mRECIST between study groups after first TACE.

	Group I Number=42		Group II Number=33	
Modified Response Evaluation Criteria in Solid Tumors (mRECIST)				
Complete Response (CR)	1	2.4%	1	3 %
Partial Response (PR)	17	40.5%	13	39.4%
Stable Disease (SD)	10	23.8%	8	24.2%
Progressive Disease (PD)	14	33.3%	11	33.3%

Table 4 showed that Group I had 1 patient with complete response (CR, 2.4%), 17 cases with partial response (PR, 40.5%), 10 cases with stable disease (SD, 23.8%), and 14 cases with progressive disease (PD, 33.3%). Group II had 1 patient with complete response (CR, 3%), 13 cases with partial response (PR, 39.4%), 8 cases with stable disease (SD, 24.2%), and 11 cases with progressive disease (PD, 33.3%). According to the independent sample t-test, there was a statistically insignificant distinction among both groups (P-value: 0.998).

Table (5): Comparing the complication between both groups.

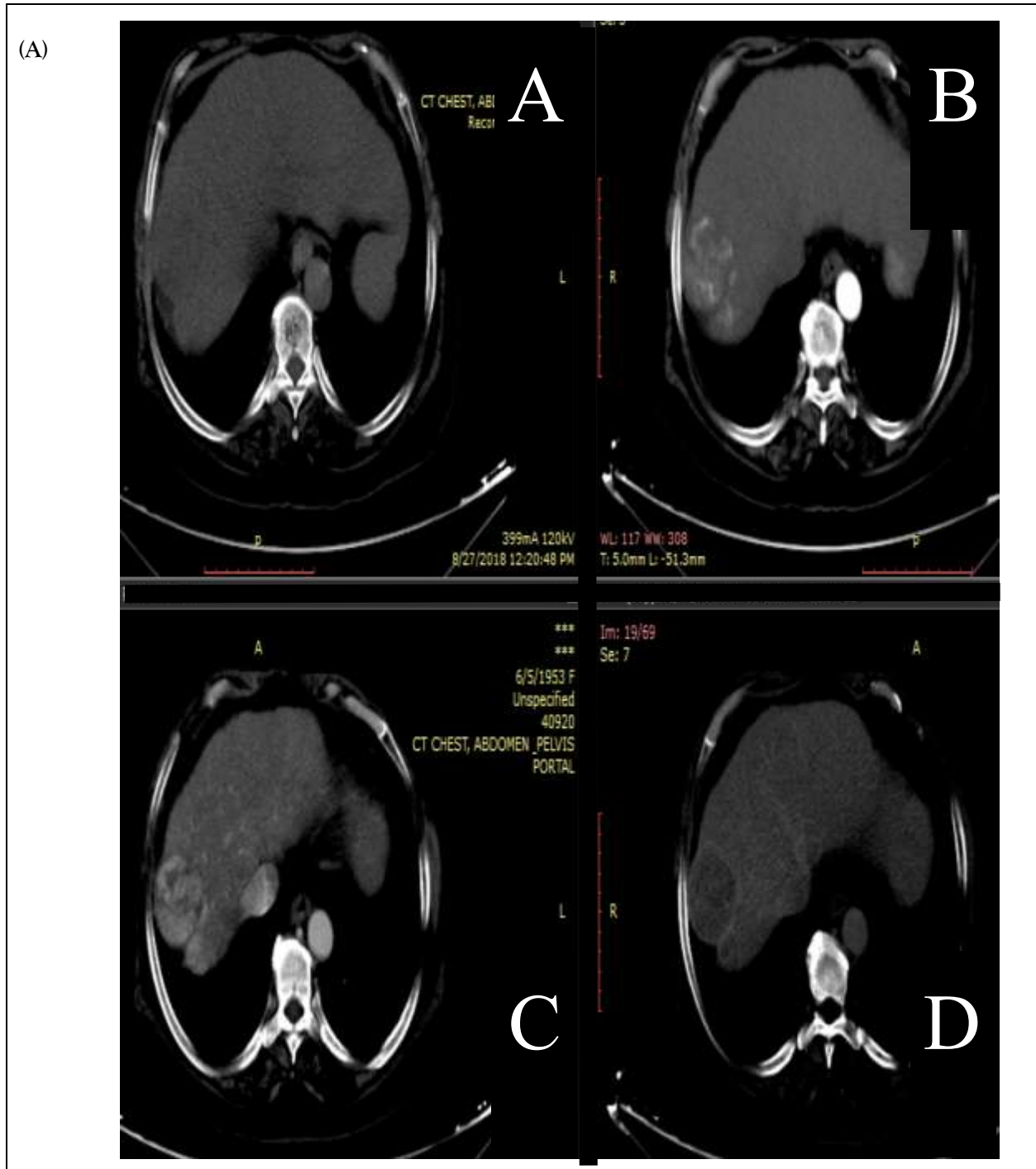
	Group I Number=42		Group II Number=33		P
Nausea					
Yes	5	11.9%	12	36.3%	0.0126*
No	37	88.1%	21	63.4%	
Vomiting					
Yes	4	9.5 %	8	24.2%	0.0865
No	38	90.5%	25	75.8%	
Pain					
Yes	7	16.7 %	13	39.4%	0.0282*
No	35	83.3 %	20	60.6%	

Table 5 showed that, in our study, 17 cases (22.7%) suffered from nausea, 12 cases (16%) suffered from vomiting, and 20 cases (26.7%) suffered from abdominal pain. There was a statistically significant distinction among both groups according to nausea and pain with a P-value of 0.0126 and 0.0282 correspondingly. However, there was no distinction according to the vomiting.

Case presentation

Case (1):

A 69-year-old female had multiple bilobar hepatic focal lesions that showed typical HCC enhancement at triphasic CT; the largest focal lesion (target lesion) was managed by a session of cTACE and in follow-up showed complete response (CR). Tumor stage: BCLC B. Liver function: CHILD A before and after cTACE.



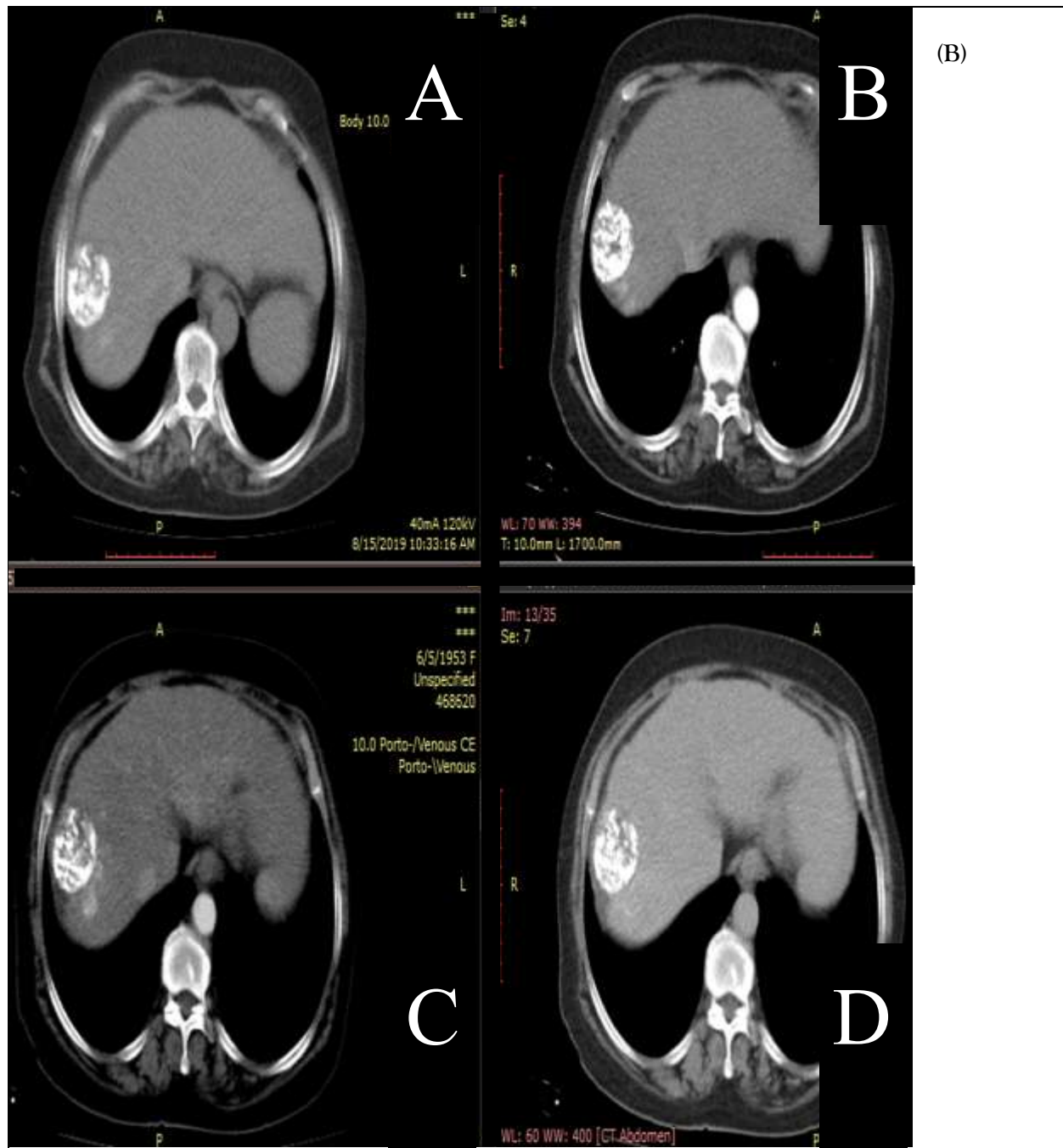
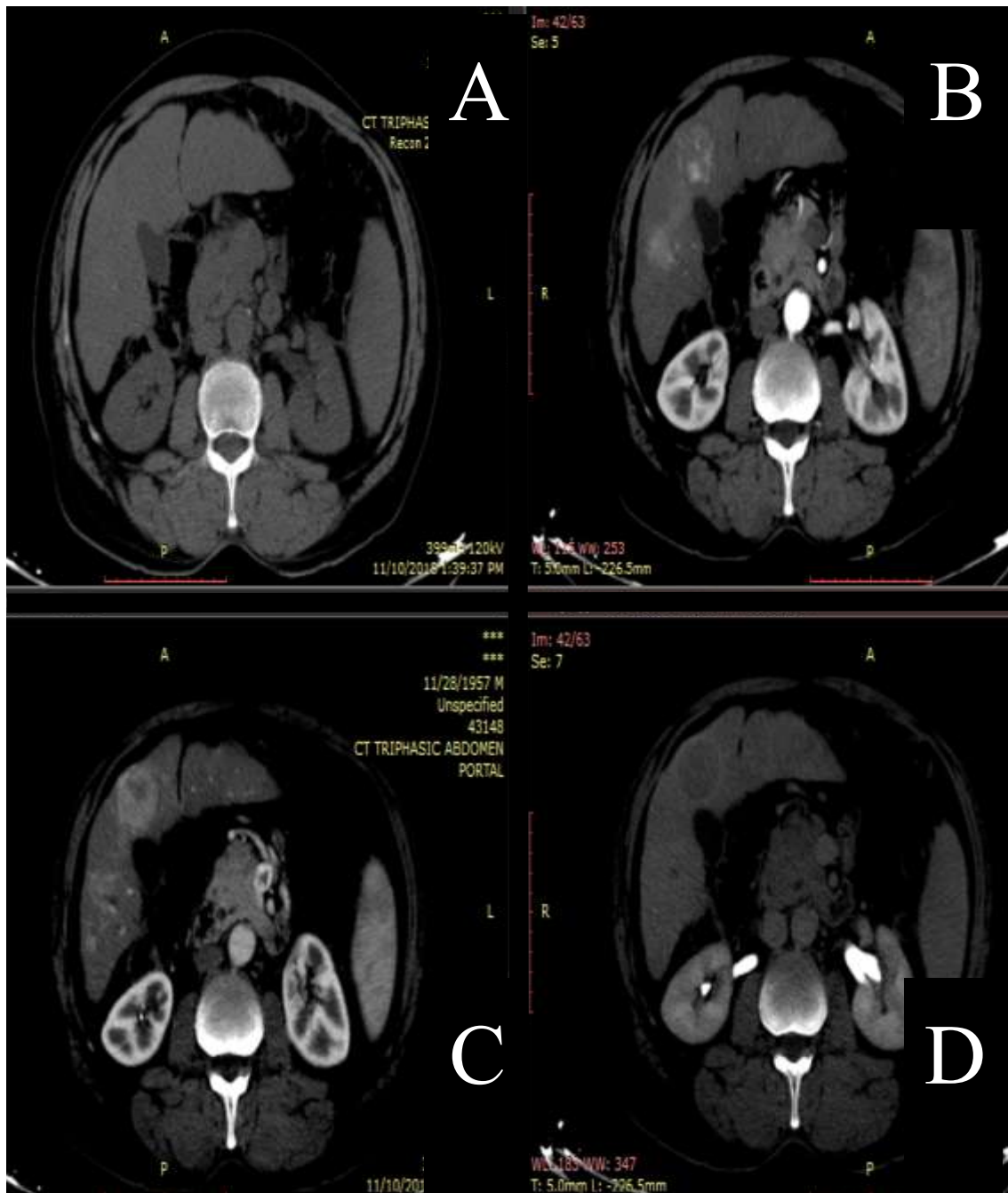


Figure (1): A: (A-D) This is the initial triphasic CT study showing the target lesion displaying an HCC enhancement pattern. B: (A-D) This is the post cTACE triphasic CT study showing the target lesion displaying no pathological HCC enhancement pattern denoting CR of this target lesion.

Case (2)

65 years old male had multiple bilobar hepatic focal lesions that showed typical HCC enhancement at triphasic CT, the target lesion was managed by cTACE and in follow up showed progressive disease (PD). Tumor stage: BCLC B at initial treatment. Liver function: CHILD B before and after cTACE.



(A)

(B) (A-D)

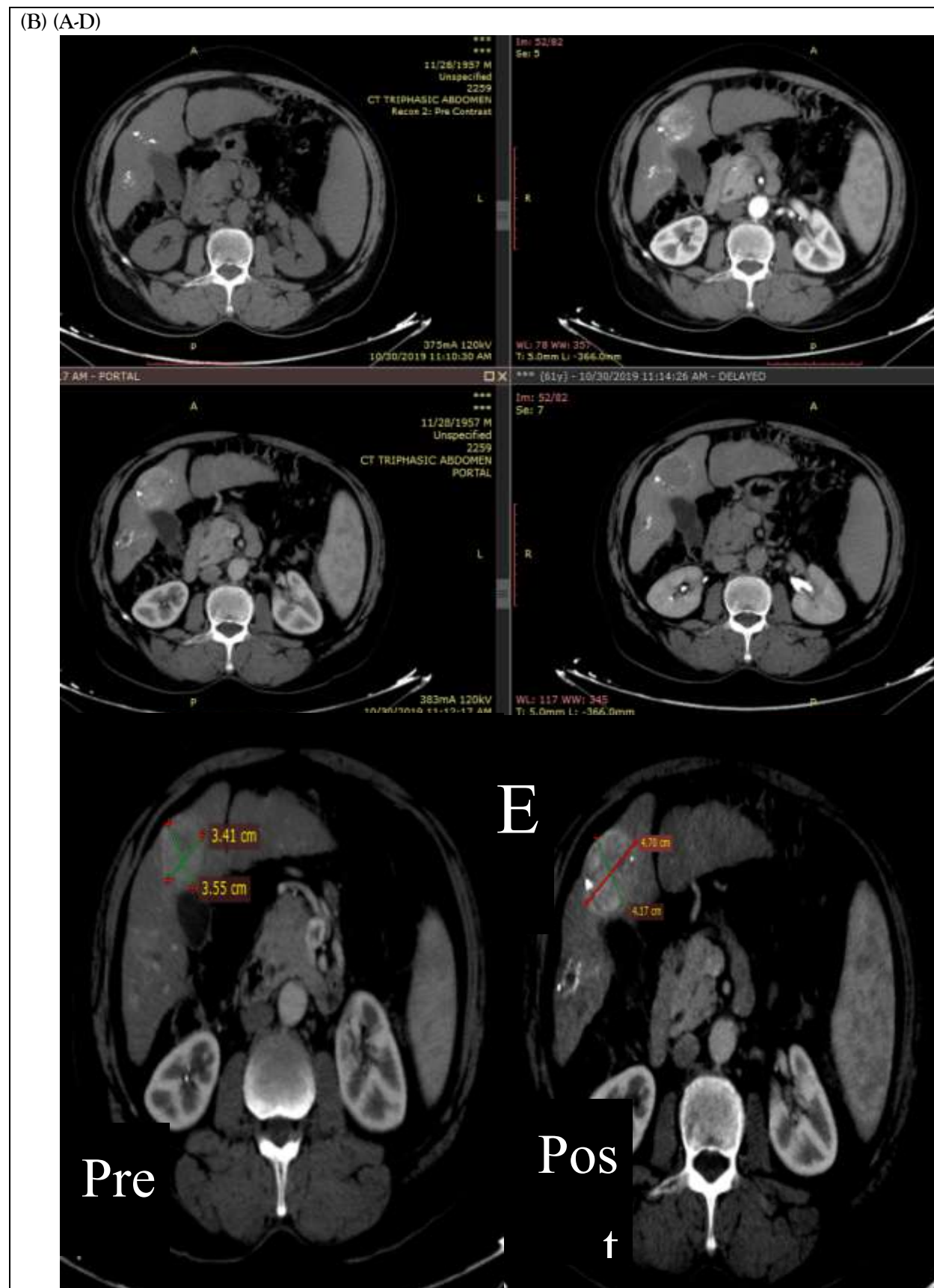


Figure (2): A: (A-D) This is the initial triphasic CT study showing the target lesion displaying an HCC enhancement pattern as well as other surrounding focal lesions.
B: (A-D) This is the post cTACE triphasic CT study showing the target lesion displaying a pathological HCC enhancement pattern and (E) showing an increase in size denoting PD of this target lesion.

DISCUSSION

For unresectable hepatocellular carcinoma (HCC), transcatheter arterial chemoembolization (TACE) is the most often utilized local-regional treatment technique (8).

This investigation has been carried out on 75 cases, which have been categorized into two groups. Group I had 42 cases and underwent conventional TACE; meanwhile, group II had 33 cases and underwent DEB-TACE. The tumor's response to the treatment was assessed using dynamic MRI or triphasic CT with mRECIST.

In our study, we showed that the seventy-five cases have been involved in this investigation; the age ranged from forty-nine to eighty-one (mean: 59.5, SD: 5.78). In group I, the age varied from forty-nine to eighty-one years (mean: 59.5, SD: 5.78). In group II, the age varied from forty-nine years to eighty-one years (mean: 59.45 years). SD: 6.23).

In our study, it was shown that the study included 75 cases, with 55 (73.3%) classified as Child-Pugh A and 20 (26.6%) classified as Child-Pugh B. Tumor enhancement characteristics revealed that 44 cases (58.7%) exhibited homogenous enhancement, while 31 cases (41.3%) had heterogeneous enhancement. Regarding infiltrative features, 10 cases (13.3%) showed infiltrative characteristics, while 65 cases (86.7%) did not demonstrate such features.

In our study, it was shown that the tumor load in this study was assessed using mRECIST. Tumor loads varied from 2.1 to 8.3 cm in group I and from 2 to 9.1 cm in group II. Regarding tumor load, there was a statistically insignificant distinction among both groups.

In our investigation, we showed that, according to mRECIST overall response after the 1st session, out of the 75 cases, we found complete response in 2 cases (2.7%), partial response in 30 cases (40%), stable disease in 18 cases (24%), and partial response in 25 cases (33.3%). Group I showed 1 patient with complete response (2.4%), 17 cases with partial response (40.5%), 10 cases with stable disease (23.8%), and 14 cases with partial response (33.3%). Group II showed 1 patient with complete response (3%), 13 cases with partial response (39.4%), 8 with stable disease (24.2%), and 11 cases with partial response (33.3%). The results show an objective response rate (ORR) of about 42.9% vs. 42.4% in the cTACE vs. DEB-TACE arm, respectively. There was a statistically insignificant distinction among both groups according to local cancer response considering overall mRECIST (p value = 0.998).

In our study, we showed that, according to complications, out of the 75 cases, 17 cases suffered from nausea, 12 cases with vomiting, and 20 cases with abdominal pain. There was a statistically significant distinction among both groups according to nausea and pain with a P-value of 0.0126 and 0.0282 correspondingly. However, there was no distinction regarding vomiting.

Our results are consistent with the majority of prior research, which has demonstrated comparable results for embolization therapy for HCC, irrespective of the delivery mode and chemotherapeutic drugs used. Certain patient groups, like those with impaired liver function or low performance status, have shown subtle distinction in the PRECISION V (9).

This study partially agrees with the PRECISION V study, in which there was no statistical significance between the two arms of the study, evidenced by CR being achieved in 24 (22.2%) vs. 25 (26.9%) cases, a PR in 23 (21.3%) vs. 23 (24.7%) cases, and SD in 9 (8.3%) vs. 11 (11.8%) cases in the cTACE vs. DEB-TACE arm, respectively. PD was observed in 44 (40.7%) vs. 30 (32.3%) cases, correspondingly at the six-month follow-up. Therefore, the objective response rate was 43.5% vs. 51.6% in the cTACE arm vs. DEB-TACE, respectively; A statistically significant superiority hasn't been found (one-sided P = 0.11) (9).

The results of this investigation are consistent with those of Karalli et al. (10), who included 202 cases in total (110 DEB-TACE and 69 cTACE). The group's Child-Pugh performance status was comparable.

Specifically, 71 Child-Pugh A and 36 Child-Pugh B in the conventional TACE group and 48 Child-Pugh A and 21 Child-Pugh B in the DEB-TACE group. The DEB-TACE group experienced fewer side effects (abdominal pain and nausea and vomiting).

In order to evaluate the distinctions between cTACE and DEB-TACE, Kloeckner et al. (2015) included a total of 250 cases ($n = 174$ cTACE; $n = 76$ DEB-TACE). In a sizable and similar cohort of cases with hepatocellular carcinoma, this investigation found insignificant distinction in the survival benefit among cTACE and DEB-TACE. Our findings are consistent with their findings. However, this study indicated that the much-reduced number of necessary managements in the DEB-TACE group would improve cost-efficiency, increase patient comfort, and potentially reduce the possibility of procedure-associated problems between these cases (108).

Zhang et al. (11) study supported our results. This investigation has been performed to compare the effectiveness and safety among cTACE and DEB-TACE in cases with infiltrative HCC (iHCC). The investigation results showed in the cTACE group, the local tumor response was as follows: no cases with complete response, four cases with partial response, eighteen cases with stable disease, and eleven cases with PD. In the DEB-TACE group, the local tumor response was as follows: no cases with complete response, six cases with partial response, forty-two cases with stable disease, and eight cases with PD. There was insignificant distinction among the cTACE group and DEB-TACE group according to the ORR ($P = 1.000$). The most frequent complications were moderate fever ($P = 0.026$) and abdominal pain ($P = 0.034$), which were more common in cases managed with cTACE compared to those managed with DEB-TACE (109).

The study done by **Yilong et al. (12)** partially supported our findings. Treatment response was evaluated in this study, which included 57 cases in the DEB-TACE group and 82 cases in the cTACE group. However, there was no distinction in the CR ($P = 0.202$) or disease control response (DCR) ($P = 0.671$) among the DEB-TACE and cTACE groups.

Our study doesn't agree with the study undertaken by **Petruzzi et al. (13)**, which involved 122 cases: 30 received cisplatin/doxorubicin/mitomycin-c/ethiodized oil, 33 received DEB-TACE, and 59 received cTACE. When compared to cases managed with cTACE, DEB-TACE, and cisplatin/doxorubicin/mitomycin-c/ethiodized oil chemoembolization demonstrated a much greater response rate, a reduced frequency of tumor progression, and fewer treatment sessions (111).

On the other hand, our research and that of **Sacco et al. (14)** demonstrate that cTACE is equal to DEB-TACE in treatment response and promotes its continued usage, especially with super-selective chemoembolization.

Our results are also consistent with an investigation by **Duan et al. (15)**, which treated 47 cases with DEB-TACE and 159 cases with conventional TACE using doxorubicin, cisplatin, and ethiodol. According to the study's findings, there are no appreciable differences in overall toxicity or responsiveness.

This study also supports the findings of **Arabi et al. (16)**, which comprised 76 procedures (DEB-TACE = 51, cTACE = 25) on a total of 54 cases (39 men and 16 women). When comparing the overall tumor objective response and disease response, which includes both target and nontarget lesions among the DEB-TACE and cTACE, there was a statistically insignificant distinction among both groups. PES were less common during DEB-TACE (7%) than cTACE (16%).

The limitations of the present investigation are the absence of randomization between groups and the small sample size.

CONCLUSION

Both procedures, cTACE and DEB-TACE, are efficient in the management of intermediate stage hepatocellular carcinoma with statistically insignificant superiority of DEB-TACE. Fewer complications are noticeable with cTACE in comparison with DEB-TACE.

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