

# The Impact of Transarterial Chemoembolization for Advanced Stage Hepatocellular Carcinoma: A Single Center Experience

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**Objective:** The present study aimed to study survival and complications of hepatocellular carcinoma (HCC) patients with Barcelona Clinic Liver Cancer (BCLC) stage C who received transarterial chemoembolization (TACE) at Rajavithi Hospital, Thailand.

**Material and Method:** The method used was a descriptive retrospective study using data collected from patient medical records from 2008 to 2012. The general information, complications, and causes of death of the patients were presented with descriptive statistics. Survival was analyzed using the Kaplan-Meier method.

**Results:** During the 5-year period, our institution performed TACE on 396 patients. While 57 cases were classified as BCLC stage C, only 44 cases had complete records. The mean age of the patients was 56.3 years with an age range from 30 to 75 years. Thirty-six cases or 81.8% were male. Twenty-six cases or 59.1% had hepatitis B infections. Thirty-five cases or 79.5% were Child-Pugh A. The median survival time was 7.1 months.

The most common complication was post-embolization syndrome which occurred in 39 patients (88.6%). Liver failure was a major procedural-related complication which occurred in 8 patients (18.2%) and was responsible for three deaths (6.8%).

**Conclusion:** TACE in HCC patients with BCLC stage C at Rajavithi Hospital was an effective and safe palliative treatment.

**Keywords:** Advanced stage hepatocellular carcinoma, Barcelona Clinic Liver Cancer stage C, transarterial chemoembolization, TACE

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Hepatocellular carcinoma (HCC) is common liver cancer especially in Asia<sup>(1)</sup>. This cancer is the 6<sup>th</sup> most common cancer. It is the 3<sup>rd</sup> most common cause of cancer related death<sup>(2)</sup>, and most of the patients are already in their moderate or advanced stage<sup>(3)</sup>

According to the Barcelona Clinic Liver Cancer Staging (BCLC Staging) treatment guideline, the patients with Eastern Cooperative Oncology Group (ECOG) status level 1-2 and/or HCC invades into the portal vein or extra-hepatic metastatic of

HCC, in this status, the patients are considered as HCC advanced stage (Stage C). For the patients in advanced BCLC stage (Stage C), "Sorafenib", a Multi-kinase inhibitor, should be offered to the patients<sup>(4)</sup>. However, a case study in Asia, found that advanced stage HCC patients treated with Sorafenib still had low median survival at 6.5 months<sup>(5)</sup>, and the access to Sorafenib is limited, especially in developing countries, due to high cost<sup>(6)</sup>; moreover, effective chemotherapy regimen for HCC patients have not been found<sup>(7)</sup>. Therefore, Transarterial Chemoembolization (TACE) is still performed as the treatment for advanced stage HCC in some institutions with reported survival benefit<sup>(1-11)</sup>.

However, TACE for advanced stage HCC patients is not generalized acceptable practice. According to BCLC guideline, TACE is offer for Child-Pugh A or B patients with large tumors or

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multifocal HCC who do not have cancer related symptoms and do not have macro-vascular invasion or extra-hepatic spread<sup>(4)</sup>, and TACE for HCC with portal vein invasion can cause serious complications such as liver failure or enhancement of tumor growth<sup>(12,13)</sup>. Therefore, the outcomes of TACE in advanced stage HCC, especially in terms of survival and procedural related complications should be verified.

## Materials and Method

The method used was a descriptive retrospective study using data collected from patient medical records from 2008 to 2012. The study protocol was approved by the Ethics Committee of Rajavithi Hospital, Study Code 57007, Document Number 006/2557. The target sample size was 42; assuming the confidence level was 95%, the desired width of the confidence interval was 0.1, and expected population proportion was 0.125 according to Kim KM et al<sup>(11)</sup>. Inclusion criteria in the present study were advanced HCC patients (BCLC stage C) who received TACE. The exclusion criteria were patients with Child-Pugh class C, patients received chemotherapy, radiation therapy, or surgery before or after TACE. Complications of TACE within 4 weeks after intervention were reported according to the National Cancer Institute's Common Terminology Criteria for Adverse Events (version 4.0)<sup>(14)</sup>. Definition and grading of post-procedural liver failure was reported according to the International Study Group of Liver Surgery<sup>(15)</sup>. Acute kidney injury definition and grading was reported according to Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for Acute Kidney Injury<sup>(16)</sup>. Post-embolization syndrome defined as abdominal pain, fever without any source of infection, nausea, and vomiting<sup>(3)</sup> was recorded as a complication of TACE.

In Rajavithi Hospital, TACE was performed under sterile technique with local anesthesia and fluoroscopic guidance. Amoxicillin/clavulanate (Augmentin) 1.2 gram was used as prophylactic antibiotic. Right common femoral artery was punctured and replaced with 5-French sheath. Then visceral angiogram was performed in celiac and superior mesenteric arteries with 5-French Simon-1 catheter. When the location of feeding vessel of the tumor was identified, Lipiodol mixed with Mitomycin-C 20 milligrams was injected to the vessel, then pieces of gelfoam were

used to embolize the artery. Computed tomography scan and serum AFP level were used to evaluate the response of TACE within 4 weeks, and the next TACE was scheduled 6 weeks after previous TACE.

During a 5 year period, there were 396 HCC patients underwent TACE in Rajavithi Hospital. While 57 cases were classified as BCLC stage C, only 44 cases had complete records. General information of the patients, laboratory investigation results, size of tumors from diagnostic radiology investigations, evidence of portal vein invasion from the tumors, metastases of the tumors to extra-hepatic organs, complications after TACE, survival after first TACE, and causes of death were collected and presented with descriptive statistics. Survival was analyzed using the Kaplan-Meier method. All statistical data analysis was performed by SPSS 17.0 (SPSS, Chicago, IL)

## Results

There were 44 BCLC stage C patients who had complete medical records. The mean age of the patients was 56.3 years with an age range from 30 to 75 years. Thirty-six cases or 81.8% were male. Mean BMI of the patients was 21.1. The majority of patients had ECOG status 1. Twenty-six cases or 59.1% had hepatitis B infections. Thirty-five cases or 79.5% were Child-Pugh A. Average AFP was 16212 IU/ml with range from 1.83-50000 IU/ml. The characteristics of the patients were shown in Table 1.

For tumor characteristics, single large tumors were found 68.2%, the average size was 11.8 cm. Tumors showed main portal vein invasion in 11 patients (25%), branch portal vein invasion in 21 patients (47%), and extra-hepatic metastases in 18 patients (40.9%). The tumor characteristics were shown in Table 2. Extra-hepatic metastases were found in 18 patients presented in Table 3, the most common sites of extra-hepatic metastases were lymph node and lung respectively.

Median survival was analyzed using Kaplan-Meier curve, the result was 212 days (range 4-999 days) or approximately 7.4 months. The 6-month survival, 1-year survival, and 2-year survival were 56.8%, 40.9%, and 8.7% respectively. Kaplan-Meier curve was demonstrated in Fig. 1.

**Table 1.** Characteristics of Patients (n=44)

Age, mean (SD), y	56.3 (10.8)
Gender	
Male, n (%)	36 (81.8)
Female, n (%)	8 (18.2)
Weight, mean (SD), kg	56.8 (9.4)
Height, mean (SD), cm	164 (6.3)
Body mass index, mean (SD) <sup>A</sup>	21.1(3.4)
ECOG <sup>B</sup> performance status at first TACE	
ECOG 1, n (%)	29 (65.9)
ECOG 2, n (%)	10 (22.7)
ECOG 3, n (%)	5 (11.4)
Child-Pugh score <sup>C</sup>	
Child-Pugh score 5, n (%)	20 (45.5)
Child-Pugh score 6, n (%)	15 (34.1)
Child-Pugh score 7, n (%)	9 (20.5)
Viral hepatitis marker	
B, n (%)	26 (59.1)
C, n (%)	14 (31.8)
HIV, n (%)	1 (2.3)
Diabetes mellitus, n (%)	9 (20.5)
Hypertension, n (%)	10 (22.7)
History of ruptured HCC <sup>D</sup> , n (%)	3 (6.8)
Alpha-fetoprotein, median(min-max), IU/mL	3273.5 (1.83-50000)

<sup>A</sup>Calculated as weight in kilograms divided by height in meter squared

<sup>B</sup>Eastern Cooperative Oncology Group

<sup>C</sup>Child-Pugh score at first TACE

<sup>D</sup>History of ruptured HCC before first TACE

There were 40 patients (90.9%) who had Procedural-related complications within 4 weeks after TACE, the most common complication was post-embolization syndrome which occurred in 39 patients (88.6%); follow by liver failure in 8 patients (18.2%), ascites in 6 patients (13.6%), and acute kidney injury in 6 patients (13.6%). Other complications were shown in Table 4. However, if the complication “post-embolization syndrome” was excluded, there were 19 patients (43.2%) having procedural-related complications.

There were 6 patients expired within 4 weeks after TACE. The serious complications which caused death were liver failure in 2 patients, renal failure in 1 patient, and upper gastrointestinal bleeding in 1 patients; there were 2 patients died due to ruptured hepatoma, and these 2 cases had ascites and pleural

effusion after TACE as procedural-related complication. The characteristic of patients with serious procedural related complications were shown in Table 5; 3 patients from 6 had BMI less than 18.5, ECOG more than 1 in 3 patients, and Child-Pugh score more than 6 in 2 patients. There were main portal vein invasion in 3 patients and 3 patients with extrahepatic metastases.

The majority of the patients in the present study were in Child-Pugh A classification, in these patients there were 14 patients with extrahepatic metastases while there were 21 patients had locally advanced disease. In these 21 locally advanced disease patients, 12 patients were not suitable for hepatic resection due to poor performance status, metastases in both lobes of liver, inferior vena cava invasion, and main portal vein invasion while there were 9 patients from 21 Child-

**Table 2. Tumor Characteristics**

Large tumor size <sup>A</sup> , mean (SD), cm	11.8 (5.2)
Number of large tumor <sup>B</sup> ,	
0,%	4 (9.1)
1,%	30 (68.2)
2,%	9 (20.5)
3,%	1 (2.3)
Presence of multiple small tumor <sup>C</sup> , %	14 (31.8)
Main portal vein invasion, n (%)	11 (25)
Branch portal vein invasion, n (%)	21 (47)
Inferior vena cava invasion, n (%)	3 (6.8)
Hepatic vein invasion, n (%)	4 (9.1)
Superior mesenteric vein invasion, n (%)	1 (2.3)
Extrahepatic metastasis, %	18 (40.9)

<sup>A</sup>Sum of diameter of tumor which are larger than 3 cm

<sup>B</sup>Number of tumor which size>3 cm

<sup>C</sup>Presence of more than 3 tumors which size 1-3 cm in diameter each

**Table 3. Extrahepatic metastases in 18 patients**

Adrenal gland, n (%)	2 (11.1)
Bone, n (%)	2 (11.1)
Left frank, n (%)	1 (5.6)
Lymph node, n (%)	8 (44.4)
Pulmonary, n (%)	6 (33.3)
Spleen, n (%)	1 (5.6)

**Table 4. Post-procedural complication (total n = 40)**

Ascites, n (%)	6 (13.6)
Pleural effusion, n (%)	2 (4.5)
Upper gastrointestinal bleeding, n (%)	2 (4.5)
Sepsis, n (%)	1 (2.3)
Acute kidney injury <sup>A</sup> , n (%)	6 (13.6)
Grade I, n (%)	3 (6.8)
Grade II, n (%)	1 (2.3)
Grade III, n (%)	2 (4.5)
Bowel ileus, n (%)	3 (6.8)
Liver failure <sup>B</sup>	8 (18.2)
Grade A, n (%)	4 (9.1)
Grade B, n (%)	1 (2.3)
Grade C, n (%)	3 (6.8)
Post-embolization syndrome, n (%)	39 (88.6)
Acute myocardial infarction, n (%)	1 (2.3)

<sup>A</sup>Acute Kidney Injury definition according to Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for Acute Kidney Injury

<sup>B</sup>Definition and grading of post-procedural liver failure by the International Study Group of Liver Surgery (ISGLS)

**Table 5.** Characteristics of patients with serious complication after TACE

Patient number	5	6	11	19	32	37
Age(Year)	75	46	71	70	64	51
Gender	Male	Female	Male	Female	Male	Male
BMI	17	21	17	20	19	17
ECOG	3	2	1	2	1	1
Underlying disease	No	HIV <sup>A</sup> HCV <sup>C</sup>	HBsAg <sup>B</sup>	HbsAg	No	HBsAg
Child-Pugh Score	5	6	7	6	5	7
AFP(ng/ml)	2538	36008	50000	955	50000	11090
Creatinine (mg/dL)	0.8	0.3	0.7	1.8	0.7	0.9
Tumor characteristics						
Large tumor size <sup>D</sup>	10	13	15	18	18	15
Number of large tumor <sup>E</sup>	2	1	1	1	2	1
Presence of multiple tumor <sup>F</sup>	No	Yes	No	Yes	Yes	No
Main PV invasion	No	Yes	Yes	No	Yes	No
Extrahepatic metastasis	Yes	Yes	No	No	No	Yes
Site of metastasis	Left frank	Pulmonary	No	No	No	Mediastinum Lymph nodes
Complications						
Ascites	No	Yes	No	Yes	No	Yes
Pleural effusion	No	Yes	No	No	No	Yes
UGIB <sup>G</sup>	No	No	No	Yes	No	No
AKI Stage II <sup>H</sup>	No	No	Yes	No	No	No
AKI Stage III <sup>H</sup>	No	No	No	Yes	No	Yes
Paralytic ileus	No	No	No	Yes	No	Yes
LF grade <sup>I</sup>	C	No	C	C	No	No
PES <sup>J</sup>	No	Yes	Yes	No	Yes	Yes
Cause of death	LF <sup>K</sup>	RH <sup>L</sup>	LF <sup>K</sup>	RF <sup>M</sup>	UGIB	RH <sup>L</sup>

<sup>A</sup>Human immunodeficiency virus test positive

<sup>B</sup>Hepatitis B Surface Antigen positive

<sup>C</sup>Anti Hepatitis C Virus positive

<sup>D</sup>Sum of diameter of tumor which are larger than 3 cm

<sup>E</sup>Number of tumor which size > 3 cm

<sup>F</sup>Presence of more than 3 tumors which size 1-3 cm in diameter each

<sup>G</sup>Upper gastrointestinal bleeding

<sup>H</sup>Acute Kidney Injury definition according to Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for Acute Kidney Injury

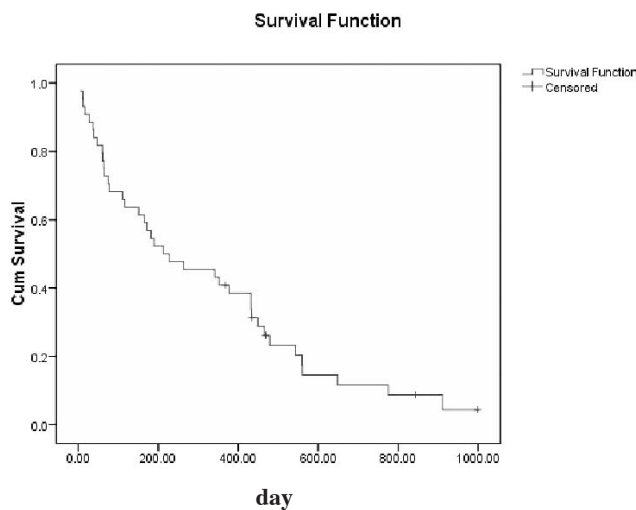
<sup>I</sup>Definition and grading of post-procedural liver failure by the International Study Group of Liver Surgery (ISGLS)

<sup>J</sup>Post-embolization syndrome

<sup>K</sup>Liver failure

<sup>L</sup>Ruptured hepatoma

<sup>M</sup>Renal failure



**Fig. 1** Kaplan-Meier Curve.

**Table 6.** Characteristic of Child-A patients with BCLC stage C who received TACE

Total number of Child-A patients, n	35
Extrahepatic metastases, n (%)	14 (40)
Adrenal gland, n (%)	2 (5.7)
Left frank, n (%)	1 (2.9)
Lymph node, n (%)	5 (14.3)
Pulmonary, n (%)	6 (17.1)
Spleen, n (%)	1 (2.9)
Locally advanced tumor, n (%)	21 (60)
Possible candidate for surgery, n (%)	9 (25.7)
Portal vein branch invasion, n (%)	7 (20)
Hepatic vein invasion, n (%)	2 (5.7)
Not suitable for surgery, n (%)	12 (34.3)
Poor performance status*, n (%)	4 (11.4)
IVC invasion, n (%)	2 (5.7)
Tumor involved both right and left lobe of liver, n (%)	1 (2.9)
Main portal vein involvement, n (%)	5 (14.3)

**Table 7.** Cause of death (Total n = 40)

Liver failure, n (%)	14 (35)
Upper gastrointestinal bleeding, n (%)	6 (15)
Septic shock, n (%)	6 (15)
Ruptured hepatoma, n (%)	5 (12.5)
Unknown, n (%)	5 (12.5)
Renal failure, n (%)	2 (5)
Stroke, n (%)	1 (2.5)
Cerebral cryptococcosis, n (%)	1 (2.5)

Pugh A patients who might be candidate for hepatic resection; however these patients did not undergo surgical treatment. The characteristics of patients with Child-Pugh A classification in the present study were shown in Table 6.

At the end of the study, 40 patients died, the important causes of death were liver failure in 14 patients (35%), upper gastrointestinal bleeding in 6 patients (15%), and septic shock in 6 patients (15%). The cause of death was un able to be identified in 6 patients (15%) due to loss of the data. Other causes of death were shown in Table 7.

## Discussion

According to BCLC guideline, TACE is recommended as treatment for patients with Child-Pugh level A or B who have ECOG status grade 0 and large or multifocal HCC without tumor invasion to portal vein; for HCC advanced stage (BCLC Stage C) patients, Sorafenib, is a treatment of choice<sup>(4)</sup>. However, there were many studies which showed survival benefits with acceptable complications in HCC patients with portal vein invasion or extra-hepatic metastasis<sup>(1,6,8,9,17,18)</sup>.

In the present study, median survival of HCC patients with BCLC Stage C who were performed TACE was 7.1 months, and 6-month survival, 1-year survival, and 2-year survival were 56.8%, 40.9%, and 8.7% respectively. The median survival from the present study was comparable with previous studies which had median survival range from 4-14.9 months<sup>(1,8,9,17)</sup>. The procedural related complications in 1 month after TACE occurred in 40 patients (90.9%). The most common complication was post embolization syndrome which occurred in 39 patient (88.6%), the result was similar to the meta-analysis by Xue TC et al. which had post embolization syndrome range from 35-94%<sup>(6)</sup>. However, serious complications which caused procedural related mortality within 4 weeks after TACE was liver failure which occurred in 3 patients (6.8%), the procedural related mortality in the present study resembled a systematic review by Zhao Y et al. and meta-analysis from Xue TC et al which showed procedural related mortality range from 0-14%<sup>(6,8)</sup>. The complications from TACE which excluded post-embolization syndrome such as ascites, pleural effusion, upper gastrointestinal bleeding, sepsis, acute kidney injury, liver failure, acute myocardial

infraction, and bowel ileus occurred in 19 patients (43.2%), the complication rate from this study was higher than the study reported by Chung et al which had 25% complication rate<sup>(1)</sup>; however, the majority of the complications in our study were controllable and subsided without aggressive management.

## Conclusion

TACE for HCC patients with BCLC stage C was effective treatment with acceptable procedural-related complications in comparison with previous studies. Therefore, TACE might be the effective alternative treatment for HCC patients who cannot access to sorafenib treatment or develop intolerable side effect of sorafenib. However, the limitations of the present study were retrospective manner, limited sample size, and loss of the data; moreover, there were 9 patients in the present study who might be candidate for liver resection, but they did not receive operative treatment; survival of these patients could interfere the overall survival of HCC patients with BCLC stage C who underwent TACE in the present study.

## What is already known on this topic?

TACE for treatment of advanced stage HCC according to BCLC is controversy. There were some studies which advocated TACE in advanced stage HCC while some studies did not supported TACE in this group of patients.

## What is this study adds?

TACE in the context of this study is effective and safe in comparison with previous studies.

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## Potential conflicts of interest

None.

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การศึกษาผลการรักษามะเร็งเซลล์ตับระยะลุกลามด้วยวิธีการให้สารเคมีบำบัดเฉพาะที่ผ่านทางหลอดเลือดแดง

นิสิต ตงศิริ, สมบูรณ์ ทรัพย์วงศ์เจริญ, สอาด ศรีพงษ์ภรณา

**วัตถุประสงค์:** เพื่อศึกษาการรอดชีพในผู้ป่วยมะเร็งเซลล์ตับระยะลุกลามที่อยู่ในระดับ *Barcelona Clinic Liver Cancer (BCLC) stage C* ที่ได้รับการรักษาด้วย TACE ในโรงพยาบาลราชวิถี และศึกษาถึงผลแทรกซ้อนที่เกิดขึ้นจากการ TACE ในผู้ป่วยกลุ่มดังกล่าว

**วัสดุและวิธีการ:** เป็นการศึกษาย้อนหลังโดยทำการรวบรวมข้อมูลจากเวชระเบียนของผู้ป่วยมะเร็งเซลล์ตับที่ได้รับการรักษาด้วยวิธีการ TACE ระหว่างปี พ.ศ. 2551 ถึงปี พ.ศ. 2555 โดยข้อมูลทั่วไปของผู้ป่วย, ผลแทรกซ้อนที่เกิดจากการทำหัตถการ, สาเหตุการเสียชีวิตจะถูกแสดงโดยใช้สถิติเชิงพรรณนา การรอดชีพจะถูกคำนวณโดยใช้วิธี *Kaplan-Meier*

**ผลการศึกษา:** ในช่วงระยะเวลา 5 ปี ในโรงพยาบาลราชวิถีได้ทำการรักษาผู้ป่วยโดยใช้วิธีการ TACE ในผู้ป่วยมะเร็งเซลล์ตับ 396 ราย ในจำนวนนี้เป็นผู้ป่วยที่อยู่ใน *BCLC stage C* จำนวน 57 ราย แต่มีเพียง 44 ราย ที่มีข้อมูลครบถ้วน อายุเฉลี่ยของผู้ป่วย 56.3 ปี โดยช่วงอายุจะอยู่ในช่วง 30 ถึง 75 ปี ผู้ป่วยเพศชาย 36 ราย (81.8%) ผู้ป่วย 26 ราย เป็นโรคตับอักเสบชนิดบี (59.1%) ผู้ป่วย 35 รายมีการทำงานของตับอยู่ในระดับ *Child-Pugh A* (79.5%) การรอดชีพเฉลี่ย 7.1 เดือน ผลแทรกซ้อนที่พบได้บ่อยที่สุดคือ *Post-embolization syndrome* เกิดขึ้นในผู้ป่วย 39 ราย (88.6%) ผลแทรกซ้อนรุนแรงที่เกี่ยวข้องกับการทำหัตถการคือภาวะตับวายเกิดขึ้นในผู้ป่วย 8 ราย (18.2%) และเป็นสาเหตุการเสียชีวิตในผู้ป่วย 3 ราย (6.8%)

**สรุป:** การ TACE ในผู้ป่วยมะเร็งเซลล์ตับระยะลุกลามที่อยู่ในระดับ *Barcelona Clinic Liver Cancer (BCLC) stage C* เป็นการรักษาแบบประคับประคองที่ได้ผลดี โดยที่ผลแทรกซ้อนอยู่ในระดับที่ยอมรับได้

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