Clinical Features and Prognostic Factors for Liver Cancer from a Referral Center in Northern Thailand

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Background: *Primary liver cancer, included hepatocellular carcinoma (HCC) and cholangiocarcinoma (CCA), is the leading cancer with high mortality in Thailand. We aim to evaluate the overall survival and predictor of mortality in patients with HCC and CCA.*
Material and Method: *We reviewed medical records of 786 patients with liver mass between July 2007 and June 2010, 287 patients were HCC and 449 patients were CCA. The overall survival and prognostic variables for survival were analyzed.*
Results: *The mean age of HCC patients and CCA patient were 53.8 years and 59.2 years. Male was predominant, 85% and 74% in HCC and CCA. By BCLC staging for HCC, patients at early stage (A), intermediate stage (B), advanced stage (C), and terminal stage (D) were 40 (13.9%), 105 (36.6%), 95 (33.1%), and 43 (15.0%). Among 449 CCA patients, 143 (31.8%) were intrahepatic type and 306 (68.2%) were ductal type. The mean follow-up time for HCC and CCA patients were 20.1 and 16.7 months. The 1-year, 2-year, and 3-year survival of HCC and CCA were 55%, 34%, 31.3% and 54%, 21.2%, 19.1%, respectively. Predictor of death in HCC patients included portal vein thrombosis and did not receive any treatment ($p<0.05$). Meanwhile, the predictor of death in CCA patient included intrahepatic type, total bilirubin >2 mg/dl, CA 19-9 >100, and unresectable tumor ($p<0.05$).*
Conclusion: *The survival of patients who received any type of treatment was much better than in the past. Still, in patients with advanced disease whom only supportive treatments were provided, the prognosis is grave.*

Keywords: *Hepatocellular carcinoma (HCC), Cholangiocarcinoma (CCA), Survival*

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Cancer of the liver is the fifth most common cancer in the world and the third cause of cancer-related death[1]. Primary liver cancer comprise two major types of cancer with distinguishing histological characteristics and origin namely hepatocellular carcinoma (HCC), which derives from hepatocytes, and cholangiocarcinoma (CCA), which derives from bile duct. The incidence of liver cancer differs between different geographical regions and between countries or geo-economic zones within the country.

Primary liver cancer is the top five causes of cancer death in both male and female in Thailand, with 27,500 deaths for the year 2004[2]. The late presentation and the difficulty of surgical approach mean that the overall survival is poor. In Thailand, the majority of liver cancers are found in the north and northeast where CCA is predominant[3]. Between 1988 and 1991, Khon Kaen, the second-largest of the northeastern provinces of Thailand, was reported to have the highest incidence of CCA in the world with ASRs of 94.8 and 39.4 per 100 000 in male and female, respectively[4,5]. In Chiang Mai, the five-year relative survival rate of liver cancer was 2.5% in male and 5.6% in female[6]. However, there was no previous report of the natural history of patients with HCC and CCA in this high-risk area. The present study aimed to evaluate the overall survival and predictor of mortality in patients with HCC and CCA from a tertiary medical center in northern Thailand.

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Material and Method

The study was approved by the Institutional Review Board (IRB, also the Ethics committee) of Chiang Mai University, Thailand. The authors reviewed the medical records of 786 patients with liver mass who visited the Hepatology Clinic and Hepatobiliary surgery Clinic, Maharaj Nakorn Chiang Mai Hospital,

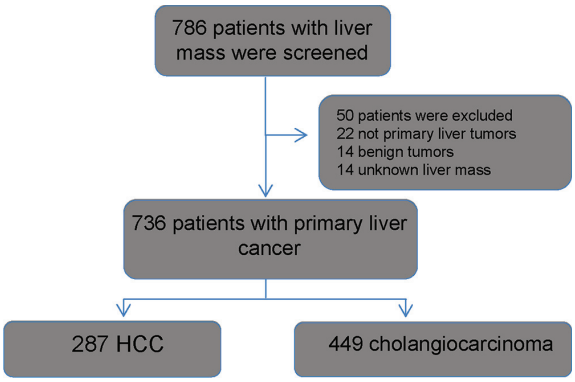


Fig. 1 Flowchart of patients in the study.

Chiang Mai University between July 2007 and June 2010. Of those, 287 patients were diagnosed with HCC and 449 were CCA. Exclusion criteria include benign liver disease and metastatic tumor (Fig. 1).

The diagnosis of HCC was based on either histopathology or noninvasive criteria. The noninvasive diagnosis of HCC was established on the basis of imaging techniques and alpha fetoprotein (AFP) levels as proposed by the European Association for the Study of the Liver (EASL 2000)[7]. Those include the radiological criteria of two coincident imaging technique showing focal lesion larger than 2 cm with arterial hypervascularization or combined criteria of one imaging technique associated with AFP defines as focal lesion larger than 2 cm with arterial hypervascularization with AFP >400 ng/mL.

Cholangiocarcinoma (CCA) was diagnosed by histopathology or presumed diagnosis using detailed clinical evaluation, serum biochemistry, and abdominal and biliary imaging studies include ultrasonography (US), computed tomography (CT), magnetic resonance imaging (MRI), magnetic resonance cholangiopancreatography (MRCP) and endoscopic retrograde cholangiopancreatography (ERCP).

A series of demographic, clinical and biochemical data collected at the time of diagnosis included age, sex, type of visit, serum level of albumin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), total bilirubin, alkaline phosphatase, prothrombin time, serology for hepatitis B and C, and tumor markers include alpha fetoprotein (AFP), carcinoem- bryonic antigen (CEA), carbohydrate antigen 19-9 (CA19-9) were analyzed. The morphological characteristics of the tumor were also evaluated included number of lesions, lobar distribution, and presence of portal vein thrombosis.

Stage of tumor

The authors staged HCC by using all 3 popular methods. The Okuda classification (stage I, II, III) includes parameters related to the liver functional status such as albumin, ascites, bilirubin, and the tumor stage, more or less than 50% of liver area involved[8]. The Cancer of the Liver Italian Program (CLIP) score[9], which stage by early stage = 0 point, intermediate stage = 1-3 points, and advanced stage = 4-6 points. Finally, the Barcelona-Clinic Liver Cancer (BCLC) staging classification which classified into very early (0), early (A), intermediate (B), advanced (C), and end-stage (D)[10].

Cholangiocarcinoma is classified as intra-hepatic type and ductal type by radiologic imaging study.

Treatment

Treatment of HCC patients were categorized as hepatic resection, ablative therapy by direct ethanol injection (DEI) or radiofrequency ablation (RFA), and transarterial chemoembolization (TACE). Meanwhile, the treatment options for CCA were categorized as hepatic resection, palliative biliary drainage by endoscopic retrograde cholangiopancreatography (ERCP) with stent or percutaneous transhepatic biliary drainage (PTBD). Patients who did not qualify for surgical or locoregional therapies were offered either chemotherapy or supportive care.

Survival analysis

The authors used the national citizen identification number of patients in medical records to match with the mortality database established by the National Registration of Thailand to determine the survival of patients.

Statistical analysis

Statistical analyses were performed using SPSS version 17.0 (SPSS, Inc., Chicago IL). Results are reported as means ± standard deviation (SD) or frequency (i.e., percentage), as appropriate. Continuous variables were compared using the two-tailed Student's t-test. Categorical data were compared using the Chi-square test. Variables of predictor for mortality with a p-value of <0.05 on univariate analysis were further analyzed by multiple logistic regression to determine the independent determinants of outcome

variables. The survival was analyzed using the Kaplan-Meier method and using the date of the diagnosis as time zero (baseline) and patient who survived were censored on the date 31 December 2011. The effect of individual variables upon survival was compared using log-rank tests. When assessing the effects of multiple variables on survival, Cox regression was used.

Results

Patient characteristics

Of 786 patients with liver mass, only 85 patients underwent liver biopsy for histological diagnosis. Clinical characteristics of patients with HCC and CCA are presented in Table 1. The mean age of HCC patients and CCA patient were 53.8 years and 59.2 years. The proportion of male patient was more than female in both HCC and CCA. At the time of diagnosis, CCA patients had significant higher serum total bilirubin level and alkaline phosphatase than HCC patients. Among 449 CCA patients, 143 (31.8%) were intrahepatic type and 306 (68.2%) were ductal type.

Table 1. Baseline characteristics of the patient population

	HCC (n = 287)	CCA (n = 449)
Age, year	53.8±10.9	59.2±10.6
Sex		
Male*	244 (85.0%)	331 (73.7%)
Female	43 (15.0%)	118 (26.3%)
Albumin, g/dl	3.3±0.6	3.2±0.8
Bilirubin*, mg/dl	3.2±6.8	13.2±14.2
ALP*, IU/mL	204.6±151.2	399.8±335.0
AST*, IU/mL	131.8±143.2	91.0±101
ALT, IU/mL	69.2±75.4	67.6±62.9
Radiologic study		
US	168 (58.7%)	217 (48.3%)
CT	239 (83.9%)	374 (83.5%)
MRI	17 (5.9%)	5 (1.1%)
Treatment		
Surgery	27 (9.6%)	34 (7.6%)
Ablative therapy	7 (2.1%)	0
TACE	65 (22.6%)	1 (0.2%)
Biliary drainage	0	140 (31.2%)
Chemotherapy	8 (2.8%)	42 (9.4%)
No treatment	180 (62.7%)	229 (51.0%)

Results are expressed as mean ± standard deviation, frequency (%)

* $p<0.05$

HCC = hepatocellular carcinoma; CCA = cholangiocarcinoma; ALP = alkaline phosphatase; AST = aspartate aminotransferase; ALT = alanine aminotransferase; US = ultrasonography; CT = computed tomography; MRI = magnetic resonance imaging; TACE = transarterial chemoembolization

Staging of HCC

Among 287 HCC patients, tumors classified by the Okuda stage I, II and II were 76 (27.0%), 159 (55.4%) and 45 (15.7%), respectively. According to CLIP score that classified into three categories, early stage (CLIP 0), intermediate stage (CLIP 1-3) and advanced stage (CLIP 4-6) were 54 (18.8%), 144 (50.2%) and 75 (26.1%). By BCLC staging system, patients at stage A with early HCC were 40 (13.9%), intermediate stage (B) were 105 (36.6%), advanced stage (C) 95 (33.1%), and terminal stage (D) were 43 (15.0%).

Risk factors as viral hepatitis

In the 287 patients with HCC, 218 had serology for HBV infection and 163 had serology for HCV infection. Of those, 145 patients (67%) were infected with hepatitis B and 37 patients (22.7%) were infected with hepatitis C. For patients with CCA, 10 of 105 patients (9.5%) had positive serology of HBV and nine of 202 patients (4.5%) had positive serology of HCV infection.

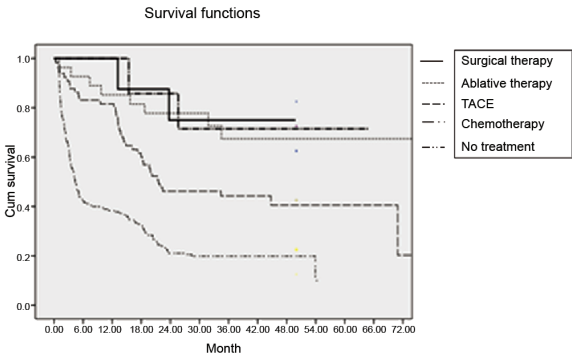
Survival and treatment

HCC: The mean follow-up for HCC patients was 20 months (range 0.3-373.1). During the follow-up period, 91 patients (31.7%) died and the overall median survival time was14.4 months (95% CI, 10.2-18.5). Majority of HCC patients (62.7%) were not receiving the definite treatment due to advanced disease and lost to follow-up. Moreover, some of the patients refused any treatment by themselves. The 5-year survival of HCC patients was 27.6%. Fig. 2 shows the survival according to treatment modalities.

CCA: The mean follow-up for CCA patients was 16.7 months (range 0.1-118.5). During the follow-up period, 84 patients (18.7%) died and the overall median survival time was 14.2 months (95% CI, 10.6-17.7). Overall survival of CCA patients with ductal type was better than intrahepatic type (median survival 14.5 and 13.3 months). The 5-year survival of CCA patients was 19.1%. Fig. 3 shows the survival according to treatment modalities.

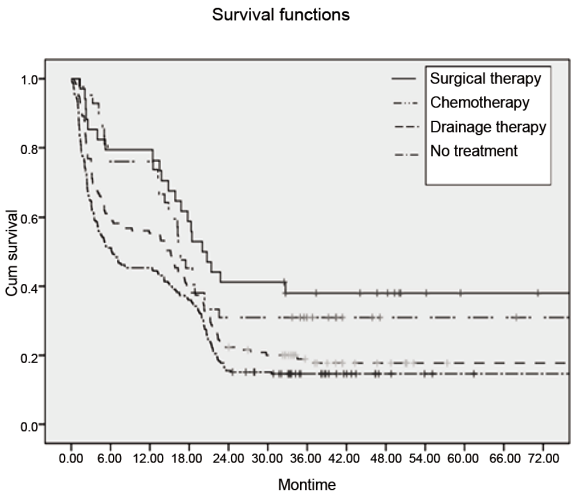
Factors associated with patient survival in HCC

On univariate analysis, older age, high total bilirubin, advanced cirrhosis (Child B and C),



Treatment (n = 287)	1 year	2 year	3 year
Surgery (n = 27)	85.2%	77.8%	67.4%
ablative (n = 7)	100%	85.7%	71.4%
TACE (n = 65)	80.6%	43.6%	41.5%
Chemotherapy (n = 8)	87.5%	75.0%	75.0%
No treatment (n = 180)	37.7%	21.0%	16.2%

Fig. 2 Cumulative survival of HCC patients according to treatment.
HCC = hepatocellular carcinoma; DEI = direct ethanol injection; TACE, transarterial chemo-embolization



Treatment (n = 445)	1 year	2 year	3 year
Surgery (n = 34)	79.7%	41.8%	32.3%
Chemotherapy (n = 42)	73.7%	31.0%	21.4%
Drainage therapy (n = 140)	55.7%	22.1%	11.4%
No treatment (n = 229)	46.3%	17.0%	9.6%

Fig. 3 Cumulative survival of CCA patients according to treatment.

AFP >400 ng/mL, tumor size >50%, and portal vein thrombosis were associated with poor prognosis. When the benefits for patients who received any modality of treatment were evaluated in multivariate analysis, portal vein thrombosis and those who did not receive any treatment were the independent prognostic factors for overall survival (Table 2).

Table 2. Multivariate analysis for overall survival in HCC patients

Parameter	n	Hazard ratio (95% CI)	p-value
Cirrhosis			
Child B and C	123	1.25 (0.94-1.68)	0.13
Child A	152		
AFP			
>400 ng/mL	128	1.18 (0.81-1.69)	0.38
<400 ng/mL	149		
Portal vein thrombosis			
Yes	98	1.47 (10.6-2.05)	0.02
No	183		
Tumor size			
>50%	151	1.01 (0.78-1.27)	0.94
<50%	132		
Treatment			
No	180	2.25 (1.58-3.21)	<0.001
Yes	107		

Factors associated with patient survival in CCA

The factors associated with patient survival are presented in Table 3. By multivariate analysis and adjusting for treatment, intrahepatic type, total bilirubin >2 mg/dL, CA 19-9 >100, and unresectable tumor were independently associated with overall mortality.

Table 3. Multivariate analysis for overall survival in CCA patients

Parameter	n	Hazard ratio (95% CI)	p-value
Ductal type	302	0.59 (0.42-0.81)	0.001
Intrahepatic type	142		
Total bilirubin			
>2 mg/dL	226	1.74 (1.28-2.37)	<0.001
<2 mg/dL	163		
CA 19-9			
>100	313	1.76 (1.34-2.30)	<0.001
<100	86		
Surgery			
Yes	34	0.58 (0.36-0.92)	0.02
No	411		

Discussion

Outcomes of primary liver cancer have been reported in many studies in different countries with varied survival outcomes depending on risk factors and treatment modality. In the present study, the authors report the outcome of patients with primary liver cancer, both HCC and CCA, at a tertiary medical center in northern Thailand that had a high incidence and mortality of liver cancer. Most patients who were diagnosed with primary liver cancer were in the fifth decade of life. Patients with CCA were older than HCC, and initially presented with intermediate to advanced stage of disease. Among the HCC patients, 67% had hepatitis B infection and 22.7% had hepatitis C infection similar to other reports from Asian countries with high prevalence of HBV infection[11]. Hepatitis C virus (HCV) infection and liver cirrhosis have been suggested as potential risk factors for CCA in some large population-based and hospital-based case-control studies in Europe, US, and Eastern Asia[12-15]. In this study, the percentage of HCV infection in our CCA patients was significantly higher than the seroprevalence HCV in Thai blood donors that was about 0.51%[16].

In the present study, the authors collected a large amount of data over a 3-year period from HCC and CCA patients and analyzed data for the survival outcome according to the clinical staging and treatment method. Overall survival of HCC and CCA patients were not different. The median overall survival of HCC was14.4 months and 5-year survival was 27.6%. Corresponding to previous studies[17,18], the BCLC staging provide the best results in term of prognosis stratification. Unsurprisingly, the survival of patients who did not receive any treatment was significantly lower than the patients who were treated. The 1- and 2-year survival rates were 37.7% and 21.0%, which are comparable to previous report of the 1- and 2-year survival rates of untreated HCC patients randomized within 25 randomized controlled trials (RCTs) that were 10 to 72% and 8 to 50%, respectively[19]. Meanwhile, the patients who underwent treatment had satisfactory survival up to 60 to 75% after three years. Interestingly, the survival of patients with systemic chemotherapy was better than other modality of treatments. However, this group of patients was selected by clinical trials of new chemotherapy, included targeted therapy, which exclude incompetent persons from the treatment.

Compared to the CCA patients in the recent studies, the overall median survival was not significantly different between our patients (14.2 months; 95% CIs: 10.6-17.7) and CCA patients from western countries[4,20]. The liver flukes, *Clonorchis sinensis* and *Opisthorchis viverrini*, have been largely described to be risk factors for CCA in the Far East and Southeast Asia including Thailand[14,21,22]. Meanwhile, the risk factors of CCA in the United States and Europe are noninfectious causes[23,24].

In most of the studies, hepatic functional reserve as indicated by Child-Pugh classification, serum albumin level and serum AFP level were generally identified to be independent predictors of long-term outcome[25-27]. However, our data from multivariate analysis have not found that serum AFP level, tumor size, and Child-Pugh classification played any role in predicting an unfavorable for HCC patients.

The limitation of this study is similar to other retrospective study that we could not complete the information about risk factors and progression of disease. In this study, most of the patients with liver mass did not undergo liver biopsy and some of them refused treatment even if the tumor was curative because of their culture and fearful of treatment. Other limitation was referral bias from excluding the patients who looked too sick by advising them to have symptomatic and supportive treatment at their local hospital.

In summary, in the present study, the authors saw more patients in early and intermediate stage, the survival of these patients who received any type of treatment was much better than in the past. Still, in patients with advanced disease who received only supportive treatments were provided, the prognosis is grave.

Potential conflicts of interest

None.

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ลักษณะทางคลินิกและปัจจัยการพยากรณ์โรคมะเร็งตับในประเทศไทย

อภิญญา ลีรพันธ์, ลักขณา ไทยเครือ, พิเศษ พิเศษพงษา, ธเนศ ชิตาพนารักษ์, องอาจ ไพรสณฑรางกูร, ศตวรรษ ทองสวัสดิ์

วัตถุประสงค์: *เพื่อศึกษาลักษณะทางคลินิก อัตราการตาย และปัจจัยการพยากรณ์โรคของผู้ป่วยมะเร็งตับที่มารับการรักษาที่โรงพยาบาลรับการส่งต่อผู้ป่วยในประเทศไทย*

วัสดุและวิธีการ: *การศึกษานี้ได้เก็บข้อมูลของผู้ป่วยมะเร็งตับ 287 ราย และมะเร็งท่อน้ำดี 449 ราย ตั้งแต่เดือนกรกฎาคม พ.ศ. 2550 จนถึงเดือนมิถุนายน พ.ศ. 2553 เพื่อนำมาวิเคราะห์อัตราการตายและปัจจัยการพยากรณ์โรค*

ผลการศึกษา: *ผู้ป่วยมะเร็งตับและมะเร็งท่อน้ำดีมีอายุเฉลี่ย 53.8 ปี และ 59.2 ปี โดยส่วนใหญ่เป็นเพศชาย เมื่อแบ่งมะเร็งตับตามระยะของ BCLC พบมีผู้ป่วยระยะแรกร้อยละ 13.9 ระยะกลางร้อยละ 36.6 ระยะลุกลามร้อยละ 33.1 และระยะสุดท้ายร้อยละ 15 โดยมีอัตราตายที่ 1 ปี 2 ปี และ 3 ปี ร้อยละ 55 ร้อยละ 34 และร้อยละ 31.3 ตามลำดับ ส่วนผู้ป่วยมะเร็งท่อน้ำดีพบเป็นชนิด intrahepatic ร้อยละ 31.8 และชนิด ductal ร้อยละ 68.2 โดยมีอัตราตายที่ 1 ปี 2 ปี และ 3 ปี ร้อยละ 54 ร้อยละ 21.2 และร้อยละ 19.1 ตามลำดับ ผู้ป่วยมะเร็งตับที่มีหลอดเลือดดำพอร์ตัลอุดตัน หรือ ไม่ได้รับการรักษาที่เหมาะสมเป็นปัจจัยการพยากรณ์โรคที่ไม่ดี ในขณะที่ปัจจัยการพยากรณ์โรคของผู้ป่วยมะเร็งท่อน้ำดีได้แก่ ชนิด intrahepatic ค่าบิลลิรูบินมากกว่า 2 มก./ดล. ค่า CA19-9 มากกว่า 100 และมะเร็งที่ไม่สามารถผ่าตัดได้ ($p<0.05$)*

สรุป: *ผู้ป่วยมะเร็งตับที่ได้รับการรักษาที่เหมาะสมจะมีอัตราการรอดชีวิตที่ดีกว่าในอดีต ในขณะที่ผู้ป่วยระยะลุกลามแล้วจะมีการพยากรณ์โรคที่ไม่ดี*