Factors Related to Post-operative Recurrence of Intrahepatic Cholangiocarcinoma

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Background: *An incidence of intrahepatic cholangiocarcinoma (ICC) is high in Thailand and rising worldwide. Because of a dismal prognosis and a high recurrence rate after surgery.*
Objective: *To identify influential factors of cancer recurrence after liver resection.*
Material and Method: *A retrospective chart review was carried out in 66 patients who underwent R0 and R1 resection for ICC between 2002 and 2014 at Ramathibodi Hospital. Demographics data, pathological results and long term outcome were collected. Univariate and multivariate analysis were conducted to assess the risk factors of tumor recurrence.*
Results: *The median follow-up time was 18 months (range: 2 to 123 months), most of the patients experienced cancer recurrence in first year after surgery. The median time to recurrence was 9 months (range: 6.0 to 14.0), 5-year recurrence free survival (RFS) was 16.67%. The most common site of recurrence was the liver, followed by the lymph node. The most common pattern of recurrence was simultaneous intra- and extra-hepatic. The independent risk factor of the tumor recurrence after liver resection was tumor size >10 cm (HR, 2.804; 95% CI, 1.24 to 6.32; p = 0.013).*
Conclusion: *Large tumor size was the bad prognostic factor in ICC patients resulting in great risk of recurrence.*

Keywords: *Intrahepatic cholangiocarcinoma, Post-operative recurrence*

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Intrahepatic cholangiocarcinoma (ICC) is the 2nd most common primary liver cancer after hepatocellular carcinoma[1]. This cancer originates from the bile ducts epithelium with features of cholangiocyte differentiation[2]. Although the potentially curative treatment is complete resection, which can achieve 5-year overall survival (OS) rates ranging from 28 to 39.8% and a median OS up to 21 to 39 months[3-6]. A prognosis after liver resection is unsatisfactory, with a high incidence of locoregional recurrence and/or distant metastases, which is 53 to 58%[7,8]. Data from literatures revealed that a large tumor size, multiple tumors, nodal metastasis and a short margin width are poor prognostic factors[3,4,7-9]. Most of the patients who have these factors will eventually develop a tumor recurrence in short period after liver resection and most of them die soon afterward. Understanding of the factors that relate to tumor recurrence and the pattern of recurrence could be the promising information to develop more effective treatments for this disease.

The aim of our study was to identify factors that relate to cancer recurrence and pattern of recurrence in patients undergoing liver resection for ICC.

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Material and Method

Between February 2002 and October 2017, the retrospective study was conducted on patients who underwent curative-intent liver resection for intrahepatic cholangiocarcinoma (ICC) at Ramathibodi Hospital, Mahidol University. The study included only pathological confirmed ICC patients. The study was approved by the institutional review board. Exclusion criteria were a diagnosis of mix cholangiocarcinoma and hepatocellular carcinoma and the patients who died after surgery in that admission.

Data collection

Data of patient demographics, tumor characteristics from pre-operative imaging (Magnetic resonance imaging or computed tomography), pre-operative tumor marker level, type of resection and data of tumor recurrence were collected. The specimens of

tumor were sent to be evaluated by pathologist to determine the pathologic features that included tumor size, number of tumors, margin width, lympho-vascular invasion, lymph node metastasis and surrounding organ invasion. An R0 resection was classified as the absence of macroscopic or microscopic disease within area 1 mm from the surgical margin, R1 resection was classified as presence of microscopic tumor within area of 1 mm from the surgical margin and R2 resection was classified as macroscopic presence of tumor at the surgical margin. Tumor size was defined as the maximal diameter of the biggest tumor. Type of surgery were collected, with major liver resection defined as resection of at least three Couinaud segments[10]. Patients were followed until tumor recurrence, death, lost follow-up or until end of follow-up. Recurrence tumor was defined as highly suspicion of tumor recurrence from abdominal imaging. Site of tumor recurrence in term of intrahepatic, extra-hepatic or both were collected.

Statistical analyses

Baseline characteristic which was categorical variable were reported as percentages and compared using the chi-squared test. Continuous variables were reported as median (range). Time to recurrence was calculated in months from time of primary resection until tumor recurrence was detected. Follow-up time also was calculated in months from the time of primary resection until the follow-up date or death. Recurrence free survival was calculated using Kaplan-Meier method. Variables found to be significant associate with the endpoint on univariate analysis ($p<0.05$) was input into a Cox proportion hazards model to identify independent predictors. A p-value of <0.05 was considered as significant value on multivariate analysis. Analysis was carried out using STATA program Version 14.2.

Results

Patient characteristics

In our study, 69 patients underwent curative intent liver resection for ICC. Three of these patients had an R2 resection and were excluded from the study. For the remaining 66 patients, there were 37 men (56%) and 29 women (44%). Most patients had a solitary tumor (80%). The tumor size in the recurrence group was larger, which median tumor size was 6 cm compared to 3.75 cm in the no recurrence group ($p<0.05$). Major liver resection was performed in 55 patients (83%) and minor liver resection was performed in 11 patients (17%). Negative resection margin (R0 resection) could be achieved in 37 patients (56%). Nearly half of the patients (48%) had no information of lymph node involvement because lymphadenectomy was not performed at the time performing liver resection nevertheless the number of patients who had lymph node metastasis was higher in recurrence group compared to no recurrence group (35.4% vs. 5.6%). About a half of the patients had lympho-vascular invasion (46%). In post-operative period, 11 patients (16%) underwent adjuvant chemotherapy or radiotherapy.

Recurrence patterns

During a median follow-up of 18 months. Median recurrence-free survival (RFS) was 9 months (95% CI, 6.0 to 14.0). 1-, 2- and 5-year RFS was 42.42%, 25.76% and 16.67%, respectively. Forty-eight patients (72.7%) developed tumor recurrence. The recurrence occurred most commonly in the pattern of simultaneous intra- and extra-hepatic recurrence (41%), followed by only intra-hepatic (35.4%) and only extra-hepatic recurrence (22.9%) (Table 1). The organs of extra-hepatic recurrence included lymph node (n = 18), peritonium (n = 8), lungs (n = 7), bone (n = 3), adrenal gland (n = 2) and ovary (n = 1).

Based on univariate analysis, the significant influential factors for cancer recurrence were tumor size >10 cm (HR, 3.328; 95% CI, 1.54 to 7.20; $p = 0.002$) and lymph node metastasis (HR, 2.496; 95% CI, 1.08 to 5.75; $p = 0.032$). Number of tumors, R0 and R1 resection, margin width, type of liver resection and adjacent organs invasion were not significant risk factors. Tumor maker CEA and CA19-9 were also evaluated. We used CEA value 5.5 ng/ml and CA19-9 <200 ng/ml as a reference value, according to normal value of our hospital and previous study[11], respectively. The univariate analysis showed both of them were not a significant risk factor for cancer recurrence. The multivariate analysis showed that only the tumor size >10 cm was an independent risk of tumor recurrence (HR, 2.804; 95% CI, 1.24 to 6.32; $p = 0.013$) (Table 2).

Discussion

An incidence of cholangiocarcinoma is increasing worldwide[12]. In East Asia including Thailand, parasite infestation with liver fluke is the strong risk factor for bile duct carcinogenesis[13]. Despite an aggressive surgical procedure, the satisfactory result of ICC treatment still cannot be achieved[14]. After surgical resection, Reported recurrence rates were 54% to 79%[7-9,15,16]. The current study showed similar rate of tumor recurrence (73%).

Table 1. Clinicopathological characteristics of patients

Characteristic data	No recurrence (n = 18)	Recurrence (n = 48)	*p*-value	95% CI
Age (year), mean (SD)	59.17 (11.01)	57.50 (10.83)	0.581	55.29 to 60.61
Min-max	38 to 76	37 to 82		
Resection margin (mm), median (IQR)	5 (1 to 8)	6 (1 to 10)	0.709	5.24 to 9.23
Min-max	1 to 20	1 to 25		
Time to recurrence (month), median (IQR)	-	6 (3.5 to 13.5)	-	6.47 to 14.40
Min-max	-	1 to 87		
Follow-up time (month), median (IOR)	73 (37 to 91)	12 (7 to 22)	-	23.67 to 39.96
Min-max	8 to 123	2 to 112		
Age, n (%)				
<60 year	10 (55.56)	29 (60.42)	0.721	
≥60 year	8 (44.44)	19 (39.58)		
Tumor size, n (%)				
<5 cm	12 (66.67)	16 (33.33)	0.038	
5 to 10 cm	6 (33.33)	25 (52.08)		
>10 cm	0	7 (14.58)		
LN metastasis, n (%)				
Positive	1 (5.56)	17 (35.42)	0.038	
Negative	6 (33.33)	10 (20.83)		
Unknown	11 (61.11)	21 (43.75)		
Surgical margin, n (%)				
Negative (R0)	12 (66.77)	25 (52.08)	0.288	
Positive (R1)	6 (33.23)	23 (49.92)		
Margin width, n (%)				
<10 mm	7 (70.00)	12 (52.17)	0.455	
≥10 mm	3 (30.00)	11 (47.83)		
Lympho-vascular invasion, n (%)				
Positive	5 (27.78)	26 (54.17)	0.030	
Negative	5 (27.78)	3 (6.25)		
Unknown	8 (44.44)	19 (39.58)		
Type of resection, n (%)				
Major liver resection	15 (83.33)	40 (83.33)	1.000	
Minor liver resection	3 (16.67)	8 (16.67)		
Site of recurrence, n (%)				
Intra-hepatic		17 (35.41)		
Extra-hepatic		11 (22.92)		
Simultaneous intra- and extra-hepatic		20 (41.67)		
Adjacent organ invasion, n (%)	6 (33.33)	14 (29.16)	0.743	

In this study, most of the patients (n = 35, 53%) developed recurrence in first year. The median time to recurrence was 9 months. Even though, it was far shorter than other previous studies conducted in western countries[7-9,15]. It was comparable to the result of the other study from Thailand conducted in Khon Kaen University which found median RFS 188 days[17]. The explanation for this event might be the difference in etiology of disease and more aggressive nature of cholangiocarcinoma in Thailand.

The independent factor of increased risk of recurrence of the present study was the tumor size >10 cm (HR, 2.804; 95% CI, 1.24 to 6.32; $p = 0.013$). All of the patients who had tumor size > 10 cm developed tumor recurrence within 1 year after liver resection (Fig. 2). Some previous studies mentioned the same result that larger tumor size was one of the significant risk of tumor recurrence[7,12,20]. The previous study identified that an incidence of microscopic vascular invasion and tumor size were interrelated and tumor size was associated with worsening tumor grade which meant a large tumor likely harbors worse pathologic features[21]. This could

Table 2. Predictors of cancer recurrence after primary resection (results of multivariate analysis)

Variable	Univariate		Multivariate	
	HR (95% CI)	*p*-value	HR (95% CI)	*p*-value
Age (<50)				
≥50	0.902 (0.49 to 1.68)	0.745		
Gender (female)				
Male	0.951 (0.52 to 1.74)	0.870		
Tumor size (<10 cm)				
≥10 cm	3.328 (1.54 to 7.20)	0.002	2.804 (1.24 to 6.32)	0.013
Tumor number (solitary)				
Multiple	1.343 (0.67 to 2.66)	0.399		
Lymph node status (N0)				
Unknown	1.727 (0.79 to 3.77)	0.170	1.728 (0.77 to 3.86)	0.182
N1	2.496 (1.08 to 5.75)	0.032	1.898 (0.79 to 4.55)	0.151
Lympho-vascular invasion (negative)				
Positive	1.299 (0.39 to 4.31)	0.669		
Unknown	0.742 (0.21 to 2.58)	0.639		
Surgical margin, negative (R0)				
Positive (R1)	0.727 (0.41 to 1.29)	0.280		
Margin width (1 to 9 mm)				
≥10 mm	0.737 (0.30 to 1.78)	0.501		
Type of resection (major resection)				
Minor resection	1.636 (0.73 to 3.68)	0.234		
Adjacent organ invasion (absence)				
Presence	1.428 (0.78 to 2.61)	0.248		
CEA (<5.5 ng/ml)				
(≥5.5 ng/ml)	1.219 (0.56 to 2.66)	0.618		
CA 19-9(<200 ng/ml)				
≥200 ng/ml	1.138 (0.55 to 2.36)	0.727		

RR = relative risk; CI = confident interval; CEA = carcinoembryonic antigen; CA 19-9 = carbohydrate antigen 19-9

explain the aggressive behavior of a large tumor.

Many previous reports revealed that LN involvement or nodal status was a significant risk factor of tumor recurrence and overall survival[7-9,12,16,18,19,22]. Interestingly, the current study did not revealed lymph node involvement as the independent risk factor, it might be because nearly half of the patients (48%) did not undergo lymph node dissection at the time of surgery so the genuine information of lymph node metastasis was not obtained.

According to data from previous reports, incidence of lymph node metastasis in ICC patients who underwent LN dissection was 29.8% to 42.5%[23-25]. Currently, the value of routine lymph nodes dissection for ICC, in terms of survival benefit have not been confirmed. The study from Japan proposed that regional LN dissection might prevent further spreading of LN metastasis beyond the regional LN and might be necessary to improve the prognosis of patients whose tumor extended into the hepatic hilum or hepatoduodenal ligament[18]. Another previous study, collecting the data from Surveillance, Epidemiology, and End Results (SEER) database, proposed that the therapeutic LN dissection (removal >3 LNs) may associated with improvement in survival, particularly in young patients with larger tumor[27]. Another study from Korea revealed that the regional LN dissection combine with LN along common hepatic artery, celiac axis, retro-pancreatic and para-aortic LN dissection enhanced the survival outcome[25]. But other studies did not reveal the same result. One study from Korea proposed that Routine LN dissection for ICC did not show any survival benefits[22]. Another study showed that number of LN retrieved from a specimen did not improve overall and recurrence free survival[16] and another study revealed that there was no

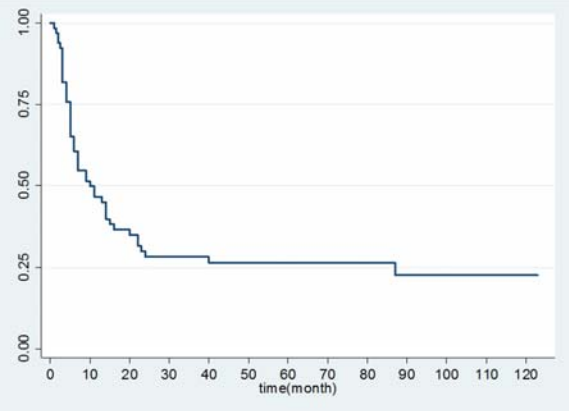

Fig. 1 Median RFS was 9.0 months (95% CI, 6.0 to 14.0). Overall 1-, 2-, and 5-year actuarial RFS was 42.42%, 25.76% and 16.67%, respectively.

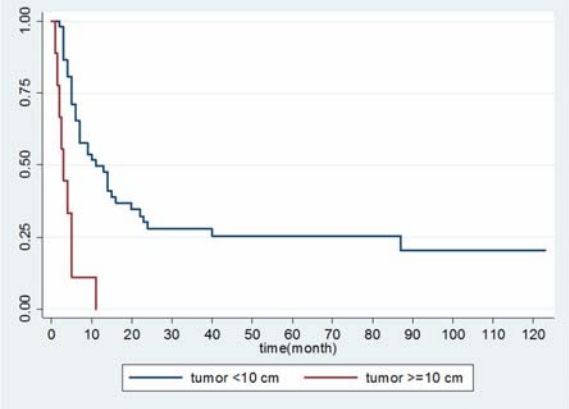

Fig. 2 Patients with tumor size ≥10 cm had a worse RFS than those with smaller tumors.

relationship between lymph node dissection in the first operation and regional lymph node recurrence[17]. However, lymph node dissection, in terms of providing prognosis and accurate staging has been strongly advocated[22,24-27].Taken together, even though survival benefit of routine LN dissection is still debatable, It should be carry out at the time performing hepatectomy to provide nodal staging that is essential information to predict outcome and decide whether to apply adjuvant treatment for each patient.

Although resection margin was not an independent factor in the current study. It was one of the important factors of recurrence ICC after surgery, according to many published studies. A previous study showed an incremental worsening RFS and OS as margin width less than 10 mm[9], another previous study found that a cut-off width of resection margin 1 cm was associated with improved disease-free survival[21], however, another study did not show different survival between margin width 5 to 9 mm and 10 cm or greater[19]. All of these studies showed worse survival in positive margin, so effort to achieve wide surgical margins whenever possible should be performed, particularly more than 1 cm.

Many studies that were published in literatures showed that intra-hepatic recurrence was the most common pattern of recurrence[7-9,15,17]. Interestingly, the most common tumor recurrence pattern of this study was simultaneous extra- and intra-hepatic recurrence. Despite of difference of pattern of recurrence, the common sites of recurrence was comparable, which were the liver and the intra-abdominal LN. Post-operative chemotherapy seem to be a promising treatment for ICC patients, according to the high recurrence rate and the recurrence pattern but unfortunately there are no any reliable studies to support.

The limitation of this study was small sample size and retrospective study. Furthermore, a technique of surgery and lymph node dissection were not uniform as well as post-operative adjuvant chemotherapy.

Conclusion

Currently, surgery is the only chance for cure for ICC, despite the aggressive surgical procedure, the recurrence rate is still high. Large tumor size is a bad prognosis for tumor recurrence.

What is already known on this topic?

The large tumor size is one of the bad prognostic factors of ICC patients. Most of such patients developed early tumor recurrence.

Margin width might associate with tumor recurrence. Liver resection to get wide resection margin should be performed to all patients.

What this study adds?

The behavior of cholangiocarcinoma is different between the parts of the world because of the different etiology. It seems as if cholangiocarcinoma in Thailand has more aggressive behavior and biology than the west, according to the data that showed we have far shorter median recurrence free survival comparing to the west.

Potential conflicts of interest

None.

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ปัจจัยที่มีผลต่อการกลับเป็นซ้ำของมะเร็งท่อน้ำดีในตับหลังผ่าตัด

วิกรานต์ สุรกุล, ณรงค์ศักดิ์ รุ่งสกุลกิจ, ปรมินทร์ ม่วงแก้ว, พงศธร ตั้งทวี, สมคิด มิ่งพฤฒิ

ภูมิหลัง: *มะเร็งท่อน้ำดีในตับ (Intrahepatic cholangiocarcinoma) เป็นมะเร็งที่พบมากในประเทศไทยและพบมะเร็งชนิดนี้พบได้มากขึ้นเรื่อย ๆ ในประเทศอื่นทั่วโลก ปัจจุบันการผ่าตัดยังเป็นวิธีการรักษาที่มีประสิทธิภาพมากที่สุด แต่ผลการรักษากลับไม่ดีมากนัก เนื่องจากมีอัตราการกลับเป็นซ้ำที่สูง*

วัตถุประสงค์: *หาปัจจัยที่มีผลต่อการกลับเป็นซ้ำของมะเร็งท่อน้ำดีในผู้ป่วยหลังผ่าตัด*

วัสดุและวิธีการ: *เก็บข้อมูลย้อนหลังในผู้ป่วยมะเร็งท่อน้ำดีในตับ (Intrahepatic cholangiocarcinoma) ที่ได้รับการผ่าตัดรักษาในโรงพยาบาลรามาธิบดีตั้งแต่ เดือนกุมภาพันธ์ พ.ศ. 2545 ถึง เดือนตุลาคม พ.ศ. 2557*

ผลการศึกษา: *พบว่าผู้ป่วยที่เข้าร่วมการศึกษา 66 คน จากระยะเวลาติดตามผู้ป่วยโดยเฉลี่ย 18 เดือน พบว่าผู้ป่วย 48 คน กลับเป็นซ้ำ คิดเป็นร้อยละ 78 ของผู้ป่วยทั้งหมด ระยะเวลาเฉลี่ยในการกลับเป็นซ้ำเท่ากับ 9 เดือน ปัจจัยที่มีผลต่อการกลับเป็นซ้ำได้แก่ ขนาดก้อนมะเร็งที่ใหญ่กว่า 10 เซนติเมตร และพบว่าผู้ป่วยทั้งหมดที่มีมะเร็งขนาดใหญ่กว่า 10 เซนติเมตร กลับเป็นซ้ำในปีแรกหลังผ่าตัดอวัยวะที่พบการกลับเป็นซ้ำบ่อยที่สุด คือ ตับ รองลงมา คือ ต่อมน้ำเหลือง*

สรุป: *ปัจจุบันการผ่าตัดยังเป็นการวิธีการรักษาวิธีเดียวที่มีโอกาสทำให้ผู้ป่วยมะเร็งท่อน้ำดีหายขาดจากโรคได้ ขนาดก้อนมะเร็งที่ใหญ่กว่า 10 เซนติเมตร เป็นปัจจัยเสี่ยงต่อการกลับเป็นซ้ำหลังผ่าตัดในผู้ป่วยมะเร็งท่อน้ำดีในตับ (Intrahepatic cholangiocarcinoma).*