Incidence and Risk Factors of Biliary Tract Complications after Liver Transplantation at Siriraj Hospital

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Objective: *Biliary tract complications remain one of the major problems after orthotopic liver transplantation (OLT), causing several consequent morbidities and mortalities. Therefore, the incidence and risk factors of these complications were studied to identify preventable causes and improve the outcomes.*

Material and Method: *Adult cadaveric-donor OLT patients at Siriraj Hospital between January 2002 and July 2014 were retrospectively reviewed. The patients who developed biliary complications were analyzed. Clinical factors and outcomes of treatment modalities were evaluated.*

Results: *A total of 195 patients underwent OLT, 16 patients had biliary complications after OLT. The overall incidence of biliary complications was 8.2%, including bile leakage rate of 2.1% and anastomotic stricture rate of 7.2%. Intra-operative blood transfusion ($p = 0.04$), platelet transfusion ($p = 0.04$) and fresh frozen plasma transfusion ($p = 0.02$) are the risk factors associated with biliary tract complications. Nevertheless, no independent risk factor was identified by the multivariate analysis.*

Conclusion: *Biliary tract complications after OLT cause significant morbidities to the patients. Intra-operative blood and its components such as platelet and fresh frozen plasma transfusion were the risk factors for biliary tract complications after OLT.*

Keywords: *Biliary, Complication, Deceased donor, Liver transplantation*

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Liver transplantation was one the standard treatment for selected cases of end-stage liver disease after the first successful case performed by Starzl et al in 1963[1]. The outcome of liver transplantation has been continuously improving due to the advance in organ procurement, immunosuppression, surgical technique and better management of complications especially in the past three decades. However, complications, especially biliary tract complications are still an important cause of morbidity, graft loss, and mortality related to liver transplant[2-4].

Biliary complications led to graft loss in some patients, but more commonly, these patients required long term medication, multiple hospitalizations for cholangitis, frequent endoscopic and radiologic procedures as well as potentially surgical revisions, which consume a considerable amount of health care resource[5].

Several risk factors have been reported to be associated with biliary complications after liver transplantation. The use of t-tube, prolonged warm and cold ischemic time, donor after cardiac death, advanced age, preoperative bilirubin, international normalized ratio of prothrombin time (INR), model for end-stage liver disease (MELD) score, advanced donor age, partial or split liver graft, graft macrosteatosis and era of transplantation have been found to be associated with biliary complications[3,6,7]. However, these risk factors also depended on type of liver graft (living donor vs. deceased donor liver transplantation, donor after cardiac death (DCD) vs. donor after brain death (DBD)) and different surgical techniques of each liver transplant center.

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In this study, the retrospectively review of the results of liver transplantation at Siriraj Hospital was performed. The incidence and risk factors of post-transplant biliary complications were recorded and analyzed.

Material and Method

From January 2002 to July 2014, 195 consecutive deceased donor adult orthotopic liver transplantations were performed at Siriraj Hospital and were retrospectively reviewed. All patients were followed-up for at least 6 months. Information on clinical and demographic characteristics of recipients were also obtained from prospectively recorded liver transplant recipient registration files, which record recipients' age, sex, primary cause of end-stage liver disease, pre-operative laboratory including liver function test, creatinine level and coagulogram. The obtained donor characteristics consisted of cold and warm ischemic time. Intra-operative findings included type of biliary reconstruction, and amount of blood component transfusion, while post-operative complications included biliary leakage, biliary stricture, hepatic artery thrombosis, primary graft non-function, and management of biliary complications. All data for the current study were collected in accordance with Siriraj Institutional Review Board, Faculty of Medicine Siriraj Hospital, Mahidol University.

Patients were divided into 2 groups. Group 1 consisted of patients without biliary tract complications after liver transplantation and group 2 included patients with biliary tract complications after liver transplantation. Patients without and with biliary tract complications were compared in terms of pre-operative, intra-operative, and post-operative variables as previously described.

The univariate analysis was performed by using Mann-Whitney test and Fisher exact test as appropriate. The risk factors with *p*-value <0.20 were entered into a multivariate logistic regression analysis which was also adjusted for demographic characteristics such as age and gender. All statistical analyses were performed using PASW Statistics software version 18 (SPSS Inc., Chicago, IL, USA). A *p*-value of less than 0.05 was considered statistically significant.

Notably, the biliary reconstruction in this study was performed in 2 techniques including duct-to-duct (end-to-end) choledochocholedochostomy (CC) and Roux-En-Y hepaticojejunostomy (HJ). In the majority of the cases, end-to-end choledocho-choledochostomy was performed by interrupted stitch technique with external knotting using 5-0 maxon™ monofilament absorbable sutures (Covidien, Minneapolis, MN, USA). End-to-side roux-en-Y hepaticojejunostomy anastomosis with interrupted stitch external knotting technique using 4-0 coated vicryl (Ethicon Inc., Somerville, NJ, USA) was selected in some cases who was not feasible for choledochocholedochostomy due to anatomical reasons for examples: non-comparable of the diameters of both ends of bile duct, the distance between both ends was more than 4 centimeters or significant tension after end-to-end anastomosis. Moreover, the patients who had underlying of biliary tract diseases such as sclerosing cholangitis and post Kasai procedure were also chosen for hepaticojejunostomy anastomosis. The reason for external knotting is to avoid the possibility of bile cast formation. None of the cases were used internal or external biliary stent or t-tube.

Results

A total of 195 liver transplantations were studied. The median (interquartile range) age of the recipients was 54 (48 to 60) years old, and 127 patients (65.1%) were male. Indications for liver transplantation are shown in Table 1. The most common indication for liver transplantation was hepatocellular carcinoma (41%), followed by chronic hepatitis C cirrhosis (14.9%) and chronic hepatitis B cirrhosis (13.3%). Biliary reconstruction was performed with either end-to-end CC (n = 188) or roux-en-Y HJ (n = 7).

The overall biliary complication rate was 8.2% (16 in 195 transplantations). Bile leakage occurred in 4 transplantations (2.1%), where the source of bile leakage all came from anastomotic leakage. The patients developed bile leakage between 10 and 46 days after transplantation. The first patient was treated with percutaneous drainage and the leakage resolved within 3 months. The second patient underwent emergency re-exploratory laparotomy with drainage from bile peritonitis, followed by conversion of choledocho-choledochostomy to hepatico-jejunostomy anastomosis a week later. After the operation, this patient had no further biliary complications. The others two patients had bile leakage and subsequent anastomotic stricture which required endoscopic retrograded cholangiography (ERC) with bile duct stenting and percutaneous drainage. Cholangiography showed persistent leakage after endoscopic treatment. Therefore, one of them underwent re-exploratory and suturing biliary

Table 1. Indications for liver transplantation of patients without and with biliary complications

	No biliary complication (n = 179)	Biliary complication (n = 16)
Hepatocellular carcinoma	72 (40%)	8 (50%)
Chronic hepatitis C cirrhosis	28 (16%)	1 (6%)
Chronic hepatitis B cirrhosis	22 (12%)	4 (25%)
Alcohol and cryptogenic cirrhosis	28 (16%)	2 (13%)
Primary biliary cirrhosis	7 (4%)	1 (6%)
Acute fulminant hepatic failure	5 (2.8%)	0
Autoimmune hepatitis	3 (1.6%)	0
Biliary atresia	3 (1.6%)	0
Primary sclerosing cholangitis	3 (1.6%)	0
Wilson's disease	3 (1.6%)	0
Other	5 (2.8%)	0

anastomosis over stenting, and the other required re-transplantation due to the presence of late hepatic artery thrombosis. Finally, all the biliary leakages were cured within 6 months of several of treatments.

Biliary stricture occurred in 14 transplantations (7.2%), with all of them being anastomotic stricture. Two of them also had simultaneous bile leakage and stricture as described above. Almost all presented with jaundice between 2 to 17 months. Notably, the earliest onset of biliary stricture without leakage was about 3 weeks after transplantation. ERC with stenting was the first procedure to treat bile duct stricture in all patients, at least one plastic stent was successfully placed across the stenotic point in almost all cases (13 of 14 cases) except one case due to the kinking of bile duct. However, the patient who had bile duct kinking and intermittent jaundice was unexpectedly improved in 36 months without requirement of any further procedures. Four cases of biliary stent placement had completed recovery within 6 to 12 months with stents placement alone. Three cases required subsequently percutaneous trans-hepatic biliary drainage (PTBD) with balloon cholangioplasty to dilate stricture point whereas one patient needed the conversion of end-to-end choledochocholedochostomy anastomosis to hepaticojejunostomy because of the failure of endoscopic and intervention therapy. Nevertheless, uncontrollable sepsis likely from severe cholangitis occurred in 3 patients during the course of intervention treatment and all of them were consequently dead.

Univariate analysis revealed that the significant predictors for biliary complications included intra-operative blood transfusion ($p = 0.04$), fresh frozen plasma transfusion ($p = 0.02$) and platelet transfusion ($p = 0.04$). Other variables were not significantly associated with biliary complications (Table 2). For the multivariate logistic regression analysis, there was no independent risk factor predicting biliary complications after liver transplantation.

In terms of outcome after biliary complications, 6 of 16 patients (31%) with biliary complications died. The most common cause of death in these patients was severe sepsis. The causes of death of the patients are shown in Table 3. However, the mortality rate for patients with biliary complications was not significantly different from that for patients without biliary complications (38% vs. 29%, $p = 0.57$).

Discussion

Biliary leakage and anastomotic stricture are the most common biliary complications with the incidence of 2% to 32% of patients undergoing liver transplantation[3,8-10]. Other reported complications include papillary dyskinesia, ampullary dysfunction, biliary filling defects (bile stones, sludge and cast), mucocele and hemobilia[11,12]. Akamatsu et al[6] presented a systematic review reporting the incidence of biliary complications in 11,547 deceased donor liver transplantations. The incidence of biliary stricture and biliary leakage were 12% and 7.8%, respectively. Zimmerman et al[13] reported overall biliary complications in deceased donor liver transplantation of 25%, including biliary stricture of 14.5% and biliary leakage rate of 9.5%. The incidence of biliary complications after liver transplantation in this study is 8.2%, which is in concordance with previous publications. The incidence of biliary stricture was 7.2%,

Table 2. Univariate analysis of patients without and with biliary tract complications

Parameters	No biliary complication (n = 179)	Biliary complication (n = 16)	*p*-value
Gender			0.18
Male	114 (64%)	13 (81%)	
Female	65 (36%)	3 (19%)	
Age at transplant (year)	54 (50 to 62)	57 (50 to 62)	0.28
Hepatocellular carcinoma	68 (38%)	6 (38%)	0.99
Preoperative blood chemistry			
Creatinine (mg/dl)	1.0 (0.8 to 1.6)	1.0 (0.8 to 1.3)	0.93
Aspartate aminotransferase-AST (U/L)	69 (45 to 100)	59 (49 to 130)	0.96
Alanine aminotransferase-ALT (U/L)	39 (25 to 63)	43 (31 to 52)	0.58
Total bilirubin (mg/dL)	3.2 (1.5 to 11.9)	3.4 (1.9 to 14.4)	0.78
Direct bilirubin (mg/dL)	1.6 (0.8 to 8.6)	2.1 (0.8 to 11.5)	0.81
Albumin (mg/dL)	3.0 (2.5 to 3.4)	2.9 (2.5 to 3.5)	0.63
INR	1.35 (1.2 to 1.8)	1.54 (1.3 to 1.8)	0.29
Cold ischemic time (hours)	5.9 (3.6 to 8.1)	6.2 (2.8 to 9.6)	0.74
Warm ischemic time (minutes)	53 (45 to 62)	56 (47 to 69)	0.41
Pack red cell transfusion (mL)	1,719 (780 to 2,789)	3,534 (1,830 to 5,069)	0.04*
Fresh frozen plasma transfusion (mL)	1,374 (838 to 2,031)	1,995 (1,570 to 2,788)	0.02*
Platelet transfusion (mL)	350 (250 to 569)	577 (450 to 652)	0.04*
Type of biliary anastomosis			0.99
Duct-to-duct choledochocholedochostomy	172 (96%)	16 (100%)	
Hepaticojejunostomy	7 (4%)	0	
Mortality cases	51 (28.5%)	6 (37.5%)	0.57

Results are presented in medians (interquartile ranges) or numbers (percentages).
* Statistically significant at *p*-value <0.05

Table 3. The causes of death of patients without and with biliary tract complications

	No biliary complication (n = 179)	Biliary complication (n = 16)	Total
Septicemia	12 (24%)	3 (50%)	15
Recurrence or metastasis of carcinoma	8 (16%)	1 (17%)	9
Severe pneumonia	4 (8%)	0	4
Primary graft non-function	6 (12%)	0	6
Acute respiratory distress syndrome	4 (8%)	0	4
Hepatic artery thrombosis	1 (2%)	0	1
Graft rejection	0	1 (17%)	1
Others	16 (30%)	1 (17%)	15
Total	51	6	57

and that of anastomotic leakage was 2.1%, which are acceptably low comparing to the previous reports.

A number of risk factors associated with biliary complications have been reported in several publications. Risk factors can be divided into three groups: recipient factors, donor factors, and operative factors. Recipient factors include old age (>70 years), high preoperative bilirubin and INR, high MELD score, smoking. Donor factors that are associated with biliary complications are advanced donor age, female sex, macrosteatosis of liver graft, DCD status, and split liver graft. Operative factors that increase the risk of biliary complications include prolonged cold and warm ischemic time, CC anastomosis (compared to HJ),

t-tube placement after biliary anastomosis, tension at the anastomosis and type of suture materials[3,6,7,14-19]. Moreover, the specific types of biliary complications were also significant related with type of liver transplantation, for examples, non-anastomotic stricture was strongly associated with DCD graft, while anastomotic stricture was related with living donor liver transplantation[11].

The range of reported incidence of biliary complications in previous literature widely varies and may reflect the difference in surgical techniques of biliary reconstruction in each liver transplant center. Regarding different surgical techniques for bile duct reconstruction, Several publications reported the t-tube placement and duct-to-duct CC significantly affected biliary complications compared to HJ[20]. The technique used in this study was duct-to-duct CC anastomosis without t-tube placement, and the rate of biliary complications remained in the low range, suggesting the biliary reconstruction remains an appropriate technique. The duct-to-duct CC anastomosis allows the possibility to perform endoscopic treatment should biliary complications occur. Interestingly, biliary complications in 16 patients among 188 patients were duct-to-duct CC (8.5%), but none in 7 patients who had HJ reconstruction (0%). However, due to limited sample size, this difference was statistically insignificant.

In the univariate analysis, the intra-operative blood, fresh frozen plasma, and platelet transfusion were significantly associated with biliary complications. Nonetheless, no independent risk factor was identified in the multivariate logistic regression analysis. The pathogenesis why transfusion is related with biliary complications remains speculative and is likely to be multifactorial. A few studies[21-23] have found an association between intra-operative blood products transfusion and poor outcomes after liver transplantation. Lui et al[22] found that the intra-operative transfusion of cryoprecipitate was significantly associated with higher rate of biliary complication. They speculated that the complex ingredients in cryoprecipitate might cause micro-thrombus and immune rejection leading to biliary injury and stricture. However, the relationship between blood transfusion and biliary complications could not be demonstrated. This study is the primary data to demonstrate the association between blood transfusion, fresh frozen transfusion and platelet transfusion and biliary complications after liver transplantation. In general, blood product transfusion reflects more intra-operative blood loss which can be from more severe portal hypertension associated with worse primary liver disease, or more difficult liver transplant surgery[24]. Another possible explanation is that direct injury to cholangiocytes by immune rejection of bile ducts and damage to the peribiliary vascular plexus by micro-thrombus may lead to ischemia of biliary epithelial cells causing biliary stricture and leakage[22,25].

This study not only reported the incidence of biliary complications after liver transplantation, but also identified risk factors for emerging those complications. This may lead to the awareness of these complications and modify the procedures to improve the outcomes. Meticulous technique in hemostasis and necessary transfusion of blood component are required to reduce the complication rate and to improve results. However, the study certainly has some limitations with respect to its retrospective nature and limited sample size.

Conclusion

The incidence of biliary complications was comparable with previously reported literatures. Biliary complications remain common after liver transplantation. Intra-operative blood and blood components transfusion increased biliary complications after liver transplantation. Intra-operative hemostasis and liberal transfusion of blood component might reduce the biliary complication rate and improve the outcome.

What is already known on this topic?

The biliary complication is one of the most common complications after liver transplantation. Incidence of biliary complications after liver transplantation ranges between 2% and 35%.

What this study adds?

This is the first report of incidence of biliary complications after liver transplantation in Thailand (8.2%), which is comparable with international standard. Blood, fresh frozen plasma and platelet transfusion significantly increase biliary complications.

Potential conflicts of interest

None.

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อุบัติการณ์และปัจจัยเสี่ยงการเกิดภาวะแทรกซ้อนทางเดินน้ำดีภายหลังการผ่าตัดปลูกถ่ายอวัยวะตับในโรงพยาบาลศิริราช

ประเวชย์ มหาวิทิตวงศ์, วราพรรณ นุ่มประสิทธิ์, ยงยุทธ ศิริวัฒนอักษร, สมชัย ลิ้มศรีจำเริญ, ประวัฒน์ โฆสิตะมงคล, สุปรีชา อัสวกาญจน์, ชุติวิชัย โตวิกกัย, เวธิต ดำรงกิตติกุล

ภูมิหลัง: *การเกิดภาวะแทรกซ้อนทางเดินน้ำดียังคงเป็นหนึ่งในปัญหาสำคัญภายหลังการผ่าตัดปลูกถ่ายอวัยวะตับ นำมาซึ่งภาวะทุพพลภาพภายหลังการรักษารวมถึงเสียชีวิตได้ ดังนั้นการทราบถึงอุบัติการณ์และปัจจัยเสี่ยงจะทำให้ช่วยป้องกันปัญหาและเกิดผลลัพธ์ที่ดีได้*

วัสดุและวิธีการ: *ศึกษาย้อนหลังเวชระเบียนผู้ป่วยที่ได้รับการผ่าตัดปลูกถ่ายอวัยวะตับในโรงพยาบาลศิริราชจากผู้บริจาคที่เสียชีวิต ระหว่างเดือนมกราคม พ.ศ. 2545 ถึง เดือนกรกฎาคม พ.ศ. 2557 วิเคราะห์ข้อมูลของผู้ป่วยที่เกิดภาวะแทรกซ้อนทางเดินน้ำดีทั้งสาเหตุที่เกี่ยวข้อง วิธีการรักษา และผลการรักษา*

ผลการศึกษา: *ผู้ป่วยที่ผ่าตัดปลูกถ่ายอวัยวะตับทั้งหมด 195 ราย พบว่ามีภาวะแทรกซ้อนทางเดินน้ำดีรวม 16 ราย อุบัติการณ์คิดเป็นร้อยละ 8.2 ได้แก่ อัตราการเกิดท่อน้ำดีรั่วร้อยละ 2.1 และอัตราการเกิดท่อน้ำดีตีบร้อยละ 7.2 ปัจจัยเสี่ยงที่สัมพันธ์กับภาวะแทรกซ้อนทางเดินน้ำดี ได้แก่ การให้เลือดในระหว่างผ่าตัด (p = 0.04) การให้เกล็ดเลือด (p = 0.04) และการให้ fresh frozen plasma (p = 0.02) อย่างไรก็ตามจากการวิเคราะห์ทางสถิติไม่พบว่ามีปัจจัยอิสระ*

สรุป: *ภาวะแทรกซ้อนทางเดินน้ำดีภายหลังการผ่าตัดปลูกถ่ายตับ เป็นผลให้เกิดภาวะทุพพลภาพในผู้ป่วย ปัจจัยเสี่ยงที่เกี่ยวข้องได้แก่ การให้เลือดและสารประกอบของเลือดในระหว่างการผ่าตัด*