Influence of technical refinement on biliary complications of donors of living donor liver transplantation: a retrospective comparative study

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Background
Biliary complications (BCs) of living liver donors are of serious concern as they threaten the donor's health and life. Technical problems are the main cause of these complications.
Aim
We conducted a retrospective analysis of the incidence, types, and management polices of BCs in our cohort of donors of living donor liver transplantation, with special emphasis on the impact of technical refinement of bile duct stump closure.
Patients and methods
Data were reviewed from a prospectively maintained database of all donors who underwent hepatectomy. The incidence and types of and management options for BCs in living liver donors were compared in two successive phases of our program of living donor liver transplantation. The first period included 140 donors in a procedure in which the bile duct stump was closed using continuous sutures or interrupted sutures, whereas the second period comprised 100 donors in a procedure in which the bile duct stump was closed using a newly designed technique by combining suturing and reinforcement with a metallic clip just below the suture line. Before abdominal closure, the intraoperative cholangiogram was repeated.
Results
The overall incidence of BCs among donors was 14.2%. On comparison of BCs in the two studied phases we found significant differences in the rate of BCs: 20% in the first phase and 6% in the second phase. Further, a significant difference was documented in the two periods with respect to age less than 30 years, male donors, BMI more than 25%, left lobe or left lateral graft, and one duct ($P<0.05$). Moreover, there were significant differences between the two periods regarding operative time, length of ICU stay, and length of hospital stay.
Conclusion
Our newly adopted technique of bile duct stump closure as well as the performance of two intraoperative cholangiographies before cutting and after closure of the stump resulted in significant improvement in and reduction of BCs. This new technique is safe, simple, and reproducible and does not prolong the surgery.

Keywords:
donor biliary complication, living donor liver transplantation

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Introduction

In living donor liver transplantation (LDLT), donor safety is of primary concern [1]. Biliary complications (BCs) in living liver donors are of serious concern as they threaten the donor's health and life. They constitute the main cause of morbidity after right lobe donation. Further, these complications affect the donors and their families psychologically, physically, and economically [2]. These complications comprise biliary leakage, bilomas, and biliary strictures. The overall incidence of BCs in living liver donors ranges from 0.4 to 13%, and the rates of biliary leaks and strictures range from 0 to 12.6% and from 0 to 5.8%, respectively [3].

BCs in living liver donors are usually technical in nature and may be directly linked to bile duct division; they constitute the majority of the clinically significant donor complications in many reports [4–9]. Therefore, the occurrence of BCs should be avoided. This can be achieved by increasing the learning curve, by technical refinement, and by applying innovative management strategies on preoperative donor assessment and whenever a complication occurs.

Closure of the donor's bile duct stump is a very crucial step in avoiding BCs in the form of leak or stenosis. Several surgical techniques to deal with the bile duct stump have been developed, which differ between centers. In our center, a new modified technique combining suturing of the bile duct stump and reinforcement by metallic clip application has been adopted Shoreem *et al.* [10]. Therefore, the aim of our study was to analyze the incidence, patterns, and management strategies of BCs in living liver donors in our series of LDLT. We also compared BCs of the living liver donors before and after the application of our newly adopted technique of bile duct stump closure.

Patients and methods

This is a retrospective cohort hospital-based study in which we reviewed the data on BCs in 240 consecutive living liver donors at the National Liver Institute Hospital, Menoufiya University, between April 2003 and October 2015. The study was approved by the National Liver Institute Ethical Committee.

Donor demographic data, graft type, and postoperative outcomes and complications were recorded from our prospectively maintained database. The details of donor evaluation and donor lobar hepatectomy have been described previously elsewhere [11,12].

BCs of living donors were recorded and compared in two different periods during our program of LDLT, as we applied two different techniques in dealing with the bile duct stump. The first period was from April 2003 to September 2011 (140 donors), when we closed the bile duct stump with fine prolene sutures either as continuous running sutures in the first 94 donors or as interrupted sutures in the next 46 donors. The second period was from September 2011 to October 2015 (100 donors), when we modified our technique for bile duct stump closure by applying a surgical metallic clip (small or medium size) just below the fine suture line (prolene 0/6) [10]. Before abdominal closure, an intraoperative cholangiogram was repeated to show the anatomy of the remaining biliary and to confirm the absence of biliary leakage or jeopardized biliary lumen. In the first period (140 donors), this repeated intraoperative cholangiogram was not routinely performed.

Surgical procedure for dissection of donors' bile duct

The anterior aspect of the hepatoduodenal ligament is dissected, the hepatic artery and portal vein are isolated, and the common bile duct is identified avoiding excessive mobilization of the bile ducts to prevent ischemic damage. After the right or left hepatic duct (LHD) has been identified, a small hemostatic clamp is applied to the predetermined cut line on the bile duct. An intraoperative cholangiography is performed by means of a 4 Fr silicone tube inserted from the cystic duct in cases of right hepatectomy or through a 24 G puncture needle inserted into the common bile duct in cases of left hepatectomy. After identifying the anatomical pattern of the biliary tree, hepatic parenchymal transection is performed without any hepatic vascular occlusion using a harmonic scalpel Cavitron Ultrasonic Aspirator (Valley Lab Inc., Boulder, Colorado, USA), as well as bipolar diathermy, until we reach the proposed bile duct stump demarcated by the hemostatic vascular clamp. If the identity of the bile duct can be clearly ascertained – that is, whether it is a right or a left bile duct – it is cut sharply. If not, another intraoperative cholangiography is performed for documenting the site of cutting.

Protocol for management of biliary complications

A bile leak is defined as the presence of bile-stained fluid, of any amount, in the abdominal drain after the third postoperative day. Biloma is defined as bilirubin-rich intra-abdominal fluid collection seen by aspiration and/or by placement of a percutaneous tube drain under sonographic control. Liver donors developing any complications related to the biliary tract were promptly diagnosed and managed. In our protocol, the bilirubin content in the drain effluent was routinely measured until the content was less than the serum bilirubin level. Minor bile leaks were monitored carefully as they usually resolved spontaneously; however, if the patient became symptomatic, on the basis of clinical and/or laboratory measures, an abdominal computed tomography scan and/or magnetic resonance cholangiopancreatography was performed immediately. With all relevant information of a given donor, a detailed discussion took place between the surgeon, the endoscopist, and an interventional radiologist to reach a consensus on the appropriate intervention. These therapeutic options included ultrasound (US)-guided aspiration, endoscopic retrograde cholangiography-based procedures, percutaneous transhepatic dilatation, or surgical intervention.

BCs treated by US-guided aspiration and insertion of a pigtail catheter were followed up by serial US examinations. The decision to remove the pigtail was made when the volume of bilious discharge was less than 50 ml/day or in the presence of clear discharge free of bile for 2 successive days with abdominal US

documenting complete disappearance of any abdominal collection.

Statistical analysis

Data were presented as mean±SD and range where appropriate. Comparisons between groups were made using Fisher's exact test and one-way analysis of variance. Values of *P* less than 0.05 were considered statistically significant. All statistical analyses were conducted using SPSS, version 21 software (SPSS Inc., Chicago, Illinois, USA).

Results

Donor characteristics

The overall mean age of donors was 27.5±6.5 years with a range of 18–45 years. There was no difference in the mean ages of donors in the first and second periods (mean of 36.2 and 34.9 years, respectively). There were 152 male (63.3%) and 88 female (36.7%) patients. There was no difference between the two groups in terms of donors' sex and BMI (25±3.9 vs. 25.3±2.9 kg/m^2). Liver biopsy and histopathological examination were routinely performed and showed a normal liver in 181 donors (75.4%), whereas in 13 (5.4%) donors the liver was steatotic less than 10%, and in 46 (19.2%) donors the examination revealed a minimal to mild periportal fibrosis. Ten donors with steatosis had a BMI greater than or equal to 25 kg/m^2, whereas in the remaining three steatotic donors the BMI was less than 25 kg/m^2.

Table 1 Donor Characteristics, Operative Data and Outcomes of Donors: Comparisons between Our Two periods of Experience

	Period 1 N=140	Period 2 N= 100	*P* value
Donor characteristics			
Age			
• Mean ± SD	27.3 ± 6.8	27.8 ± 6.1	Ë 0.05
Sex			
• Male	89 (63.6%)	63 (63%)	Ë 0.05
• Female	51 (36.4%)	37 (37%)	
BMI /kg/m2			
• Mean ± SD	25 ± 3.9	25.3 ± 2.9	Ë 0.05
Intra-operative data			
Graft type			
• Right	113 (80.7%)	75 (75%)	Ë 0.05
• Left	27 (19.3%)	25 (25%)	
Calculated Graft size (g)			
• Mean ± SD	798 ± 297	816.5 ± 310.6	Ë 0.05
Calculated Graft/donor weight (GRWR)			
• Mean ± SD	1–3 ± 0.5	1.37 ± 0.65	Ë 0.05
Actual Graft size (g)			
• Mean ± SD	744.1 ± 259.3	743.5 ± 287.3	Ë 0.05
Actual Graft/donor weight (GRWR)			
• Mean ± SD	1.27 ± 0.6	1.28 ± 0.62	Ë 0.05
RLV			
• Mean ± SD	47.6 ± 16.7	48 ± 16.8	Ë 0.05
No of bile duct			
• One duct	76 (54.3%)	46 (46%)	Ë 0.05
• Ë one duct	64 (45.7%)	54 (54%)	
Operative time (h)			
• Mean ± SD	6.3 ± 1.1	5.7 ± 0.6	Ë 0.05
ICU stay (d)			
• Mean ± SD	2.4 ± 0.9	1.9 ± 0.6	Ë 0.05
Hospital stay (d)			
• Mean ± SD	16 ± 9.7	8.2 ± 2.9	Ë 0.05

Operative details and outcomes

The intraoperative data of all the donors and the differences between the two groups are presented in Table 1. Right lobe grafts represented the majority of grafts procured. The types of grafts were distributed as follows: 188 (78.3%) were the right lobe with one graft (0.4%) was the posterior segments (VI and VII), left lobe grafts in 14 (5.8) cases, left lateral segments in 38 (15.8%) cases [one of these case the graft was reduced to a monosegment]. There was no significant difference between the two periods regarding the graft type, calculated and actual graft size, graft/recipient weight ratio, remnant graft volume, and number of bile ducts. However, a significant difference between the two groups concerning the operative time, length of ICU stay, and length of hospital stay was observed ($P<0.05$ for each).

Donor biliary complications

BCs occurred in 34 (14.2%) donors, with biliary leak in 32 donors (13.4%) and biliary stricture in two donors (0.8%). According to graft type, the distribution of BCs was nonsignificant, with 28 (14.9%) donors of right lobe graft and six (11.5%) donors of left lobe graft ($P>0.05$). On comparison of BCs in the donors in the two periods we noticed a significant difference in the rate of complications (Table 2). In the first period, the rate of BCs was 20%, which was much higher than the 6% in the second phase. Other significant differences include age less than 30 years, male donors, BMI less than 25%, left lobe or left lateral graft, and one duct ($P<0.05$). However, no significant differences were noticed in the remnant liver volume less than 35 or more than 35 and operative time less than 6 h or greater than 6 h ($P>0.05$).

Management of biliary complications

BCs in the donors were managed as follows: there were five cases with a biliary leak with an operative drain (mean 80 ml/day; range 30–160 ml/day), which improved on conservative treatment. Those donors had no intraperitoneal collections or any signs of

Table 2 Comparisons of biliary Complications between the Two periods

		Period 1 N=140	Period 2 N=100	*P*-value
Biliary complication	No	112	94	< 0.001
	yes	28	6	
Age Ë 30 years	No Leak	74	58	< 0.004
	Leak	20	3	
	Stricture	0	0	
Age Ë 30 years	No Leak	38	36	> 0.05
	Leak	7	2	
	Stricture	1	1	
Male	No Leak	71	61	< 0.009
	Leak	17	2	
	Stricture	1	0	
Female	No Leak	41	33	> 0.05
	Leak	10	3	
	Stricture	0	1	
BMI Ë 25	No Leak	61	50	< 0.012
	Leak	14	1	
	Stricture	1	0	
BMI Ë 25	No Leak	51	44	> 0.05
	Leak	13	4	
	Stricture	0	1	
Left lobe graft	No Leak	21	25	< 0.015
	Leak	6	0	
	Stricture	0	0	
Right lobe graft	No Leak	91	69	> 0.05
	Leak	21	5	
	Stricture	1	1	
No. of bile duct One duct	No Leak	64	44	< 0.047
	Leak	12	2	
	Stricture	0	0	
No. of bile duct Ë One duct	No Leak	48	50	> 0.05
	Leak	15	3	
	Stricture	1	1	
Remnant liver volume Ë 35	No Leak	97	89	> 0.05
	Leak	22	5	
	Stricture	1	1	
Remnant liver volume Ë 35	No Leak	15	5	> 0.05
	Leak	5	0	
	Stricture	0	0	
Operative time Ë 6 h	No Leak	50	60	> 0.05
	Leak	9	4	
	Stricture	0	0	
Operative time Ë 6 h	No Leak	62	34	> 0.05
	Leak	18	1	
	Stricture	1	1	

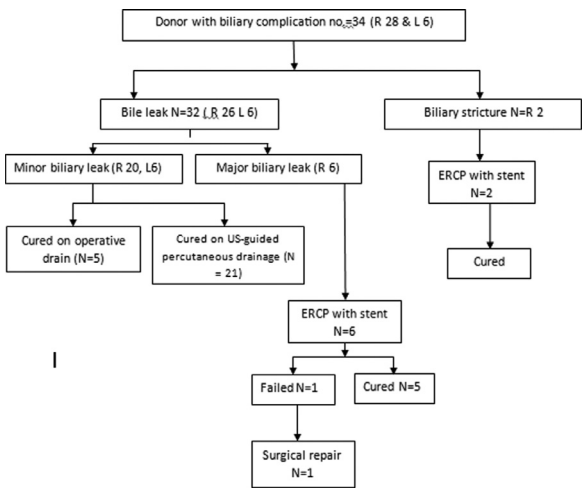
sepsis. The leak reduced gradually and resolved spontaneously within a mean of 7 days (range 3–15 days). Twenty-one cases were managed by an US-guided percutaneous drainage, with pigtail catheter insertion in 20 donors and repeated aspiration in one donor [the mean volume of drain output was 130 ml (range of 60–190 ml)]. Six donors underwent endoscopic retrograde cholangiopancreatography (ERCP) and stent insertion due to major biliary leak (amount of leak more than 250 ml/day). In one of these last six donors with major biliary leak after an ERCP and stenting, there was no improvement, and therefore surgical treatment with a Roux-en-Y hepaticojejunostomy was performed 1 month later. Two cases with biliary stricture were treated with insertion of a biliary stent through an ERCP (Fig. 1).

Discussion

With the increasing use of LDLTs, morbidity and mortality in donors have become unavoidable problems associated with the procedure. Donor morbidity is a distressing complication that generates a lot of legitimate concerns regarding the safety of living donation. Donor morbidity ranges from 9.4 to 75% depending on the criteria, and the most common procedure-related postoperative complications among donors in LDLT involve the biliary tract [6,9,13–17].

BCs are one of the most common problems associated with living liver donation [18]. For this reason, BCs constitute the major cause of morbidity after living donor hepatectomy. Unresolved BCs may lead to sepsis, multiorgan failure, and death [19]. In a

Figure 1



Flow diagram of the outcomes of 34 donors in LDLT with biliary complications. Values in parentheses show the numbers of right lobe donors (R) and left lobe donors (L). ERCP, endoscopic retrograde cholangiography; US, ultrasound.

metachronous analysis by Middleton *et al.* [20] reviewing 131 publications in the same context, the donor BC rate was found to be 13.5%.

In our study, BCs occurred in 14.2% of donors, which was similar to the observations of El-Meteini and colleagues [21–23]. However, the rate of BCs after adopting our new technique was much lower than that in the previously mentioned studies. Biliary leak occurred in 32 donors (13.4%) and biliary stricture in two donors (0.8%). The A2ALL study in the USA described almost 400 patients who donated the right lobe and found an incidence of 9% for bile leak or biloma and an incidence of 0.5–1.5% for postoperative biliary strictures as no biliary anastomosis is required in the donor [24,25]. Most bile leakages occur from cut surfaces, and others may originate from biliary radicles draining the caudate lobe. Less common BCs are cholecystitis and intraoperative injury to the donor's bile duct [19,26,27].

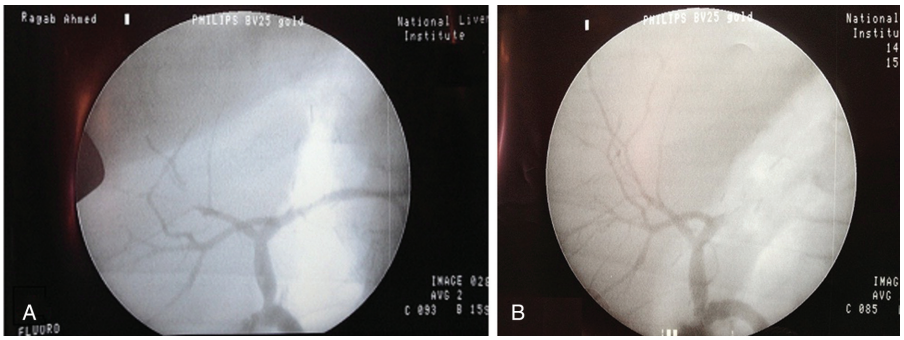
In our study, there was no statistically significant difference in biliary leak between right and left lobe donation (14.9 vs. 11.5%, respectively). In the literature, however, the rate of BCs vary considerably between donor hepatectomy procedures (i.e. from 10 to 12% in right lobe procedures and 2 to 4% in left lobe procedures) [22,28]. Anatomic variations in the biliary tract appear to be one of the most important factors contributing to the higher incidence of biliary leakage among right lobe donors. The right hepatic duct (RHD) must be resected within a few millimeters distal to the bifurcation because the anterior and posterior segmental branches of the RHD often diverge at a point that is immediately proximal to the bifurcation of the RHD and LHD. In contrast, the LHD can be resected several millimeters beyond the bifurcation. Furthermore, 39.1–60.4% of right lobe grafts have multiple biliary orifices, whereas left lobe grafts usually have a single orifice. Right lobe donors also have larger biliary stumps, a large transection surface, and extensive dissection of the right hepatic artery below the main bile duct compared with left lobe donors. The anatomical complexity of the biliary tract in right lobe donors probably contributes to the fragility of the biliary stump, and consequently results in the higher rate of biliary leakage among these donors [29–31].

In the report of Pamecha *et al.* [32], three out of seven donors who underwent left lateral segmentectomy had bile leaks, prolonging their hospital stay and delaying drain removal. The bile leaks were probably from the cut surface of segment IV, which was ischemic because of division of its arterial and portal supply, unlike in right and left hemihepatectomies, where no major pedicles are encountered along the transection plane, which is perhaps another factor for the increased incidence of bile leaks. The results of Pamecha and colleagues were in agreement with our rate of biliary leak from left lobe donation in the first phase of our program. Further, in the present study we found that donors younger than 30 years had a significant rate of biliary leak, an observation that has been noticed by other reports [33,34]. Shin and colleagues were not certain why the BC rate was inversely related to donor age but offer the following hypothesis. Bile ducts possess smooth muscle fibers within their walls. The smooth muscle component may provide the morphologic basis for narrowing of the duct. With donor age, the smooth muscle may become thinner and the ducts less elastic. Finally, duct diameter enlarges. This senile change may reduce the incidence of biliary strictures. At the same time, performance of suture or ligation of the bile duct radicles is easier for dilated ducts, reducing the incidence of bile leakage [33].

In the present report, we documented a significant decrease in the rate of BC after adoption of our novel technique of closure of the donor's bile duct stump. The rate of BCs dropped significantly from 20% in the first to 6% in the second phase of our LDLT program. Also we noticed a significant difference in the two phases concerning other variables like age less than 30 years, male donors, BMI less than 25%, left lobe or left lateral graft, and one duct ($P<0.05$). Although our novel technique may theoretically slightly prolong the procedure duration as it implies the performance of two intraoperative cholangiographies, one before cutting and the other after closure of the bile duct stump, it contributed significantly to improving the outcome of our donors and surprisingly did not prolong the duration of hepatectomy (Fig. 2). The mean operative time was shorter in the second period ($P<0.05$). This can be attributed to two reasons: the first is the increased learning curve of the surgical team and the second is the organization in the operating room as a result of increased experience of nurses. In contrast, Kim and Kim [35] reported that they have stopped performing intraoperative cholangiographies and have not seen any increase in BCs.

There was significant difference between the two periods regarding the length of ICU and hospital stay, which can be attributed to the improvement in overall complications, including the biliary. However, many authors reported that hospital stay was significantly longer in patients who developed postoperative biliary leakage/bilomas [32,34].

Figure 2



(a) Intraopertive cholangiogram (right posterior duct arising from the left duct). (b) IOC after left hepatectomy preserving the right posterior duct with no leakage. IOC, intraoperative cholangiogram.

Early intraoperative recognition of bile leakage and avoiding its occurrence are the most essential steps to preventing these complications. Most BCs can be treated by nonsurgical procedures. Some cases of minor bile leakage will resolve spontaneously. However, moderate bile leakage and biliary stricture require interventional procedures such as percutaneous placement of a peritoneal drain, percutaneous biliary drainage, or endoscopic biliary drainage. A combination of balloon dilatation and/or stenting is effective for treating biliary strictures. A serious bile leak often needs to be treated surgically [36,37]. Shio and colleagues analyzed the treatment procedures of 55 donors with BCs. Twenty-four cases were cured by conservative therapy and one case was converted to surgical repair because of severe paralytic ileus caused by biliary ascites. Twenty-four cases were successfully treated by endoscopic treatment. The remaining six patients underwent surgery because of difficulties with cannulation (n=2), excessive biliary leakage (n=2), and complete biliary obstruction (n=2) [29].

Several factors may contribute to the development of post-treatment biliary stricture in right lobe donors. Shio and colleagues discovered severe deformities in the biliary tract and a substantially smaller angle between the LHD and Common hepatic duct (CHD) in these donors. They emphasized that, although the deformity in the left biliary tract could not be corrected in these donors, cholestasis improved after insertion of a 7 Fr endoprosthesis [29]. They indicated that postsurgical deformity in the bile duct and edema due to inflammation are the major factors contributing to the development of strictures after effective treatment of biliary leakage. They offered several explanations for the deformity that occurs in the left biliary system after right lobe donation. First, adhesion of the small and large intestines to the resected surface of the left lobe of the liver may create a retraction force that severely bends the biliary tract. Second, unstable attachment of the ligamentum falciforme hepatis may promote deformity in the bile ducts because it is resected before the right lobe is harvested and reattached. Third, after right lobe donation, the residual left lobe of the liver regenerates rapidly, reaching 80% of its preoperative volume within 1 year after resection [38,39].

Conclusion

Our novel technique for management of the bile duct stump resulted in significant and marked decrease in the rate of BCs in living liver donors. It is a safe, simple, and reproducible technique and does not prolong the procedural duration. The routine intraoperative cholangiogram should be performed twice, before transection and after stump closure, as it provides proper visualization of the biliary anatomy and promptly controls any bile leak.

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Conflicts of interest

There are no conflicts of interest.

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