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ROLE OF ERCP IN MANAGEMENT OF BACTERIAL CHOLANGITIS IN LIVING-DONOR LIVER TRANSPLANT RECIPIENTS WITH BILIARY COMPLICATIONS: A SINGLE CENTER STUDY

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Abstract

Biliary complications are still frequent after liver transplantation especially living donor liver transplantation (LDLT). Bacterial cholangitis is a potentially life-threatening complication. Management is based on antimicrobial therapy and surgical drainage. Bile cultures can play a role in determining the causative agent and optimizing antibiotic therapy.

This study assessed the incidence of bacterial cholangitis among recipients of LDLT and evaluated the role of endoscopic retrograde cholangiopancreatography (ERCP) in management of potential biliary infection.

This study was conducted at Ain Shams Organ Transplantation Center between February 2019 and April 2022. The selected 39 LDLT recipients developed post-transplant cholangitis on top of biliary complications. Liver function tests, imaging, ERCP were performed in all patients.

The results showed that incidence of biliary complications were 38.2%. Imaging and ERCP findings were consistent regarding the anastomotic stricture diagnosis. Stones were detected by ERCP in 12 patients when magnetic resonance cholangiopancreatography detected them in only one patient. Significant improvement as regard inflammatory markers (CRP-Procalcitonin) ,liver enzymes and Total bilirubin before and after ERCP.

Keywords: Living Donor Liver Transplantation, Acute cholangitis, MRCP, ERCP.

Introduction

Liver transplantation (L.T.) is the definitive management of end-stage cirrhosis and acute liver failure (Valenzuela *et al,* 2019). Bile duct reconstruction is named the Achilles' heel of L.T. Biliary complications vary between different institutions and range from 10% to 45%. Different biliary complications have been reported, including strictures, leaks, and stones. Generally, bile leaks are present in the early postoperative period (first three months), while strictures are usually delayed in presentation (Mukund *et al,* 2020). Strictures are the most common biliary complication. Biliary complications are reportedly more common with living donor L.T. (LDLT) compared to the deceased donor L.T. (DDLT) due to details related to the surgical technique, such as the small diameter of bile ducts of the anastomoses from the donor right hepatic lobe (Ranjan *et al,* 2016)

Although bile functions as a biological defense mechanism against infection, transplant recipients are prone to postoperative infections because of the poor general condition, the use of immunosuppressive agents, and bile stasis because of stricture formation (Shah and John, 2022). Montasser *et al.* (2017) reported that all infection episodes in their study occurred in the first postoperative month. Bacterial infections account for more than half the infections post-LDLT. A significant problem facing the diagnosis of such infections is that the clinical manifestations as fever and leucocytosis, may need to be differentiated from acute rejection.

Cholangitis is a dangerous infection in patients with biliary obstruction. For the clinical diagnosis, Charcot triad (pain, fever, and jaundice) is particular yet poorly sensitive (Ahmed, 2018).

Thus, the visualizing biliary tract dilatation

obstruction was crucial for confirmation.

Pan and Guo (2016) reported that imaging modalities including the ultrasound (U.S.), magnetic resonance cholangio-pancreatography (MRCP), and endoscopic retrograde cholangiopancreatography (ERCP). Acute chollangitis treatment has two main pillars, antimicrobial therapy and biliary tract drainage (Sokal *et al,* 2019). Compared to surgery, a minimally invasive procedure like ERCP was the better option for transplant patients (Alves *et al,* 2018). But, ERCP was more difficult with LDLT, & anastomosis DDLT was low-placed, and biliary tree anatomy preserved (Mukund *et al,* 2020).

The present study aimed to assess the bacterial cholangitis incidence among the LDLT recipients, and to evaluate the role of ERCP in managing potential biliary infection.

Subjects and Methods

Ethical considerations: This study was app roved by the Research Board of Ethics Committee, Faculty of Medicine, Ain Shams University, Cairo, No. FWA000017585. After explaining the study aim and that the privacy of each participant is a must, written consent was obtained from all of them.

Study design and setting: The descriptive longitudinal study was done at Ain Shams Center for Organ Transplantation (ASCOT), Cairo between February 2019 & April 2022.

Patients' selection: From 102 consecutive LDLT cases, 39 recipients above 18 years old who developed post-transplant cholangitis on top of biliary complications were selected. But, patients with hepaticojejunostomy or with primary sclerosing cholangitis were excluded.

Sample size calculation: Size of all patients received living donor liver transplantation at ASCOT was determined by the given formula:

$$n = p\left(1-p\right)\left(\frac{z}{E}\right)^2$$

Where Z = value from standard normal distribution reflected confidence level used (e.g., Z = 1.96 for 95%), E = desired margin of error, and the value of population proportion (p) was 0.5. Thus, the sample size was calculated as 39 patients giving the study a power of 80%.

Case identification of transplanted patients with cholangitis: A patient was diagnosed with cholangitis as having a fever (>38℃), abnormal liver function tests, and the exacerbation of jaundice (if any), with or without right upper quadrant pain.

All patients were subjected to history taking, clinical examination, and laboratory investigations including CBC, liver profile, C-reactive protein, erythrocyte sedimentation rate, procalcitonin, before and after ERCP, as well as radiological assessments by pelvi-abdominal U.S. and MRCP.

Endoscopic treatment (ERCP) was carried out for patients diagnosed with biliary anastomotic stricture with or without stone (using sonography and MRCP). Direct cholangiography aimed to confirm MRCP findings and evaluate bile duct anatomy and features of the stricture (location, length, intrahepatic anatomy). The biliary sphincterotomy was done (if not done before), followed by passing through stricture with a 0.018-, 0.025-, or 0.035-inch hydrophilic guide-wire (J-shaped or straight). Then, a balloon (4-, 6- or 8-mm diameter) or mechanical dilation (up to 10 Fr) of the stricture was performed. If there were stones, they were removed. A stent was then inserted. Selection of the stent diameter and length depended on the stricture morphology and the anatomy of the bile ducts. We used the maximum size of plastic stents (7, 8.5, 10 Fr) according to the stricture tightness and the size of the bile ducts above and below stricture. Planned endoscopic re-evaluation after three months for stent removal, cholangiography (to assess stricture morphology, extraction of sludge/ casts when needed), and re-insertion of larger stents if possible. The stents were removed when the stricture appeared entirely resolved at occluding cholangiography with the Fogarty balloon.

Statistical analysis: Data were analyzed by using the Statistical Package for Social Sci-

ences (IBM SPSS), version 26 (IBM Corp., were summarized as frequencies and percentages. Numerical variables were summarized as means ± S.D. or medians and ranges. Comparisons of means between participants with and without comorbidities were done using Student T-Test. Mann-Whitney test was used for pairwise comparisons as a post hoc analysis if the test showed differences between groups. Categorical variables were compared using $\chi 2$ or Fisher exact tests. P-value < 0.05 was significance.

Results

The 39 patients (34 males & five females) with biliary cholangitis were on top of biliary complications after LDLT, with ages ranged from 49 to 68 years (average 56). The median time interval between transplantation to the biliary complications developmment was seven months. Median hospital stay was five months. More than half the patients were indicated for L.T. due to HCV-related cirrhosis. Others included HCC, cryptogenic cirrhosis, HBV-related cirrhosis, and primary biliary cholangitis (10, four, three, & one, respectively). The transplantation candidates were highly selected, and only comorbidities were 8 patients with diabetes mellitus and 10 with hypertension. MELD score ranged from 11 to 22. By Child-Pugh score, 20 patients were categorized stage B & 19 stage C.

Laboratory results significant improved Armonk, N.Y., USA). Categorical variables after ERCP, except albumin levels were significantly lower. All patients graft showed mild intra-hepatic biliary radicle dilatation, except for one with aparenchymatous graft. Portal vein and hepatic artery Doppler showed lumen patency with average velocity in 38 patients, except one developed portal vein thrombosis with portal vein stenting in early postoperative period. Another patient developed hepatic artery thrombosis in early postoperative period. All had anastomotic strictures, with intrahepatic biliary radicle dilatation (consistent with ultrasound). Patients (38) had homogenous grafts except one with a parenchymatous graft. Pancreas was normal in 32 patients, but 7 showed pancreas bulky head. Pancreatic ducts were normal in all, but one had a picture suggestive an anastomotic leak, biliary stones were detected in one patient, but none developed ascites.

ERCP showed anastomotic strictures in all but, bile leaks in a patient. Patients (56.42%) had one stricture, (16) had two strictures and (1) had three strictures, Patients (38) responded to balloon or mechanical dilation, followed by inserting plastic stents. One had a very tight anastomotic stricture necessitated percutaneous biliary drainage. Stones were removed by a sweeping balloon from 12 patient. Biliary leak was managed by leak cover age stent. Details were given in tables.

Table 1: Demographics and baseline characteristics of patients (n=39)

Parameter	N=39
Age (years)	Range: 49-68, Median: 56, Mean ±SD: 55.89±4.61, 95% CI: 54.4030 to 57.3918
Male, no. (%)	34 (87.18%)
Female, no. (%)	5 (12.82%)
Time since transplantation (months)	Range: 3-50, Median: 7, Mean ±SD: 12.205±11.834, 95% CI: 8.369 to 16.042
Hospital stay (months)	Range: 4-14, Median: 5, Mean ±SD: 6.23±2.331, 95% CI: 5.539 to 6.922
Indication for transplantation, no. (%)	
HCV-related cirrhosis	21 (53.84%)
HBV-related cirrhosis	3 (7.69%)
HCC	10 (25.64%)
Primary biliary cholangitis	1 (2.56%)
Cryptogenic cirrhosis	4 (10.25%)
Comorbidities, no. (%)	
Diabetes mellitus	8 (20.51%)
Hypertension	10 (25.64)
MELD score	Range: 11-22, Median: 17, Mean ±SD: 16.41±2.672, 95% CI: 15.544 to 17.277
Child-Pugh score, n (%):A Child-Pugh score, n (%):B Child-Pugh score, n (%):C	0 (0) 20 (51.28%) 19 (48.71%)
Temperature at enrollment (^{O}C)	Range: 37-39, Median: 38, Mean ±SD: 38.162±0.419, 95% CI: 38.0000 to 38.2000

SD: Standard deviation; CI: Confidence interval; MELD: Model for End-Stage Liver Disease

Table 2: Laboratory data of patients before and after ERCP (n=39)

Parameters	Before ERCP				After ERCP				P value
	Range	Median	Mean ± SD	95% CI	Range	Median	Mean ± SD	95% CI	
Total bilirubin (mg/dL)	0.9-5.8	2.1	2. 3± 1.83	2.058 to 2.604	0.3-0.9	0.7	0.677± 0.12	2_0.638 to 0.716	<0.0001*
ALT (IU/L)	22-178	43	54.7179± 32.0911	44.3152 to 65.1207	15-95	34	39.435 ± 18.1177	33.5628 to 45.3090	0.0272*
AST (IU/L)	17-164	47	58.23± 32.59	47.6652 to 68.7964	20-93	37	40.8461 ± 15.294	35.8882 to 45.8041	0.0098*
Alkaline Phosphatase (U/L)	432-1321	821	792.9± 193.7683	730.1363 to 855.7611	132-692	256	297.512 ± 119.7855	258.6828 to 336.3428	< 0.0001*
Serum Albumin (g/dl)	3.4-4.1	3.8	3.77± 0.187	3.7163 to 3.8376	3.4-4.2	3.8	3.7923 ± 0.1752	3.7355 to 3.8491	0.6575
C-reactive protein (mg/L)	0.5-15	5.1	5.517± 3.219	4.7604 to 6.273	0.3-0.9	0.95	1.220± 0.9023	1.0088 to 1.433	< 0.0001*
ProCalcitonin (ng/mL)	0.3-5.2	2.2	2.3± 1.24	1.9181 to 2.7229	0.2-1.3	0.5	0.6± 0.3	0.5028 to 0.6972	<0.0001*

*Significant.

Table 3: Ultrasonography findings (n=39)

Parameter	Ultrasound finding	Number	Percentage
Biliary system	Dilatation	39	100
Graft	Homogenous	38	97.43
Portal Vein	Patent	38	97.43
	Thrombosis	1	2.56
Hepatic Artery	Patent	38	97.43
	Thrombosis	1	2.56

Table 4: MRCP findings (n=39)

Parameter	MRCP finding	Number	Percentage
Biliary System	Dilatation	39	100
	Stricture	39	100
Graft	Homogeneity	38	97.43
Pancreas	Normal	32	82
	Bulky	7	18
Pancreatic duct	Normal	39	100
Ascites	No	39	100
Leak	Positive	1	2.56
G.B.	Removed	39	100
Stones	Positive	1	2.56

MRCP: magnetic resonance cholangiopancreatography

Table 5: Initial ERCP findings (n=39)

Parameter	ERCP finding	Number	Percentage
Anastomosis	Strictures	39	100
CRE balloon dilatation or mechanical dilatation by dilator	Occurred	38	97.43
Stent	Placement of stent	38	97.43
Stone	Positive	12	30.7
Number of strictures	One	22	56.42
	Two	16	41.02
	Three	1	2.56
Bile Leak	Positive	1	2.56

Discussion

In the present study, of 102 transplant patients, 39 suffered from biliary complications. The median time from transplantation to the onset of biliary complications was seven months. Biliary complications included anastomotic strictures (100%) biliary leaks and biliary stones. Ultrasound, MRCP, and ERCP findings were consistent regarding diagnosing anastomotic stricture. However, ERCP detected stones in 12 patients, while MRCP detected them in only one patient.

In the present study, biliary complications incidence in LDLT recipients was 38.2%. This agreed with Jung *et al.* (2020), who reported 7.4% to 39% of biliary complications in LDLT recipients. Also, Glowka *et al.* (2021) reported that 42% of 102 LT recipi-

ents, suffered from the biliary complications. Living donor liver transplantation was associated with a higher biliary complications incidence than DDLT (Mukund *et al,* 2020; Nishikawa *et al,* 2022). Many factors can contribute to this, including the smaller size of the bile duct orifices of anastomosis compared to DDLT using the whole liver (Jung *et al,* 2020). Among Egyptian patients, bile was the major sites of bacterial infection post LDLT (Mukhtar *et al,* 2014; Montasser *et al,* 2017). But, Soin *et al.* (2010) in India reported a low biliary stricture incidence (3.3%) due to the successful techniques for biliary anastomosis. One of the present patient (2.56%) had biliary leaks. But, Arslan *et al.* (2018) in Turkey reported (9.3%).

Biliary complications after LDLT include anastomotic strictures, leaks, and stones. Strictures can predispose to leaks by increasing the biliary system pressure. Likewise, leaks can cause strictures by causing scar formation. Bile leaks were reported to be an early complication, mostly in the 1st three months after transplantation (Gotthardt *et al,* 2013; Mukund *et al,* 2020). This agreed with the present results, where the time from transplantation to the complications development ranged from three to 36 months, considering that all present patients suffered from biliary stricture and one patient had a biliary leak.

In the current study, cholangitis diagnosis was based on fever (> 38C), abnormal liver function tests, and jaundice exacerbation, with or without right upper quadrant pain, with elevated liver function tests. Charcot's triad diagnosed acute cholangitis. However, its low sensitivity (50% to 70%) limited its use. Kiriyama *et al.* (2018) reported that Tokyo the guidelines criteria for definite diagnosis of acute cholangitis were systemic inflammation (fever or evidence of inflammatory response), cholestasis (jaundice or abnormal liver functions), and dilatation or evidence of etiology in imaging

In the present study, U S detected biliary duct dilatation in all patients suffering from anastomotic strictures, which agreed with the MRCP and ERCP anastomotic stricture diagnosis. Allard *et al.* (2020) in UK reported that ultrasound is primary diagnostic tool in many centers, especially in absence of MRCP with positive predictive value, especially when biliary duct dilatation. But, Potthoff *et al.* (2013) in Germany in retrospective study reported a very low sensitivity (24%) of U.S. to detect strictures; they added that the lack of systematic examination caused that misdiagnosis. This lack was demonstrated as the examination of the common bile duct was on one side only (not on the donor and recipient sides). Besides, they reported an overall (100%) specificity of U.S. in detecting biliary pathologies.

There is an increased use of MRCP in the diagnosis of biliary strictures, due to certain anatomic features on the complex biliary tree in LDLT recipients can only be provided by MRCP, thus helping to choose the appropriate endoscopic technique for management (Arain *et al,* 2013). In the present study, all patients had anastomotic strictures detected by MRCP, which agreed with ERCP results, particularly as one patient had a biliary leak. The only difference was that MRCP could detect stones in only one patient compared to 12 patients treated by ERCP. This agreed with Akbar *et al.* (2018), who reported that on 39 patients with biliary complications after L.T. who had an MRCP followed by either ERCP or PTC, MRCP showed low sensitivity but high specificity for diagnosing strictures.

In the present study, only two were clinically significant among nine cases with B.S. missed by MRCP but, identified by endoscopic techniques. Valenzuela *et al.* (2019) disagreed with the present results. The agreement between the MRCP & ERCP findings was 56.8%. Biliary abnormalities were detected by ERCP after normal MRCP in eight patients, and four patients had normal ERCP after abnormal MRCP.

ERCP was a preferred modality in L.T. patients because of their critical clinical condition. In the present study, 38 patients with

anastomotic strictures were successfully managed with ERCP, as demonstrated by marked improvement as regard clinical and laboratory parameters (Inflammatory markers, Liver enzymes and total bilirubin). Gotthardt *et al.* (2013) reported anastomotic stricture as the most common finding in ERCP. The present high success rate (97.4%) was more than comparable with other rates (Valenzuela *et al,* 2019; Larghi *et al,* 2019). One present study patient had a tight stricture and ERCP failure. Mukund *et al.* (2020) reported that the length and location of stricture were two independent factors for inadequate response to ERCP. Rao *et al.* (2017) in India reported that other factors included narrow strictures, multiple duct anastomoses, anastomosis near the hilum, non-anastomotic stricture, and sharp angulation of anastomotic bile ducts. This highlights the importance of initial MRCP in proving the appropriate approach. Others reported that multiple the ERCP sessions to achieve success; Chang *et al.* (2010) found that a mean of 3.2 ERCPs was required to achieve a success rate of 79.6%; Kato *et al.* (2009) reported a success rate of 51%, and Ranjan *et al.* (2016) reported a median of four sessions per patient. But, Gad *et al.* (2022) in Egypt reported that the multiple biliary anastomoses and post liver transplantation, hepatic artery thrombosis and/or stenosis led to the poor biliary outcome, and the cholangitis, cholangitis' abscesses and sepsis led to the poor graft and patient outcomes

Conclusion

The biliary complications are common in LDLT recipients. They included strictures, leaks, stones, and casts. The U.S., MRCP, and ERCP findings were consistent regarding all patients suffering from anastomotic strictures. The ERCP was diagnostically superior concerning stones.

So, the endoscopic retrograde cholangiopancreatography (ERCP) proved to be the golden standard model therapy for managing the bacterial cholangitis in living-donor liver transplant recipients with biliary complications.

Recommendation

The proper management of the biliary complications is a mandatory to improve these patients' outcomes.

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