



Digestive Endoscopy

Endoscopic versus surgical management of biliary complications – Outcome analysis after 1188 orthotopic liver transplantations



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ABSTRACT

Background and aim: After liver transplantation, the endoscopic approach has become the standard treatment modality for biliary complications. Aim of this study was to compare primary endoscopic with primary surgical management.

Patients and methods: A retrospective review on 1188 consecutive liver transplant patients between 1989 and 2009 was performed. Management strategies (endoscopic, surgical or combined approach) were evaluated for treatment success as well as patient survival.

Results: Biliary complications after liver transplantation were diagnosed in 211 (18%) patients.

Initial endoscopic approach ($N = 162$, 77%) was successful in 97 of 162 (60%) patients. In 80% of patients, success was achieved within a median of four ERCPs.

Sixty-one patients (38%) were referred to surgery after non-successful ERCP.

Initial surgical approach was performed in 49/211 patients (23%) with successful management in 38/49 (78%) of patients.

Patients presenting with intraluminal objects needed a significantly higher number of ERCPs to reach treatment success (median 3 versus 2 interventions, $p = 0.001$) but had an equal endoscopic success rate ($p = 0.427$).

Patients with successful endoscopic treatment showed lower mortality compared to patients with primary surgical treatment ($p = 0.029$).

Conclusions: Endoscopic management should be considered as the primary approach for biliary complications after liver transplantation.

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1. Introduction

Despite the advancements in organ procurement, immunosuppression and transplantation technique, biliary complications (BC) remain a frequent cause of morbidity after orthotopic liver transplantation (oLT). In previous studies the rate of BC after oLT were reported to be between eight and 30% [1–5].

Biliary complications include leaks, anastomotic strictures (AS) or non-anastomotic (NAS) strictures, complicated by stones, cast or debris. In some cases patients might develop more than one complication [6–9].

Over the last two decades, endoscopic retrograde cholangiopancreatography (ERCP) has emerged to the gold standard for diagnosis and treatment of BC after oLT [7,9–12] despite low grade evidence. Limited data is available comparing a primary endoscopic versus primary surgical treatment approach for BC. With endoscopy biliary leaks can be sealed by bile-duct stenting, anastomotic strictures are treated by dilatation and temporary stent placement, non-anastomotic strictures are treated by stents, stones or debris can be removed in many patients [13]. Nevertheless in some cases ERCP might not result in a definitive treatment for patients presenting with biliary concretions or strictures [14–16] resulting in multiple endoscopic re-interventions. Furthermore, long-term follow-up data on outcomes and complications after ERCP in liver transplant patients is scarce [17].

Surgical therapy of BC after oLT is reported as primary intervention and as secondary approach after endoscopic intervention.

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Surgical treatment consists of simple bile duct revision with or without placement of a T-Tube for leaks, choledochojejunostomy and hepaticojejunostomy [18,19].

The aim of this study is to evaluate the primary endoscopic, primary surgical or combined approach for treatment of biliary complications after oLT in terms of success rate, postoperative/post-interventional complications and survival.

2. Patients and methods

The study population consisted of all patients who underwent liver transplantations at the Medical University of Vienna between 1989 and 2009. Data were prospectively collected in the transplant surgery database of the Medical University Vienna and analyzed retrospectively. Parameters included baseline demographic data, indication for liver transplantation, age at oLT, time from oLT to diagnosis of BC, type of BC, type of intervention, number of interventions required for success, intervention related complications, standard liver function tests including bilirubin, gamma GT and AP before intervention and one month after intervention. Donor related factors included donor age, cold ischemia time (CIT) and type of perfusion. Patients under the age of 18, as well as patients receiving a split liver graft and patients receiving re-transplantation were excluded. This study was approved and registered by the Ethics-Committee of the Medical University of Vienna (research ethics reference 354/2010).

2.1. Classification of biliary complications

Biliary complications were defined as morbidity related to the reconstructed biliary tract requiring endoscopic or surgical intervention.

All ERCPs performed were reviewed by an independent gastroenterologist. In all surgical cases operative notes were reviewed.

Biliary complications were classified as follows:

- Strictures involving the donor common bile duct or bifurcation, not related to the anastomosis in presence of a patent hepatic artery – non anastomotic strictures, NAS
- Strictures of the biliary anastomosis – anastomotic strictures, AS
- leakage of the reconstructed biliary system – LEAK

Presence of bile duct stones, cast or sludge was classified as intraluminal obstruction (ILO) – with or without relation to NAS, AS or LEAK.

If more than one complication was present, combinations were recorded as separate entities.

Successful intervention (either endoscopic or surgical) was defined as permanent reduction of bilirubin, gamma glutamyl-transferase and alkaline phosphatase within one month after intervention, and not requiring further endoscopic, percutaneous procedures or surgery/re-transplantation. In contrast to previous studies patients receiving even more than four endoscopic interventions were considered successful, if above criteria were met [6].

2.2. Surgical technique for oLT

Orthotopic liver transplantation was performed using hepatectomy with cavo-caval resection. Generally no veno-venous bypass was performed.

Biliary anastomosis was performed as choledocho-choledochostomy using a running PDS 6×0 suture. T-tubes were used in few selected cases based at the surgeons discretion.

2.3. Primary immunosuppression

The primary immunosuppressive regimen consisted of antithymocyte globulin (ATG) induction for three days with delayed introduction of calcineurin inhibitors (CNI) as published before [20].

2.4. ERCP

Endoscopic retrograde cholangiopancreatography in this cohort was performed by experienced (>400 ERCPs performed) endoscopists only. All patients were investigated either under sedation with midazolam, propofol and nalbuphine or were put under general anesthesia for the procedure.

In all cases a therapeutic side view endoscope (Olympus TJF 160, Olympus, Japan) was used.

In case of stones or cast, removal was performed with stone extraction baskets (Flower basket, Olympus, Japan) and extraction balloons (Extraction Retrieval, Boston Scientific, USA). In case of anastomotic or non-anastomotic strictures, dilation with a balloon dilator (Hurricane Rx, Boston Scientific, USA) was performed.

In case of leakage or for treatment of stenosis, plastic stents up to a maximum size of 10 French and a maximum number of five were inserted.

In select cases naso-biliary drainage was applied for up to 10 days.

Complications after ERCP were registered as pancreatitis, bleeding requiring transfusion of packed red blood cells, severe bleeding requiring intervention, and pancreatitis as described in previous studies [21].

2.5. Surgical intervention for BC

2.5.1. Anastomotic strictures/non-anastomotic strictures

For anastomotic strictures and non-anastomotic strictures hepaticojejunostomy was performed in an end-to-end or end-to-side fashion at the surgeons discretion as described before [15].

2.5.2. Leak

Revisions of the choledocho-choledochostomy were performed as re-anastomosis with PDS 6×0 sutures in interrupted manner. T-drains were used in selected cases at the surgeons discretion.

Complications after surgery were defined as need for transfusion of packed red cells as well as surgery within 30 days after revision for biliary complication. Interventional procedures in case of surgical treatment failure were recorded as separate entities.

3. Statistical analysis

Continuous data are given as the median and the interquartile range (IQR, range from the 25th to the 75th percentile) or as mean and standard deviation where applicable. Discrete data are presented as counts and percentages. Chi-square tests or, if appropriate, exact tests were used to compare groups of categorical data. For comparisons of continuous data non-parametric Mann–Whitney U test was applied.

Kaplan–Meier survival estimates were used to calculate survival and success rates and Log-rank tests were used to compare between groups. Cox regression analyses were used to assess the influence of potential risk factors. Hazard ratio (HR) and 95% confidence intervals (CI) are reported. A two-sided *p*-value <0.05 was considered statistically significant.

Table 1
Donor and recipient demographics.

	No BC N = 977	BC N = 211	<i>p</i>	Endoscopy first N = 162	Surgery first N = 49	<i>p</i>
Donor age, median years (range)	38 (8–82)	45 (8–86)	<0.001	46 (16–86)	44 (8–73)	0.228
CIT, mean min (±SD)	494.86 (±187.99)	472.12 (±10.30)	0.082	473.70 (±155.20)	466.70 (±141.10)	0.778
Perfusion			<0.001			0.078
UW, N (%)	422 (43)	65 (31)		44 (27)	27 (55)	
HTK, N (%)	382 (39)	133 (65)		106 (65)	21 (43)	
OTHER or N/A, N (%)	173 (18)	13 (4)		12 (8)	1 (2)	
Recipient age, median (range)	53 (18–69)	53 (21–68)	0.914	50 (21–68)	55 (22–66)	0.024
Sex						
Male, N (%)	626 (64)	160 (76)		118 (73)	42 (86)	
Female, N (%)	351 (36)	51 (24)	0.003	44 (27)	7 (13)	0.086
Indication for oLT, N ^a						
ALCI	351	86	0.318	64	22	0.511
PHCC	218	55	0.160	39	16	0.266
HCCA	217	50	0.790	37	13	0.572
PHCB	68	15	0.773	13	2	0.529
BILL	87	10	0.142	10	N/A	0.121
AUCI/CYCI	83	13	0.341	21	1	0.307
OTHER/UNKNOWN	249	23	0.032	18	5	1.000

^a Multiple diagnosis possible.

CIT, cold ischemia time; UW, University of Wisconsin perfusion; HTK, histidine tryptophan ketoglutarate perfusion, Custodiol®; N, number; SD, standard deviation; ALCI, alcoholic cirrhosis; oLT, orthotopic liver transplantation; PHCC, post hepatitis C cirrhosis; HCCA, hepatocellular carcinoma; PHCB, post hepatitis B cirrhosis; BILL, primary biliary cirrhosis and sclerosing cholangitis; AUCI, autoimmune cirrhosis; CYCI, cryptogenic cirrhosis; OTHER, other; N/A, non applicable; BC, biliary complication.

4. Results

A total of 1348 patients underwent liver transplantation between 1989 and 2009 at the Medical University Vienna. 160 patients did not meet inclusion criteria for this study, leaving 1188 patients for final analysis.

Biliary complications after liver transplantation were diagnosed in 211 of 1188 (18%) patients. Donor and recipient demographics are provided in Table 1. Patient selection flow chart is provided in Fig. 1A.

Complications (multiple diagnosis possible) were found to be LEAKS in 60/211 patients, anastomotic strictures AS in 80/211 patients and non-anastomotic strictures in 68/211 patients and other complications (solitary stones, papillary dysfunction, cholangitis) in 30/211 patients. Intraluminal objects (stones, sludge, cast) in addition to main diagnosis were seen in 88/211 patients. Intraluminal objects were diagnosed as sludge in 32, cast in 37 and stones in 73 cases. Multiple diagnoses were possible for all entities. Median time (IQR) from oLT to diagnosis of BC in NAS, AS or LEAK was 122 (377.5) days, 62 (193) days and 21 (84.75) days, respectively.

Significant risk factors for development of biliary complications in this cohort were donor age ($p < 0.0001$) and HTK as perfusion solution ($p < 0.0001$). Underlying disease, and cold ischemia time did not show to be significant risk factors for development of biliary complications.

In this cohort the presence of biliary tract complications showed no influence on long-term overall survival compared to patients without biliary complications (Fig. 2A).

4.1. Complication management

The great majority of patients who developed BC received ERCP as primary treatment 162 (77%) compared to 49 (23%) who received surgery as primary treatment.

Detailed information on frequency of BC according to type and treatment strategy is provided in Fig. 1B and Table 2.

Patients receiving endoscopy were slightly younger with 50 years compared to 55 years for patients receiving surgery ($p = 0.024$). No significant imbalance in other baseline variables (underlying disease, cold ischemia time, donor age, perfusion

Table 2
Frequency of biliary complications according to type and treatment.

	ERCP	Surgery	Surgery after ERCP
NAS, N	50	17	24
(with ILO)	(23)	(10)	(10)
AS, N	78	2	24
(with ILO)	(41)	(0)	(15)
LEAK, N	31	30	13
(with ILO)	(9)	(0)	(4)

ERCP, endoscopic retrograde cholangiography; N, number; NAS, non anastomotic stricture; AS, anastomotic stricture; LEAK, leak; ILO, intraluminal objects.

solution) was seen comparing endoscopy and firstline surgery, detailed data is shown in Table 1.

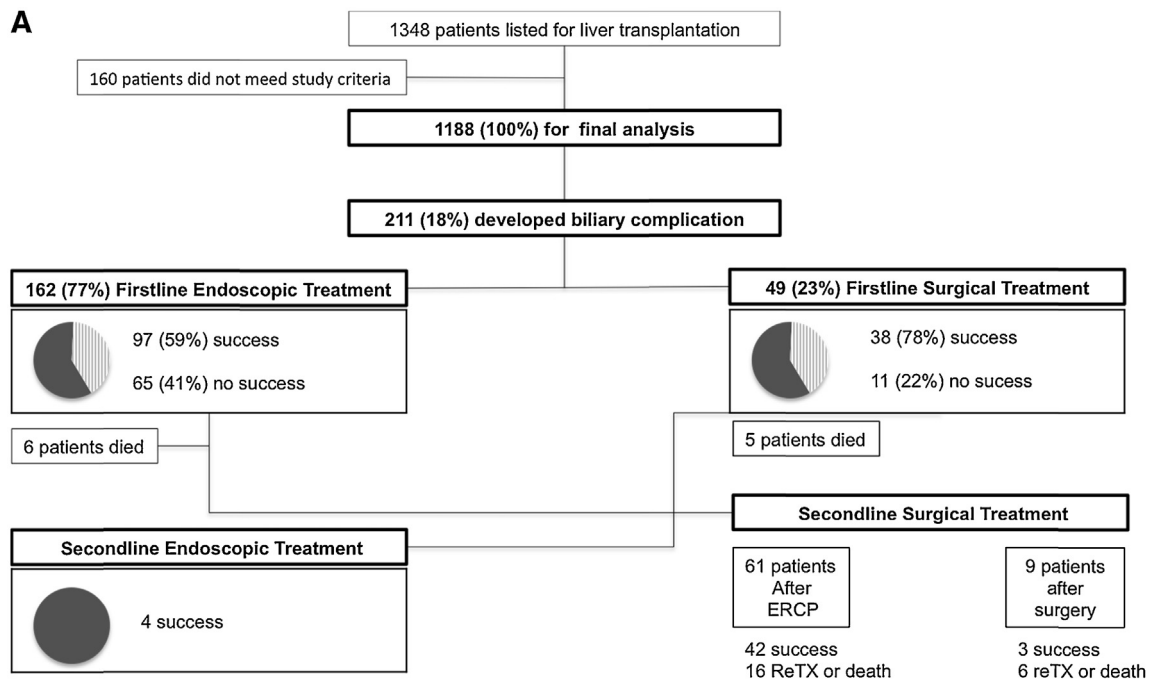
4.2. Endoscopy

ERCP was successful in 97 patients (60%). In patients with successful endoscopic management 80% of cases could be managed within a maximum of four interventions (Table 3). Patients with successful endoscopic treatment, however, showed reduced mortality compared to patients with successful primary surgical treatment or no endoscopic treatment success ($p = 0.029$, Fig. 2B).

Endoscopic treatment was not successful in 65/162 (40%) patients. In 61 of these 65 patients further second-line surgical treatment was initiated. In 51/61 cases a hepaticojejunostomy (HJS) was performed, 8/61 cases were simple revisions of the bile duct.

Table 3
Intervention counts in successful ERCP cases.

ERCP	N	Cumulative %
1	32	33.0
2	25	58.8
3	10	69.1
4	11	80.4
5	7	87.6
6	4	91.8
7	1	92.8
8	4	96.9
10	2	99.0
11	1	100.0



B

	ENDOSCOPY FIRST 162/211 (77%)	SECONDLINE	SURGERY FIRST 49/211 (23%)
NAS*	50/162 24/50 (48%) successful 24/50 (48%) referred to surgery 2/50 (4%) died	24/50 16/24 (66%) successful 6/24 (25%) retransplanted 2/24 (9%) died	17/49 12/17 (71%) successful HJS 2*/17 referred to endoscopy 4*/17 retransplanted
AS*	78/162 51/78 (65%) successful 24/78 (30%) referred to surgery 3/78 (5%) died	24/78 19/24 (79%) successful 2*/24 retransplanted 3*/24 died	2/49 1 (50%) successful 1 retransplanted
LEAK*	31/162 17/30 (54%) successful 13/30 (42%) referred to surgery 1/30 (2%) died * Multiple diagnosis possible	13/31 10/13 (77%) successful 2/1 retransplanted 1 died	30/49 25/30 (83%) successful 2*/30 revision 1*/30 retransplanted 2/30 referred to endoscopy

Fig. 1. (A) Patient selection flow chart. (B) Management of biliary complications.

2/61 were retransplanted. 16 of 59 patients with secondary surgical treatment needed further interventions.

A total of 10/162 (6%) patients eventually needed retransplantation.

6/162 (4%) patients died due to biliary complications without successful endoscopic treatment.

Primary surgical management was successful in 32/49 patients (65%). Two of 49 patients received surgical revision, 4 of 49 had endoscopic treatment after surgery. Six of 49 patients were retransplanted. Five patients died.

4.3. Intraluminal obstacles

We identified 129 intraluminal obstacles in 89 patients additionally to their primary cause of biliary complication (89/211 patients). There was sludge in 28, cast in 31, stones in 70 patients respectively. No patients had intraluminal obstacles without either NAS, AS or LEAK.

Intraluminal obstacles did not significantly influence the primary ERCP success. Overall success rate of ERCP (NAS/AS/LEAK) in biliary complications without intraluminal objects was 55% (55/99).

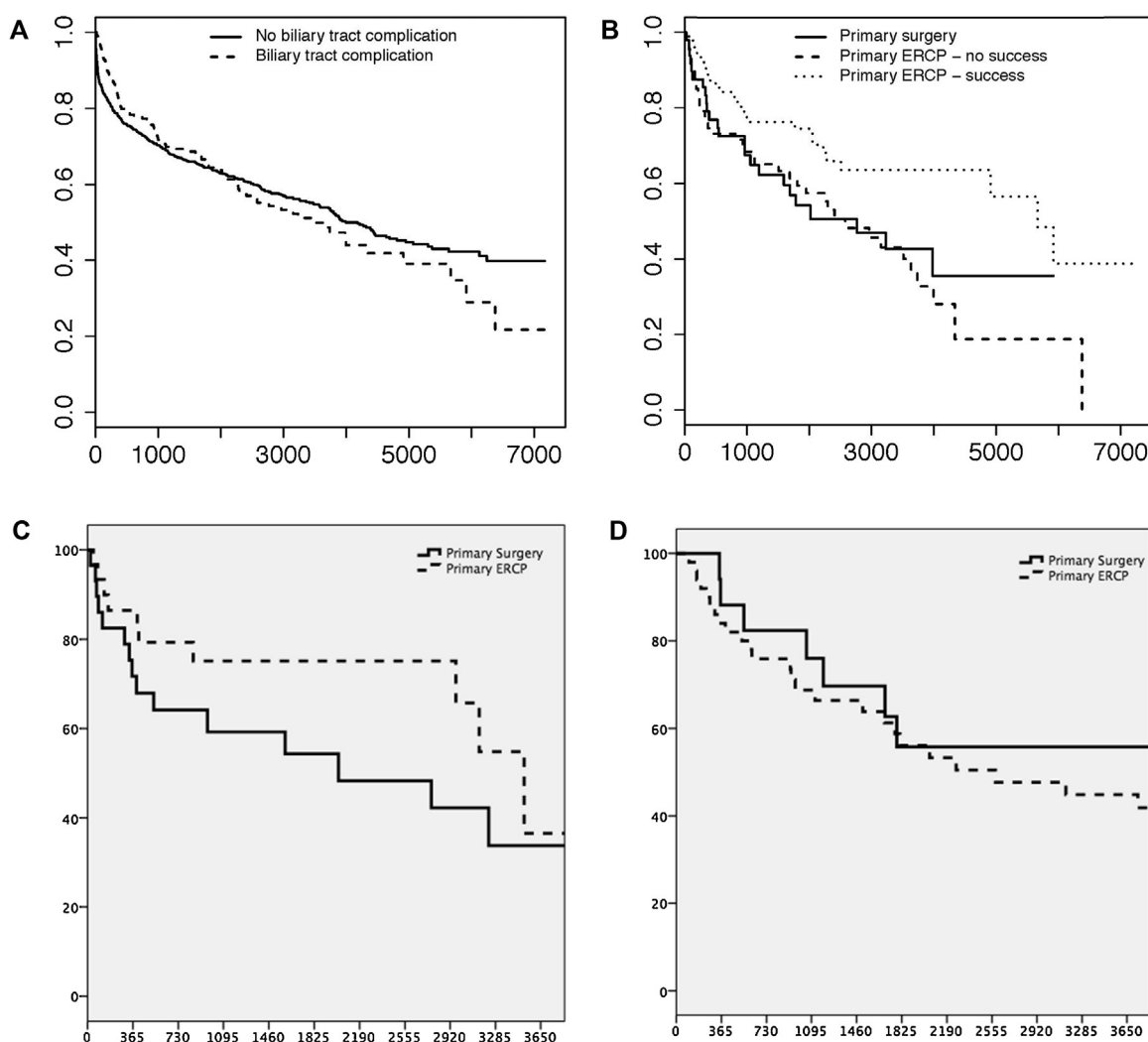


Fig. 2. (A) Kaplan–Meier survival estimated for overall survival after liver transplantation according to biliary tract complication. (B) Kaplan–Meier survival estimated for overall survival after liver transplantation comparing surgery and endoscopy in patient with LEAK. (C) Kaplan–Meier survival estimated for overall survival after liver transplantation comparing surgery and endoscopy in patient with NAS. (D) Kaplan–Meier survival estimated for overall survival after liver transplantation comparing surgery and endoscopy in patient with NAS.

Table 4

Median number (IQR) of procedures in relation to success of endoscopic interventions according to BC.

	NAS		AS		LEAK		<i>p</i>
	Success	No success	Success	No success	Success	No success	
No ILO	2 (1–4)	N/A	2 (1–3)	N/A	2.0 (1–3)	N/A	0.001
ILO	4 (2–9)	2.0 (1–3)	5 (3–6.5)	3 (1.25–4.0)	8.0 (1–8)	1.0 (1–3)	
Total	3 (2–5)	2 (1–3)	3.5 (1–5)	3 (1.25–4)	2 (1.75–3.25)	1 (1–3)	

ILO, intraluminal objects; BC, biliary complications; NAS, non anastomotic strictures; AS, anastomotic strictures; LEAK, leak.

compared to 45% (44/99) in cases with intraluminal obstacles ($p=0.427$). As reported median numbers of endoscopic procedures for all types of BC were significantly higher when complicated by intraluminal objects at median 3 (1–11) versus 2 (1–6) procedures, respectively (Table 4, $p \leq 0.001$).

4.4. Leaks

31 patients received primary endoscopic treatment for leaks, 17/31 (55%) were successful, 13/31 (42%) were referred to surgery, one (3%) patient died. A median of 2 (1.74–3.25) interventions were needed to resolve leaks endoscopically. Additional intraluminal obstacles were only observed in 3 of 31 (10%) patients with leaks

and needed a median number of 8 (3–8) treatments. The median number of interventions for LEAK was lower when compared to NAS or AS (median 2 (1.75–3.25) versus 3 (2–5) versus 3.5 (1–5) respectively), without reaching statistical significance ($p=0.744$).

13 of 31 (42%) patients diagnosed of LEAK were referred to surgery after non-successful ERCP. Twelve of 13 (92%) patients were referred to surgery after a maximum of four ERCP attempts. Three of 13 (23%) patients received HJS, 7/13 (54%) patient received simple revision. Two of 13 (15%) patients needed re-transplantation, 1 (8%) patient died.

Thirty patients were had surgery as primary treatment. Six (20%) patients were treated with HJS and 24 had simple revision, which was successful in 80% (19 patients), 2 patients (8%) required HJS,

one patient (4%) re-transplantation. In 2 patients (8%) endoscopic intervention after a primary surgical approach was performed.

When comparing endoscopy to surgery showed a trend towards higher survival rates in the endoscopy group, but did not reach statistical significance ($p = 0.06$) (Fig. 2C).

4.5. Non-anastomotic strictures

Out of 50 patients who received primary endoscopic treatment for NAS, 24 (48%) were successful, 24 (48%) patients were referred to surgery, 2 died unrelated to the NAS or intervention (Fig. 1B).

For successful therapy of NAS, a median number of 3 (IQR 2–5) endoscopic interventions were needed. Success rates (likelihood of successful ERCP) were lower compared to other causes of BC ($p < 0.01$). Probability of success of endoscopic therapy (success rate) was lower in cases with additional presence of intraluminal obstacles, with higher numbers of ERCP interventions needed (median (IQR), 4 (2–9) versus 2 (1–4) interventions ($p \leq 0.001$)), as shown in Table 4.

24 patients (48%) diagnosed with NAS were referred to surgery after non-successful ERCP. 23 (96%) patients were referred within the first four ERCPs attempts. 19 HJS and 2 simple revisions of the bile duct were performed, 3 patients received early retransplantation. 3 different patients were in need of retransplantation later in the course; 2 patients died (Fig. 1B).

Of 17 patients with NAS, one patient (6%) received exploration and concomitant successful liver re-transplantation.

Sixteen (94%) patients received HJS, which was successful in 12 (71%) patients, 3 patients had to be retransplanted. In 2 patients (3%) endoscopic management after HJS was attempted and successful (Fig. 1B). Comparing endoscopy and surgery, there was no difference in survival between groups (Fig. 2D).

4.6. Anastomotic strictures

Seventy-eight patients received primary endoscopic treatment for AS. 51/78 (65%) were treated successfully, 24/78 (31%) were referred to surgery, 3/78 (4%) died.

For successful treatment a median number of 3 (1–5) interventions were needed. Intraluminal obstacles required a higher number of interventions (median 5 (3–6.5)) compared to a median of 2 (1–3) in patients without ($p \leq 0.001$).

AS needed significantly more endoscopic treatment approaches for successful resolution in comparison to other endoscopically treated BC ($p = 0.034$, Table 4).

24 of 78 (31%) patients diagnosed with AS were referred to surgery after non-successful ERCP. 20 (26%) of these patients were referred to surgery within the first four ERCP attempts. 20 patients received HJS (26%), 3 (4%) patients received simple revision. One (1%) patient needed early retransplantation. One (1%) patient was retransplanted after surgical treatment, 3 (4%) patients died (Fig. 1B).

2 patients with AS were primarily treated surgically: 1 received successful HJS, the other was bridged with T-drain and had to be retransplanted within 2 months (Fig. 1B). Due to the low number of patients in the surgery arm, no comparison was performed.

5. Discussion

In this study, we evaluated the largest series of patients for endoscopic and surgical management of biliary complications after liver transplantation to date. There was no significant difference concerning efficacy as initial method in treating biliary complications – endoscopy is successful in 60%, surgery in 78% of patients.

Further our data show that the type of BC itself was not an independent risk factor for survival but patients with AS and NAS

had a lower probability for endoscopic success. This is of importance as patients with primary endoscopic success appear to have reduced mortality. Nevertheless it shows, that when endoscopy is not successful, survival is still comparable to a first line surgery approach.

Interestingly, this is not accounted to the short-term (30-day) mortality, which is comparable in both groups (12/162 compared to 3/49). A possible cause of this finding could be a selection bias by choosing “easier cases” for ERCP, which cannot be confirmed from our data, as numbers of primary surgical approach for treatment of anastomotic strictures are very low (seen only in two of 211 cases compared to 78/211 who had first line ERCP).

Furthermore, primary surgical treatment for leaks accounted for nearly two thirds of first line interventions in the surgery group. Intraluminal objects were identified in 45% of endoscopic cases compared to 22% in surgical cases ($p = 0.005$). Based on these findings, difficulty of cases was rather evenly distributed in this cohort, if not in favor for surgery.

Overall the presence of biliary tract complications in this cohort did not influence long-term overall survival compared to patients without biliary complications. This is not in concordance with previous literature, where biliary complications are alleged to have a negative impact on graft and overall survival after liver transplantation [22]. This might be explained by the fact, that the majority of patients with BC in this were treated endoscopically and if successful, survival after liver transplantation was equal to patients without biliary complications.

We are aware that several limitations of this study have to be acknowledged. Our cohort includes a high number of patients in the endoscopic cohort, who were treated successfully with low number of endoscopic interventions and groups are not distributed evenly. We recognize this factor of potential bias as the initial therapeutic choice was made independently by the physician in charge, either surgeon or gastroenterologist, who referred the patient to his preferred method. Additional bias might be based on the long period of data analysis between 1989 and 2009, where techniques and access route developed continuously, however, treatment success was not different between the first and the second decade (data not shown). Further, the cost of hospital stay and prolonged morbidity in patients with multiple endoscopic procedures compared to a single surgical procedure were not evaluated.

Primary endoscopic management of BC after liver transplantation has become standard practice despite the lack of large, prospective, randomized trials. Success-rates for endoscopic BC treatment have been reported in numerous retrospective trials and vary between 5 and 32% percent, depending on the underlying BC [23].

Overall endoscopic success rate in this cohort was comparable (60%) to previously published literature [6,8,14,24]. Patients with AS and NAS needed significantly more interventions than patients treated for leaks, which also has been seen in previous reports [6,8]. Nevertheless, patients with successful ERCP, even after a high number of procedures performed, had better outcome than patients who needed a secondary surgical intervention after ERCP.

From our cohort, one can expect 65% success rates for endoscopic treatment of AS, 60% for LEAKS and 50% for NAS.

Our analysis shows, that if ERCP is a successful initial strategy, 80.4% of these successful cases were managed within 4 ERCPs. The success rates continuously drop with the number of ERCPs and surgical management should be considered after the 4th ERCP. Second line surgery shows to be effective in up to 73% of our initially endoscopically treated patients. It is noteworthy that these patients have a comparable outcome and survival to initially surgically treated patients. This leads to the recommendation to treat patients first with ERCP, as this might not result in lower success rates or decreased survival when treatment fails.

In conclusion, our data suggests that first approach for biliary complications after oLT should be endoscopy, if both methods seem to be a valid option. The number of endoscopic interventions needed for patients with NAS and AS may be higher, however if successful, these patients have excellent results. Surgical management as initial method showed inferior long-term outcome and should be restricted to patients with endoscopic treatment failure.

Conflict of interest

None declared.

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