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Research Article

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Biliary Complications in Patients Undergoing Liver Transplantation after Previous TACE Treatment

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Abstract

Background and Aims: Transarterial chemoembolization (TACE) are widely used as bridging or downstaging therapy in patients with hepatocellular carcinoma (HCC awaiting liver transplantation (LT). However, concerns persist regarding potential ischemic or cytotoxic effects of TACE on the biliary system and their impact on post-transplant biliary complications.

Methods: We retrospectively analysed 109 patients who underwent liver transplantation for curative treatment of HCC between 2008 and 2020 at a single tertiary centre. Eighty patients received pre-transplant TACE, while 29 served as controls. Biliary complications were defined by cholestatic laboratory abnormalities combined with confirmatory imaging findings and classified as anastomotic strictures, non-anastomotic strictures (ischemic-type biliary lesions), or biliary leakage. Group comparisons were performed using non-parametric and categorical tests. Multivariable logistic regression was conducted to identify independent risk factors for biliary complications, including number of TACE procedures, ischemia times, and cardiovascular comorbidities.

Results: Overall, biliary complications occurred in 29/109 patients (26.6%). Incidences did not differ significantly between the TACE and control groups (22.5% vs. 37.9%, p = 0.141). Rates of anastomotic strictures, non-anastomotic strictures, and biliary leakages were comparable between groups and showed no significant differences. Combined arterial and biliary complications were rare (3.6%) and occurred exclusively in patients without prior TACE. In multivariable analysis, neither the number of TACE procedures nor ischemia times or cardiovascular comorbidities emerged as independent predictors of biliary complications.

Conclusion: Pre-transplant TACE was not associated with an increased risk of biliary complications following liver transplantation. These findings support the safety of TACE as a bridging or downstaging strategy in transplant candidates with HCC.

Lay Summary: This study evaluated whether transarterial chemoembolization (TACE) before liver transplantation in patients with hepatocellular carcinoma is associated with an increased risk of postoperative biliary complications. The results showed no significant difference in biliary complication rates between patients who received TACE and those who did not, indicating that pre-transplant TACE appears to be treatment option for bridging and downstaging prior to transplantation.

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Keywords: TACE; Liver Transplantation; Hepatocellular carcinoma

Abbreviations

TACE – Transarterial chemoembolization

HCC – Hepatocellular carcinoma

LT – Liver transplantation

cTACE – Conventional transarterial chemoembolization

DSM-TACE – Degradable starch microsphere transarterial chemoembolization

DEB-TACE – Drug-eluting beads transarterial chemoembolization

EE – End-to-end anastomosis

SS – Side-to-side anastomosis

ES – End-to-side anastomosis

BDA – Biliodigestive anastomosis

DM – Diabetes mellitus

pAD – Peripheral arterial disease

CHD – Coronary heart disease

HF – Heart failure

MASH – Metabolic dysfunction-associated steatohepatopathy

CIT – Cold ischemia time

WIT – Warm ischemia time

AS – Anastomotic stenosis

NAS – Non-anastomotic stenosis

ITBL – Ischemic-type biliary lesion

Introduction

Liver transplantation has been established as the gold-standard for the curative treatment of hepatocellular carcinoma (HCC). In the framework of transplantation, add-on neoadjuvant transarterial chemoembolization (TACE) can be performed as bridging or downstaging therapy prior to transplantation as well as palliative tumor control. During TACE, chemotherapeutics combined with an embolic agent are selectively injected into the HCC supplying arteries, thus causing a cytostatic and ischemic therapeutic effect. Currently, a multitude of different application protocols of TACE exist beyond the conventional method with doxorubicin-lipiodol (cTACE), such as degradable-starch-microsphere TACE (DSM-TACE) and drug-eluting-beads TACE (DEB-TACE). The different protocols allow for higher accumulation of chemotherapeutics in the tumor while maximizing the embolic effect. It is recommended that assessment of treatment response should be done after 2 – 3 TACE sessions with an interval of 4 – 6 weeks between the sessions, since studies have shown that in most patients, a tumor response will occur after 2 TACE sessions [1,2]. However, up until today there is no clear recommendation as to how many TACE procedures can or should be performed en-route to transplantation [3-5]. Currently, there are no widely accepted standardized protocols available for the application of TACE, which accounts for heterogeneity in interventional radiological expertise as well as center expertise in assessment and treatment of patients with HCC. Approximately 20% of patients develop a complication in the biliary system after liver transplantation in the framework of curative HCC treatment [6-8]. Risk factors for the development of these complications have been defined in previous studies and include prolonged intraoperative ischemia time, preexisting cardiac comorbidities, presence of arterial complications as well as factors related to the operative technique [8-10]. Among these factors, the role of TACE as a risk factor for development of postoperative arterial and biliary complications has also been discussed [9-14]. TACE was linked to these postoperative complications via ischemic and cytotoxic side-effects in previous studies; however the exact association remains unclear with recent research supporting the safety of TACE in this regard [15,16]. The present study aims to explore the occurrence of biliary complications in patients after liver transplantation for curative HCC treatment and to assess its potential relation to application of pre-transplantation application of TACE.

Methods

This study was conducted in accordance with the ethical standards laid down in the 1964 declaration of Helsinki and its later amendments. The local ethics committee of the Christian-Albrechts-University in Kiel approved this retrospective study (protocol no. D 439/22).

Population

All patients who underwent liver transplantation for curative HCC treatment at our center between 2008 and 2020 were retrospectively included in this analysis, independent of having received TACE prior to transplantation. All liver transplantations were realized by post-mortem liver donation. Parts of this cohort have been assessed in previous research studies from our group on the development of arterial complications [17].

Study Definitions

Patients who received TACE prior to transplantation are referred to as the "TACE group" while patients who did not receive TACE are defined as "control group". A biliary complication was present when both of the following conditions were met: 1) elevated serum levels for cholestasis (bilirubin, gGT, transaminases) and 2) corresponding findings

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in imaging examinations including endoscopic retrograde cholangiopancreatography (ERCP), sonography as well as CT and/or MRI. Biliary complications have been classified into strictures and leakages. Strictures were further differentiated into lesions close to the bile duct anastomosis (≤ 1cm) and strictures distant from the anastomosis (> 1cm). As for the perioperative factors, cold and warm ischemia times were gathered from the internal transplantation database. Warm ischemia time represents the perfusion time after donor death until liver explantation and cold perfusion, whereas cold ischemia time notes the cold perfusion time until organ transplantation. Furthermore, the operative technique of bile duct anastomosis was assessed, whereby anastomosis was performed as either end to end (EE), side to side (SS), end to side (ES) or biliodigestive anastomosis (BDA). The presence of cardiac comorbidities including coronary heart disease and heart failure was assessed alongside baseline clinical parameters.

TACE Procedure

All indications for TACE were discussed in an interdisciplinary HCC-board involving hepatologists, surgeons, and interventional radiologists. TACE was performed as a bridging or downstaging therapy prior to transplantation in standardized fashion by experienced interventional radiologists. Following femoral or radial arterial access, selective catheterization, angiography and cone-beam CT imaging of the hepatic vasculature and tumor-supplying arteries was performed for embolization planning. Embolization was then carried out using doxorubicin combined with lipiodol, degradable starch microspheres or drug-eluting beads at the interventionalist's discretion. Depending on lesion size and number, between 40–120 mg of doxorubicin was administered per TACE session. Follow-up imaging with CT or MRI was performed every 6–8 weeks, and TACE was repeated until transplantation if indicated.

Imaging in the framework of transplantation

As first diagnostic assessment after successful liver transplantation, point-of-care sonography of the hepatic graft was performed to assess complications involving the arterial, venous, or biliary anastomoses. If a pathology was suspected, ERCP or multiphase contrast-enhanced CT was carried out. Follow-up imaging after transplantation with CT or MRI was completed every three to six months postoperatively to monitor the transplanted liver and to detect HCC recurrence within 24 months of surgery.

Statistical analysis

Data were processed using Microsoft Office and R and are presented as the mean (range) or median. Analysis of continuous and categorical variables was conducted with the Wilcoxon-Test, Mann–Whitney U Test and Fisher Exact Test as indicated. The level of significance was set at an alpha = 0.05. Multivariate logistic regression analysis was performed to identify preoperative factors predisposing liver transplant recipients of developing a biliary complication.

Results

Population

This study encompasses 109 patients after liver transplantation in the framework of curative treatment of HCC. Demographics and baseline clinical characteristics are displayed in table 1. Overall, 80 patients underwent TACE therapy prior to transplantation (TACE group = 80/109, 73%), with a mean number of TACE procedures of n = 4, ranging from n = 1 – 23 per patient.

Table 1: Cohort Overview (AFP = alpha-Fetoprotein; BC = biliary complication; BD = bile duct; BDA = biliodigestive anastomosis; cHD = coronary heart disease; DM = diabetes mellitus; HF = heart failure; MASH = metabolic dysfunction associated steatohepatopathy; Milan = Mailand criteria for liver transplantation; pAD = peripheral arterial disease; UCSF = Universitiy of California, San Francisco criteria for liver transplantation; AS = anastomotic stenosis; NAS non-anastomotic stenosis).

	TACE group (80)	Control group (29)	p-value
sex (f/m) (n)	16/64	Sep-20	0.302
mean age at LTx (yrs)	62.06	59.94	0.055
AFP positive HCC (n)	43	9	0.05
Milan In (n)	51	15	0.275
UCSF In (n)	9	2	0.724
mean waiting time (d)	229	165	0.747
size largest tumor (cm)	3.6	2.5	0.002
number of lesions (n)	1.88	1.62	0.205
vascular invasion radiologic (V1) (n)	11	3	0.755
max. AFP value (ng/dl)	258.35	273.93	0.023
DM (n)	33	17	0.13
pAD (n)	7	1	0.678
Hypertension (n)	43	15	1
Smoking (n)	8	4	0.729
cHD (n)	12	2	0.345
i.v. drugs (n)	4	1	1
HF (n)	12	4	1
C2-toxic (n)	28	18	0.052
hepatitis A (n)	3	2	0.621
hepatitis B (n)	17	3	0.176
hepatitis C (n)	31	4	0.019
hepatitis D (n)	1	1	0.489
hepatitis E (n)	0	1	0.284
MASH (n)	8	6	0.215
alpha 1 antitrypsin deficiency (n)	0	1	0.284
autoimmun-related (n)	0	1	0.284

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cold ischemia time (CIT) (min)	557.3	612.3	<0.001
warm ischemia time (WIT) (min)	45	46.8	0.831
Retransplantations	7	1	
<14d to Tx (n)	5	0	0.322
>14d to Tx (n)	2	1	1
Biliary complications (n)	18	11	0.141
AS (n)	12	8	0.166
NAS (n)	9	2	0.723
BD leak (n)	4	3	0.382
BD EtoE (n)	77	28	1
BD EtoS (n)	1	0	1
BDA (n)	2	1	1

Analysis of types and occurrences of biliary complications

An overview of the biliary complications is given in table 2. Overall, a postoperative biliary complication was found in 29 patients (29/109; 26.6%) in this cohort, whereby 18 patients showed a complication in the TACE group (18/80; 22.5%) compared to 11 patients in the control group (11/29; 37.9%). A significant difference of the overall occurrence of a biliary complication based on status of preinterventional TACE was not present (p=0.141). In our cohort, we found a total of 31 bile duct strictures, whereby 21 were seen in the "TACE group" vs 10 in the "control group". The overall occurrence of strictures did not differ significantly between the groups (p=0.473). Bile duct strictures were further classified into anastomotic stenoses (AS) or distal of it (non-anastomotic stenosis NAS, ITBL). No significant differences could be detected between the groups (AS: "TACE group" 12 vs. "control group" 8, p = 0.166; NAS: "TACE group" 9 vs. "control group" 2, p = 0.723; Figures 1 and 2). A total of 7 cases of bile leakage at the biliary anastomosis were found in this cohort. However, there was no statistical difference detectable between the groups ("TACE group" 4 vs. "control group" 3, p = 0.382; Figure 3).

Table 2: Overview of patients with postoperative biliary complications. *Due to simultaneously occurring types of biliary complications overall sums may differ from subgroups.

	Overall	TACE Group	Control Group	p-value
Biliary Complications	29*	18*	11*	0.141
Strictures	31	21	10	0.473
AS	20	12	8	0.166
NAS/ITBL	11	9	2	0.723
Leakage	7	4	3	0.382

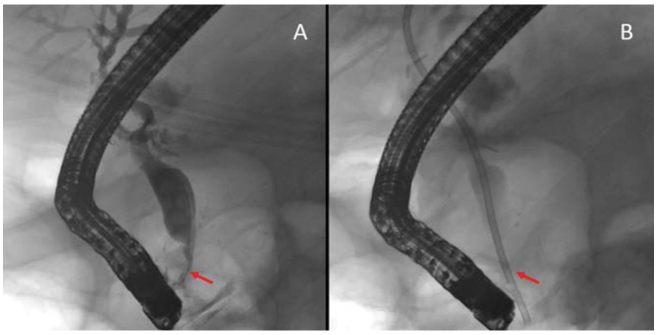

Figure 1: Stenosis of the biliary anastomosis after liver transplantation.

After liver transplantation, this patient was seen to have a severe stenosis of the biliary anastomosis in the ERCP examination (Arrow, Figure A). In order to ensure sufficient drainage, a biliary drain was placed over the anastomosis to bridge the bile flow (Arrow, Figure B).

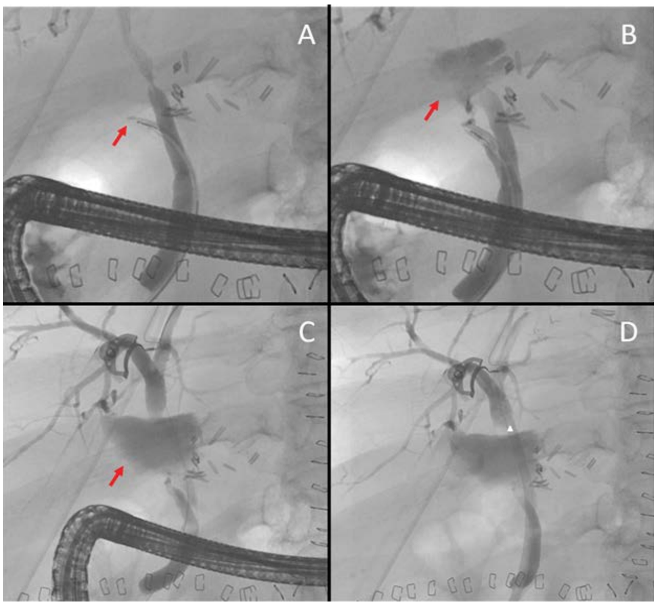

Figure 2: Biliary Leakage after liver transplantation.

In this patient, ERCP shows residual contrasting of the cystic duct of the liver graft (Arrow, Figure A). Subsequently, a clear biliary leakage out of the remaining cystic duct can be seen with contrast media extravasation (Arrow, Figure B). To treat this complication, a wire is placed into the left hepatic duct over which subsequently a large-lumen biliary drain is placed to cover the leakage site (Arrow, Figure C; Triangle, Figure D).

In this patient, liver transplantation was successfully performed, however elevated serum bilirubin was detected six months after transplantation. Upon MRI imaging, a dilatation of the intrahepatic bile ducts limited to the left liver lobe is depicted (Arrows, Figures A and B). ERCP imaging confirms an intrahepatic biliary stricture distant from the anastomosis, consisting with an ischemic-type biliary lesion (Arrow, Figure C).

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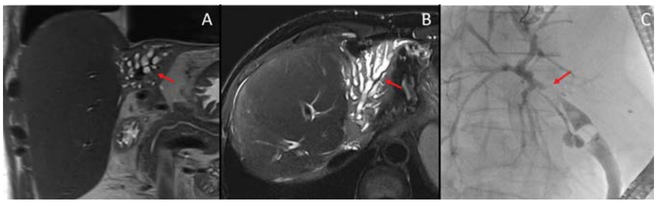

Figure 3: Ischemic-type biliary lesion after liver transplantation.

Analysis of risk factors for biliary complications

In regard to the surgical technique of the biliary anastomosis, there was no significant difference between the groups (EE: "TACE group" 77 vs. "control group" 28, p = 1.00; ES: "TACE group" 1 vs. "control group" 0, p = 1.00; BDA: "TACE group" 2 vs. "control group" 1, p = 1.00).

Cold and warm ischemia times are shown in table 1. There was a significantly longer cold ischemia time in the control group ("TACE group" 557.3 min vs. "control group" 612.3 min, p <0.001), whereas warm ischemia times showed no significant differences ("TACE group" 45.0 min vs. "control group" 46.8 min, p = 0.831). Combined biliary and arterial complications were seen in 4 patients (4/109; 3.6%), whereby none of these patients had undergone TACE prior to transplantation. Arterial stenosis was present in all of these cases and was managed conservatively given preserved hepatic perfusion. Furthermore, all cases showed a stenosis of the biliary anastomosis, whereby in one case a concomitant anastomotic leakage was present. Presence of coronary heart disease, hypertension and heart failure showed no significant differences between the groups (cHD "TACE group" 12 vs. "control group" 2, p = 0.345; hypertension "TACE group" 43 vs. "control group" 15, p = 1; HF "TACE group" 12 vs "control group" 4, p = 1).

Logistic Regression Analysis for identification of risk factors for biliary complications

Multivariable logistic regression analysis was performed to investigate the role of number of TACE procedures, cold and warm ischemia times as well as donor age and presence of CHD, HT and HF as risk factors for development of biliary complications. However, none of these factors emerged as independent predictors of biliary complications in the multivariable analysis (Supplementary Table 1).

Discussion

The relationship of TACE application and both the direct and indirect development of biliary complications has been addressed with inconsistent findings regarding its impact [11,17,18]. The aim of this study was to explore the role of preoperative TACE as a potential risk factor for the development of postoperative biliary complications after transplantation. The main findings of this study are: 1) We found no statistically significant difference in the occurrence of biliary complications in patients after liver transplantation who underwent preoperative TACE therapy vs. those who did not. 2) Pre-transplantation application of TACE could not be identified as a risk factor for occurrence of postoperative biliary complications after liver transplantation. 3) There was no significant correlation between the occurrence of biliary and arterial complications. Biliary complications are a heterogeneous group of pathologies that affect the biliary system after liver transplantation and poses a significant challenge in postoperative patient care. Their reported incidence across multiple studies from 2004 to 2018 varies between 20 – 40% [19-23]. Besides differences in patient population, this large heterogeneity reflects differences in center expertise, operative techniques and factors related to the graft and complication assessment as well as reporting standards in the framework of continuously expanding transplantation criteria, which needs to be considered when interpreting this data [12,24].

TACE and occurrence biliary complications after liver transplantation

Our study showed an overall occurrence of biliary complications in 26% of patients after transplantation, however we found no significant difference between the TACE group and the control group (22.5% vs. 37.9%, p = 0.141). A cohort study by Goel et al. including 456 patients after liver transplantation reports an overall rate of 19% of biliary complications. In their subgroup analysis, no difference between patients with and without preoperative TACE could be detected ("TACE group" 19.8% vs. "control group" 16.4%; p = 0.40) [18]. Their findings are in good agreement with our study. This study was included in a meta-analysis by Sneiders et al. covering 7 studies, noting a range of 14.8% – 55% of postoperative biliary complications in a total of 638 patients after TACE [11]. Similarly to our findings, no significant differences of occurrences of biliary complications after transplantation based on preoperative TACE are reported [11].

Biliary anastomotic stenoses, non-anastomotic stenoses and leakages

We found no significant differences between occurrences of AS ("TACE group" 15% vs, "control group" 27.5%; p = 0.166) and NAS/ITBLs ("TACE group" 11.3% vs. "control group" 6.9%; p = 0.723). In a study by Dhamija et al in 2015, biliary complications following TACE are described as rare at an incidence of 1.9% of TACE procedures [25]. In a review by Ryu et al, ischemic and reperfusion injuries, especially elongated cold and warm ischemia times, are mentioned as the most significant factors influencing the occurrence of biliary strictures in the graft, which is plausible [26]. In synopsis, in patients after transplantation, where a new hepatic tissue is introduced, preoperative TACE is therefore very unlikely to be the underlying cause for anastomotic or non-anastomotic strictures. Postoperative leakage of the extrahepatic biliary

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system did not differ significantly between the groups ("TACE group" 5% vs. "control group" 10.3%; p = 0.382). In a review by Verdonk et al, the occurrence of postoperative biliary leakage after transplantation is noted at 5 – 7% of cases, which is in good agreement with our findings [27]. We note a slightly higher rate in the no TACE group, which can most likely be explained by the relatively small group size. In a study of 15 patients after hepatectomy, preoperative TACE is mentioned to be associated with prolonged biliary leakage, however the authors could not identify it as a risk factor for development of a leakage [28]. Similarly, the multivariate logistic regression analysis in our study showed no significant impact of TACE on developing biliary complications, including leakages or strictures.

Combined arterial and biliary complications

Combined biliary and arterial complications were seen in 4 patients, all of whom did not undergo preoperative TACE (4/109; 3.6%). Biliary complications are known to be associated with impaired hepatic perfusion, especially biliary strictures distant from the anastomosis [26,29]. In this setting, especially early arterial thrombosis and elongated cold and warm ischemia times are discussed as relevant risk factors for non-anastomotic stricture development [30,31]. Nevertheless, in synopsis with our previous work on arterial complications, we could not identify TACE as a risk factor for either biliary or arterial complications [17]. Finally, the pathogenesis in these four cases was attributed to the significantly longer cold ischemia time in the control group likely causing ischemic injury of the bile ducts.

Limitations and Future Perspectives

This retrospective study has several limitations in need of consideration when interpreting the results. Firstly, given the retrospective single-center design, there was an overall low number of patients, especially in the control group. Secondly, the results are associated with local practice and expertise in management of patients with HCC, therefore the overall generalizability of our findings is limited. Thirdly, the number of observed biliary complications was relatively small, which limits the statistical power of the multivariable logistic regression model. As a result, only large effect sizes would likely have been detectable. The regression findings, therefore, should be interpreted cautiously and considered exploratory. Given the heterogeneity of TACE protocols, graft quality, and recipient characteristics between transplantation centers, future work should focus on prospective, ideally multicenter studies with harmonized definitions of biliary complications and clear documentation of TACE technique and cumulative treatment intensity. Quantitative biomarkers of ischemia–reperfusion injury may help clarify whether graft-related ischemia surpasses the effects of pre-transplantation chemical and mechanical arterial manipulation. Moreover, studying modern locoregional therapies such as DEB-TACE, DSM-TACE, and combination therapies (e.g., TACE + immunotherapy) in the pretransplant setting will be crucial to ensure their safety as selection and bridging strategies continue to evolve.

Conclusion

Pretransplant TACE was not associated with an increased rate of biliary complications after liver transplantation. Rates of biliary anastomotic strictures, ITBLs, and biliary leakages were comparable between groups, and no link between TACE and biliary or combined arterial-biliary complications were found. These findings further support the safety of TACE as a bridging or downstaging therapy in candidates for liver transplantation.

S.W. and K.M. were involved in formulating the research question, study design, and generation of the datasets that were subsequently analyzed. S.W., K.M., J.A., and J.P.G. contributed to data acquisition and clinical data verification. S.W. and K.M. performed the statistical analysis. K.M. generated all figures and tables. S.W. and K.M. drafted the initial manuscript. T.B., M.L., J.M., and C.C.C. contributed to data interpretation and critically revised the manuscript for important intellectual content. F.B. and J.P.S. provided senior supervision. All authors read and approved the final version for submission.

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