

A biodegradable polymer plug for liver tract embolization after percutaneous or surgical placement of transhepatic biliary drainage tubes: a feasibility study

Ein bioresorbierbarer Polymer-Plug für die Stichkanalembolisation nach perkutan oder chirurgisch angelegten transhepatischen Gallendrainagen: eine Machbarkeitsstudie

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ABSTRACT

Purpose To evaluate the feasibility of liver tract embolization after transhepatic biliary drainage using a biodegradable polymer plug (IMPEDE-FX, Shape Memorial Medical, Santa Clara, CA, USA).

Materials and Methods In a retrospective observational study, 15 plug embolizations were performed in 13 patients at risk for tract-related adverse events (AEs). Risk factors included coagulopathy, cirrhosis, central bile duct puncture, previous drain-related bleeding, malignant obstruction, large tract diameter, or multilevel strictures. Clinical and imaging follow-up was performed at 24 hours, 3 months, and 6 months. Primary endpoints were technical and clinical success. Technical success was defined as plug deployment in the intended position. Clinical success was defined as the absence of biliary,

infectious, or bleeding AEs. To assess clinically occult bleeding or biliary obstruction, periprocedural hemoglobin, hematocrit, and bilirubin levels were compared. Secondary endpoints were plug migration, plug oversizing, and plug visibility on imaging.

Results The technical success rate was 100%. The clinical success rate was 84.6%. There were no infectious or bleeding AEs. In 2 cases where the persistence of biliary congestion was clinically underestimated prior to drain removal, 2 biliary AEs occurred (2 biliocutaneous fistulas including 1 plug migration within 24 hours; 15.4% SIR grade 3 AEs). The median plug oversizing relative to the diameter of the hepatic tract was substantially lower in unsuccessful cases than in successful cases (27% vs. 86%). The plug was visible on ultrasound and CT. On MRI, no plug-related artifacts occurred.

Conclusion The plug could be an option when a non-permanent, precisely deployable device is desired for tract embolization. Adequate plug-to-tract oversizing and biliary decongestion are essential to achieve durable tract closure. Therefore, the plug seems unsuitable for patients with multilevel strictures where complete drainage of the biliary system is not feasible.

Key Points

- The polymer plug can be precisely delivered within the liver tract.
- Plug-to-tract oversizing and biliary decongestion are essential for durable tract closure.
- The plug appears unsuitable for endoscopically incompletely relievable multilevel biliary strictures.

Citation Format

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ZUSAMMENFASSUNG

Ziel Evaluation der Machbarkeit einer Stichkanalembolisation nach transhepatischer Gallendrainage mit einem bioresor-

bierbaren Polymer-Plug (IMPEDE-FX, Shape Memorial Medical, Santa Clara, CA, USA).

Material und Methoden In einer retrospektiven Beobachtungsstudie wurden 15 Plug-Embolisationen bei 13 Patienten durchgeführt, die ein erhöhtes Risiko für stichkanalbezogene unerwünschte Ereignisse (AEs) aufwiesen. Zu den Risikofaktoren zählten Gerinnungsstörung, Zirrhose, zentrale Gallengangpunktion, stattgehabte Blutung im Stichkanal, maligne Gallengangstenosen, breiter Stichkanaldurchmesser oder multifokale Gallengangstrikturen. Klinische und bildgebende Nachuntersuchungen erfolgten nach 24 Stunden, 3 Monaten und 6 Monaten. Primäre Endpunkte waren technischer und klinischer Erfolg. Als technischer Erfolg galt das präzise Absetzen des Plugs. Als klinischer Erfolg galt das Ausbleiben von biliären, infektiösen oder blutungsbedingten AEs. Um klinisch okkulte Blutungen oder Gallengangobstruktionen zu erfassen, wurden Hämoglobin-, Hämatokrit- und Bilirubinwerte vor und nach dem Eingriff verglichen. Sekundäre Endpunkte waren Plug-Migration, Plug-Oversizing und das Verhalten des Plugs in der Bildgebung.

Ergebnisse Die technische Erfolgsrate war 100%. Die klinische Erfolgsrate betrug 84,6%. Infektiöse oder blutungsbedingte AEs traten nicht auf. In 2 Fällen wurde klinisch die Persistenz einer Galleabflussbehinderung verkannt und es resultierten

2 biliäre AEs (2 biliokutane Fisteln, darunter eine Plug-Migration innerhalb von 24 Stunden; 15,4% SIR AE Grad 3). Das mediane Plug-Oversizing in Relation zum Stichkanaldiameter war bei den klinischen Versagern wesentlich geringer als bei den erfolgreichen Fällen (27% vs. 86%). Im Ultraschall und in der CT war der Plug sichtbar. In der MRT gab es keine Plug-bedingten Artefakte.

Schlussfolgerung Der Plug ist eine Option, wenn ein resorbierbares und präzise zu platzierendes Embolisat für die Stichkanalembolisation verwendet werden soll. Angemessenes Plug-Oversizing in Relation zum Stichkanal und vollständige Entstauung des Gallensystems sind für einen dauerhaften Verschluss wesentlich. Daher scheint sich der Plug nicht für Patienten mit multifokalen Strikturen zu eignen, bei denen eine vollständige Entlastung des Gallensystems nicht möglich ist.

Kernaussagen

- Der bioresorbierbare Polymer-Plug kann präzise platziert werden.
- Plug-Oversizing und Entstauung der Gallenwege sind für dauerhaften Stichkanalverschluss essenziell.
- Der Plug scheint ungeeignet bei endoskopisch nur unvollständig entlastbaren biliären Mehretagenstenosen.

Introduction

A variety of benign and malignant conditions require biliary drainage, either to relieve biliary obstruction or to divert bile in cases of postoperative bile leakage. Radiologically placed percutaneous transhepatic biliary drains (PTBDs) or surgically placed transhepatic biliary drains (STBDs) are preferred when endoscopic biliary access is inappropriate or fails.

In most cases, PTBD/STBDs can be safely removed when the drains have served their purpose in a decompressed biliary system. However, in some cases, tract-related biliary, infectious, or bleeding adverse events (AEs) occur leading to re-interventions and prolonged care, which can affect the patients' quality of life [1].

Preventive transhepatic tract embolization is one measure to reduce tract-related AEs [2]. The few available studies on tract embolization after biliary interventions have shown a reduction in bleeding AEs and post-procedural pain [1, 3]. Prevention of peritoneal irritation caused by bleeding or bile leakage is assumed to be the reason for pain relief [3]. Although there are no comparative studies available proving the effect of tract embolization on bile leakage, the reported cumulative incidence of bile leaks after PTBD/STBD removal with tract embolization was lower than without embolization [2]. Therefore, preventive tract embolization appears particularly beneficial in vulnerable patients with potential risk factors for developing tract-related AEs.

Several embolic agents have been described to occlude the liver tract [4, 5, 6, 7, 8, 9, 10, 11, 12]. However, none of the available techniques is suitable for every clinical scenario, as each method

has specific drawbacks depending on the type of application and the embolization material itself.

The objective of this feasibility study was to estimate the technical and clinical success rates of liver tract embolization using a biodegradable polymer plug.

Materials and Methods

Patient characteristics and study design

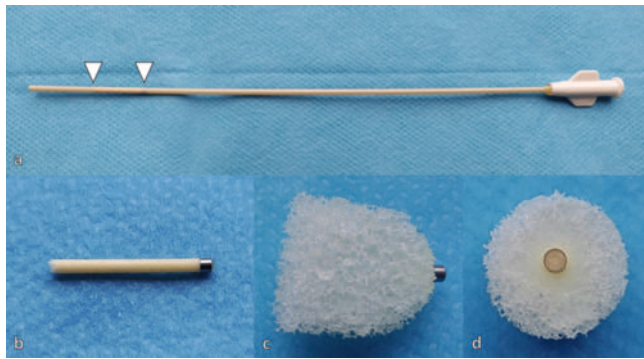
A retrospective, observational, descriptive, and longitudinal single-center feasibility study from a prospectively obtained database was conducted between February 2022 and February 2023. The study was approved by the institutional review board, which raised no fundamental ethical or legal concerns based on the information available (reference number 20240111 01). STROBE guidelines were followed.

Adult patients were eligible for polymer plug embolization of the tract if they were scheduled for routine PTBD/STBD removal and had at least one patient- or technique-related risk factor for developing a tract-related AE. Two categories of risk factors have been defined based on the literature and our clinical experience: First, risk factors for bleeding AEs, i. e., coagulopathy, cirrhosis, central bile duct puncture, or previous drain-related hemorrhage; second, risk factors for bile leakage, i. e., immature tracts (catheter dwell time <2–3 weeks), large tract diameters, malignant obstruction, or multilevel strictures [13, 14, 15, 16, 17].

If none of the above risk factors were present in the patients' clinical and imaging records, tract embolization with gelatin deri-

▶ Table 1 Patient characteristics.									
Patient	Age/ gender	Underlying disease	Indication for PTBD/ STBD	Insertion technique	Access side	Bile duct entry level	PTBD/STBD-related adverse events	Rationale for PTBD/ STBD removal	
1	59 M	Cholestasis + cholangitis; CRC liver metastases	Failed ERCP	P	R	3		Endoscopic internaliza- tion	
2	27 M	Cholestasis + cholangitis; PSC recurrence after LTx	Failed ERCP	P	R	2		Strictures widened	
3	56 F	CCC (Bismuth 3A)	Preparation for surgery	P	L	2		Endoscopic internaliza- tion	
4	59 F	Cholangitis + biliary peritonitis; IBDI after CCE for cholecystitis	Preparation for surgery	P	R	2	PsA + arterio-biliary fistula, shock	Bile leak resolved	
5	63 M	BEA insufficiency after pancreatico-duodenecto- my for pancreatic NET	BEA splinting + decompression	P	R	0	PsA + arterio-biliary fistula, shock	Bile leak resolved	
6	78 M	BEA insufficiency after extended surgery for CCC (Bismuth 3B)	BEA splinting + decompression	S	R	1		Bile leak resolved	
7	69 M	Duodenal stump fistula after surgery for chole- cystitis and cholecysto-duodenal fistula	Bilio-duodenal decom- pression	P	R	2	Recurrent bleeding from PsA + arterio-bili- ary fistula, shock	Bile leak resolved	
8	53 M	Biliary strictures + cholangitis; IBDI after CCE for cholecystitis	Failed ERCP	P	R	2		Endoscopic internaliza- tion	
9	66 M	CCC (Bismuth 3A)	BEA splinting	S	L	2		BEA healed	
10	60 M	Cholangitis + biliary peritonitis; IBDI after CCE for cholecystitis	BEA splinting	S	R	2		BEA healed	
11	62 M	Cholangitis + cholelithiasis; H.o. distal gastrectomy + Roux-Y reconstruction	Failed ERCP + liver hematoma	P	R	2		Bile stone extraction with internalization	
12	71 M	BEA stricture; H.o. pancreatico-duodenectomy for pancreatic cancer	Failed ERCP	P	R	2		BEA stricture widened	
13	68 F	IBDI after CCE for cholecystitis; CCC as incidental finding	BEA splinting (3 bile ducts)	S	R	2		BEA healed	

Abbr.: BEA: Bilio-enteric anastomosis; CCC: Cholangiocarcinoma; CCE: Cholecystectomy; CRC: Colorectal cancer; ERCP: Endoscopic retrograde cholangiopancreatography; F: Female; H.o.: History of; IBDI: Iatrogenic bile duct injury; L: Left liver lobe; LTx: Liver transplantation; M: Male; NET: Neuroendocrine tumor; P: Percutaneous/radiological; PsA: Pseudoaneurysm; PSC: Primary sclerosing cholangitis; PTBD: Percutaneous transhepatic biliary drainage; R: Right liver lobe; S: Surgical/intraoperative; STBD: Surgically placed transhepatic biliary drainage.
Bile duct entry/obstruction levels: 0 Central/right or left hepatic duct/bifurcation/BEA, 1 Lobar, 2 Segmental, 3 Subsegmental



► **Fig. 1** IMPEDE-FX polymer plug. **a** Plug introducer (arrowheads indicate the crimped plug). **b** Crimped polymer plug. Fully expanded plug shown in a lateral **c** and proximal view **d**.

vatives was performed according to our institutional standard of care. [5]

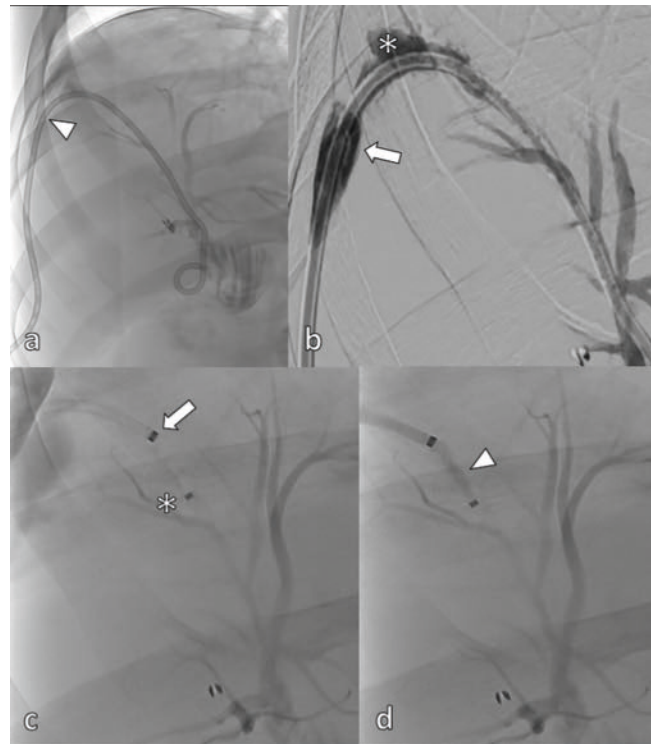
Removal of the PTBD/STBD and plug embolization was contraindicated in cases where clinical evidence pointed to persistent biliary congestion, the presence of a necrotic cavity, biloma, or hematoma at the intended plug position, persistent postoperative bile leak, uncontrolled or untreated infection, or a known intolerance to one of the plug components.

Of the 27 patients scheduled for PTBD/STBD removal during the study period, 13 patients (10 males; median age 61 years [IQR 9]) were enrolled. The 13 participants underwent 15 liver tract embolizations with 15 plugs (12 × 1 plug per patient and 3 plugs in one patient with 3 bilioenteric anastomoses (BEA)). Indications for PTBD/STBD removal included: planned endoscopic internalization, resolved postoperative bile leaks, healed bilioenteric anastomosis, or widened benign biliary strictures. The median time between the first biliary drainage and tract embolization was 90 days [IQR 34]. Eight patients had non-dilated ducts and five patients had dilated ducts. Patient characteristics are presented in ► **Table 1** ► **Table 1**.

Liver tract embolization technique and plug design

Written informed consent was obtained from all patients prior to the procedure. The procedures were performed under local anesthesia in an angiography suite by a board-certified interventionalist with 27 years of experience. Antibiotic treatment was not routinely administered. For hepatic tract embolization, the PTBD/STBD was replaced by a braided 7 Fr introducer sheath. A contrast-enhanced tractogram was performed to determine the tract diameter and biliary access point. When the tip of the sheath was located anterior to the biliary access point, the sheath was flushed with 5–10 ml of a sodium chloride solution pre-warmed to 37 °C. In each case, 12 mm plugs were selected.

The pushable plug (IMPEDE-FX Embolization Plug, Shape Memorial Medical, Santa Clara, CA, USA) consists of a self-expanding, biodegradable, low-density polyurethane polymer and a platinum/iridium marker band (► **Fig. 1**) [18]. The plug is available in sizes of 6 × 10, 8 × 10, and 12 × 15 (diameter × length in mm). The proximal marker measures between 0.813 and 1.651 mm. During expansion, the polymer reacts with bile, lymphatic fluid,



► **Fig. 2** Liver tract embolization after STBD via a long and steep access route. **a** Initial finding. Note the elevated diaphragm. The access point at the Glisson's capsule is marked with a suture (arrowhead). **b** Magnitude of the cholangiography. The repetitive motion of the elevated diaphragm and the steep access contributed to a widening of the tract with pericatheter bile leakage causing intrahepatic (asterisk) and extrahepatic (arrow) biloma. **c** Plug with radiopaque marker (asterisk) deployed through a kink-resistant 7 Fr sheath (arrow). **d** Gentle injection of contrast medium (arrowhead) demonstrates complete occlusion of the tract 5 minutes after plug deployment.

or blood leaking from the liver parenchyma. The presumed mechanism of plug action is to prevent or stop bleeding from the peribiliary plexus as well as from inadvertently traversed blood vessels within the portal triad, and to block the reflux of bile from the bile duct into the tract. On account of the viscosity of bile and the low pressure within the biliary system, the polymer, with average pore sizes ranging from 0.85 to 2.20 mm, creates multiple zones of stagnation for the bile [19]. This allows the hepatic tract to recoil and heal. Plug expansion takes approximately 10 minutes [18]. Polymer degradation takes approximately 90–180 days [18].

As soon as the plug was released proximally to the biliary access point, the sheath was slightly withdrawn. After 5 minutes, contrast medium was gently injected through the sheath to check tract occlusion. The sheath was removed when the tract was completely sealed (► **Fig. 2**).

Post-procedure follow-up

Follow-up consisted of clinical and ultrasound evaluations at 24 hours, 3 months, and 6 months. One patient did not undergo a pre-discharge ultrasound examination due to his decision to

leave the hospital prior to the scheduled examination. If indicated by the underlying disease, computed tomography (CT) or magnetic resonance imaging (MRI) was performed. Moreover, the clinical and imaging records of all patients were reviewed to obtain further demographic, clinical, and imaging information about the patients' medical history and follow-up.

The median follow-up period was 10 months [IQR 9]. At 2 and 16 months of follow-up, two patients died from progression of the underlying malignancy. One patient was lost to follow-up after 4 months. ► **Table 2** summarizes procedure and follow-up data (► **Table 2**).

Study endpoints and definitions

The primary study endpoints were technical and clinical success. Technical success was defined as successful plug deployment in the intended position. Clinical success was defined as the absence of biliary AEs (bilio-cutaneous fistula, biloma, and choleperitoneum/cholethorax), infectious AEs, or bleeding AEs within 6 months of follow-up. The grading of AEs was conducted in accordance with the guidelines of the Society of Interventional Radiology [20].

Additionally, to assess clinically inapparent hemorrhage or biliary obstruction, pre- and post-procedural hemoglobin, hematocrit and bilirubin levels were compared. Secondary endpoints included plug migration, plug oversizing, and plug visibility on ultrasound, CT, and MRI.

Plug migration within 24 hours was defined as early migration. In addition, migration and oversizing were analyzed regarding the presence of dilated or non-dilated ducts. Bile ducts were considered dilated if the diameter of an intrahepatic peripheral bile duct was wider than 2 mm or if the diameter of the bile duct exceeded that of the accompanying portal vein. Bile duct and liver tract diameters were determined by periprocedural tractography, cholangiography, and ultrasound. Plug oversizing was calculated with respect to the diameters of the liver tract and the accessed bile duct.

Statistical analysis

Statistical analysis was performed using GraphPad Prism (version 10.1.2 (324), GraphPad Software Inc., San Diego, CA, USA). Normal distribution was tested using the Shapiro-Wilk test. Categorical variables are expressed as numbers with percentage. Normally distributed variables are presented as mean and standard deviation (SD), non-normally distributed variables are shown as median and interquartile range (IQR). Statistical testing was performed using Fisher's exact test and Wilcoxon matched-pairs signed rank test, where appropriate. A p-value less than 0.05 was considered statistically significant.

Results

Technical and clinical success

The technical success rate was 100% (15/15 plugs). The clinical success rate was 84.6% (11/13 patients). Two patients with dilated ducts developed bilio-cutaneous fistulas. In both cases, the persistence of relevant biliary obstruction was clinically underestimated

prior to drain removal: One patient had a long-term (460 days) 14 Fr internal-external biliary drain for the treatment of a BEA stricture due to scarring. After one week of uneventful clamping of the external part of the drain, the anastomosis was considered wide enough to allow adequate trans-anastomotic bile outflow into the efferent bowel loop. However, a bilio-cutaneous fistula occurred after PTBD removal, indicating persistent biliary congestion. In this case, bile leakage was present for 3 days until successful endoscopic BEA stenting. The second patient with multilevel strictures due to cholangitis had a bilio-cutaneous fistula after removal of a right-sided PTBD. Before removal, the external part of the drain was disconnected without any signs of biliary obstruction. In this case, the fistula persisted for 5 months because endoscopic stenting was successful only in the left hepatic duct. Secretion from the fistula finally ceased after completion of bilateral stenting. However, undulating subcutaneous swelling at the former percutaneous access site for the next 10 months indicated persistence of the tract. Apart from the two fistulas, there were no biliary, infectious, or bleeding AEs within 6 months of follow-up.

Periprocedural hemoglobin and hematocrit levels were unremarkable, excluding clinically occult bleeding. The median delta was 2% [IQR 2.2] ($p=0.463$) for hematocrit and 0.7 mg/dl [IQR 0.95] ($p=0.673$) for hemoglobin. Pre- and postintervention bilirubin levels differed insignificantly by a median of 0.6 mg/dl [IQR 0.28] ($p=0.502$).

Beyond the 6-month study period, a post-liver transplant patient developed a subcapsular biloma 9 months after plug embolization within the previously obliterated tract. At that time, the patient had progressive cholestasis due to worsening of sclerosing cholangitis within the graft. The plug marker was in a stable position. The biloma resolved after endoscopic intervention.

Migration

Early plug migration within 24 hours occurred in the above patient who had a fistula for 3 days until endoscopic biliary decompression. In the second clinical failure case mentioned above, the plug marker was in a stable position. Five late plug marker losses were noted. In these cases, the tracts healed without delay and no migration-related biliary obstruction or tract reopening occurred. Four of the five late marker losses were encountered in cases with non-dilated ducts at 30, 123, 130, and 286 days. 3 months after plug embolization, the fifth marker migrated into a dilated common hepatic duct in a case with a malignant stenosis.

As a result, clinical failure occurred in 2 out of 13 patients including one case of early plug migration resulting in a 15.4% rate of Grade 3 AEs.

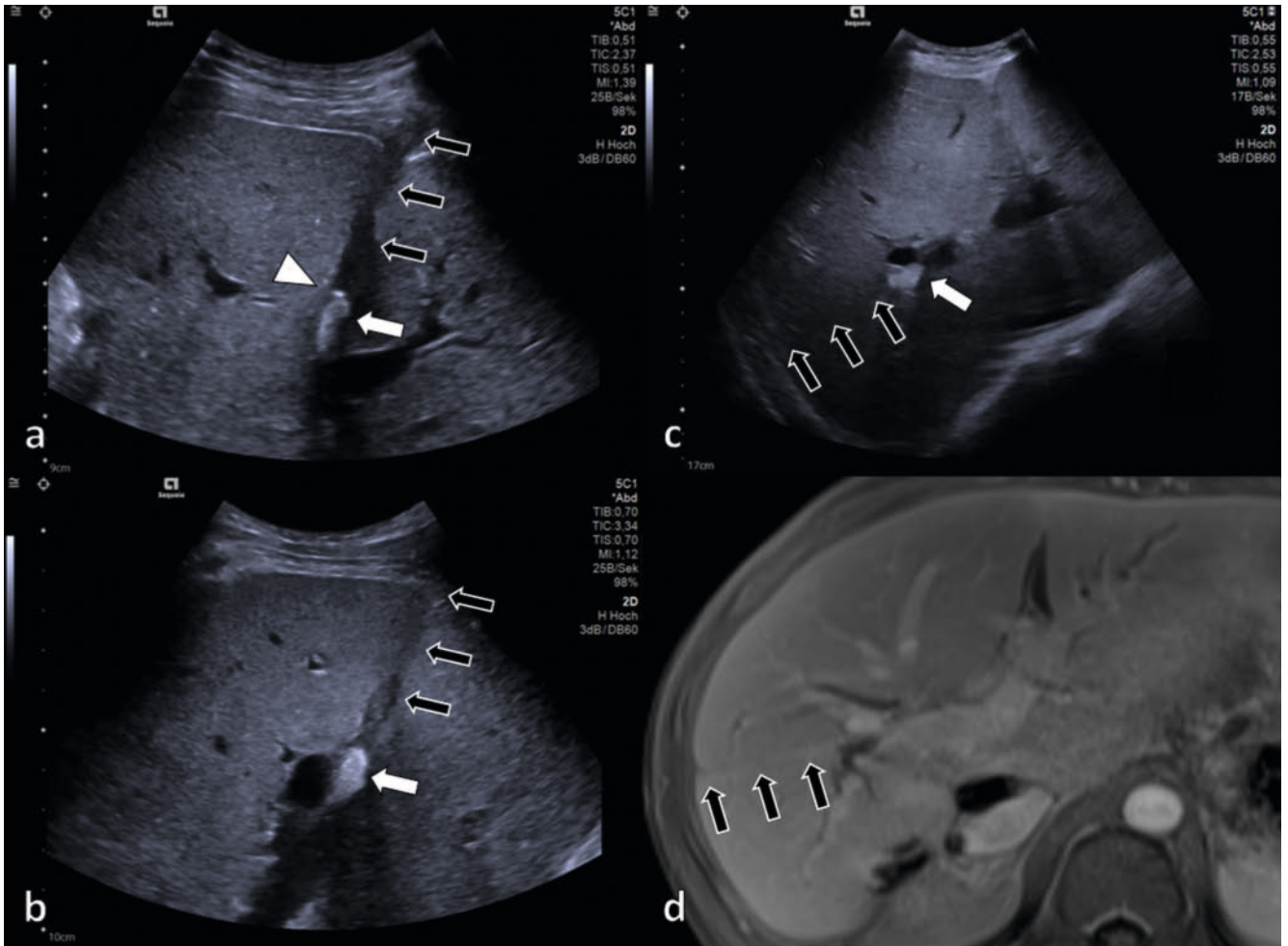
Oversizing

Bile duct diameters at the PTBD entry point ranged from 3 to 10 mm (median 5 mm [IQR 1.37]). The diameter of the tract within the liver parenchyma ranged from 3 to 10 mm (median 7 mm [IQR 2]). The median plug-to-duct oversizing was 173% [IQR 60] and the median plug-to-tract oversizing was 86% [IQR 50]. Regarding plug-to-tract oversizing in patients with immediate tract closure, the median oversizing was 150% [IQR 125] in the dilated subgroup and 76% [IQR 14.5] in the non-dilated sub-

► **Table 2** Procedure data and follow-up.

Patient	Plug number	PTBD/STBD diameter (Fr)	Catheter dwell time (days)	Dilated bile ducts	Plug-to-tract oversizing (%)	Technical success	Clinical success	Detected plug marker migration (days after implantation)	Tract obliterated within 6 months	Plug marker detectable on imaging (months)	Adverse events/findings during follow-up	Overall follow-up (months)
1	1	8.5	65	Y	300	Y	Y	56	Y	10	The patient died 16 months after plug embolization due to CRC progression	16
2	2	14	242	Y	50	Y	Y		Y	15	Subcapsular biloma within the former liver tract 9 months after embolization due to PSC progression	15
3	3	8.5	41	Y	100	Y	Y		Y	2	The patient died 2 months after plug embolization due to CCC progression	2
4	4	12	97	N	71	Y	Y		Y	6		6
5	5	12	62	N	71	Y	Y		Y	12		12
6	6	10.2	68	N	50	Y	Y	30	Y	1		20
7	7	10.2	44	N	71	Y	Y		Y	6		6
8	8	8.5	85	Y	33	Y	N		N	11	Bilio-cutaneous fistula	15
9	9	8.5	15	N	100	Y	Y		Y	4	Lost to follow-up after 4 months	4
10	10	10.2	10	N	71	Y	Y		Y	14		14
11	11	8.5	5	N	100	Y	Y		Y	6		6
12	12	14	460	Y	20	Y	N	1	Y	0	Bilio-cutaneous fistula	9
13	13	8.5	49	N	NE	Y	Y	130	Y	4		10
14	14	8.5	54	N	NE	Y	Y	286	Y	4		10
15	15	6	54	N	NE	Y	Y	123	Y	10		10

Abbr.: CCC: Cholangiocarcinoma; CRC: Colorectal cancer; Fr: French; N: No; NE: Not evaluated; PSC: Primary sclerosing cholangitis; PTBD: Percutaneous transhepatic biliary drainage; STBD: Surgically placed transhepatic biliary drainage; Y: Yes



► **Fig. 3** Visibility of the plug on imaging. B-mode ultrasound images at 17 hours **a**, 3 months **b**, and 6 months **c** after plug embolization. The expanded polymer (white arrow) is visible in a stable position as an echogenic structure within the progressively obliterating liver tract (black arrows). A sharp reflex indicates the proximal marker (white arrowhead). **d** Transverse contrast-enhanced fat-saturated T1-weighted 3D Volumetric Interpolated Breath-hold Examination magnetic resonance image 5 months after plug placement showing a thin scar remnant (black arrows) of the healed liver tract. The plug does not induce artifacts.

group. In the 2 cases of clinical failure, the plug-to-tract oversizing was considerably lower (33% and 20%). There was no statistically significant association between clinical success and the presence of non-dilated or dilated ducts ($p=0.095$). The association between clinical success and more than 50% plug-to-tract oversizing was statistically significant ($p=0.015$).

Visibility on imaging

The plug was visible as an echogenic structure on ultrasound (► **Fig. 3**). The marker induced minimal beam hardening artifacts on CT images. The plug could not be clearly identified on MRI, especially in the presence of aerobilia. MRI was not affected by plug-related artifacts.

Discussion

The polymer plug was precisely deployed within the liver tract without inadvertent propagation into the bile ducts, even in long

and steep access routes of surgically placed drains (► **Fig. 2**). This is a potential advantage over liquid agents such as gelfoam slurry or glue [2, 5]. Contrary to glue, coils, or metal plugs, the plug polymer degrades. Temporary agents for parenchymal tract embolization are considered superior to permanent materials or agents [11]. As episodes of cholestasis or cholangitis are common after major hepatobiliary surgery, treatment of iatrogenic biliary injury, or liver transplantation, a permanent embolic material may serve as a trigger for chronic or recurrent infection [11]. In addition, unlike certain metallic devices, the polymer plug does not interfere with future liver imaging.

In the present study, tractograms showed that the diameter of the tract could be considerably larger than the size of the indwelling catheter. Steep access angles may contribute to a continuous widening of the tract by repetitive diaphragmatic motion as shown in ► **Fig. 2**. Therefore, to ensure adequate filling of the tract, the plug size should be determined based on the diameter of the hepatic tract, rather than on the size of the indwelling drain. To obtain a more precise estimation of the tract diameter,

it is recommended to perform a contrast-enhanced tractogram after the PTBD/STBD has been replaced over a guidewire by an introducer sheath.

This is particularly important as the clinical failures observed were due to a combination of suboptimal plug sizing and inadequate biliary decompression. As previously reported, biliary decompression is a prerequisite for successful and durable tract occlusion [10]. Regardless of the device used, bile leakage cannot be permanently prevented if the biliary obstruction persists or recurs. For this reason, the plug does not appear to be suitable for patients with multilevel benign or malignant biliary strictures where complete drainage of the biliary system is not feasible (e. g., sclerosing cholangitis or Bismuth ≥ 3).

Based on this preliminary experience, the authors suggest substantial oversizing of more than 50% for this particular plug in relation to the liver tract diameter. In cases where sufficient plug-to-tract oversizing is not possible due to the unavailability of appropriate plug sizes, tract embolization with more than one plug could allow for sustained tract occlusion. However, this needs to be further investigated.

It should also be noted that in the present study the biliocutaneous fistulas occurred after long periods of catheterization (85 and 460 days), as bile leaks are usually more common after shorter catheter dwell times.

The mechanism of clinically inapparent late marker migration remains unclear. One may speculate that this is caused by polymer degradation or inadequate plug integration, which would be of concern as the plug may have negatively impacted the healing of the tract. However, this needs to be studied further with a larger number of cases.

One may discuss whether the use of the plug in the liver tract is covered by the instructions for use. The intended indication for use of the plug is to obstruct or reduce the rate of blood flow in the peripheral vasculature [18]. The instructions do not explicitly state what type of vessel is meant or that the plug has to be deployed exclusively in the lumen of a blood vessel. It is, therefore, our considered opinion that the deployment of the plug in the transition zone between the bile duct and the liver parenchyma, including the portal triad, where the bile duct, peribiliary plexus, branches of the portal vein, and hepatic artery are in close proximity, with the aim of either stopping or preventing bleeding complications and bile leakage, could be considered a combined use in peripheral blood and bile vessels. This is in accordance with the prevailing view in the hepatologic literature regarding the portal triad as a functional vascular-biliary unit, with biliary and vascular structures linked by a close anatomic and functional association [21, 22].

In view of the study results, the plug should be used in appropriate cases after careful consideration. In the authors' opinion, it may be an option for select patients with a definitively decompressed biliary system who are at risk for bleeding complications, including central bile duct puncture with inadvertent passage through large blood vessels and known erosion of the PTBD into accompanying blood vessels with previous bleeding episodes. Patients with benign or malignant multilevel biliary strictures who are at risk for persistent or recurrent bile flow obstruction are not

good candidates for liver tract embolization with the polymer plug.

This study has several limitations. It represents a single institution, non-randomized preliminary experience with a small sample size and a heterogeneous patient population. The efficacy of tract embolization cannot be clearly assessed due to the lack of a control group without embolization.

Conclusion

Polymer plug embolization of the liver tract after PTBD/STBD is technically feasible. The plug could be an option in select cases complicated by patient- or insertion technique-related risk factors for the development of tract-related bleeding AEs where a non-permanent embolic device that can be precisely delivered is desired. However, the plug does not appear to be suitable for patients with multilevel strictures where complete drainage of the biliary system is not possible. Further studies including a larger sample size are needed for appropriate patient selection for embolization using this device.

Clinical relevance

- The biodegradable polymer plug can be precisely delivered within the liver tract.
- Plug sizing should be based on the diameter of the hepatic tract, rather than on the size of the indwelling catheter to ensure adequate filling of the tract.
- Adequate plug-to-tract oversizing and biliary decompression are essential to achieve successful and durable tract closure.
- The plug appears unsuitable for patients with multilevel biliary strictures where complete drainage of the biliary system is not feasible.

Conflict of Interest

R.K. received speaker honoraria from BD and Cordis.

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