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Biodegradable biliopancreatic stents could help conserve health care resources during the COVID-19 pandemic: An observational multicenter study

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ABSTRACT

Background: Considering limited resources for follow-up due to COVID-19, we used biodegradable stents (BPBS) for a range of biliopancreatic diseases.
Aims: This observational multicenter study aimed to evaluate technical safety and give first insights into clinical utility.
Methods: Technical success, clinical success, and necessity of follow-up visits for BPBS placed at three Austrian tertiary care hospitals between April 2020 and January 2021 were retrospectively analyzed.
Results: 63 stents were deployed in 60 patients. Main indications were prophylaxis of post-ERCP pancreatitis (PEP; $n = 30/63$; 48%) and bridging of prolonged waiting times to cholecystectomy ($n = 21/63$; 33%). Median time to surgery was 47 days (range: 136 days). The technical success rate was 94% ($n = 59/63$; 95% CI [0.84, 0.98]). Technical difficulties primarily arose with dislocations. Clinical success was achieved in 90% ($n = 57/63$; 95% CI [0.80, 0.96]). Clinical failure despite successful deployment was caused by papillary bleeding (1 patient) and cholestasis (1 patient). Both required reinterventions. No follow-up visits were needed in 97% of cases ($n = 57/59$; 95% CI [0.88, 1.00]).
Conclusion: Biodegradable stents could help conserve health care resources without compromising treatment standards for PEP prophylaxis, which is particularly valuable in times of restricted resources. First insights into feasibility as bridging to cholecystectomy indicate a favorable safety profile.

1. Introduction

Various clinical settings call for biliary or pancreatic stenting. Indications include, e.g., biliary strictures, prevention of post-ERCP pancreatitis, or choledocholithiasis with failed biliary stone extraction [1–5]. At present, plastic and self-expandable metal stents are most widely used [1,2]. While they are safe and effective, the necessity of follow-up (for, e.g., radiological evaluation of passage, endoscopic exchange or removal) is a disadvantage [2–4,6]. On the one hand, these procedures are an organizational and financial burden for hospitals and patients. On the other hand, failure to retrieve stents can cause adverse events, like stent obstruction and cholangitis [2,5–9].

Absorbable stents are being developed to mitigate this issue [7,10–12]. Ongoing research has led to a biodegradable pancreaticobiliary (BPB) stent design (ARCHIMEDES™ BPS Biodegradable Pancreaticobiliary Stent; amg International, Winsen, Germany) comparable to traditional plastic stents. In addition to a central channel for guidewire loading and flow of fluids, these BPB stents feature a sinusoidal helical-channel shape to facilitate additional flow on the outer surface. Proximal and distal flaps seek to reduce unwanted migration. No special insertion device is needed. Stents are available in three outer diameters (2 mm [6 Fr], 2.6 mm [8 Fr], and 3.4 mm [10 Fr]) and various lengths (ranging from 4 to

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22.5 cm). Different polymeric compositions allow for three degradation profiles (fast [12 days], medium [20 days], and slow [11 weeks]) [8,13]. In a prospective pilot study by Anderloni et al., endoscopic placement of these BPB stents was successful in a variety of indications, with a promising safety profile. Reliable biodegradation was radiologically confirmed in all cases. No patients were readmitted or needed additional treatments during follow-up [8].

Technical feasibility of BPB stents has already been demonstrated. Yet, there is a lack of published clinical experience to recommend usage outside of academic centers.

2. Materials and methods

2.1. Study setting

In the ongoing COVID-19 pandemic, endoscopy centers have now repeatedly been faced with contractions of capacity [14–16]. In order to avert potential complications with extended indwelling times due to unclear prospects for plannable repeat endoscopies and surgeries, we placed BPB stents for a range of pancreatic and biliary diseases. The main indication for pancreatic stents was prophylaxis of post-ERCP pancreatitis. Regarding biliary stents, prolonged and unpredictable waiting times for elective cholecystectomies led to the decision to place biodegradable stents as bridging. The intention was to reduce adverse events, since intervals of more than 2 weeks have repeatedly been associated with recurrent biliary events and heightened surgical conversion rates [17–19].

Based on retrospective observational analysis of these interventions, the aim was to scrutinize previous results on technical feasibility and provide first clinical efficacy data for BPB stents in a non-selected patient population. Specifically, safety regarding endoscopic placement as well as post-procedural pancreatitis and cholangitis was to be assessed.

The study was conducted in three Austrian tertiary care hospitals (University Hospital St. Pölten, Ordensklinikum Linz and Kepler University Hospital Linz). It conforms to the ethical guidelines of the 1975 Declaration of Helsinki. Ethical approval was obtained from the Committee for Scientific Integrity and Ethics at Karl Landsteiner University of Health Sciences (GS1-EK-4/712-2021). All ERCP procedures performed in routine clinical settings between April 2020 and January 2021 were analyzed. Inclusion criteria were 1) age $\geq$ 18 years at time of intervention and 2) usage of an BPB stent. Cases with inability to pass a guidewire through the target duct prior to an attempt at stent placement were excluded.

2.2. Endoscopic procedure and periprocedural clinical care

Written informed consent was obtained from all patients as per local pre-procedural standards. Endoscopic interventions were performed as per indication (e.g., extraction of bile duct stones). If stenting was deemed necessary, stent type (plastic, metal, or BPB) as well as stent characteristics (length, diameter, degradation profile, and number) were chosen at discretion of the clinician performing the procedure. A range of devices was used for pushing, including ERCP cannulae with tapered tips. Regarding BPB stents, only fast and slow degradation profiles were available. To avoid morphologic duct changes [20], endoscopists were limited to fast-degrading stents (12 days) for prophylaxis of post-ERCP pancreatitis. For bridging to cholecystectomy, waiting times of up to several weeks were anticipated due to the ongoing pandemic. Stents with a slow degradation profile (11 weeks) were therefore used exclusively. Except for patients with a life expectancy of less than the anticipated stent degradation time, malignant strictures were considered a contraindication for the use of biodegradable stents.

2.3. Postprocedural follow-up

Patients were evaluated as per local clinical standards. Inpatients were assessed as part of ward rounds. To reduce personal contacts during the ongoing pandemic, clinical practice was adapted and outpatients were followed up via phone. Routine calls were made ten to 14 days after the procedure. For stents with a slow degradation profile, additional calls were conducted after twelve weeks. Patients were asked for symptoms of stent occlusion (e.g., epigastric pain, fever, or jaundice). Furthermore, they were advised to call in should symptoms arise. Since reliable biodegradation of the specific stent design used had already been confirmed in a prospective study [8], no routine radiological assessments of degradation were conducted. Imaging or interventions for stent removal were only ordered in case of clinical suspicion of stent dysfunction.

2.4. Outcome variables

The primary outcome variable was technical success, defined as trans-papillary deployment of the stent into the bile or pancreatic duct with visible drainage of biliary or pancreatic juices.

Secondary outcome variables included clinical success, follow-up visits (for radiological evaluation of passage or repeat endoscopy) as well as the following adverse outcome variables: stent migration; development of post-ERCP pancreatitis, biliary obstruction, or obstructive cholangitis; delayed bleeding; need for an unintended repeat ERCP; need for rescue surgery; transfer to IMCU or ICU; death.

Stent dislocation was defined as immediate proximal or distal movement away from the intended position following deployment. Movement after intervention was termed migration. Post-ERCP pancreatitis was defined according to the revised Atlanta classification (two or more of the following: lipase >3x ULN, epigastric abdominal pain, or imaging evidence of acute pancreatitis). Biliary obstruction was defined as bilirubin $\geq$34 µmol/L or abnormal liver chemistries in combination with imaging showing biliary dilation. Obstructive cholangitis was defined as biliary obstruction with additional evidence of systemic inflammation (fever and/or shaking chills or laboratory evidence of an inflammatory response). Transfer to an intermediate or intensive care unit, surgery due to stent complications, as well as periprocedural death were considered major adverse events. Cases with technical success and freedom from adverse events were termed clinical success.

Clinical courses were analyzed until 12 weeks after stent placement. As cholecystectomies were also performed in external hospitals, surgical data are incomplete. Outcomes in participating centers were tracked until March 2021.

2.5. Statistical analysis

Anonymized data were collected at the three centers and merged for analysis. Categorical variables were reported as frequencies and proportions (for denominators of at least 50). For binomial proportions (with a denominator of at least 50), 95% confidence intervals were calculated using the modified Wald method. Continuous metrics were reported in terms of median and range. All statistical analyses were performed using GraphPad Prism version 9 (GraphPad Software, Inc.; Boston, USA). The raw data are available on request and in accordance with data privacy regulations.

Table 1
Demographics and indications for ERCP.

Demographics	
Age, years [median (range)]	71 (65)
Female sex [n (%)]	27/60 (45%)
ASA score III-IV [n (%)]	34/60 (57%)
Indications for ERCP	**n (%); total 63**
Biliary disease	62 (98%)
- Choledocholithiasis	37 (59%)
- Benign biliary stricture	10 (16%)
- Papillary adenoma (ampullectomy)	7 (11%)
- Malignant biliary stricture	3 (3%)
- Sphincter of Oddi dysfunction	3 (3%)
- Cholangiocellular carcinoma	1 (2%)
- Biliary leak	1 (2%)
Pancreatic disease	1 (2%)
- Chronic pancreatitis	1 (2%)

Table 2
Indications for stent placement during ERCP.

	Stents placed n (%); total 63
Biliary	32 (51%)
- Bridging to cholecystectomy for choledocholithiasis	21 (31%)
- Prophylactic stenting after papillectomy	4 (6%)
- Benign biliary stricture	2 (3%)
- Malignant biliary stricture	1 (2%)
- Bile leak	1 (2%)
- Prophylactic stenting in cholangitis	1 (2%)
- Bleeding after endoscopic papillotomy	1 (2%)
- Slow biliary drainage after endoscopic papillotomy	1 (2%)
Pancreatic	31 (49%)
- Prophylaxis of post-ERCP pancreatitis	30 (48%)
- Pancreatic duct stricture	1 (2%)

3. Results

3.1. Patient and device characteristics

A total number of 60 patients (median age: 71 years; age range: 65 years) had BPB stents placed (Table 1). 34 (57%) of these 60 interventions were done under elevated periinterventional risk (ASA III-IV) [21,22].

Most ERCPs were performed for choledocholithiasis, followed by benign and malignant bile duct strictures (Table 1). Only one procedure was done for pancreatic disease (pancreatic duct strictures due to chronic pancreatitis).

63 BPB stents were deployed (Table 2). Of these, 31 (49%) were pancreatic duct and 32 (51%) were biliary duct stents. With one exception, pancreatic stents were exclusively placed for prophylaxis of post-ERCP pancreatitis (n = 30; 48%). One pancreatic stent was used for treatment of chronic pancreatic duct stenosis. The majority of biliary stents (n = 21; 33%) were placed as bridging to cholecystectomy. The remaining stents (n = 11; 17%) were used for prophylactic common bile duct stenting after papillectomy (n = 4; 6%), biliary leaks, bleeding after endoscopic papillotomy, insufficient biliary drainage, and common bile duct stenoses (each n = 1). On three occasions, both a biliary and a pancreatic stent were deployed in the same session. No multi-stenting of the same duct was performed.

BPB stents with fast degradation profile were used for PEP prophylaxis and insufficient biliary drainage after papillotomy in sphincter of Oddi dysfunction. For bridging to cholecystectomy and treatment of pancreatic duct strictures, slow degradation was chosen exclusively. Stent measurements were: biliary stents 10 Fr x 10 cm, 10 Fr x 8 cm, 10 Fr x 6 cm, and 6 Fr x 4 cm; pancreatic stents 6 Fr x 4 cm and 10 Fr x 8 cm.

Table 3
Technical and clinical outcome variables.

	Total (n = 63) n (%)	Biliary (n = 32) n	Pancreatic (n = 31) n
Stent dislocation	3 (5%)	1	2
Stent release failure	1 (2%)	0	1
Adverse events	4 (6%)	1	2
- Migration	0 (0%)	0	0
- Post-ERCP pancreatitis	3 (5%)	0	2
- Obstruction	1 (2%)	1	0
- Obstructive cholangitis	0 (0%)	0	0
- Delayed bleeding	1 (2%)	1	0
- Reintervention	2 (3%)	2	0
Major adverse events	0 (0%)	0	0
- Transfer to I(M)CU	0 (0%)	0	0
- Rescue surgery	0 (0%)	0	0
- Death	0 (0%)	0	0
Technical success	59 (94%)	31	28
Clinical success	57 (90%)	29	28

3.2. Biliopancreatic stenting

Overall, the technical success rate was 94% (n = 59/63; 95% CI [0.84, 0.98]; biliary stenting: n = 31/32; pancreatic stenting: n = 28/31; Table 3). Technical failures were caused by dislocation (5%; n = 3/63; 95% CI [0.01, 0.14]) and unsuccessful stent release (2%; n = 1/63; 95% CI [0, 0.09]). Clinical success was achieved in 90% (n = 57/63; 95% CI [0.80, 0.96]; biliary stenting: n = 29/32; pancreatic stenting: n = 28/31).

3.3. Prophylaxis of post-ERCP pancreatitis

Technical success for stents placed as prophylaxis of post-ERCP pancreatitis was achieved in 27 out of 30 cases. Two stents dislocated into the main pancreatic duct after release. In one patient, the stent was retrieved from the pancreatic duct. The patient moved on to develop mild pancreatitis. He was discharged three days after the procedure. No issues were reported on follow-up. As for the second patient, concerns about elevated pancreatitis risk with further manipulation led to the decision to leave the stent in place. This patient also suffered from mild pancreatitis but could be discharged on day two. The stent was no longer present on an abdominal X-ray taken 12 days after ERCP. One stent could not be released after placement into the main pancreatic duct. Removal was successful, and a traditional plastic stent was placed subsequently.

All 27 stents successfully deployed in the main pancreatic duct resulted in clinically successful postinterventional courses. No pancreatitis occurred during follow-up. Two cases of lipase elevation did not reach the diagnostic criteria of pancreatitis. They were therefore not regarded as clinical failure.

3.4. Bridging to cholecystectomy

Technical success for biliary stents placed as bridging to cholecystectomy was achieved in 20 out of 21 cases (Fig. 1, a-d). One stent dislocated into the cystic duct while pushing a plastic stent into the pancreatic duct (Fig. 1, e-f). It was initially left in place. Five weeks later, the patient presented with cholangitis, possibly due to insufficient drainage of the common hepatic duct. On reintervention, the stent was removed without issues.

Clinical success was recorded in 18 of these 20 cases. For the remaining two cases, reintervention was necessary. In one patient, cholestasis persisted despite successful stent deployment. For the second patient, papillary bleeding on the second post-

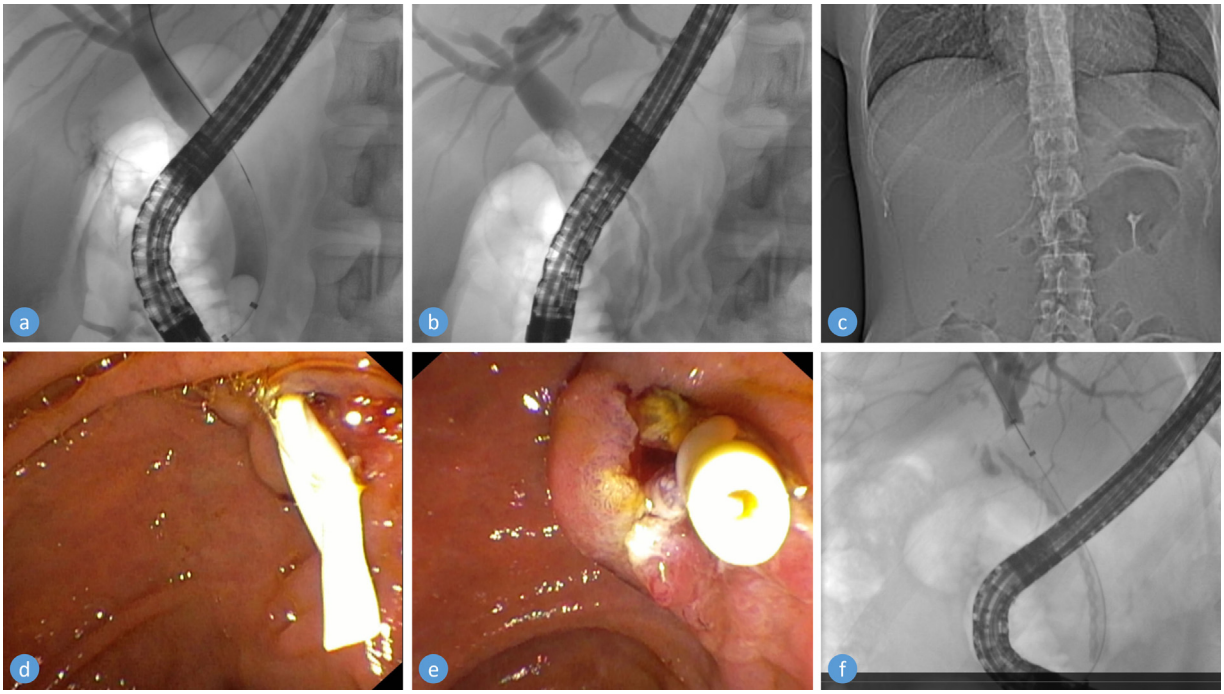

Fig. 1. **(a-d)** Bridging to cholecystectomy in a 27-year-old woman (ASA I) with symptomatic choledocholithiasis. **(a)** Dilation assisted extraction of a single stone in the common bile duct on fluoroscopy. **(b)** 10 Fr x 8 cm biliary BPB stent placed as bridging to cholecystectomy. **(c)** 10 Fr x 8 cm biliary BPB stent on radiography. **(d)** 10 Fr x 8 cm biliary BPB stent in endoscopic visualization. **(e-f)** Stent dislocation in a 78-year-old man (ASA III) with biliary pancreatitis. **(e)** 10 Fr x 10 cm biliary BPB stent placed as bridging to cholecystectomy. **(f)** BPB stent dislocation into the cystic duct. BPB stent, biodegradable pancreaticobiliary stent.

interventional day made exchange for a covered metal stent necessary. One additional case of cholangitis following ERCP showed no obstruction on imaging. The patient was treated with antibiotics. No reintervention was needed. The incident was thus not classified as a clinical failure.

Surgical follow-up data were available for 17 of the 20 successfully placed stents. Two patients refused cholecystectomy, and two patients were not planned for surgery on grounds of prohibitive comorbidities. For the other 13 patients, median time from ERCP to cholecystectomy was 47 days (range: 136 days). The minimum waiting time was 2 days, whereas the longest interval from ERCP to surgery was 19 weeks and 5 days. For only 3 patients, the recommended time frame of 2 weeks was met. Regarding intraoperative circumstances, difficult preparation of Calot's triangle due to adhesions with iatrogenic lesion of the common bile duct was noted in one patient. Conversion to open surgery was required. While the most probable reason was a previous episode of biliary pancreatitis, a foreign body reaction might also have contributed. All remaining cholecystectomies were performed laparoscopically. No further surgical adverse events attributable to the BPB stents were recorded.

3.5. Other indications

Placement was technically successful for all 12 stents (1 pancreatic stent and 11 biliary stents). Regarding the one stent placed for pancreatic duct strictures due to chronic pancreatitis, lipase was elevated >3x ULN after ERCP. The patient stayed asymptomatic. There was no need for reintervention. All other postinterventional courses were unremarkable.

3.6. Potential reduction of follow-up visits

For biliary stents placed as bridging to cholecystectomy, repeat endoscopies were not necessary in 18 out of 20 cases. In both patients needing reintervention, problems became clinically apparent within two days after the index intervention and before discharge. As for the remaining 39 biliary and pancreatic stents (27 stents for prophylaxis of post-ERCP pancreatitis and 12 for other indications), no routine or emergent follow-up endoscopies were needed. Furthermore, patients did not have to undergo radiological examinations to evaluate passage of pancreatic stents. In total, no repeat visits for abdominal X-rays or endoscopies were needed in 97% of cases (n = 57/59; 95% CI [0.88, 1.00]). No patients had to be admitted from outpatient care during follow-up.

3.7. Economic considerations for prophylaxis of post-ERCP pancreatitis

At the participating institutions, plastic pancreatic stents are removed without prior radiological evaluation. The cost of biodegradable stents was consequently related to the cost of equivalent plastic stents including removal costs. Applicable compensation guidelines value a gastroscopy with sedation and removal of a stent at up to USD 283.23 (EUR 290.00) [23]. Transportation costs for distances of up to 50 km amount to USD 12.11 (EUR 12.40) [24]. With a price of approximately USD 127.81 (EUR 130.00) for a traditional plastic stent with pusher, direct health care costs added up to USD 423.15 (EUR 432.40). The biodegradable stents used were priced at USD 684.07 (EUR 700.00) per piece. There were no follow-up costs for X-rays or endoscopic stent removal after discharge. In total, the difference in direct health care costs between plastic and biodegradable stents was thus estimated at USD 260.92 per case.

4. Discussion

The results of this multicenter study support recent data that BPB stents can be placed safely for securing drainage of both biliary and pancreatic ducts. A significant advantage is that existing

equipment can be utilized without modification. Technical issues were rare and did not result in major adverse events. For pancreatic stenting, our data show that loss of the stent into the pancreatic duct after release is a possibility and warrants attention by endoscopists. In both cases recorded, patients suffered from mild, self-limiting pancreatitis. Regarding the stent left in place, it is reasonable to assume that sufficient drainage was maintained by the helical-channel design with flow through the inner lumen as well as on the outer surface. Given the self-degrading nature, no intervention to remove the dislocated device was necessary. It might therefore be safer to forego attempts at removal, as further manipulation could increase the risk of pancreatitis. One possible explanation for these dislocations as well as for issues with stent release could be the 6 Fr pancreatic stents' V-shaped flap design. Usage of ERCP cannulae with tapered tips for pushing might also have contributed, as these tips can get stuck in the V-shape at the distal stent end. Design improvements to the flaps could alleviate these issues. At the moment, it might be recommendable to use devices with non-tapered tips for pushing. Though less common in our data, dislocation can also happen when deploying stents in the biliary duct, particularly with subsequent manipulation.

Beyond aspects of technical safety, we give first insights into clinical utility for areas especially important in resource-constrained settings, like the ongoing COVID-19 pandemic [14–16,25]. By reducing the number of follow-up visits and endoscopies necessary for stent retrieval, biodegradable stents could prove to be valuable for conserving health care resources while upholding quality of care. We identified and provided first results for two areas where health care providers and patients might benefit from BPB stents: prophylaxis of post-ERCP pancreatitis and bridging to cholecystectomy.

Temporary prophylactic stenting of the main pancreatic duct is established in high-risk situations for post-ERCP pancreatitis [2]. These stents must pass spontaneously or be removed five to ten days after deployment to prevent irreversible duct changes. Until now, radiological follow-up evaluations or repeat endoscopies have therefore been unavoidable [2]. Using BPB stents, we could eliminate routine follow-up visits, with satisfactory technical success rates as well as favorable clinical outcomes. In light of limited capacity, scarce endoscopy slots could be made available for other interventions. Another promising aspect is the reduction in endoscopies for patients with increased periinterventional risk. As these interventions call for the attendance of a second physician or are done under anesthesia, organizational complexity could significantly be reduced with fewer procedures [21,22].

From an economic perspective, biodegradable stents exhibited an estimated direct cost disadvantage of USD 260 per case. Though the difference is likely to narrow if indirect societal impacts (e.g., lost productivity, paid sick leave, or disrupted schedules) are factored in, these costs are difficult to objectify and rarely budgeted. Routine replacement of plastic with biodegradable stents is therefore not feasible at the current market price. For special use cases, the benefit of fewer interventions can still outweigh the added cost. Examples include limitations on endoscopy slots, patients with elevated periinterventional risk, and end-of-life situations. When time is the limited resource, any reduction in follow-up procedures can translate to quality of life gains.

Concerning choledocholithiasis, biodegradable stents might help bridge prolonged waiting times to surgery. The European Society of Gastrointestinal Endoscopy recommends performing laparoscopic cholecystectomy within 2 weeks from ERCP to minimize adverse events and surgical conversion rates [17]. Even before COVID-19, this interval was often overstepped [26–28]. In the ongoing pandemic, plannable surgeries for benign diseases have regularly been de-prioritized, further extending waiting times for cholecystectomies [29]. A corresponding picture was painted in our dataset, with the recommended time window only being adhered to for a fraction of patients. This contraction of surgical capacity puts patients with cholelithiasis at risk of recurrent biliary obstruction and, subsequently, cholangitis, cholecystitis or pancreatitis [26,29–31]. Evidence is increasing that temporary stenting of the common bile duct could prove to be a viable remedy: (a) It is already established for initially irretrievable biliary stones as bridging to bile duct clearance [1,17,31,32], (b) long-term stenting has repeatedly been discussed as an option for patients unfit for elective surgical procedures [32–34], and (c) a recent randomized, controlled clinical trial for stenting as bridging to cholecystectomy in severe biliary pancreatitis showed a statistically significant reduction of recurrent biliary events [19]. So far, concerns about stent obstruction in the waiting time and possible negative repercussions for surgical conditions have impeded widespread usage of traditional plastic stents in this indication [17,35,36]. Since biodegradable stents do not have to be exchanged or removed, a certain degree of protection from recurrent biliary events while waiting for surgery might be provided. Again, our results show a promising trend, with no major adverse events, satisfactory surgical conditions and outcomes, and a marked reduction in follow-up endoscopies. Whereas concerning rates of post-procedural obstructive cholangitis were repeatedly described for braided PDX stents, our data are in line with previous results for the specific type of BPB stents used [7,11,37,38]. Obstruction during degradation might indeed be prevented by the dual-drainage design as intended.

For indications like chronic pancreatitis or bile duct stenoses, our experience is anecdotal. That no technical issues or adverse clinical events were recorded in our dataset is still encouraging.

Limitations include the retrospective and observational study design, the small sample of patients, and the limited availability of different stent lengths and degradation profiles. The choice of stent types based on individual clinical judgement entails a significant risk of bias. That more than half of the patients in our study presented with elevated periinterventional risk (ASA III or higher) nevertheless underlines the safety of the biodegradable devices used. Apart from methodological caveats, bridging to cholecystectomy is not yet regarded an established indication for biliary stenting, even though significant rates of recurrent biliary events have repeatedly been reported with longer intervals to surgery. In a non-pandemic setting, a prospective, randomized, and controlled design to evaluate treatment effects would clearly have been preferable. Considering the clinical reality of a global health care crisis, it was opted to use the stents available to the benefit of the patients at risk. Though purely descriptive, results are reassuring. While the general feasibility of BPB stents has been demonstrated before, the data presented here offer additional insights regarding safety, device handling, and opportunities for design improvements. Further research might eventually translate to changes in guidelines. For pancreatic stents placed as prophylaxis of post-ERCP pancreatitis, non-inferiority compared to plastic stents must be demonstrated in prospective, randomized settings. A cost-benefit-analysis modeling direct and indirect effects for health care providers and society is also required. Regarding bridging to cholecystectomy, studies are needed to confirm a reduction in recurrent biliary events and, subsequently, lowered morbidity and mortality. Furthermore, repercussions for surgical conditions must be evaluated. Here, only studies with long-term follow-up in cooperation with surgical departments will provide definitive answers.

Conflict of interest

The authors declare that they have no conflicts of interest.

Ethics approval

Committee for Scientific Integrity and Ethics at Karl Landsteiner University of Health Sciences (GS1-EK-4/712-2021).

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Supplementary materials

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