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ORIGINAL ARTICLE

Clinical outcome of endoscopic treatment of symptomatic Hepaticojejunal anastomotic strictures after pancreatoduodenectomy

David M. de Jong[1], Yoklan L. Mulder[1], J.L. van Dam[2], Bas Groot Koerkamp[2], Marco J. Bruno[1] & Pieter Jan F. de Jonge[1]

[1]Department of Gastroenterology and Hepatology, Erasmus MC University Medical Center, Wytemaweg 80, 3015 CN, Rotterdam, the Netherlands, and [2]Department of Surgery, Erasmus MC Cancer Institute, Wytemaweg 80, 3015 CN, Rotterdam, the Netherlands

Abstract

Background: Hepaticojejunostomy anastomotic stricture (HJAS) is an adverse event after pancreatoduodenectomy (PD) which can result in jaundice and/or cholangitis. With endoscopy, HJAS can be managed. However, few studies report the specific success and adverse event rates of endoscopic therapy after PD.

Methods: Patients with symptomatic HJAS, who underwent an endoscopic retrograde cholangiopancreatography at the Erasmus MC between 2004-2020, were retrospectively included. Primary outcomes were short-term clinical success defined as no need for re-intervention <3 months and long-term <12 months. Secondary outcome measures were cannulation success and adverse events. Recurrence was defined as symptoms with radiological/endoscopic confirmation.

Results: A total of 62 patients were included. The hepaticojejunostomy was reached in 49/62 (79%) of the patients, subsequently cannulated in 42/49 (86%) and in 35/42 patients (83%) an intervention was performed. Recurrence of symptomatic HJAS after technically successful intervention occurred in 20 (57%) patients after median time to recurrence of 7.5 months [95%CI, 7.2–NA]. Adverse events were reported in 4% of the procedures (8% of patients), mostly concerning cholangitis.

Discussion: Endoscopic treatment for symptomatic HJAS after PD has a moderate technical success rate and a high recurrence rate. Future studies should optimize endoscopic treatment protocols and compare percutaneous versus endoscopic treatment.

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Correspondence.

Pieter Jan F. de Jonge, Department of Gastroenterology and Hepatology, Erasmus MC University Medical Center, Rotterdam the Netherlands. E-mail: p.dejonge@erasmusmc.nl

Introduction

Development of a hepaticojejunostomy anastomotic stricture (HJAS) is an important adverse event after pancreatoduodenectomy (PD) observed in 2.6–8.0% of patients.[1–3] It usually occurs within the first 3 years after surgery.[4,5] HJAS impairs bile flow, and often results in jaundice, recurrent cholangitis, choledocholithiasis or even liver abscesses. Restoration of bile flow is essential and intervention is therefore often indicated.

Initial treatment modalities for HJAS are stricture dilation by means of surgical revision, percutaneous transhepatic biliary drainage (PTBD) or endoscopy. Although PTBD has high success rates, it is also associated with several adverse events, such as bleeding and cholangitis, that necessitate re-intervention.[6–9] Patients may experience a decrease in quality of life following PTBD. This is due to the external catheter that is left in situ, which can lead to pain, bile leakage and re-interventions. Endoscopic therapy has been suggested as an alternative treatment modality, which includes balloon dilatation of the HJAS and/or biliary stent placement, and has been associated with shorter hospitalization and fewer procedures as

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compared to PTBD.[9] However, identifying the hepaticojejunostomy (HJ) site by endoscopy may be difficult, as deep intubation of the endoscope can be hampered by loop formation, postoperative adhesions and sharp angulated anastomoses. In addition, cannulation of the bilio-digestive anastomosis can be cumbersome, as the direction of cannulation is not always in direct line with the working channel of the endoscope and in patients with Roux-Y reconstruction reaching the HJ site is more difficult. Also the traditional enteroscopes limit the degrees of freedom you have regarding scope manipulation and the devices you can use through the scope.

The available evidence to guide decisions on the use of endoscopic therapy mostly comes from small uncontrolled retrospective studies from Asia,[4,10–12] with only few reports from Western centres.[13,14] A systematic review and meta-analysis of Inamdar et al. reported a low procedural success rate for endoscopic treatment for HJAS (61.7%).[15] The validity of this outcome however was limited by the low number and heterogeneity of the studies, but also the different definitions of procedural success. For example, it seems important to differentiate PD from other surgical procedures with HJAS, i.e. liver transplantation, hemi-hepatectomy, to guide decisions on the appropriate biliary drainage strategy. Even in a homogenous PD population however, individual outcome data are scarce.

Overall, there are only a few studies reporting on the clinical success rate of endoscopic therapy in patients with HJAS after PD. The current study therefore aimed to analyse the success rate (visualization rate, cannulation rate and interventional success rate) of endoscopic therapy for HJAS and identify predictive factors for successful treatment in a well-defined PD population.

Methods

Study design and study population

A single-centre retrospective cohort study was performed at the department of Gastroenterology and Hepatology of a Dutch tertiary referral centre for pancreaticobiliary diseases. All patients who underwent an endoscopic biliary intervention (EBI) between November 2004 and December 2020 for treatment of a symptomatic HJAS after PD, were identified from the local endoscopy database. In this dedicated electronic endoscopic reporting system all endoscopic procedures and reports are prospectively registered. Patients were eligible for inclusion if a benign symptomatic HJAS had been confirmed on cross-sectional imaging prior to EBI. HJAS was diagnosed in case of intrahepatic dilatation of the bile ducts and/or enhancement of the bile duct without a mass on cross-sectional imaging. The indications for EBI were clinical symptoms including fever, cholangitis, jaundice, pain, stone formation and liver abscesses.

In our center, EBI was the first choice of treatment for all patients presenting with a symptomatic HJAS. PTBD was only performed in case there was an contraindication for undergoing EBI. Some patients that were referred from other hospitals and initially underwent PTBD were also treated by EBI initially at our center. Previous treatment of HJAS by PTBD or ERCP prior to PD were both not considered an exclusion criterion. Patients with suspicion of a malignant HJAS or surgical revision of HJAS prior to initial ERCP were excluded from the study. The work-up to exclude recurrent malignancy consisted of cross-sectional imaging, tumour markers, and in selected cases a percutaneous biopsy. Patients who had other indications for a biliary-enteric anastomosis than PD such as liver transplant recipients or post-cholecystectomy injury revisions, were excluded. This study was conducted according to the Helsinki declaration guidelines and was approved by the ethics committee of the Erasmus MC University Medical Centre, Rotterdam, the Netherlands (MEC-2020-0476).

Endoscopic biliary intervention

All patients underwent EBI under either conscious (midazolam and fentanyl) or propofol sedation. Antibiotic prophylaxis was administered according to local clinical practice guidelines, such as cholangitis, but not routinely to every patient. All interventions were performed or supervised by interventional gastroenterologists experienced in EBI (by four endoscopists with 100–200 ERCP per year or trainee under supervision of one of them). EBI was performed using a paediatric colonoscope (Olympus PCF-H180) or standard colonoscope (Olympus CF-H180). Whenever the HJAS was not reached, the endoscopist could switch to a single balloon enteroscope (Olympus SIF-Q180) or double balloon enteroscope (Fujinon EN-580T). A cap on the tip of the endoscope was routinely used.

At first, the endoscope was introduced into the afferent loop identifying the HJ site. From 2010 onwards CO_2 insufflation was used in all procedures. Subsequently, the bile duct was cannulated with a single or double lumen catheter over a guidewire, dependent on the diameter of the orifice. Contrast enhanced visualization under fluoroscopic control was performed to examine the severity of HJAS stenosis, and the presence of choledocholithiasis or additional strictures. In our clinical practice, HJAS at first EBI procedure was treated by balloon dilatation and recurrences were treated by balloon dilatation in combination with plastic and/or self-expandable metal stent (SEMS) placement. Occasionally, at the discretion of the endoscopist, plastic stents were placed at initial ERCP. Balloon dilatation was performed under endoscopic visualization and fluoroscopic monitoring by using a controlled radial expansion (CRE) balloon dilation catheter (CRE RX Biliary Balloon dilatation catheter, Boston Scientific). The size of the balloon depended on the diameter of the upstream dilated bile duct. The balloon was gradually inflated with a diluted contrast agent target and maintained inflated in position for at least 30 s. Stent placement was performed with either 7 Fr or 10 Fr straight plastic stents or fully covered SEMS with a maximum diameter of 8 mm. In case intraductal stones were present, these were removed by an extraction balloon or basket.

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Study definitions

The primary outcome measure was successful cannulation/opacification and interventional success. Cannulation and opacification success was defined as successful scope insertion to afferent loop, identification of the HJ orifice, biliary cannulation and cholangiography. When a stricture was successfully dilated with a balloon, a stent was placed or stone extraction was performed, this was defined as interventional success. The secondary outcome measure was short – and long term clinical success, short term clinical success was defined as no need for re-intervention at three months after endoscopic technically successful intervention. Long term clinical success was defined as the absence of recurrence of HJAS after intervention for a period of twelve months. Recurrence was defined as recurrence of symptoms with radiological or endoscopic confirmation of recurrent of refractory HJAS. Scheduled EBI for progressive stenting was not counted as failure. Adverse events were defined according to the ASGE guidelines.[16]

Data collection

Each individual patient record was systematically reviewed by two reviewers. Data were anonymously collected on demographical factors (*e.g.*, age, sex), surgical factors (*e.g.,* type of resection, pathology outcomes), clinical factors (*e.g.,* symptoms), EBI characteristics (*e.g.,* stent placement, balloon dilatation, other) and PTBD characteristics (*e.g.,* stent placement, drain placement). Patients' records were reviewed for recurrences of symptomatic HJAS and subsequent re-interventions. Patients were followed until death or last follow-up.

Statistical analysis

Descriptive statistics were used for continuous and categorical variables. Continuous variables were described using mean and standard deviation for normally distributed variables or using median and range for non-normally distributed variables. Categorical variables were described using frequencies and percentages. The Shapiro Wilk test was used to check the normality of the variables. Univariate logistic regression was performed. A Kaplan–Meier curve with competing risk analysis was constructed with recurrence as primary outcome using 'ggsurvplot' function. Patients were censored at time of death or loss to follow-up. A 2-sided p-value of <0.05 was considered statistically significant. The statistical analyses were performed using R Version 4.0.3.

Results

Baseline characteristics

During the study period, a total of 62 patients underwent an ERCP for benign symptomatic HJAS. The majority of patients were female 36 (58%) with a median age of 69 years [IQR: 59–75]. Thirty-seven patients (60%) had undergone a pylorus-resecting PD, 25 patients (40%) underwent a pylorus-preserving PD (PPPD). Roux-Y reconstruction was performed in 8 patients (13%). PD was performed for malignant disease in 32 (52%) patients. The majority of patients presented with an episode of cholangitis (62%). Jaundice without cholangitis was the presenting symptom in 12 patients (18%). Prior to ERCP, four patients (7%) had one or more percutaneous treatments for HJAS. Median follow-up time after initial ERCP was 21.1 months [IQR: 6.2–43.1]. Baseline characteristics are shown in Table 1.

Visualization of HJ site, cannulation and interventional success

The HJ could be identified by endoscopy in 49 of the 62 patients (79%). This was achieved at first ERCP in 44/62 patients (71%). Twelve patients underwent a 2nd ERCP identifying the HJ in another five patients. In the 13 patients without visualization of the HJ, 3 patients had a Roux-and-Y reconstruction. DBE was used in four, SBE in two and a colonoscope in seven.

Cannulation and subsequent opacification of the bile duct was performed in 42 of the 49 (86% of those in whom the HJ was visualization, 68% of the total cohort). In one patient a wide-open HJ was found with no relevant abnormalities of the bile

Table 1 Characteristics of the patients at baseline

Characteristics	Symptomatic HJAS (n = 62)
Female sex – no. (%)	36 (58.1%)
Age at diagnosis HJAS (year) – Median (IQR)	69 (59–75)
Surgery type – no. (%)	
- pylorus-resecting PD[a]	37 (59.7%)
- pylorus preserving PD[b]	25 (40.3%)
Roux-Y reconstruction – no. (%)	8 (12.9%)
Robot-assisted PD – no. (%)	19 (30.7%)
Biliary drainage prior to surgery – no. (%)[c]	17 (27.4%)
Pathology – no. (%)	
- Benign	30 (48.4%)
- Malignant	32 (51.6%)
Time to HJAS in months from surgery – median (IQR)	13.1 (4.9–45.8)
Symptoms – no. (%)[d]	
- Cholangitis	37 (59.7%)
- Jaundice	24 (38.7%)
- Pain	24 (38.7%)
- Stone formation	12 (19.4%)
- Liver abscess	1 (1.6%)
Percutaneous treatment prior to ERCP – no. (%)	4 (6.4%)

[a] one patient with additional total pancreatectomy.
[b] one patient with additional extended right hemi-hepatectomy.
[c] missing in 11 patients.
[d] multiple symptoms per patient are possible.

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ducts and further intervention was not indicated. In the six patients without successful cannulation, the reason was inadequate scope position in two, intestinal wall perforation with catheter, and a severe HJAS in three that could not be passed by a catheter or wire.

In the 42 patients with successful cannulation, a technically successful intervention was performed in 35 patients (83% in successful cannulation group, 57% of total cohort) and treatment was not indicated in seven patients (17% in successful cannulation group, 11% of total cohort). In these seven patients no clear stenosis was found upon cholangiography. In the 35 patients with an intervention, this consisted of balloon dilatation in 25, plastic stent placement in seven, and another treatment type in three (stone removal, surgical anastomotic stent removal, and extraction of a percutaneously inserted uncovered SEMS). A flowchart of these patients is shown in Fig. 1. Two cases of successful balloon dilatation of a HJAS are shown in Video 1 and Video 2.

Supplementary video related to this article can be found at https://doi.org/10.1016/j.hpb.2023.05.362

Clinical success

Short-term clinical success at three months was achieved in 29 of the 35 patients (83%), who underwent an endoscopic intervention (i.e. 48% of the total cohort). In the remaining six patients, whom all had recurrence of symptoms related to cholestasis, a repeat EBI was performed within 3 months for suspected symptomatic HJAS recurrence. Long-term clinical success at twelve months was achieved in 20/35 patients (57%) (i.e. 32% of the total cohort).

As shown in Fig. 2, 15/20 recurrences (75%) occurred within one year. These were treated by balloon dilatation in twelve patients, plastic stent placement in two, and SEMS placement in one. One patient developed a cholangitis due to an occluded SEMS. In five patients a recurrence was identified after one year follow-up, for which balloon dilatation was performed in three and stent placement in two. Eight patients developed a second recurrence, three patients developed a third recurrence and two patients developed a fourth recurrence. Overall, 20 (57%) patients developed a recurrence with a median follow up time of 17.9 months [IQR: 10.6–40.6]. Median time to recurrence was 7.5 months [95%CI: 7.2 – NA].

A total of three patients (9%) underwent surgical revision: one patient developed a second recurrence after which surgical revision was indicated; one patient developed a recurrence after placement of a SEMS and the other patient finally underwent surgical revision after the fourth recurrence. During follow-up, 6/35 patients (17%) died, of which five died due to recurrence of malignancy and one due to a stroke.

Predictive factors for HJAS visualization, technical success and clinical success

To analyse potential predictive factors for HJAS visualization, visualization and opacification success and short term clinical success, univariate logistic regression analysis was performed (Tables 2, 3). Pylorus-resecting PD was associated with lower visualization and opacification success [OR: 0.32; 95%CI: 0.11–0.90, p = 0.034]. No factors were identified that were associated with visualization or short term clinical success (see Tables 2, 3).

Post-procedure adverse events

Adverse events occurred in five (8%) patients. Of the 142 ERCPs that were performed, five (4%) were associated with an adverse event. Post-procedure cholangitis was reported in two patients (3%). Post-ERCP bleeding was reported in one (2%), which was self-limiting. In two patients (3%) a catheter-guided perforation of the intestinal wall occurred, which was treated directly by clipping the perforation site and antibiotic treatment.

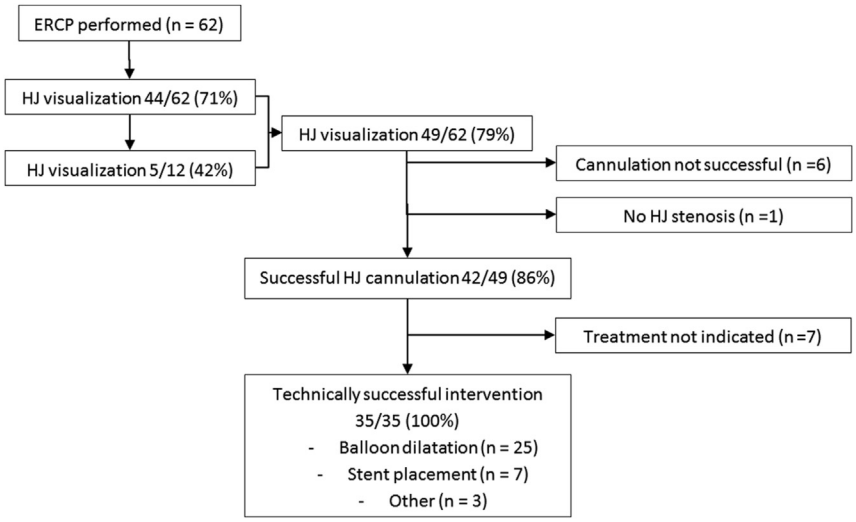

Figure 1 Flow chart of patients undergoing ERCP for suspected HJAS after PD

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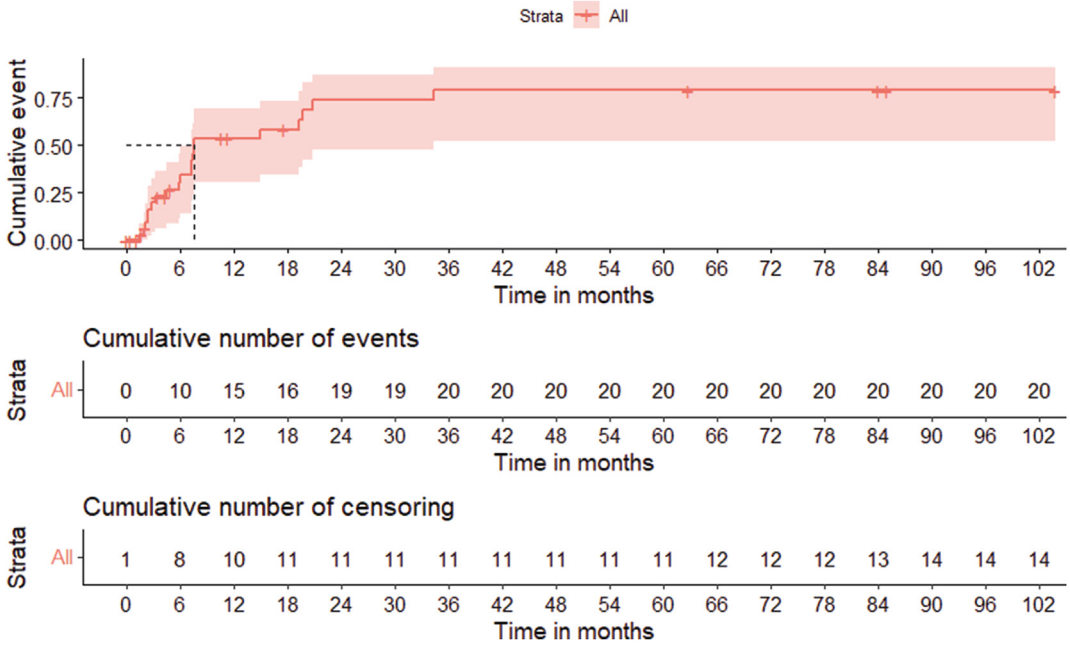

Figure 2 Kaplan–Meier curve for overall recurrence probability after technically successful HJAS intervention

Discussion

In the present study we report the outcomes of endoscopic treatment in patients with a symptomatic HJAS after PD. Cannulation and opacification was successful in 65%, with technically successful endoscopic intervention in 54%. On the long term, endoscopic treatment benefitted patients only in 57% (32% of total cohort). Although recurrence after treatment was relatively frequent, necessitating additional endoscopic intervention, these treatments were safe and associated with a low adverse event risk. However, 40% of the patients developed a second recurrence after treatment of the initial recurrence. These findings suggest that endoscopic treatment with balloon dilatation could be considered as a safe but at most only a moderately effective first line treatment for HJAS.

In the current literature, there are only few studies available reporting on the efficacy of endoscopic treatment of HJAS.[4,6,10,12,13,17,18] There are no studies available that solely focus on the effectiveness of EBI in PD patients with symptomatic HJAS. Most studies include other biliary-enteric anastomosis as well. In a German study, overall success (definition of technical success comprised reaching the HJAS, successful cannulation and biliary intervention of any type) of 216 endoscopic procedures among 120 patients with prior Whipple surgery was 56.7%, with an adverse event rate of 6.5% per procedure.[6] Our study showed a similar technical success rate and adverse event rate for endoscopic procedures. However, comparison of the two studies is difficult, as the indication in the German study of the intervention was unspecified. Our study only included patients with high suspicion of symptomatic HJAS, whereas this study included all patients undergoing ERCP to restore biliary drainage with Billroth-II, Roux-Y or Whipple anatomy for different reasons.

Hammad et al. compared endoscopic versus percutaneous treatment modalities in patients with a HJAS after liver transplantation, complicated cholecystectomy, or PD.[9] They reported comparable success rates but fewer procedures, less hospitalization days, and shorter duration to reach clinical success for the endoscopic treatment arm. This study was limited, however, by the very small number of only nine included PD patients, and a subset analysis was not performed. Our study is the first to assess the effectiveness of EBI in a well-defined homogeneous population of only PD patients with uniform definitions of HJAS.

Although endoscopic treatment appeared to be moderately effective in our patient group on the short term, 57% of the patients required a second endoscopic intervention because of recurrence of HJAS. This is in line with previous reports. Mizukawa et al. reported on the use of endoscopic balloon dilatation using short double-balloon enteroscopy in 46 patients with PD, with a similar recurrence rate (51%) of HJAS after initial treatment as we have found.[4] Time to recurrence was relatively long, with a median of 1.2 years [IQR: 0.6–2.9] after balloon dilatation and subsequent naso-biliary drain placement, while in our cohort in the 75% of the recurrences occurred within one year after ERCP.

Considering the relatively high rate of recurrences after endoscopic treatment, the question remains how treatment protocols can be optimized to further increase long term success rates. Currently there a no standard treatment protocols available. Prospective studies comparing different endoscopic treatment strategies are lacking. In a retrospective study, patients with

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Table 2 Results of univariate analysis of potential predictive factors for HJ visualization and visualization/opacification success

	HJ visualization			Visualization and opacification success		
	OR	CI	P	OR	CI	P
Pylorus-resecting PD	0.5	0.14–1.72	0.27	0.32	0.11–0.90	0.034*
Robot surgery (Yes)	6.97	1.22–132.2	0.07	2.07	0.68–6.83	0.21
Roux Y reconstruction	0.38	0.08–2.09	0.23	0.41	0.78–1.86	0.26
Malignant disease	0.39	0.10–1.39	0.16	0.76	0.27–2.07	0.59

treatment-naïve HJAS after four different types of hepatobiliary surgery, were treated by both balloon dilatation and plastic stenting.[19] At three and six months after ERCP, balloon dilatation and plastic stent placement were repeated. After a median of 21.3 months of follow-up, recurrence was observed in 10.7% with a median time to recurrence of 4.3 months. This lower recurrence rate may be due to direct placement of multiple plastic stents after balloon dilation or by the routinely performing a repeat ERCP. Another recent retrospective study of Tomoda et al. compared balloon dilation combined with stenting versus balloon dilation alone and found that combination therapy resulted in longer bile duct patency.[5] However, plastic stent placement was associated with stent occlusion or migration, both necessitating re-ERCP.

Standard deployment of a fully covered SEMS could also be considered. A study on the use of fully-covered SEMS in patients with a HJAS, reported a low recurrence rate of 5.9% during a median follow up period of 11.9 months [IQR: 7.5–18.0].[20] This study consisted of a heterogeneous group of patients including 14 patients after PD with both refractory and untreated HJAS. Fully-covered SEMS were removed endoscopically after three months, if migration had not yet occurred. An advantage of fully-covered SEMS is that patency is improved compared to a plastic stent and that, at least in theory, its bigger diameter may ensure a better and more durable dilation of the HJAS. In case a fully covered SEMS is placed through the HJAS, depending on anatomy, there is however a risk of occluding the left or right hepatic duct if the common hepatic duct proximal to the HJ is too short to deploy a SEMS. To avoid this, a plastic stent could be placed to the contralateral side alongside the fully-covered SEMS. Choice for type of endoscopic treatment, optimal duration of stent therapy, and criteria for termination of treatment should be further studied in preferably large prospective studies of patients with symptomatic HJAS.

Table 3 Results of univariate analysis of potential predictive factors for clinical success (3 months)

	Clinical success		
	OR	CI	P
Late HJAS diagnosis (>1 year)	0.81	0.13–5.05	0.82
Age (per Year)	1.06	0.97–1.18	0.24
Treatment type (Other vs balloon)	0.64	0.1–5.3	0.64
ERCP as first treatment	2.7	0.11–34.1	0.45
Robot Surgery (Yes)	0.53	0.08–3.3	0.48

Endoscopy was performed when patients presented with signs, symptoms, and abnormal lab values associated with biliary obstruction or cholangitis. Some patients had a suspected HJAS on cross-sectional imaging, but visualization of the HJ at endoscopy did not show a stenosis. Indeed, in the current literature there is no clear definition of HJAS on imaging. Features that are most often associated with HJAS are intra- and extrahepatic bile duct dilatation, ductal narrowing at the HJ, non-depiction of part of the duct or an anastomosis with clear depiction of the duct on one side or the other with stones or sludge in the ducts. Of the eight patients in which an EBI found a normal HJ, seven (88%) presented with an episode of cholangitis and one with pain. These patients most likely had biliary reflux. Reflux of bowel contents into the biliary tree can be demonstrated with oral contrast. Oral contrast may spread upstream in the afferent limb towards the HJ and may even result in a cholangiogram. These patients benefit from a Roux-en-Y reconstruction.

Strengths of our study are the inclusion of a large cohort of consecutive PD patients with symptomatic HJAS and a relative long period of FU. Another strength is the description of interventions for recurrences. However, there are also some limitations which should be considered when interpreting our results. Firstly, data was collected retrospectively and follow-up was not standardized. However, follow-up was relatively systematically documented as patients were seen at standard follow-up intervals. There were a few patients with relatively short FU after initial EBI and therefore the HJAS recurrence rate may be underestimated. Secondly, our sample size limited our power regarding logistic regression analysis. As a result, we were unable to identify predictors for successful HJ visualization and factors associated with risk of recurrence after treatment. Thirdly, we are unable to report the incidence of HJAS in our PD population, as patients were also referred to our hospital from non-academic centers. Based on the current literature, recent studies report incidence rates between 6.1% and 12%.[21,22]

In conclusion, endoscopic treatment for symptomatic benign HJAS after PD in an expert treatment centre has a high technical success rate and is associated with a low risk of adverse events. Unfortunately, long term success rates are hampered by recurrences necessitating repeat endoscopic interventions. Future studies should focus on a direct comparison between PTBD and EBI, and optimization and standardization of endoscopic treatment protocols, preferably within large multicentre prospective trials.

Disclosures

D.M.J., Y.M., J.L.D., B.G.K. and P.J.F.J. report no conflicts of interest. M.J.B. serves as a consultant, support for industry and

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Declaration of competing interest

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.hpb.2023.05.362.

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