



# Benign anastomotic biliary strictures untreatable by ERCP: a novel percutaneous balloon dilatation technique avoiding indwelling catheters

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Received: 11 March 2018 / Revised: 16 April 2018 / Accepted: 3 May 2018 / Published online: 6 July 2018

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## Abstract

**Objective** To evaluate long-term patency rates of a novel percutaneous threefold balloon dilatation protocol in benign anastomotic biliary strictures.

**Methods** Patients with a benign biliary stricture after hepatobiliary surgery or liver transplantation, untreatable with endoscopy, underwent a percutaneous treatment cycle consisting of a 20-min balloon dilatation session on day one, repeated on days three and five. No catheters were left behind after the last dilatation session. Technical and clinical success as well as complications were analysed. Mean primary and secondary patency times were assessed. Cumulative primary and secondary patency rates at 6 months and 1, 2 and 3 years were determined.

**Results** Seventy patients underwent 135 dilatation treatment cycles (mean 1.9) with a technical success rate of 99%. Clinical success was achieved in 87% of the patients. Fifty-eight of 135 (43%) patients had minor and 15/135 (11%) had major complications. Mean primary and secondary patency times were 26 months and 46 months, respectively, with a median follow-up of 69 months. Cumulative primary patency rate at 6 months was 67%, at 1 year 56%, at 2 years 41% and at 3 years 36%. The cumulative secondary patency rate at 6 months was 83%, at 1 year 79%, at 2 years 70% and at 3 years 64%.

**Conclusion** In benign anastomotic biliary strictures, a percutaneous threefold balloon dilatation treatment is effective. As long indwelling catheters are avoided, patient comfort improves.

## Key Points

- *Percutaneous threefold balloon dilatation treatment is effective in benign anastomotic biliary strictures.*
- *As indwelling catheters after dilatation are avoided, patient comfort improves.*
- *The dilatation protocol can be repeated efficiently in case of recurrent stricture.*

**Keywords** Bile ducts · Stricture · Dilatation

**Electronic supplementary material** The online version of this article (<https://doi.org/10.1007/s00330-018-5526-8>) contains supplementary material, which is available to authorized users.

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## Abbreviations

ALP	Alkaline phosphatase
ALT	Alanine aminotransaminase
AST	Aspartate aminotransaminase
ERCP	Endoscopic retrograde cholangiopancreatography
ESM	Electronic supplementary material
GGT	Gamma-glutamyltransferase
HAD	Hepatic artery disease
OLT	Orthotopic liver transplantation

## Introduction

Post-surgical anastomotic biliary strictures are complications of orthotopic liver transplantation (OLT) and hepatobiliary surgery. In OLT, biliary strictures occur in 5–37% of patients and exert major impact on morbidity and survival [1, 2]. After

hepatobiliary surgery (e.g. liver resection, post-cholecystectomy bile duct injury, pancreatoduodenectomy) the risk of anastomotic biliary strictures is lower, ranging from 0.5% to 4.3% [3–5]. Endoscopic retrograde cholangiopancreatography (ERCP) with balloon dilatation and plastic stents is the first-line therapy, and is feasible in more than 90% of patients [6]. ERCP provides a long-term patency rate of 77–90% for anastomotic strictures [7–9].

If biliary anatomy is unfavourable or inaccessible for ERCP, treatment should be converted into a percutaneous transhepatic approach. Balloon dilatation with short-term indwelling catheters enable repetitive bilioplasty over a long period without the need for re-puncture. However, patency ranged widely (28–70%) as protocols were arbitrary and inconsistent [10–13]. We set up a standardised protocol to simplify the procedure and shorten the treatment period. The protocol should also improve patient comfort by avoiding indwelling catheters. To boost the balloon dilatation effect, bilioplasty was repeated three times within 1 week. All catheters were removed after the treatment. Shortly after the start of the study, Saad et al. referred to a personal communication by Zajko that he too would adhere to a similar dilatation protocol [14]. Later during the study period, we were challenged by other percutaneous dilatation techniques promoting long indwelling and large-bore catheters. The reported 3-year patency rates were very promising, ranging between 71% and 91%, albeit based on estimations by life-time table analysis [15–19]. To facilitate a more realistic patency time comparison, we decided to extend the follow-up time to 36 months for all patients.

## Materials and methods

### Patients

From April 2007 on, all patients with a benign postoperative anastomotic biliary stricture entered a new percutaneous dilatation protocol. Retrospective analysis of this prospective dataset was approved by the local ethics committee (number B670201732961). Exclusion criteria were malignant strictures, non-postoperative strictures, strictures at a non-anastomotic level and strictures treatable with ERCP.

Biliary obstruction was suspected because of clinical symptoms and/or abnormal laboratory results, e.g. total serum bilirubin, alanine aminotransaminase (ALT), aspartate aminotransaminase (AST), alkaline phosphatase (ALP) or gamma-glutamyltransferase (GGT). The biliary stricture was confirmed by magnetic resonance cholangiopancreatography.

### Dilatation technique

Under general anaesthesia and prophylactic broad-spectrum antibiotics, right and/or left bile ducts were percutaneously

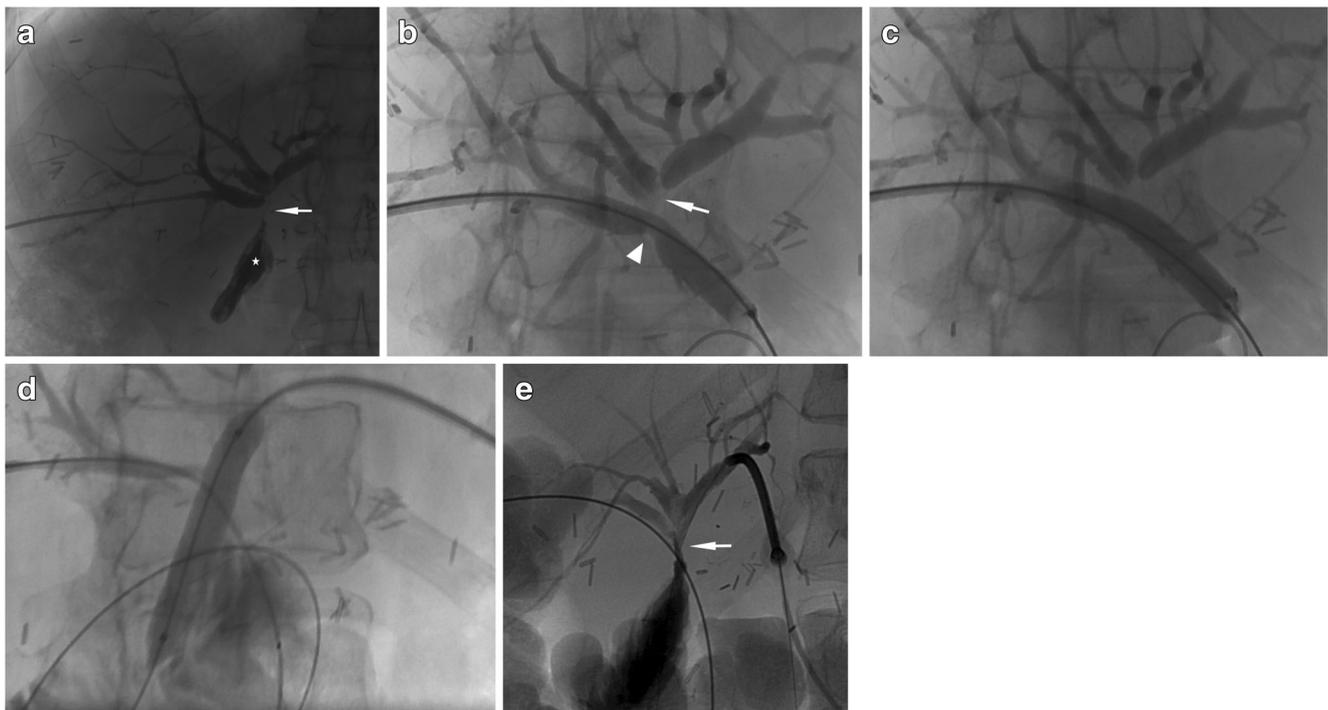
approached using a coaxial puncture set (AccuStick set, Boston Scientific). A cholangiogram was performed to visualise the stricture. After introduction of a 5–6-F sheath (Terumo Europe), the stricture was passed with suitable guide wires, eventually steered by a diagnostic catheter. The stricture was dilated with a 6- to 8-mm semi-compliant conventional angioplasty balloon (NyloTrack-35 balloon catheter, Optimed). Smaller balloons were used in children. In adults, we started with an 8-mm balloon. The balloon was manually inflated until no residual waist was observed and was kept inflated for 20 min. For a second recurrence, we introduced adjunctive cutting balloon bilioplasty in the first dilatation session [20, 21]. A cholangiogram was performed to evaluate the effect of dilatation. Then, a 5-F diagnostic catheter (Cook medical) was placed across the stenosis, just to maintain the entrance track. The catheter was capped externally. On days three and five the procedure was repeated with a gradually upscaled balloon (8–10 mm). In children, the maximum balloon size used was 8 mm. After the third dilatation, a final cholangiogram was performed to prove free contrast flow through the anastomosis (Fig. 1). If blood leakage was observed at the entry point after pulling back the sheath over the guide wire, the entrance track was embolised with glue (a 1/1 mixture of Histoacryl (Braun) and Lipiodol (Guerbet)). Bile was sampled in each session and antibiotics switched according to the antibiogram.

### Follow-up

After treatment, patients underwent clinical and biochemical check-ups every 4 weeks until normalisation and then on a 3-monthly basis. Recurrent strictures could be re-treated with the same dilatation protocol when alternative options such as indwelling large-bore catheters or reconstructive surgery were declined. The inclusion was halted in May 2014, warranting a follow-up of at least 36 months.

### Definitions and endpoints

One percutaneous dilatation treatment consisted of a cycle of three consecutive balloon dilatations in 1 week (one dilatation every other day). Technical success was defined as completion of the dilatation treatment without a balloon waist. Clinical success was defined as disappearance of the clinical symptoms and/or abnormal biochemical results within 60 days. Clinically unsuccessful treatments resulted in re-dilatation or an alternative treatment (indwelling large-bore catheters or reconstructive surgery). Events occurring within 30 days after treatment were considered as postoperative complications, classified according to the guidelines of the Society of Interventional Radiology [22]. Cholangitis was defined as an episode of fever and inflammatory laboratory results with a positive bacterial bile sample. Sepsis and septic shock were defined as life-threatening organ dysfunctions without or with vasopressor requirement, respectively [23].



**Fig. 1** (a) Percutaneous transhepatic cholangiography in an OLT patient shows a stricture at the level of the biliodigestive anastomosis (arrow) extending to the right and left bile ducts with limited contrast passage to the bowel (asterisk). (b) Inflation of an 8-mm balloon at the level of the stricture shows a waist (arrowhead). Extension of the stricture to the left

hepatic duct is clearly visible in the right oblique position (arrow). (c) The balloon could be fully inflated and was kept inflated for 20 min. (d) In the same procedure, the stricture was also dilated for 20 min with a balloon inserted from the left side. (e) After three balloon dilatations in 1 week there is no significant stenosis left

The primary endpoint was reached when the stricture re-appeared and required re-treatment. The secondary endpoint was defined as the re-appearance of biliary obstruction but treated by other means than dilatation. Patients who underwent re-transplantation for other reasons than stricture recurrence and patients who died without signs of biliary obstruction were censored in the lifetime table analysis. The overall endpoint was death. Endpoints were determined at 36 months. Primary patency time was defined as the time interval between the first treatment cycle and re-occurrence of stricture. Secondary patency time was defined as the time interval between the first treatment cycle and the moment that surgery was required for a recurrent stricture. Surgery could consist of anastomotic reconstruction, (re)-transplantation or stenting.

Cumulative primary and secondary patency rates at 6 months and 1, 2 and 3 years were calculated. Subgroups based on the type of surgery, anastomosis and the presence of hepatic artery disease (HAD) in OLT patients were created and compared to detect significant differences. Additionally, a specific subgroup of only OLT patients was created to detect outcome differences in children (up to 18 years of age) versus adults.

In view of the wide range of reported 3-year patency rates of dilatation treatments with indwelling catheters, we assumed that a 60% 3-year patency rate would be acceptable. If the outcome would not be attainable with a single dilatation treatment cycle (primary patency), repeated treatment cycles for recurrent

strictures (secondary patency) would be taken into account. Secondary hypotheses were that patency would be dependent on the type of biliary surgery (OLT vs. hepatobiliary surgery), the anastomosis type (duct-to-duct anastomosis vs. biliodigestive anastomosis) [13], the age of patients [24] and the presence of HAD in OLT patients [13].

### Statistical analysis

All statistical analyses were executed with IBM SPSS Statistics for Windows, Version 24. Time-to-event data analysis was performed by calculating Kaplan-Meier curves with the log-rank test. Outcomes of subgroups were compared by Fisher's exact test, calculating the Odd's ratio and the relative risk (RR) at 3 years. Cox regression multivariate analysis was modelled to identify independent factors (age, type of surgery and anastomosis) associated with recurrence. Pre- and post-dilatation liver parameters were compared using McNemar's test (normalisation) and by the Wilcoxon Signed-Ranks test (absolute values). A  $p$  value of  $<.05$  was considered significant.

### Results

From April 2007 until April 2014, 73 consecutive patients were included. Three patients were lost to follow-up and excluded

from further analysis. Patients' demographics, clinical presentation and surgical details are summarised in Table 1.

Seventy patients underwent 135 treatment cycles of three balloon dilatations (mean 1.9, median 1): 38 patients underwent one treatment cycle, 14 patients two, nine patients three, five patients four, three patients five and one patient eight treatment cycles. The median time interval between the treatment cycles was 331 days (24–1,780 days). In 7/18 (39%) patients with a second recurrence, the treatment cycle started with a cutting balloon. No evidence in favour of an adjuvant cutting balloon was found (see additional Tables 1–3 in the Electronic Supplementary Material (ESM)).

All first treatment cycles were technically successful. Of all subsequent treatments, two (1%) procedures technically failed. Both patients underwent reconstructive surgery: one because of a false route and one for persistent stricture.

Clinical success was achieved in 87% after the first treatment cycle (61/70). Total serum bilirubin and liver enzymes

values before the first treatment and 1 month later were available in 60 patients (86%). Median bilirubin and liver enzyme values showed a significant decrease (Table 2). In a significant number of patients, ALT and AST serum levels normalised.

Major complications occurred in 15/135 (11%) treatment cycles (Table 3). Septic shock led to early in-hospital death in two patients. Minor complications occurred in 58/135 (43%) treatments. Cholangitis was the most frequent minor complication (30%). In 28 patients (40%) all treatments were uneventful.

Median follow-up was 69 months (interquartile range (IQR) 43).

Outcome at 36 months is summarised in Fig. 2. Twenty-five (36%) patients had no event after a single treatment cycle, whereas 20 (28%) patients were doing well with repeated treatment cycles. Twenty-one (30%) patients had reached the secondary endpoint. At 36 months, 11 patients had died. Three (4%) patients had reached their primary endpoint but died in septic shock (2 at days 9 and 52) or from unexpected metastatic disease (1 at day 38). One patient (1%) died in septic shock 6 days after the third treatment cycle. Two patients died in biliary obstruction after reaching their secondary endpoint (at day 121 and 760). Five patients died without signs of biliary obstruction and were censored in patency time calculations. All (re)-transplanted patients had a stricture recurrence and were considered as events in patency time calculations.

Cumulative primary and secondary patency rates were 67% and 83% at 6 months, 56% and 79% at 1 year, 41% and 70% at 2 years and 36% and 64%, respectively, at 3 years.

Kaplan-Meier survival analysis estimated a mean primary patency time of 39 months (with a median of 16 months) (Fig. 3) and a mean secondary patency time of 70 months (with a median of 73 months) (Fig. 4).

In OLT patients, angiography and/or CT-angiography revealed a hepatic artery stenosis in 2/53 (4%) and an occlusion in 2/53 (4%). Subgroup analysis of the presence of HAD, the type of anastomosis and the type of surgery did not reveal a significant difference in patency.

At 36 months, the subgroup of children did significantly better than the adult OLT patients in reaching their secondary endpoint (RR=0.38) ( $p=0.04$ ). Eighty-one percent of the children had a patent anastomosis compared with 51% of the adult OLT patients. Their estimated secondary patency rates diverted as well but did not reach statistical significance ( $p=0.05$ ) (Fig. 5). Univariate and multivariate analysis could not identify an independent risk factor for stricture recurrence at 36 months (additional Table 4 in ESM).

**Table 1** Patient characteristics and clinical presentation at the time of treatment

	No. of years (range)	
Age of all patients (N=70)		
Mean	41.5 (0–89)	
Median	47.5	
Age of children (N=16)		
Mean	5.3 (0–16)	
Median	3.5	
	No. of patients	%
Children	16	23
Adults	54	77
Sex		
Female	30	43
Male	40	57
Type of surgery		
OLT	53	76
Liver resection <sup>1</sup>	5	7
Extrahepatic surgery <sup>2</sup>	12	17
Type of anastomosis		
Duct-to-duct	13	19
Biliodigestive	57	81
Clinical presentation		
Jaundice	7	10
Cholangitis	33	47
Pruritus	10	14
No biliary obstruction symptoms	20	29

<sup>1</sup> Non-malignant cause N=1; cholangiocarcinoma N=2; colorectal carcinoma N=2

<sup>2</sup> Whipple operation N=2; after complicated cholecystectomy with bile duct injury N=7;

after Billroth 2 operation N=1; primary sclerosis cholangitis N=1; colitis ulcerosa N=1

## Discussion

With the presented threefold treatment, we achieved a primary patency rate of 36% at 3 years. Only by repeating the protocol

**Table 2** Bilirubin and liver enzyme serum levels before and after treatment

	Before treatment median value	After treatment median value	<i>p</i> value
Bilirubin, mg/dl available in N=61 patients	3.2	1.7	<0.01*
ALT, U/L available in N=61 patients	69	40	<0.01*
AST, U/L available in N=62 patients	89	47	<0.01*
ALP, U/L available in N=62 patients	329	230	<0.01*
GGT, U/L available in N=60 patients	261	106	<0.01*

\*Statistically significant ( $p < .05$ )

ALT alanine aminotransaminase, AST aspartate aminotransaminase, ALP alkaline phosphatase, GGT gamma-glutamyltransferase

for recurrent strictures (secondary patency), we managed to keep the failure rate below 40%.

The 64% secondary patency rate at 3 years was based on a high technical success rate combined with a low number of clinical failures and the potential to repeat the treatment. In 99% of all treatments we managed to dilate the stricture, a result that is comparable with the 85–100% technical success rate of other dilatation studies [13, 18, 25, 26]. Biliary balloon dilatation is nowadays a well standardised intervention. With the development of dedicated catheter systems, failures are becoming rare.

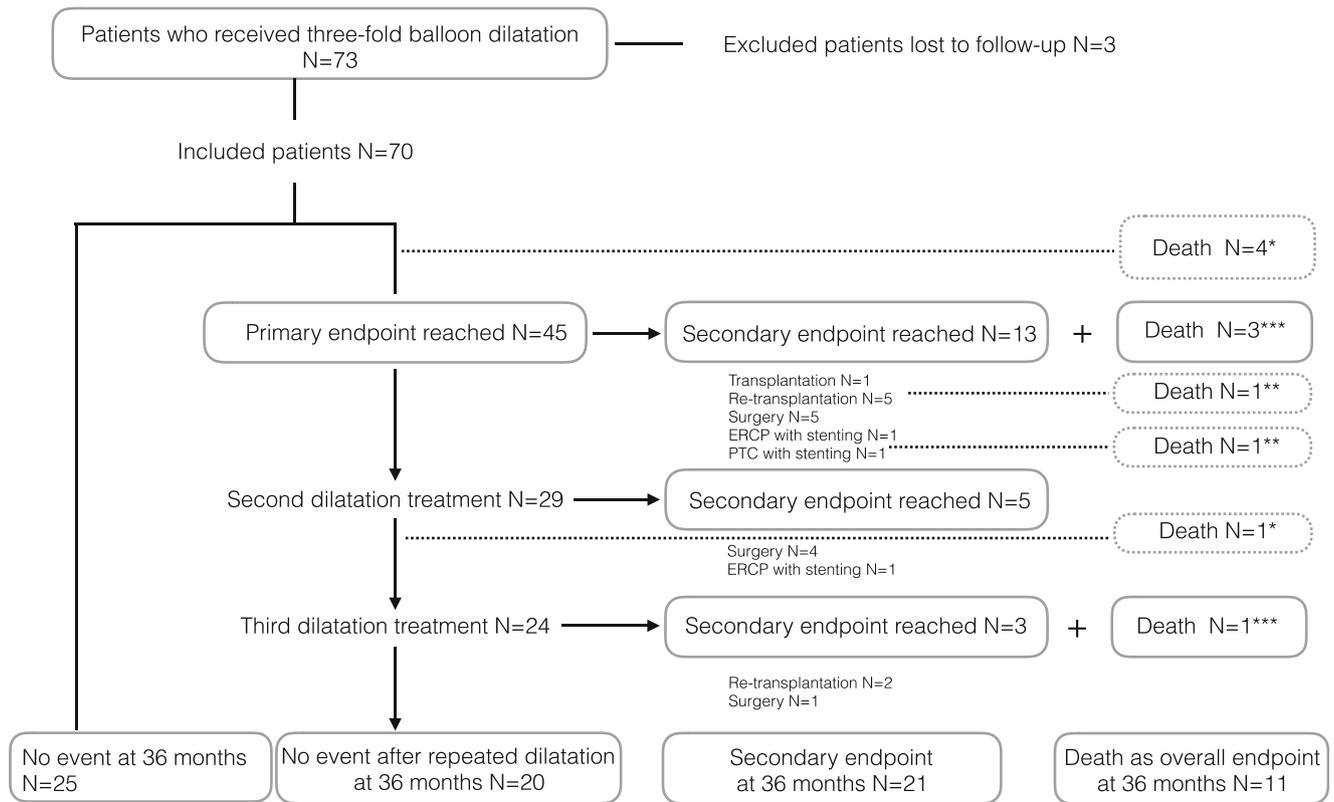
The 87% clinical success rate is within range of the best results of dilatation studies with short-term indwelling catheters (51–89%) [10, 12, 24, 27]. A significant decrease of bilirubin and liver enzymes combined with normalisation of ALT and AST substantiated clinical success in our series. Other investigators found a significant decrease and normalisation of all liver parameters [18]. As long indwelling

catheters were used, laboratory tests were probably performed more than 60 days after dilatation, giving more time for bilirubin and enzymes to normalise. Moreover, specific serum levels were available only in a limited number of patients. In our series, serum bilirubin levels were moderately elevated at the start of the treatment (mean 2.7 mg/dl). Hepatologists proactively referred patients before overt symptoms of biliary obstruction (e.g. jaundice) were obvious. In the competitive studies, little information is given on the referral pattern. At least mean bilirubin levels seem higher [28] but in most studies absolute values are lacking.

The 1- and 3-year primary patency rate in the current study was 56% and 36%, respectively, which lies in the range of similar studies with indwelling catheters (36–73% at 1 year after correction for clinical failures) [10, 12, 13, 24]. Dilatation regimens were similar to ours but with longer intervals (1–2 weeks) and indwelling catheters up to 6 weeks [10, 13]. Secondary 3-year patency of the presented study was 64%,

**Table 3** Overview of the complications per dilatation treatment

Minor complication N=58	First dilatation treatment N=	Second dilatation treatment N=	Third dilatation treatment N=	Fourth–eighth dilatation treatment N=
Cholangitis	19	13	7	1
Bile track leakage	3		1	
Haematoma	2	1	1	
Melaena/haemobilia	2		1	1
Pneumonia	2	1		
Pleural effusion		2	1	
Major complication N=15				
Biloma (drainage)	1			
Abcess (drainage)	2			
Arterio-biliary fistula (embolisation)				1
Bleeding requiring embolisation	1			
Pneumothorax		2	1	
Sepsis	3			
Septic shock		1	2	1



\*died without biliary obstruction; these patients were considered as not having a primary or secondary endpoint  
 \*\*died in biliary obstruction after having reached the secondary endpoint  
 \*\*\*died in biliary obstruction before re-dilatation or other treatment could be performed

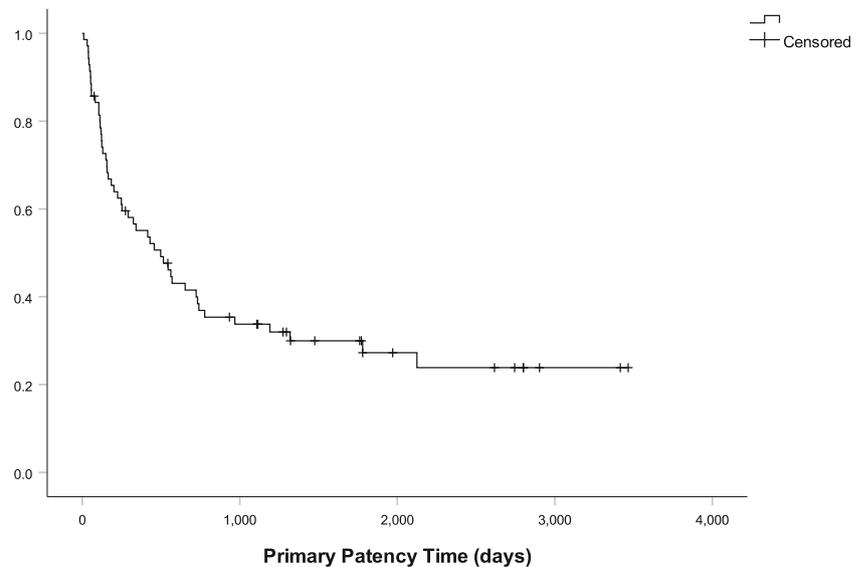
Fig. 2 Overview of all endpoints at 36 months

approximating the best results of Zajko et al. (70%), but without indwelling catheters [10]. Zajko et al. censored all re-transplanted patients and deaths because of patent biliary anastomoses. The absence of biliary aetiology is not comprehensible and a contradiction to the findings in the present

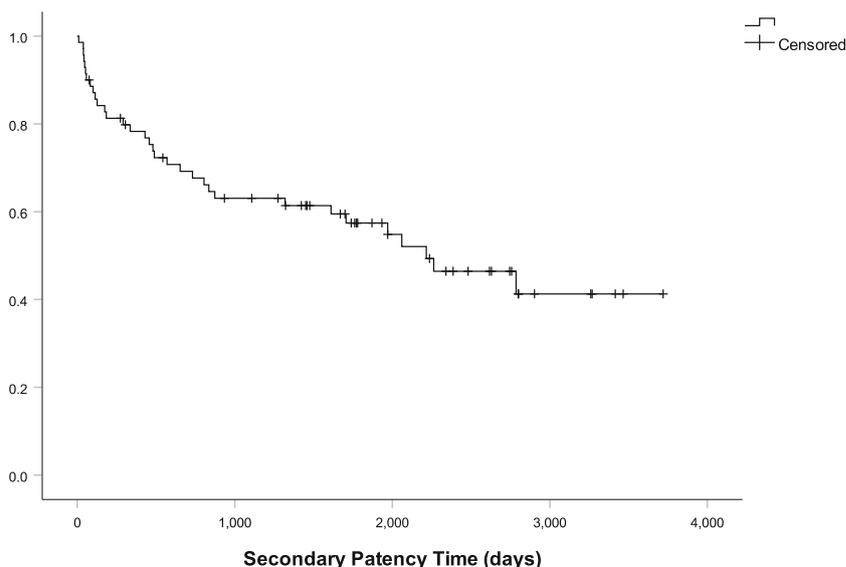
study. We encountered 14 extra endpoints in (re)-transplanted patients (N=8) and in patients who died (N=6).

Studies with long indwelling large-bore catheters report 1-year and 3-year primary patency rates of 82–96% and 71–91%, respectively [18, 26].

Fig. 3 Kaplan-Meier analysis for primary patency time



**Fig. 4** Kaplan-Meier analysis for secondary patency time



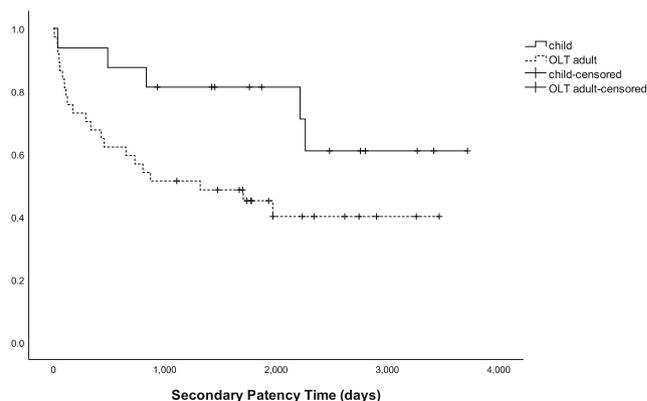
Apparently, these rates are higher than in the presented study and the studies with short-term drainage catheters.

Ko and Gwon's group improved their initial 3-year results of 81–91% by introducing an innovative dual catheter technique, thereby maximising the diameter of the indwelling catheter [16, 17]. Some inconsistencies exist concerning the period between the two publications, and the number of recruited patients. Moreover, 71% of the strictures were duct-to-duct anastomoses that are primarily amenable to ERCP. Recently, investigators recognised the mandatory correction of patency rates and also included clinical failures and dropouts [18, 28]. Patency rates become more realistic and approximate our results. For example, the 4-year patency of 96% decreases to 81% when clinical failures are included [26]. Similarly, in the study of Depietro et al. the 1- and 2-year patency rates decrease from 98% and 92% to 84% and 78%, respectively [19].

Despite the inevitable corrections, the outcome of large-bore studies remains superior. Bearing a large size catheter up to 1 year or longer requires continuous education and

motivation of the patient. Regular hospital visits are mandatory for catheter exchanges, dilatation and upscaling. Long-term patient discomfort is a major disadvantage. Prolonged treatment times could expose patients to more adverse events. The rate of minor complications ranged widely from 10–82%, in a large part due to tube dislocation [19, 26]. Inherent to the presented novel protocol, multiple treatments in one patient increased the odds of having a complication. Other dilatation protocols planned only one single percutaneous transhepatic procedure per patient [10, 13, 18, 19, 28]. Moreover, repeated manipulations during the treatment week contributed to the considerable cholangitis rate (30%). Early culture-based antibiotic treatment is mandatory to avoid septic shock. Nevertheless, in two OLT patients septic shock led to a fatal outcome, most likely due to immunosuppression combined with a bad general condition. Procedure-related mortality seems to be exceptional as other papers rarely notified it. Overall, the 11% major complication rate remained under the proposed threshold of 5% each for sepsis, haemorrhage and inflammation [29].

**Fig. 5** Kaplan-Meier analysis for secondary patency time of children versus adult OLT patients



In a similar dilatation study of OLT patients with anastomotic strictures, a significantly shorter cumulative patency rate was found in patients with arterial stenosis or occlusion ( $p=.01$ ) [13]. The number of OLT patients with HAD in the current study is low (8%). It might be that duct-to-duct anastomoses, which were encountered twice as often in the Saad et al. study (44% vs. 25%), are more vulnerable for development of strictures. Duct-to-duct anastomoses were at our institution primarily treated with ERCP.

The proposed treatment regimen is suitable both for adults and for children. More specifically in the OLT group, children did better than adults regarding the secondary endpoint at 36 months (RR=0.38) ( $p=.04$ ). The present study is unique as all other percutaneous dilatation treatments in children involved long indwelling catheters. As we achieved 81% secondary patency rate at 36 months, fully competing with the best results (60–94%), the need for indwelling catheters is questionable [30–32].

The experimental dilatation regimen was well circumscribed and technically expedient. The compact treatment was accomplished in all enrolled patients. Studies with long indwelling catheters suffer from high dropout rates of up to 25%, which at the least interfered with the interpretation of statistics [19, 28]. To ensure an accurately calculated and not extrapolated long-term patency rate, we stopped inclusion early, so that all patients reached an observation period of 36 months.

One limitation of the study was the absence of a control arm to which patients with large-bore catheters could be randomised. However, the incidence of benign biliary strictures to be treated percutaneously is low. A randomised controlled trial could only gain enough power in a multicentre design. Because our as well as other protocols had no control arm to compare with, we refrained from quality-of-life evaluation with standardised questionnaires. The willingness of the patients to undergo a repeated treatment cycle acts as a surrogate quality-of-life evaluation.

For recurrences, adjuvant cutting balloon bilioplasty has been suggested. Although of interest, the scarce data are limited to technical success in small sample sizes [20, 33]. Mukund et al. described a patency rate of 100% but with a much shorter follow-up time (mean 14 months) in a limited number of patients (N=8) [21]. In the present study, patency after adjuvant cutting balloon was not superior to conventional balloon. The number was low and the usage was only for a second recurrence: the role of cutting balloon requires further exploration.

Other alternative treatments are retrievable covered stents or biodegradable stents. These novel stents have shown promising estimated 3-year patency rates up to 70% [34, 35]. However, retrievable covered stents might migrate and still require an indwelling catheter for several months. The biodegradable stents seem to avoid these problems and might be an alternative for a future protocol.

## Conclusion

For benign biliary anastomotic strictures, the presented 1-week threefold percutaneous dilatation treatment proved to be a valuable alternative for dilatation regimens with long indwelling catheters. Treatment cycles can be repeated without the discomfort of a drain and subsequently with better quality of life.

**Funding** The authors state that this work has not received any funding.

## Compliance with ethical standards

**Guarantor** The scientific guarantor of this publication is Luc Defreyne.

**Conflict of interest** The authors of this manuscript declare no relationships with any companies whose products or services may be related to the subject matter of the article.

**Statistics and biometry** One of the authors has significant statistical expertise.

**Informed consent** Written informed consent was waived by the Institutional Review Board.

**Ethical approval** Institutional Review Board approval was obtained.

## Methodology

- prospective
- observational
- performed at one institution

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