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Evaluation of a New Metal Biliary Stent 12 Mm in Diameter: A Case Control Study

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ABSTRACT

Introduction: Currently, by expert agreement, the diameter of metal biliary stents is 10 mm. New 12 mm diameter stents are now available. The aim of our study was to compare whether the patency of 12 mm diameter stents is better than that of conventional 10 mm diameter stents.

Methods: From April 2017 to April 2018, patients with biliary strictures were treated with metal biliary stents, covered or uncovered, 12 mm in diameter. Control patients treated with stents 10 mm in diameter were identified in our center database. The primary endpoint was time to RBO (recurrent biliary obstruction).

Results: We included 24 patients in the 12 mm group (62.5% male; mean age 71 years old) and 48 patients in the control group (64.6% male; mean age 68.8 years old). The median time to RBO was 5.9 months in the 12 mm group vs. 8.3 months in the 10 mm group (p=0.28). In the malignant stricture subgroup, RBO occurred after 6.1 months and 17.1 months in the 12 mm and 10 mm groups, respectively (p=0.06). The adverse event rate in the month following biliary stent placement was 25% (n=6/24) in the 12 mm group and 2% (n=1/48) in the control group.

Conclusion: This case control study did not show better patency of uncovered 12 mm diameter metal biliary stents in cases of malignant stenosis. The placement of covered 12 mm diameter stents in cases of benign strictures should be better evaluated.

Keywords: Biliary stent drainage; 12 mm diameter biliary stent; large diameter biliary stent

Introduction

Biliary stents allow drainage of the bile ducts in palliative or preoperative conditions in cases of malignant biliary stenosis and biliary calibration in cases of benign etiological stenosis [1-3]. Initially made of plastic and of a small caliber, biliary stents have gradually increased in diameter to reduce the obstruction rate and increase their lifespan [4,5]. Despite these achievements, the obstruction rate with plastic stents remains high, occurring in 30% of cases in the first three months after installation and 70% of cases after a 6 month period [6]. Metal stents with larger diameters were then developed to double the patency time of biliary stents but at a higher cost [7]. According to the latest recommendations of the European Society of Gastro Enterology (ESGE), the use of a metal biliary stent is recommended in patients with malignant stenosis if the patient's life expectancy is more than four months. For benign strictures, recommendations promote the use of plastic biliary stents [8]. However, this approach requires an average of four endoscopic retrograde cholangiopancreatography (ERCP) procedures per year and can therefore lead to patient noncompliance. Some authors have therefore proposed the placement of covered metal biliary stents for these indications. They have the benefit of being removable and having a lower sludge obstruction rate, reducing the frequency of ERCP to 1 to 2/year [9]. The diameter of these metal prostheses is 10 mm by expert agreement. A study published in 2003 showed, by comparing biliary stents of different diameters (6 and 10 mm) and different designs or materials, that only the diameter influenced the obstruction rate of the different biliary stents tested, favoring the 10 mm diameter stent [10]. Therefore, stents with a diameter greater than 10 mm could have a reduced risk of obstruction and increased life span. Recently, a feasibility study showed the good tolerance of 12 mm metal prostheses in the case of benign stenosis [11]. Launched in 2016 in Europe and January 2017 in France, these prostheses have been approved for biliary drainage in the treatment of benign and malignant biliary strictures. Another recent study showed also in case of pre-operative pancreatic cancer biliary drainage an acceptable rate of complication with a 12 mm covered biliary stent [12]. The aim of this study was to compare the drainage efficiency and side effects of 12 mm diameter biliary stents versus 10 mm diameter stents, covered or not, depending on the indications.

Methods

Study design

From April 2017 to April 2018, at the Paoli Calmettes Institute in Marseille, 24 patients (2 per month consecutively) with benign or malignant biliary strictures were treated with a covered or uncovered Kebomed HILZO 12 mm diameter metal biliary stent (length, 4 or 6 cm). The stricture etiology was determined from a surgical specimen, from a biopsy in the event of a cancer diagnosis, or over one year of follow up in the event of benign lesions. Patients met the following inclusion criteria: (1) benign or malignant biliary stricture of the lower or median portion of the main biliary duct with indications for

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biliary stent placement, including preoperative drainage; (2) age ≥ 18 years old; and (3) Karnofsky score ≥ 40. The exclusion criteria were as follows: (1) hilar stenosis; and (2) coagulation disorder (PT<50%, platelets<80,000). "Control" patients who had been treated with a covered or uncovered Cook Evolution (Consore ®) metal, 10 mm diameter biliary stent (length, 4 or 6 cm) were identified by searching a database from January 2016 to March 2018. "Case" patients were exactly matched to the control patients at a ratio of 1:2 according to the following criteria: age (per decade), sex, pathology responsible for biliary stenosis (i.e., benign or malignant stenosis) and type of stent (i.e., covered/uncovered). The inclusion and exclusion criteria were the same. When we searched for control patients in our database, the first patient with matching criteria was included. This retrospective study was accepted by our institution's ethics committee.

HILZO-12 stent

The HILZO-12 metal stent is a new biliary stent with a large diameter of 12 mm. There are fully covered or uncovered models 40 or 60 mm in length. The external diameter of the installation system is 7.5 Fr, and its length is 1800 mm. A 0.035 inch guide can be used to place the prosthesis in the bile duct.

Procedure

The endoscopists who performed the procedures had at least 6 years of experience and worked in a center carrying out 800 to 1200 biliary drainage procedures/year Patients without contraindications received prophylactic treatment with a 100 mg indometacin suppository for post-ERCP acute pancreatitis according to the recommendations of the ESGE [13]. All procedures were performed in intubated patients under general anesthesia in the supine position. After the duodenoscope was positioned in front of the duodenal papilla, it was cannulated with a sphincterotome (Cotton CannulaTome, CCPT 25, Cook Medical©, Limerick, Ireland). After first performing cholangiography or not, a 0.035 inch guide wire was inserted into the bile ducts (Acrobat 2, Cook Medical©; Jagwire, Boston Scientific©). Cholangiography was then performed to visualize the stenosis and ensure that the guide wire was correctly positioned. An endoscopic sphincterotomy was performed before the prosthesis was placed on the guide wire. The prosthesis was then deployed, and its length was determined according to the length of the stenotic area. The lower end of the prosthesis protruded into the duodenum. In cases of benign strictures, the time before changing or removing the metal stent was determined individually by the patient's responsible physician. In cases of malignant strictures, when an obstruction of the biliary prosthesis was identified, the reintervention strategy was a new transpapillary drainage procedure. The new prosthesis was chosen at the discretion of the endoscopist at the time of the procedure.

Outcomes

The main endpoint was the time to RBO, defined as the time from stent deployment to the first biliary stent obstruction (patency). Surgery and death were considered causes for censoring, and the patients concerned were right censored on the corresponding dates. Similarly, patients without events surviving to the end of the follow up period were censored at their last follow up date. The secondary outcomes were as follows: rate of technical success, rate of procedural complications, rate of stent obstruction, time to a new procedure, and rate of new procedure success. Overall survival was defined as the time from prosthesis deployment to death and was assessed in each group. Technical success was defined as the placement of the prosthesis through the stenotic area with good evacuation of the contrast agent at the end of the procedure. Procedural complications were defined as the occurrence of one of the following adverse events: acute pancreatitis, cholecystitis, hemorrhage, perforation or death within one month of the prosthesis being placed. They were classified according to the Clavien Dindo surgical complications classification [14]. Biliary obstruction was diagnosed by the occurrence of one of the following events: obstructive jaundice, cholangitis and/or stent migration. These events were confirmed by biological analyses and imaging (ultrasound and/or abdominopelvic CT). Regarding reintervention, the success of the new procedure was evaluated as well as the method used (transpapillary or hepaticogastrostomy).

Statistical analyses

All statistical analyses were performed at a significance level of α=0.05 using SAS® software version 9.4. Demographic characteristics, treatments received and clinical events are summarized by the number (percentage) for qualitative variables and the mean (standard deviation) or median (minimum-maximum) for quantitative variables. Characteristics of the two groups were compared by chi square or exact Fisher's tests (qualitative variables) or Wilcoxon's test (quantitative variables). Follow up variables were estimated using the reverse Kaplan-Meier method. The time to RBO and the overall survival of the two groups were estimated using Kaplan-Meier's method and compared using univariate Cox models stratified by line number (matching groups). The associated median time to event and hazard ratio (HR) were estimated using Wald's bilateral confidence intervals. The patency period was also described for patients who actually underwent clearance using the mean (standard deviation) and median (minimum-maximum). Subgroup analyses were also performed according to the stricture etiology (benign/malignant). The rates of immediate complications and reoperation were estimated. When possible, univariate logistic models stratified by line number (matching groups) were used to assess the effect of the prosthetic group on the occurrence of these events. The associated odds ratios (ORs) were estimated using Wald's bilateral confidence intervals.

Results

Patients

24 patients (15 men; mean age, 71 years) were included in the 12 mm diameter metal biliary stent group. 48 patients (31 men; mean age, 68.8 years) were included in the 10 mm diameter metal biliary stent group. The clinical characteristics of the patients in both groups are summarized in Table 1. There was no statistically significant difference between the groups in the Karnofsky index, histological diagnosis or total bilirubin level at diagnosis. In each group, 75% of patients received drainage for malignant biliary strictures, mainly pancreatic adenocarcinoma, including 14 (58%) and 31 (65%) patients in the 12 mm and 10 mm diameter groups, respectively (Table 2). The median follow up time was 7.49 months in the 12 mm group compared to 8.8 months in the 10 mm group (p=0.04).

	10 mm CookN=48	**12 mm Kebo-med N=24**	**P Value***
Male, no. (%)	31 (64.6)	15 (62.5)	0.86
Age y, mean (SD**)	68.8 (12.2)	71 (11.8)	0.39
Karnofsky index, mean (SD)	82.3 (17.6)	75.8 (19.3)	0.15

Pathology, no. (%)			0.95
Pancreatic adenocarcinoma	31 (64.5)	14 (58.3)	
Cholangiocarcinoma	2 (4.2)	2 (8.3)	
Nonhepatobiliary metastasis	2 (4.2)	1 (4.17)	
Calcified chronic pancreatitis	10 (20.8)	5 (20.8)	
Benign villous tumor of main biliary duct	2 (4.2)	1 (4.17)	
Status: Benign/ Malignant, no.	36/12	18/6	1
Serum bilirubin (µmol/L), median [range]	150 [8.7-450]	103 [5.6-456]	0.31
Follow-up (months), median [range]	8.8 [7.7-11.6]	7.5 [5.7-10.2]	0.042
* Chi-square, Fisher's exact, Wilcoxon's or stratified log-rank test.			
** SD=standard deviation			

Table 1: Patients' clinical characteristics.

	10 mm CookN=36	**12 mm Kebomed N=18**
Male, no. (%)	21 (58.3)	10 (55.6)
Age y, mean (SD)	72.7 (9.6)	73.7 (9.9)
Karnofsky index, mean (SD)	80.3 (18.3)	72.8 (19.3)
Tumor diagnosis, no. (%)		
Pancreatic adenocarcinoma	31 (86.1)	14 (77.8)
Cholangiocarcinoma	2 (5.6)	2 (11.1)
Ampullary cancer	1 (2.8)	1 (5.6)
Nonhepatobiliary metastasis	2 (5.6)	1 (5.6)
Serum bilirubin (µmol/L), median [range]	154.5 [8.7-450]	128.5 [5.6-456]
Chemotherapy after biliary stent insertion, no. (%)	22 (61.1)	9 (50)
Chemotherapy, no. (%)	22/30 (73.3)	9/15 (60)
Chemotherapy regimen, no.		
FOLFIRINOX	8	4
FOLFOX	3	0
GEMZAR	7	4
GEMOX	1	0
GEMPLAT	1	0
GEMZAR-CAPECITABINE	0	1
Unknown	2	0

Table 2: Clinical characteristics of patients with malignant biliary strictures.

Successful placement of the prosthesis

The technical success rate was 95.8% and 100% in the 12 mm and 10 mm groups, respectively.

In the 10 mm group, 75% (n=36/48) of the patients underwent their first intervention at the papilla. For the other patients, the procedure consisted of a scheduled biliary stent change (10.4%; n=5/48), the placement of a new biliary stent after migration (4.2%; n=2/48) or the placement of a new stent because of stent dysfunction while still in place (10.4%; n=5/48). In the 12 mm biliary stent group, these four situations were distributed as follows: 75% (n=18/24), 20.8% (n=5/24), 4.2% (n=1/24) and 0%, respectively (Table 3). In both groups, the metal biliary stent was the uncovered type in 75% of cases. A 6 cm long stent was placed in 79.2% (n=19/24) of patients in the 12 mm group and in 75% (n=36/48) of patients in the control group. Stent placement failure occurred in the 12 mm group due to stent dysfunction during manipulation and placement, requiring immediate replacement; this occurred in the 2nd patient, who had chronic pancreatitis.

	10 mm Cook N=48	**12 mm Kebomed N=24**
Technical success, no. (%)	48 (100)	23 (95.8)
Biliary stent indication, no. (%)		
First biliary placement	36 (75)	18 (75)
Change of biliary stent due to migration of previous stent	2 (4.2)	1 (4.2)
Scheduled biliary stent change $	5 (10.4)	5 (20.8)
Removal of obstruction	5 (10.4)	0
Biliary stent length, no. (%)		
4 cm	12 (25)	5 (20.8)
6 cm	36 (75)	19 (79.2)
Type of biliary stent, no. (%)		
Covered biliary stent	12 (25)	6 (25)
Uncovered biliary stent	36 (75)	18 (75)
Adverse events (except obstruction), no. (%)	1 (2)	6 (25)
According Clavien-Dindo classification		
Grade II	1	2

Grade IIIa	0	1
Grade V	0	3
Type of adverse event		
Acute cholecystitis	0	1
Acute pancreatitis	1	0
Cholangitis	0	2
Death	0	3
Biliary stent obstruction rate, no. (%)	20 (41.7)	12 (50)
Delay before stent replacement (months), mean [range]*	4.86 [0.23-17.12]	5.13 [0.16-6.93]
Etiology of stent obstruction/migration, no. (%)		
Sludge	3 (23.1)	1 (11.1)
Tumor ingrowth	7 (53.8)	5 (55.5)
Migration	3 (23.1)	1 (11.1)
Biliary stent replacement program (chronic pancreatitis)	0	2 (22.2)
Not assessed	35	14
Surgery, no. (%)	4 (8.33)	3 (12.5)
Cephalic duodenopancreatectomy	2	2
Bilio-digestive anastomosis	2	0
Main bile duct resection	0	1
Median overall survival time (months)	26.41	Not estimable
$ Removal of the previous prosthesis at the beginning of the procedure		
* Only for patients who had a prosthesis change		

Table 3: Patient outcomes

Patency and overall survival

The median follow up duration was 7.5 (5.7-10. 2) and 8.8 (7.7-11.6) months in the 12 mm and 10 mm groups, respectively (HR=2.45 (1-5.98), stratified log rank test p=0.04). The median time to obstruction of the biliary stent was 5.9 (4.8-6.9) months in the 12 mm group vs. 8.3 (6.3 not estimable) months in the 10 mm group (HR=1.63, 95% CI (0.67-3.96), stratified log rank test p=0.28) (Figure 1). For malignant strictures, the median time to biliary obstruction was 6.1 (1.2 not estimable) months and 17.1 (6.5-17.1) months in the 12 mm and 10 mm groups, respectively (HR=3.12 (0.91-10.8), p=0.06) (Figure 2a). For benign stenosis, the median patency time was 4.9 (1 not estimable) months in the 10 mm group versus 5.9 (2.7 not estimable) months in the 12 mm group (HR=0.72 (0.18-2.94), stratified log rank test p=0.65) (Figure 2b). Among the six patients with benign stenosis in the 12 mm group, one third of the patients underwent a scheduled prosthesis change, one third had cholangitis following stent migration (n=1/6) or obstruction by sludge (n=1/6), and the last two patients maintained the 12 mm biliary prosthesis throughout the follow up period. In the 10 mm group, six patients underwent a scheduled biliary prosthesis change (50%), one patient underwent the placement of a new stent due to migration diagnosed following liver function disorder (8.3%), and two patients had cholangitis (16.7%) following sludge obstruction (n=1/12) or migration (n=1/12). Finally, three patients maintained the 10 mm prosthesis throughout the follow up period (25%). Overall survival was not statistically different between the two groups: it was 26.4 (15.2 not estimable) months in the 10 mm group, and it was not estimable in the 12 mm group because the estimated overall survival rate was still above 50% at the end of the follow up period (HR=2.43 (0.84-7.05), stratified log rank test p=0.10) (Figure 3). In the subgroup of patients with malignant strictures, the median survival duration was 15.2 months in the 10 mm group and not estimable in the 12 mm group (HR=2.51 (0.79-7.99), p=0.11) (Figure 4). Finally, in patients with benign strictures, the median overall survival duration was not estimable in either group.

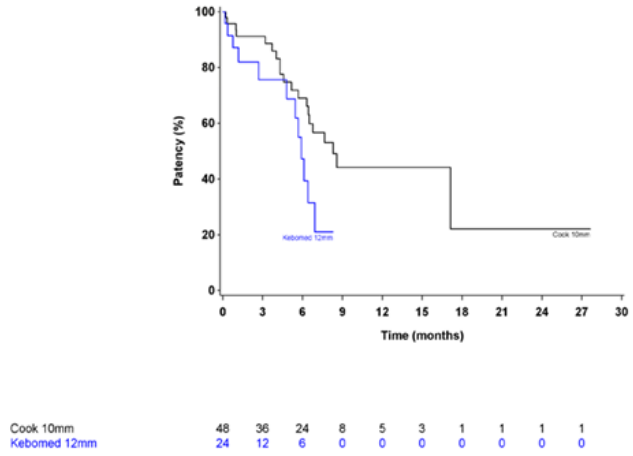

Figure 1: Patency according to prothesis diameter

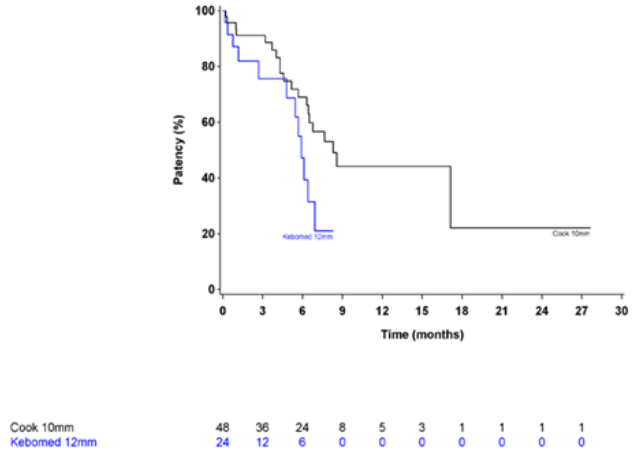

Figure2a: Patency according to prothesis diameter (malignant status patient)

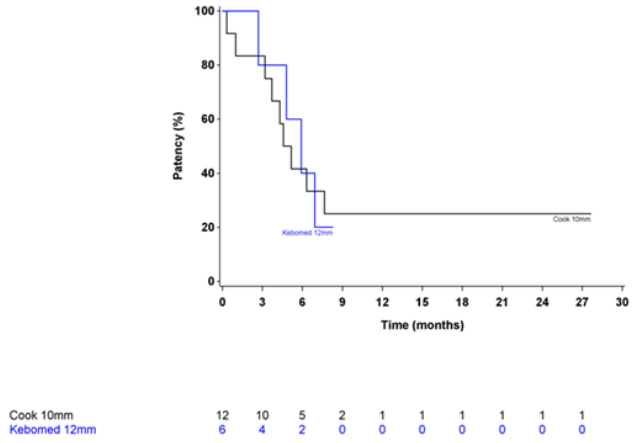

Figure2b: Patency according to prothesis diameter (benign status patient)

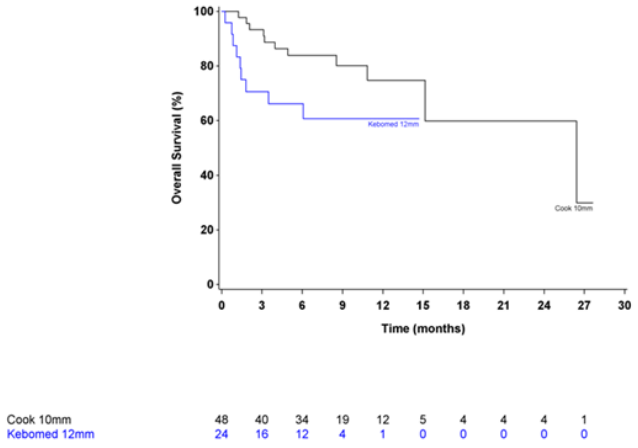

Figure 3: overall survival according to prothesis diameter

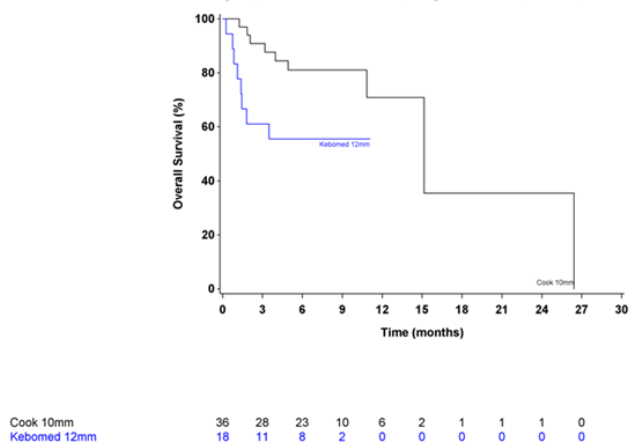

Figure 4: overall survival according to prothesis diameter (malignant status patients)

Adverse events

The rate of complications within 30 days after biliary stent placement was 25% in the 12 mm group compared to 2% in the 10 mm group (stratified ORs were not estimable). In the 12 mm group, complications included one case of cholecystitis, two cases of cholangitis and three cases of mortality. Nonsevere acute pancreatitis occurred in the 10 mm group. The 3 deaths were not directly attributable to biliary stent placement. According to the Clavien-Dindo classification [14]. There were two grade II complications, one grade IIIa complication and three grade V complications in the 12 mm group and one grade II complication in the 10 mm stent group (Table 3).

Reintervention for biliary obstruction

Twenty patients (41.6%) underwent new biliary prosthesis placement in the 10 mm group compared to 50% (n=12/24) in the 12 mm group (stratified OR=0.63 (0.19-2.04), p=0.44). One patient underwent drainage by hepaticogastrostomy in the 10 mm group due to duodenal tumor invasion (Table 4).

	10 mm Cook N=20	**12 mm Kebomed N=12**
Reintervention success rate	17 (89.5)	12 (100)
Reintervention technique		
Main biliary duct	19 (95)	12 (100)
Hepaticogastrostomy	1 (5)	0

Table 4: Reintervention for biliary stent obstruction/migration

Discussion

The purpose of this case control study was to evaluate the efficacy and safety of 12 mm biliary stents. There were no statistically significant differences between the 10 mm and 12 mm diameter prostheses in terms of technical success during placement, immediate complications, patency time, reoperation success or overall survival. In theory, a larger diameter stent, such as a 12 mm diameter stent, should have a longer patency time with lower rates of obstruction and migration. This was the case when Loew et al. prospectively compared 6 and 10 mm biliary stents; the obstruction rate was 39% for the 6 mm stents, while it varied from 21.4 to 23.9% for the 10 mm stents, depending on their composition, after a 6 month follow up period (p=0.02) (10). We did not find this effect in our population, and we even found a tendency for earlier obstruction of the 12 mm prostheses in the subgroup of patients with malignant stenosis. These results are similar to those of the series by Lee et al but in contradiction to the series of Nakaoka et al [15,16]. (Our results are similar to the study by Lee et al; however, the 12 mm stent used in this study has a central part that is 8 mm in diameter, which could explain the lower patency. As a result, it is difficult to compare our study with a 12 mm stent and this study using a stent with a smaller diameter in its central part. A key point is the contradiction with the study by Nakatoa et al, which also used a 12 mm stent. Nakatoa et al used a covered stent in malignant stenosis, and we used an uncovered stent. Increasing with the distension of the bile ducts by the uncovered 12 mm prosthesis would lead to compression ischemia at the biliary level and promote hyperplasia of the epithelial tissue. This hyperplasia is controlled in cases of covered stents, as used in the study by Nakatoa et al. This outcome has been supported by several studies that found the invasion of uncovered bile duct stents by hyperplastic tissue (not tumoral tissue) in 50% of cases [10,17]. As Loew et al. noted,

this effect could be reduced by producing so called "active" bile duct prostheses coated with a substance that slows the proliferation of epithelial tissue, as is the case for cardiac stents [18]. Another possibility would be to further enlarge the diameter of the biliary stent such that even if epithelial tissue develops, it does not obstruct the prosthesis. This possibility was developed in a study in 2018; the results showed that an uncovered prosthesis with a diameter of 14 mm extended the median time to obstruction by up to 6.22 (5.37-7.04) months, with a 6 month patency rate of 91% [19]. For benign stenosis, the opposite trend was observed, with a tendency toward a longer patency time for 12 mm prostheses (4.86 months vs. 5.9 months, p=0.06). This result might be due to the better performance of 12 mm prostheses for this type of stenosis or perhaps occurred because we used covered stents like Nakatoa et al used, which prevented the proliferation of epithelial tissue. Cholangitis could be also associated with benign stenosis and explain that 12 mm is more efficiency to drain potential thick and infected bile. There were complications apart from stent obstruction, occurring at a rate of 2% in the 10 mm group vs. 25% in the 12 mm group, without a statistically significant difference when stratifying by line number (matching groups). The typical rate of early complications described in the literature is 5% [8]. Among complications that occurred in the month following the insertion of the prosthesis in the 12 mm group were three cases of mortality: one patient died of pulmonary embolism 7 days after the procedure, and two others died 22 and 25 days after the procedure due to disease progression. Although these deaths occurred in patients with pancreatic adenocarcinoma, pathology with a poor prognosis, an effect of the diameter of the prosthesis on this increase in mortality in the 12 mm group cannot be excluded. Excessive stent expansion can injure the bile duct and obstruct the bile duct early because we did not use covered stents. Lee et al used a 12 mm diameter in proximal and distal part, but with a 8 mm size in the medium size corresponding to the localization of the tumors. They did not show more complications with this stent design [12]. It is questionable if the diameter of the stent has to be adapted to the anatomy of the patient to avoid injuries of the mucosa by compression and so inflammation and as a result early obstruction. The other three complications observed in this group were infectious in nature, with two cases of cholangitis and one case of acute cholecystitis, while there were no infectious complications in the control group. This increase in the frequency of infectious complications could be linked to the large diameter of the stent, which would increase the reflux of the digestive contents into the biliary tract and reflux with potential stasis due to prothesis inflammation (uncovered stents with epithelial proliferation), thus promoting infection. Indeed, it has been shown, after the administration of barium, that the insertion of a transpapillary prosthesis causes duodenal reflux in 100% of cases [20]. This reflux could be also a cause of stent obstruction because of early deconjugation of biliary salts, leading to sludge formation and, as a consequence, stent obstruction [21]. We did not investigate if early obstruction occurred in case of presence or not of Gall bladder with could interfere in chemical composition of the bile duct. However, the data on the involvement of this reflux in infectious complications have been contradictory when following patients treated with a 10 mm diameter prosthesis [20,22]. Nevertheless, the rate of complications was not significant, and we decided to stop the use of 12 mm uncovered metal stents for malignant stenosis because we considered the level of complications to be unacceptable.

The reintervention success rate was 89.5% in the 10 mm group vs. 100% in the 12 mm group, with no statistically significant difference; we thought that it would technically be easier to introduce a new prosthesis with a larger prosthesis already in place. When reintervention for stent obstruction is performed in cases of malignant stenosis, the stent in stent technique is most often used since the initial uncovered stent is inextirpable. This difference in reintervention success has been demonstrated for 8 mm and 10 mm prostheses [23]. Additionally, if the size of the first stent placed is large (12 mm), after the introduction of a second stent inside the first stent, the biliary tract size remains larger; therefore, there is less risk of obstruction. Unfortunately, with the limited follow up duration, this study did not allow us to answer the question of whether an initial stent with a diameter of 12 mm allows for prolonged patency of a second stent after application of the stent in stent technique. Our study has other limitations. First, it was not a randomized, controlled prospective study, and the patient sample size was small, especially for benign stenosis. Second, the follow up duration was not optimal, particularly for benign stenosis, since at the end of the follow up period, less than 50% of the patients who received a 12 mm stent experienced an event (obstruction of the stent or death), which prevented us from calculating the median overall survival.

Conclusion

This case control study does not demonstrate better patency for uncovered 12 mm diameter metal bile duct stents in the treatment of subhilar malignant strictures. The insertion of a 12 mm covered stent in the treatment of benign strictures must be better assessed since there would appear to be a benefit in this subgroup of patients. New prospective, controlled studies with a large number of patients and prolonged follow up duration should be conducted to ensure the efficacy and safety of these biliary stents.

RBO: Recurrent biliary obstruction

ESGE: European Society of Gastroenterology

ERCP: Endoscopic retrograde cholangiopancreatography

PT: Prothrombin time

OR: Odds ratio

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