Prospective randomized study comparing double layer and Tannenbaum stents in distal malignant biliary stenosis

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Abstract

Background and study aims : **This prospective randomized study compared the patency and effective drainage rate of two stents with different materials but similar design, in the palliation of inoperable malignant biliary obstruction.**

Patients and methods : **A total of 49 patients (26 women, mean age 72.55 ± 10.75 years, range : 48-91 years) with obstructive jaundice due to inoperable malignant stricture of the distal common bile duct without previous drainage procedure, were randomly assigned to receive 10F Double Layer (DLS) (n = 24) or 10F Tannenbaum (TAN) (n = 25) biliary plastic stent. The diagnosis included pancreatic cancer (n = 33), cholangiocarcinoma (n = 8), ampullary cancer (n = 7) and metastatic lymphadenopathy (n = 1). The duration of stent patency, the effective drainage, and the adverse events were analyzed.**

Results : **Stent placement was successful in all patients with minor complications. The overall median patency rates between the two groups did not differ (107.5 days for DLS group vs. 101 days for TAN group ; p = 0.066). Effective drainage rate at the end of second week was 95.8% for DLS group and 96% for TAN group, (p = 1.00). Proximal stent migration occurred in one patient with TAN stent.**

Conclusions : **The present study demonstrated that both DLS and TAN stents are comparable in terms of placement, overall stent patency, and complications.** (Acta gastroenterol. belg., **2010**, 73, **445-450**).

Key words : malignant biliary stenosis ; stent ; Tannenbaum ; Double layer ; patency.

Introduction

Biliary stent (metallic and plastic) insertion has been recognized in the last decades as a standard palliative treatment of choice for obstructive jaundice caused by inoperable pancreatobiliary malignancies (1). Despite the fact that self-expanding metal stents (SEMSs) have long patency and are preferred for inoperable patients with expectancy of life longer than 6 months, they have several drawbacks including higher costs ; the fact that the stent cannot be removed ; and the possibility to become occluded by tumor ingrowth and overgrowth (1-4). Besides, a major issue is the long-term patency of plastic stents that will eventually clog on average after 3 to 6 months ; the standard commonly used plastic stent is the Amsterdam-type polyethylene stent with a median patency of 3-6 months. Stent clogging is a phenomenon that begins with protein absorption into the inner stent surface with subsequent bacterial colonization due to duodenobiliary reflux (5-8). Apart from microbial colonization and duodenal reflux of food constituents (e.g., fibers), numerous other factors have been involved in the occlusion of plastic endoprostheses including stent design ; physicochemical properties of the constitutive materials ; surface irregularities of the devices promoting microbial biofilm formation ; and biliary sludge accumulation in the lumen (9). Changing the properties of the materials used in the manufacturing process of plastic stents has been explored having as the main target to reduce the frictional coefficient of a polymer and the amount of the encrusted materials (10). None of the published studies comparing Teflon with polyethylene stents (11-15), has shown any difference in the use of plastic prostheses of different materials and design. However, Tringali *et al*. in a prospective randomized trial comparing Double Layer (DLS) and polyethylene stents for malignant distal common bile duct strictures showed that DLS have a significantly longer patency than polyethylene stents (16).

In this prospective randomized study, taken place in two endoscopy centers in Greece, we compared the patency rate and effective drainage rate of the DLS and Tannenbaum stent (TAN) in patients with inoperable malignant distal common bile duct (CBD) obstruction.

Patients and methods

Between January 2005 and June 2009 a prospective randomized study was carried out in two centers to compare the patency and effective drainage rate of the 10F TAN stent with the distal curved DLS stent in patients presenting with malignant stricture of distal common bile duct deemed as poor candidates for curative resection. Informed consent was obtained from each patient or his/her designee before randomization. The prospective study was approved by the local ethics committee of each participating center and conformed to the ethical guidelines of the 1975 Declaration of Helsinki (6th revision, 2008) ; it was performed at two centers in Northern Greece in 49 patients randomized to receive either a TAN or a DLS stent.

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Entry criteria

Patients were included if they had obstructive jaundice due to malignancy involving the distal CBD, without having undergone a previous diagnostic ERCP or drainage procedure. Malignancy was documented by brush cytology or histopathological assessment of specimens obtained at a prior ERCP or CT-guided biopsy or was suspected based on clinical presentation, CT, MRI, and ERCP findings. All patients were initially considered for surgery and were only rejected because of the extent of disease or severe disability (old age and/or other comorbid conditions). The diagnosis of inoperability of the malignancy was established by various imaging methods (US, CT, MRI, EUS) and was confirmed after consultation with the surgeon and anesthesiologist. Patients with duodenal obstruction or hepatic hilar involvement and those with other previous malignant diseases or a previous bile duct surgery were excluded. No other therapy was used to relieve biliary obstruction during the study period.

Randomization and technique

The randomization process was carried out by two (PK, GP) of the authors using an opaque, sealed envelope and random table technique, when the patient was in the ERCP suite, after the guidewire was placed. Blinding after randomization was not applied.

All procedures were performed under fluoroscopic guidance and biliary sphincterotomy was performed using a double lumen pull-time sphincterotome (Clever-cut, Olympus) via a stiff hydrophilic guidewire (Jagwire, Microvasive). If cannulation of CBD with conventional methods failed, precut techniques (needle-knife papillotomy, transpancreatic sphincterotomy and suprapapillary fistulotomy) were used. After diagnostic ERCP, the stents were inserted with the three-layer technique (guidewire, guide-catheter, pusher). Dilation of the stricture with balloon or Soehendra dilator before stent's placement was not performed. A length that would permit the stent to extend to a minimum of 1 cm proximal and distal of the margins of the malignant stricture was selected. The length of the stricture was measured during withdrawal of the initial cannulating catheter : when the catheter was at the proximal end of the stricture, the endoscopist held the catheter just outside the biopsy port. The catheter was then withdrawn until it was seen just outside the papilla and the distance from the endoscopist's fingers to the biopsy post was measured ; the measured distance was the minimal length of stent required to cross the lesion. Successful stent insertion was defined as placement of the stent across the stricture with appropriate radiographic positioning, and immediate, obvious biliary decompression. Stents of 10F diameter were used, because studies have shown improved patency with larger diameter stents compared with 7F or 8.5F, as well as patency rate equal to those of 11.5F (17-18). All patients received two doses of ciprofloxacin (500 mg) intravenously, before and after the procedure.

Characteristics of the stents

(TAN) : It is straight Teflon stent, without side holes but anchoring flaps that do not penetrate the lumen (Fig. 1). To obtain adequate anchorage, the stent has two layers of four radial flaps, each 15 mm in length, at the proximal end and four similar flaps at the distal end (Fig. 2). The stent flaps are carved from the stent wall without penetrating the lumen. This avoids structural irregularities by maintaining the integrity of the wall.

(DLS) : It is constructed of three layers (Fig. 1). The inner layer is made of a perfluoro-alkoxy (PFA) material with a special processing method-chemically smoothed Teflon. The inner lumen is therefore extremely smooth, resulting in a small and flatter surface to prevent adhesion of lipids and proteins. The outer layer consisting of polyamide elastomer gives the stent sufficient stiffness. The PFA material alone is not strong enough to withstand the pressure from a strictured bile duct. Between the inner and outer layer, a stainless steel mesh is therefore included to give the stent more stiffness and elasticity. The mesh also helps to bond the two different plastic materials. The DLS has four distal and proximal flaps to prevent stent migration (Fig. 3).

Follow up

Follow-up visits were scheduled at the end of first and second week after stent insertion. During the office visit, symptoms, clinical findings and biochemical analysis (total and direct bilirubin, alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase and γ-glutamyltransferase) were recorded. The pre-procedural day liver function tests, especially bilirubin, were used as a baseline level for comparison with subsequent samples to estimate the efficient drainage rate. Occlusion was considered as the recurrence of silent jaundice or the development of cholangitis (fever, abdominal pain, increased liver enzymes with/without jaundice).

Subsequent treatment after first stent's obstruction was left on the endoscopist's discretion to continue patient's treatment with a new plastic stent or to proceed with SEMS placement. Complications of ERCP and sphincterotomy were evaluated according to the criteria of Cotton *et al*. (19).

End points

The primary end point of the study was to compare the two types of stent for their patency. Stent's patency (calculated in days) was defined as the time interval between stent insertion and first stent's occlusion or patient's death with patent stent. Secondary end-points were to determine the effective drainage rate of stents and complications recorded in the two groups. We judged the drainage effect from the decrease in the level

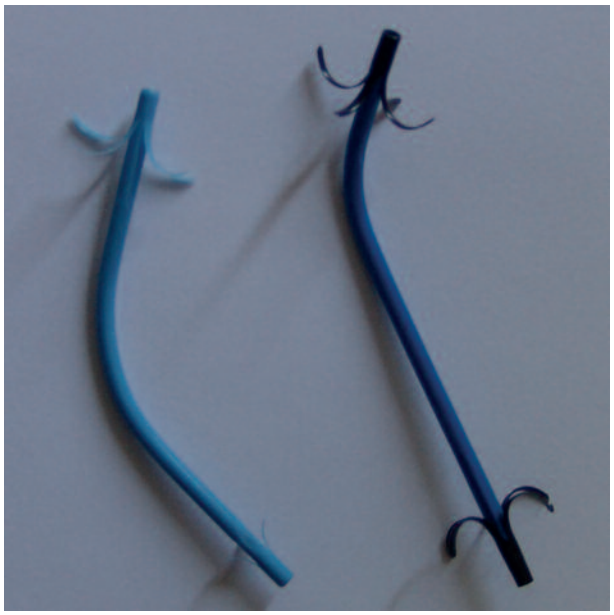

Fig. 1. — Left : the Tannenbaum stent ; right : the Double Layer stent.

of serum total bilirubin after stenting until less than 3 mg/dL in the end of second week.

Statistical analysis

The number of stents required to demonstrate statistical significance with a 5% alpha error and a 90% power was 67 and was calculated on the basis of previous data (13,20), assuming a 40% difference in patency rate between the two groups. In June 2009 the Committee of Science of Central Hospital withdrew the participation of Department of Endoscopy and Motility Unit in the study because the analysis of results of 49 patients showed no difference between the two groups and in the last year there was no inclusion of patients in the study. Therefore, with a sample size of 49 patients the power of the study was reduced to 80%.

The data were analyzed using the Statistical Package for the Social Sciences (SPSS, version 13.0 ; SPSS Inc, Chicago, IL, USA). The estimation of the cumulative patency of the two types of stents was performed using the Kaplan-Meier technique, supplemented by the log-rank test. Chi-square, Fisher's exact and Student's t tests were used to perform comparisons between the two groups. Significance was set at $p < 0.05$.

Results

Forty-nine patients at two participating institutions were recruited over a period of 4 and a half years. Of these patients, 24 were randomized to a TAN and 25 to DLS stent. Baseline characteristics of both groups were comparable regarding age, sex ratio, type of malignancy, and liver blood tests (Table 1). The most common cause of malignant stricture was pancreatic cancer (Table 1)

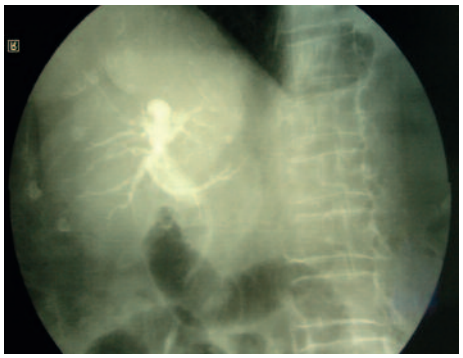

Fig. 2. — The radiograph shows a Tannenbaum stent achieving relief of jaundice due to distal cholangiocarcinoma.

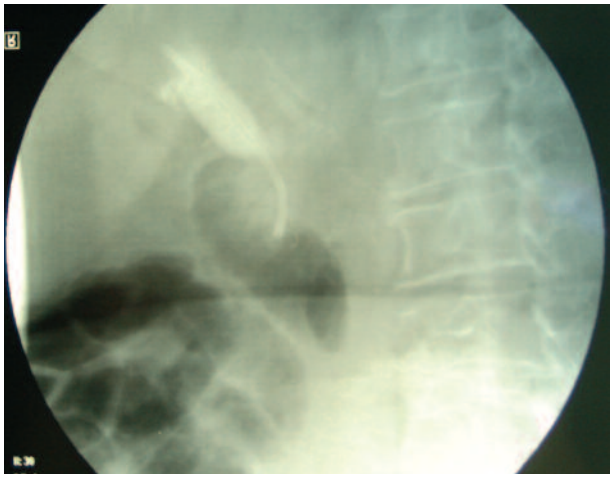

Fig. 3. — The radiograph shows biliary drainage after insertion of Double Layer stent in distal biliary stricture due to pancreatic head carcinoma.

with the majority of the strictures being in the intrapancreatic portion of the CBD. Conventional endoscopic sphincterotomy (ES) was performed in 40 patients, while precut technique was needed to gain access in the CBD in 9 patients (18%). Stent insertion was successful in all patients of both groups. There was no procedure-related mortality. Mild post-ES intra-procedural bleeding was observed in four patients (8.16%) (three patients in DLS and one in TAN group) and was successfully treated in all cases with injection of adrenaline solution (1:10,000). Proximal migration of stent occurred in one patient of TAN group, and the recurrence of jaundice was treated by placement of a new plastic stent, adjacent to the proximally migrated stent. There were no device-related complications in either group.

Stent occlusion requiring reintervention clinically presented as cholangitis in 13 patients (54.2%) of DLS group and 12 patients (48%) of TAN group and as jaundice recurrence in 4 (16.6%) and 3 (12%) patients of DLS and TAN groups, respectively. Seven patients (28%) of DLS group and 10 patients (40%) of TAN group died of underlying disease progression without

Table 1. — **Patients' baseline characteristics**

	Type of stent		p
	Double layer	**Tannenbaum**	
No of patients	24	25	
Gender (male/female)	10/14	13/12	0.469
Age (mean ± SD)	71.66 ± 11.81	73.4 ± 9.79	0.834
Type of cancer			0.768
Pancreatic cancer	17	16	
Ampullary cancer	3	4	
Cholangiocarcinoma	4	4	
Metastatic lymph nodes	0	1	
Stricture length (mm) (mean ± SD)	24.7 ± 7.3	23.9 ± 8.1	0.425
Bilirubin (mg/dL) (mean ± SD)	15.28 ± 5.31	12.84 ± 4.79	0.097
ALP (U/L) (mean ± SD)	487.71 ± 133.19	491.76 ± 143.83	0.919
γGT (U/L) (mean ± SD)	333.58 ± 90.86	322.2 ± 73.89	0.632
SGOT (U/L) (mean ± SD)	76.04 ± 24.99	77.44 ± 23.85	0.842
SGPT (U/L) (mean ± SD)	87.75 ± 25.80	87.12 ± 27.66	0.935

P = 0.05 : level of statistical significance.

clinical evidence of stent occlusion after a median of 40 days (range 25-84) and 81 days (range 62-94), respectively. Five patients (20.8%) in DLS group and one in TAN group (4%) died within 45 days after stent insertion with patent stent.

The median patency in DLS was 107.5 days (range 23-209 days) compared with 101 days (range 51-177 days) in TAN group. Comparison of the patency of the two groups by the Kaplan Meier method showed no statistical difference (p = 0.066) (Fig. 4). The effective drainage rate was 95.8% in the DLS group compared with 96% in the TAN stent group (p = 1) (Fig. 5).

Discussion

This prospective randomized study evaluated, for the first time, the duration of patency and effective drainage rate of the DLS compared with the TAN stent. Both stents performed equally well with regard to the difficulty in insertion, stent-related complications and successful initial drainage. Despite the stiffness of both stents, no duodenal or bile duct injuries was observed. The median duration of patency of the DLS was 107.5 days (range 23-209 days) compared with 101 days (range 51-177 days) for the TAN stents. We decided to set as duration of stent patency, only the interval of the stent implantation and first stent occlusion, because it is known that subsequent stent placement typically results in decreased patency rate caused by prior biliary bacterial colonization (21).

The Kaplan – Meier curve of the stent patency revealed no differences between the stent groups (Fig. 4). Despite the fact that the most common plastic stent used for comparison with TAN stent and DLS stent is the straight polyethylene prosthesis (Amsterdam type) with a single side hole at each end, we chose to compare the DLS with the TAN stent because, apart from the comparable cost, both stents have similar design. Therefore, we believe that the comparison of patency rate and effective drainage rate between the two stents is more accurate and not influenced by stent's design. With respect to stent design, it has been shown in *in vitro* (10,22) and *in vivo* (14) studies that conventional polyethylene stents with side holes accumulate significantly more sludge than stents with the same material without side hole. Moreover, *in vitro* studies (10) have suggested that stents made of Teflon have lower friction coefficient than other plastics and therefore seem to be more suitable to prevent stent blockage. The addition of perfluoro-alkoxy (PFA) material with a special processing method – chemically smoothed Teflon in DLS- seems to influence significantly the patency period in vivo compared with polyethylene stents as shown by Tringali *et al*. (16). However it is unknown if the patency rate of DLS is longer than the Teflon TAN stent.

Our study population and inclusion criteria were similar to those of the Tringali *et al*. study (16) ; the median patency of DLS was 107.5 days, significantly less than the 144 days of their study. The lower patency rate of DLS in our study is probably related with the fact that five patients (20.8%) died of the underlying disease during the time interval of 45 days with the stent patent, influencing the overall patency rate in this group with the small sample of patients. Respectively, the median patency of TAN stents in our study was 101 days similar to all (11-15) but one (20) previous studies. This study (20) has shown a longer patency period with TAN stent ; however, in this trial, the control group received stents with the same material and diameter, but with a substantially different shape (pig-tail). Based on the common

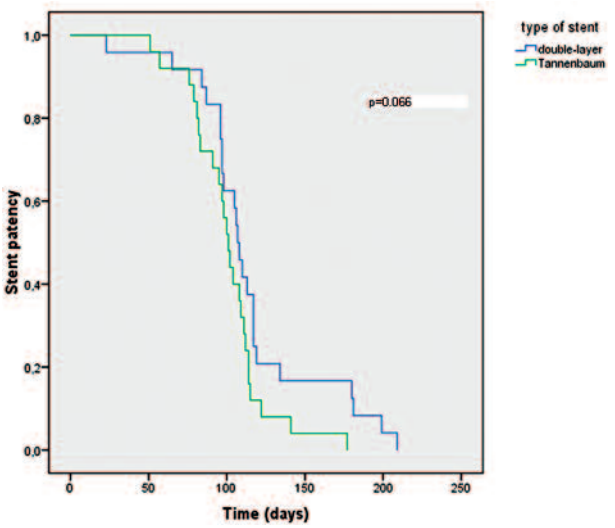

Fig. 4. — Kaplan-Meier plots of patency rates for the Double Layer (blue line) and Tannenbaum (green line) stents.

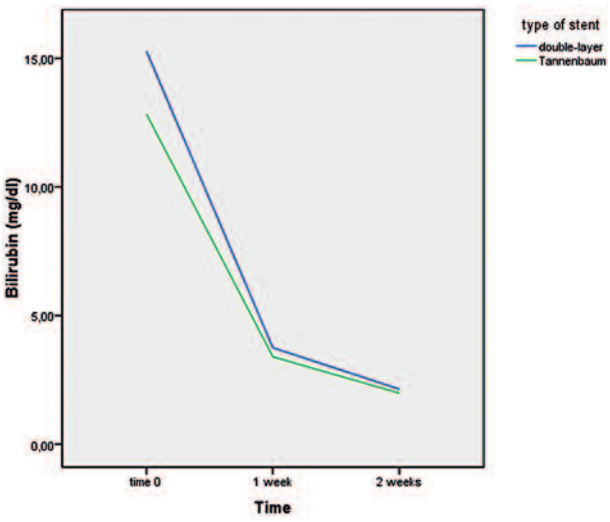

Fig. 5. — Effective drainage rate plots for the Double Layer (blue line) and Tannenbaum (green line) stents.

experience, the pig-tail shape exacerbates the turbulence of biliary flow and leads to increased sludge deposition and stent clogging (16,22).

The effective drainage rate was similar between the two stents in our study (Fig. 5) and probably reflects more consistently the coefficient of friction, a parameter related to the resistance to bacterial adherence in the stent. Previous studies that compared SEMSs with conventional polyethylene (23,24) and Teflon (Tannenbaum) (25,26) stents for endoscopic palliation of jaundice due to malignant common bile duct stenoses, showed longer overall patency for SEMSs, 2 to 3 times more stent failures in the plastic stents and greater cost-effectiveness of SEMSs. However, the high cost of SEMSs (20-30 times the cost of a plastic stent) precludes their extensive use especially in patients whose life expectancy is shorter than 3-6 months. Moreover, our study demonstrates that despite the introduction in the market of plastic stents conducted by biomaterials with low coefficient friction (DLS) to reduce stent's clogging, the patency rate has not been improved significantly to substitute SEMSs. Therefore the search for a plastic stent which is safe, inexpensive and with a patency rate comparable to SEMSs is justified.

The rate of migration, proximal and distal, was 2%, similar with previous studies (11-15) using stents with same design**,** but lower from other published reports (27-29) with conventional straight polyethylene stents, which have shown that proximal or distal displacement may occur in up to 10% of patients with malignant stricture. We believe that both stents (TAN and DLS) which are designed with radial side flaps (each 15 mm in length) that do not penetrate the lumen of the stent, improve stent's stabilization and prevent stent's dislocation.

A criticism of our study may be that we were unable to recruit 67 patients calculated to demonstrate a substantial power of the study ; the reduced sample size of 49 patients has led to a reduction in the power of our series. However, our study was prospective, randomized and monitored by two experienced pancreatobiliary endoscopists (PK, GP), and we are confident that our data is accurate.

In conclusion, modification of stent materials and design remains an active area of research in plastic stents, but at present, no technique has been found to consistently improve stent's longevity.

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