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Nitinol Stents for Palliative Treatment of Malignant Obstructive Jaundice: Should We Stent the Sphincter of Oddi in Every Case?

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Abstract

Purpose: To evaluate the necessity of metallic stenting of the sphincter of Oddi in malignant obstructive jaundice when the tumor is more than 2 cm from the papilla of Vater.

Methods: Sixty-seven self-expandable biliary stents were used in 60 patients with extrahepatic lesions of the common hepatic or common bile duct and with the distal margin of the tumor located more than 2 cm from the papilla of Vater. Stents were placed above the papilla in 30 cases (group A) and in another 30 with their distal part protruding into the duodenum (group B).

Results: The 30-day mortality was 15%, due to the underlying disease. The stent occlusion rate was 17% after a mean period of 4.3 months. No major complications were noted. Average survival was 132 days for group A and 140 days for group B. In group A, 19 patients survived $\leq$ 90 days and in eight of these, cholangitis occurred at least once. Of 11 patients in group A with survival $>$ 90 days, only two developed cholangitis. In group B, 13 patients who survived $\leq$ 90 days had no episodes of cholangitis and in 17 with survival $>$ 90 days, cholangitis occurred in three. There is a statistically significant difference ($p < 0.05$) regarding the incidence of cholangitis in favor of group A.

Conclusions: In patients with extrahepatic lesions more than 2 cm from the papilla and with a relative poor prognosis ($\leq$ 3 months), due to more advanced disease or to a worse general condition, the sphincter of Oddi should also be stented in order to reduce the postprocedural morbidity.

Key words: Percutaneous biliary intervention—Cholangitis—Metallic stents

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During the last decade, metallic endoprostheses have been used successfully for palliation of malignant obstructive jaundice [1]. A wide variety of different metallic stents have proved to have almost equally sufficient patency rates, without prolonging survival [2–8]. Percutaneous application of these devices has been established due to their low complication and mortality rates, especially in cases where endoscopy fails [2, 9]. More recently developed covered metallic stents failed to improve patency, so that their widespread use is not recommended [10, 11]. The most frequent late complication is cholangitis associated with stent occlusion and icterus [5, 6, 9]. Controversy remains about the need for stenting of the sphincter of Oddi located in the papilla of Vater, in case the tumor spares that region and does not obstruct the lower 2 cm of the common bile duct (CBD). The purpose of this study was to explore whether this technique really is helpful in preventing postprocedural morbidity associated with cholangitis without coexisting biliary obstruction.

Materials and Methods

During three consecutive years, in 150 patients with obstructive jaundice, percutaneous transhepatic cholangiography (PTC) was performed, followed in seven cases by external drainage and in 143 by external–internal drainage. Sixty patients, in whom the distal end of the tumor was at least 2 cm above the sphincter of Oddi, were selected for palliative insertion of self-expandable Nitinol stents. Hilar tumors, pancreatic head carcinoma, as well as ampullary tumors were excluded from this study. The patients were not randomly selected for the two groups in a particular way. They were selected by chance in each group during the first 30 months, then we counted the cases and made them up to 30 in each group in the last 6 months. After a patient's death, statistical data analysis (chi-square test with Yates' correction) was performed.

Table 1. Tumor type distribution in the two groups

Tumor type	Group A	Group B
Cholangiocarcinoma	18	19
Gallbladder carcinoma	5	4
Lymph node metastases	7	7

Thirty-eight patients were male and 22 were female; the age range was 42–85 years (mean 61 years). Two types of stent were used: the Diamond Ultraflex stent, manufactured for endoscopic use, was initially available to us and later also the Symphony biliary stent (both Boston Scientific, Watertown, MA, USA). The first is delivered over a 9.5 Fr catheter with a length of 190 cm, and the second over a 7 Fr catheter with a length of 65 cm.

All stents were placed under percutaneous radiological techniques. Only the right hepatic lobe was punctured and drained in all cases. During initial drainage, prophylactic antibiotics were given, starting the day before the procedure, but were not continued during the day of stent placement. In 30 cases an Ultraflex stent and in another 30 cases a Symphony stent was used. Stent length was either 40 or 60 mm. The patients were divided in two groups. In Group A ($n = 30$) the extrahepatic obstructing tumor was located more than 2 cm from the sphincter of Oddi. In this group, the distal end of the stent was always lying above the papilla. In group B ($n = 30$) the stent's distal end protruded into the duodenum. If the stent was not long enough to cross the papilla of Vater, a second stent of the same type was inserted. This was the case in seven patients in whom Symphony stents were placed. In total, 67 stents were applied in 60 patients.

Group A consisted of 18 patients with extrahepatic cholangiocarcinomas, five with gallbladder carcinomas, and seven with metastatic tumors (enlarged lymph nodes). Group B consisted of 19 patients with extrahepatic cholangiocarcinomas, four with gallbladder carcinomas, and seven with metastatic tumors (Table 1).

Follow-up was done by contacting all patients every 3 months. If a patient had any problems, their clinician asked for an ultrasonographic examination. Re-obstruction was excluded by the absence of dilated bile ducts. In the case of dilatations, a new intervention was performed to re-establish patency, either with a new stent of the same kind or just with an internal draining catheter. If no obstruction was found, conservative treatment was ordered.

Results

All stents were transhepatically inserted without any technical difficulties. Both stent-releasing mechanisms were simple to handle and caused no difficulties during deployment. The two stents are constructed from the same material, but the Ultraflex has a higher radial force, because of its knitted metal mesh. In the case of insufficient stent expansion, as occurred in 12 Symphony stents, balloon dilatation was performed.

The 30-day mortality rate was 15% and unrelated to the procedure. All patients died of their underlying disease. Average survival was 132 and 140 days for groups A and B, respectively. No major complications were noted. Minor complications, such as moderate pain, transient hemobilia, or vomiting, were found in 11 patients (19%) and were conservatively treated. In 10 cases (17%), stent occlusion was noted after a mean period of 4.3 months, so that in seven of these a second stent of the same type was inserted inside the first one. In three patients with a poor prognosis, only an internal draining catheter was left.

Table 2. Late cholangitis in relation to survival

	Survival		
	$\leq$ 90 days	> 90 days	Total
Cholangitis in group A	8/19 (42%)	2/11 (18%)	10/30 (33%)
Cholangitis in group B	0/13	3/17 (18%)	3/30 (10%)

Table 3. Cholangitis in relation to survival and stent type

Survival	Cholangitis	
	Group A	Group B
Ul $\leq$ 90 days	5/5	0/9
Sy $\leq$ 90 days	3/13	0/4
Ul > 90 days	1/5	2/11
Sy > 90 days	1/7	1/6
Total	10/30	3/30

Ul = Ultraflex Diamond stent; Sy = Symphony stent

Cholangitis as a late minor complication unrelated to stent obstruction was found in 13 of 60 patients. Patients suffered from fever, right upper abdominal pain, leukocytosis and eventually transient liver enzyme elevation and icterus. All patients had a negative ultrasonographic examination regarding bile duct dilatations. This medical condition was not the cause of death of any patient and was always treated conservatively. One patient with a Symphony stent inserted across the papilla had a mild episode of pancreatitis during the first 24 hr after stent placement, without any further consequence until his death 40 days later.

Statistical analysis of patient outcome found a difference when we separated the patients into those who lived less or more than 90 days (Table 2). A statistically significant difference regarding the incidence of cholangitis (8/19 in group A, 0/13 in group B; χ^2 7.3 before and 5.2 after Yates' correction, so that $p < 0.05$) was found in patients who lived $\leq$ 90 days after stent placement. No difference was noted when patient survival was longer than 90 days (2/11 in group A, 3/17 in group B). Analysis regarding the two stent types showed a higher cholangitis rate for the Ultraflex stent when the papilla was not stented and no difference if it was (Table 3). No difference was also noted regarding patients' age and sex. All cholangitis episodes were conservatively treated without further complications. Patients with cholangitis were discharged after 4–5 days of hospitalization.

Discussion

Metallic endoprostheses have been used with very good results during the last 10 years for palliation of malignant

obstructive jaundice [1]. Their superiority regarding longer patency rates [2, 9, 12], improved quality of life [4] and overall lower cost [2, 9] when compared with plastic stents is no longer controversial. The most important factor favoring the use of a metallic stent is the possibility of relatively long patient survival. If life expectancy is less than 3–4 months, endoscopically or percutaneously inserted plastic endoprostheses may be indicated [7, 9]. This reduces both the costs and patient discomfort, as the patient does not have to carry a hanging catheter around. Vitale et al. [7] proposed as indications for a metallic stent, long life expectancy combined with a patient's good general condition, impending proximal duodenal obstruction from a pancreatic tumor which could prevent endoscopy in the future, as well as cases where the patient lives a long distance from the medical center. The last factor, which has not been stressed enough, may also be of importance, especially if life expectancy is longer than 6 months.

Prat et al. [13] found that a tumor size of more than 3 cm predicts a survival of 3.2 months, and a size of less than 3 cm a survival of 6.6 months. This could be a very useful information when deciding whether to insert a plastic or a metallic stent. All these factors must be considered together with the patient's general condition [7]. If this is not good, a plastic stent should be inserted, or if endoscopic management is impossible, a percutaneous drainage without metallic stenting should be placed.

Our 30-day mortality rate of 15% is comparable with that of other studies [2, 3, 6, 8]. If we were to select patients for metallic stenting with stricter criteria, as mentioned above, this rate could markedly decrease. We had no incidence of major complications, although in half the cases we used large delivery catheters of 9.5 Fr outer diameter. Our stent occlusion rate of 17% after a mean period of 4.3 months is comparable with that in other studies [3, 5, 6, 8, 14].

Early postprocedural complications ($\leq$ 30 days after insertion of a plastic or metal stent) are cholangitis, abscess, acute cholecystitis, perforation, pleura empyema, hemobilia, hematoma or hemorrhage, intraperitoneal leak, subcutaneous metastasis, and pleurobiliary fistula [3, 5, 6]. Conservative, interventional, or surgical treatment may be required, mostly with satisfactory results. Late complications ($>$ 30 days postprocedural) are jaundice and cholangitis caused by reobstruction, acute cholecystitis due to cystic duct infiltration, as well as melena or subphrenic fluid collection [5]. Duodenal ulcers or perforation can be induced by mechanical pressure through the distal portion of the stent [5, 15]. To prevent this complication, the metallic mesh should not protrude for more than 1 cm beyond the papilla. One case of pancreatitis was noted in a patient in a relatively poor general condition (survival time 40 days), in whom a Symphony stent was inserted across the papilla of Vater. The episode occurred during the first 24 hr after stent placement without any tumor material occluding the pancreatic duct. Contrast medium opacified the pancreatic duct before the stenting procedure, so that this pathogenetic mechanism is more likely than duct obstruction through the metallic mesh. Nevertheless the episode was mild, did not recur, and did not influence the patient's outcome.

Cholangitis without biliary obstruction is a condition rarely mentioned in the literature. Rossi et al. [6] found a 3% rate, which was treated with intravenous antibiotics. Other authors found an even less frequent rate [5, 10, 11], including cases of covered metallic stents crossing the papilla of Vater [10, 11]. Vitale et al. [7] encountered no late cholangitis by placing the stent above the papilla, but ordered a once-daily suppressive dose of an antibiotic in all patients. We think that this minor complication could be underestimated, since we found it in 22% of our patients (13/60). Another possible explanation may be that some cases remain unknown to the interventional radiologist, since the clinicians do not consult him until an obstruction is present. Nevertheless it is a situation which causes rehospitalization, clinical examination, and additional imaging. This can increase the costs and eliminate the advantages of metallic endoprostheses in relation to plastic ones. The exact pathogenetic mechanism of late cholangitis is unknown. If it occurs in cases with the stent protruding into the duodenum, one can suppose it is caused by ascending gastrointestinal fluids. If it occurs in cases with the stent above the papilla, it has been hypothesized to be caused by preservation of the sphincter function and inherently poorer biliary drainage.

Regardless of the cause, late cholangitis was found in 10% of group B and in 33% of group A patients. When we analyzed the same data in relation to short ($\leq$ 90 days) or long ($>$ 90 days) survival, we found no late cholangitis in group B and 42% in group A (8/19) for patients who lived 90 days or less. For patients who lived longer than 90 days, the rate was 18% in both groups (Table 2). The fact that most cholangitis episodes were found in group A patients with Ultraflex stents who lived less than 90 days (5/5 Ultraflex vs 3/13 Symphony stents) remains unexplained (Table 3). All episodes were conservatively treated, without the need for reintervention.

Our data suggest that in patients with extrahepatic tumors 2 cm or more from the papilla, a stent should be inserted across the sphincter of Oddi, in order to prevent late cholangitis. This could provoke better bile drainage across the sphincter. Especially in patients with a low life expectancy of less than 3 months and who usually do not have a high quality of life after stent placement, is very important to reduce morbidity and discomfort after jaundice palliation.

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