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The Importance of Biliary Drainage Catheter Diameter in Malignant Stricture

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Abstract

Purpose: Efficacy of 8F and 10F biliary drainage catheters compared in patients with malignant stenosis.

Method: Between 2010 and 2012, 106 patients presenting to interventional radiology for malignant biliary obstruction were assessed and 54 patients were included in the study. Liver function tests (AST, ALT, GGT, ALP, direct and total bilirubin) and amylase values were monitored before and for 5 days after the procedure. Potential complications were noted. The catheters to be inserted were selected randomly and independently of the patients.

Results: An 8F catheter was inserted in 18 male and 9 female patients, while a 10F catheter was used in 20 male and 7 female patients. There was no statistically significant difference between the two groups regarding the level of stenosis, age, and gender. The 10F catheter group showed a significant decrease in bilirubin compared to the 8F group starting from the fourth day of drainage ($p<0,05$). No statistically significant difference was found between the two groups in the rate of decline of other liver function tests (AST, ALT, GGT, ALP) ($p>0,05$). A significant increase in amylase values was observed in the 10F catheter group on the first day of drainage ($p<0,05$). There was a lower rate of complications in the 10 F group, but this did not reach statistical significance.

Conclusion: Both catheters showed significant improvements in liver function in short-term follow-up. The 10F catheter is more effective in improving bilirubin levels and causes an increase in amylase levels on the first day after the procedure. Complication rates were similar in both groups.

Keywords: Drainage; Biliary; Liver function; Amylase; 10F; 8F.

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Introduction

The bile system has two vital functions: the regulation of digestion and absorption of certain elements, and the removal of metabolic waste products from the liver [1]. Elevated bilirubin levels lead to deterioration of kidney function, weakening of the immune system and delayed wound healing. Malignant strictures are the most common cause of biliary obstruction after gallstones. Blockage of the bile duct requires urgent intervention. Percutaneous Biliary Drainage (PBD) is a procedure used to improve liver function and help treat malignant obstructions. Effective biliary drainage reduces hospital stays and speeds up treatment [2-4]. Biliary drainage is conducted using 8F and 10F drainage catheters in our interventional radiology department. Our aim in this study is to determine the effectiveness of catheter diameter in bile drainage.

Methods

Following the decision of the ethics committee of Erciyes University Faculty of Medicine, a total of 106 patients presenting with biliary obstructions between October 2010 and February 2012 were assessed at the Department of Interventional Radiology. There were 20 benign occlusions (stone, stenosis, iatrogenic type, etc.), 13 intrahepatic bile duct occlusions, 9 patients treated in other healthcare facilities, 8 of whom were below 5 mg/dl and 2 of whom were treated early. In total, 52 cases were ruled out. A total of 54 patients with malign obstruction were enrolled who met the study criteria, had total bilirubin >5 mg/dL and did not have focal biliary obstruction. PBD was carried out using an 8F catheter in 27 cases and a 10F catheter in the other 27 cases. Liver function tests (total bilirubin, direct bilirubin, AST, ALT, GGT, ALP), amylase levels and complications were monitored and recorded for five days.

Percutaneous Transhepatic Cholangiography (PTC) was performed under local anaesthesia using digital fluoroscopy (Philips Integris 5000, Philips Medical Systems, Netherlands) to determine the level of obstruction. A second access was made to the most appropriate bile duct, and the PBD catheter was put in place. External drainage catheter was placed in six cases where the stenosis level could not be exceeded, and external-internal drainage catheter was placed in 48 cases. The laboratory tests were recorded before the process and for a period of five days after the process. Daily laboratory values were used to determine drop rates and mean drop values for both catheter types. Complication rates were calculated for each catheter. Data were analysed using SPSS for Windows (version 15). Non-parametric tests (Chi-Square, Mann-Whitney-U, Spearman's rho, and Wilcoxon W, etc.) were used for the statistical analysis.

PBD technique: After the informed consent form had been received, the patients were placed in the supine position on the table under digital fluoroscopy (Philips Integris 5000, Philips Medical Systems, The Netherlands). Local anaesthesia (15 mL of 1% lidocaine) was applied after appropriate cleansing of the area and antibiotic prophylaxis (cefazolin-sodium 1 g iv/im). A Chiba needle (21G,15 cm) was inserted via the midaxillary line through the appropriate intercostal space. Non-ionic contrast agent (Ultravist 300 mOsm / L) was used to determine the degree of obstruction. After filling the biliary tree with contrast, a second entry was made through the appropriate peripheral bile duct. A thin (0.018») guidewire (Medtronic Vascular, Danvers, USA) was placed through the needle and the needle was pulled out. A 4F dilator (Boston Scientific Accustick II introducer system) was advanced through the guidewire. Thin guidewire exchanged for 0.35 in guidewire (Medtronic 150 cm guidewire). A 35 cm PBD catheter (8F or 10F Boston Scientific Biliary drainage catheters with radiopaque marker-flexima material) was placed over the guidewire with the tip in the duodenum. There were 12 holes in both drainage catheters, 7 at the level of the distal shaft and 5 at the curved tip (Figure 1). The string was pulled to lock the tip of the catheter. The catheter was then sutured to the skin. Two highly experienced interventional radiologists carried out all of these procedures.

Results

A total of 54 cases of malignant obstruction were included in the study. An 8F catheter was used in 27 cases (18 male and 9 female), and a 10F catheter was used in the other 27 cases (20 male and 7 female). In the 10F catheter group, patients ranged in age from 47 to 92 years, with a mean age of 66.2+11. The 8F group ranged in age from 42 to 87 years (mean 64.7±9). For age and gender, there was no statistically significant difference between the two groups (p>0.05) (Table 1).

The level of stenosis was categorised as 1/3 proximal, 1/3 middle and 1/3 distal from the main hepatic duct to the distal common bile duct. The stenosis was proximal in 9, middle in 12 and distal in 6 cases in the 8F group. In the group of 10 F cases, 11 cases were proximal, 8 cases were middle and 8 cases were distal. There was no significant difference in the level of stenosis between the two groups (p>0.05) (Table 1).

Internal-external and external biliary drainage catheters were placed in 24 and 3 cases respectively in both groups. There was no significant difference in the type of drainage between the two groups (p>0.05). In the 8F case group the mean common bile duct diameter was 17.5 ± 5 mm, and for the 10F case group, it was 18.1 ± 4 mm. For the common bile duct width, there was no significant difference between the two groups (p>0.05) (Table 1).

In the 8F group, total bilirubin levels fell from 17±6 mg/dl to 11,5±5,9 mg/dl before and after the procedure. The total bilirubin level decreased from 18±5 mg/dl to 9,4±5 mg/dl in the 10F group. A statistically significant decrease in total bilirubin levels favouring the 10F catheter was observed after 4th day compared to first day (p<0.05) (Figure 2).

In the 8F group, direct bilirubin levels fell from 12.2±4.5 mg/dl to 8,4±4,3 mg/dl before and after the procedure. The direct bilirubin level decreased from 11.9±4.3 mg/dl to 6.1±3.6 mg / dl in the 10F group. A statistically significant decrease in total bilirubin levels favouring the 10F catheter was observed after 4th day compared to first day (p<0.05) (Figure 2).

In the 8F group, the mean AST levels fell from 130±82 U/L to 79±69 U/L before and after the procedure. The mean AST levels decreased from 148±109 U/L to 70±35 U/L in the 10F group. There was no significant difference in the mean AST levels between the two groups (p>0.05) (Figure 3).

In the 8F group, the mean ALT values fell from 137±89 U/L to 78±60 U/L before and after the procedure. The mean ALT values decreased from 162±148 U/L to 73±42 U/L in the 10F group. There was no significant difference in the mean ALT levels between the two groups (p>0.05) (Figure 3).

In the 8F group, the mean GGT values fell from 493±359 U/L to 219±144 U/L before and after the procedure. The mean GGT values decreased from 604±398 U/L to 293±210 U/L in the 10F group. There was no significant difference in the mean GGT levels between the two groups (p>0.05) (Figure 4).

In the 8F group, the mean ALP values fell from 552±263 U/L to 308±137 U/L before and after the procedure. The mean ALP values decreased from 643±337 U/L to 350±144 U/L in the 10F group. There was no significant difference in the mean GGT levels between the two groups (p>0.05) (Figure 4).

There was a statistically significant reduction in all liver tests in both groups compared to pre-procedure levels (p<0.05).

Pre-treatment and 1-5 days median amylase values in group 8F; 65 (38-128) U/L, 104 (42-222) U/L, 77 (45-117) U/L, 58 (40-96) U/L, 58 (41-87) U/L. Amylase levels did not show a statistically significant difference compared to pre-treated levels (p>0.05) (Figure 5).

Pre-treatment and 1-5 days median amylase values in 10F group; 55(39-95) U/L, 120 (40-460), 68 (26-98) U/L, 62 (37-91) U/L, 76 (32-227) U/L. Amylase levels showed a statistically significant difference compared to pre-treated levels (p<0.05) (Figure 5). Despite high amylase levels, no acute pancreatitis occurred.

Complications were observed in 13 cases of the 8F group, including nine cases of bacterial growth on the catheter, three cases of cholangitis, and one case of an infected biloma. Nine complications were noted in the 10F group, including six cases of bacterial growth on the catheter, one case of cholangitis, one subcapsular haematoma and one infected biloma. Complication rates were not significantly different between groups (p>0.05).

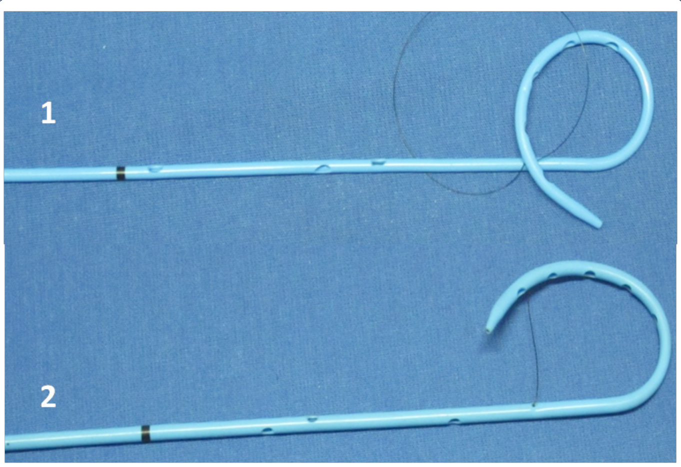

Figure 1: Picture showing the distal parts of the 8F **(1)** and 10F **(2)** catheter. The black area indicates the radiopaque marker. There are 12 holes in both drainage catheters, 7 at the level of the distal shaft and 5 at the curved tip.

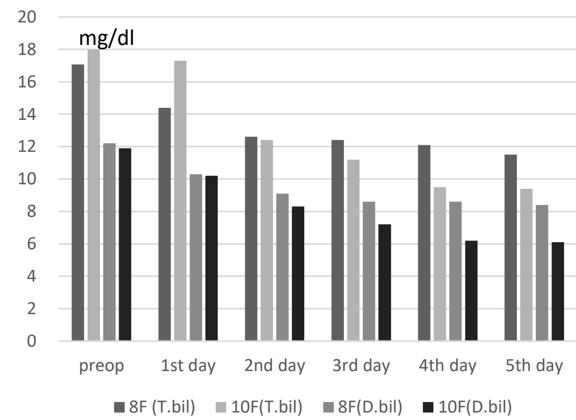

Figure 2: Diagram showing reduction in total and direct bilirubin values.

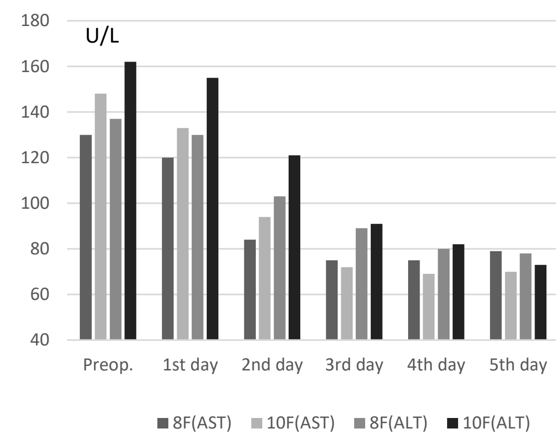

Figure 3: Diagram showing reduction in AST and ALT values.

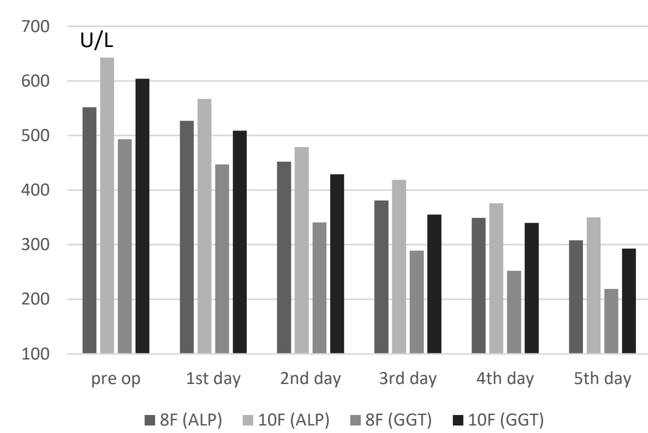

Figure 4: Diagram showing reduction in ALP and GGT values.

Discussion

Treatment options for malignant biliary obstruction include surgery, percutaneous biliary drainage and stenting, and chemotherapy. Improving patient comfort and longevity involves using appropriate combinations of treatments. Elevated bilirubin levels lead to deterioration of kidney function, weakening of the immune system and delayed wound healing [3,4]. If the patient has a chance for surgery, the main treatment method is surgical excision. Surgical excision is the primary treatment method, if the patient is suitable for surgery. However, elevated bilirubin levels and impaired liver function pose significant surgical and anaesthetic risks [2,5]. There are reports in the literature that suggest bile drainage reduces postoperative complications when the total bilirubin level is above 5 mg/dl [6,7]. Raising bilirubin levels limits the use of chemotherapy, as some agents cannot be used when bilirubin levels are at 2 mg/dl and above due to their metabolism by the biliary system [8].

Preoperative biliary drainage reduces postoperative morbidity and mortality, although conflicting studies exist in the literature [7,9]. Currently, no published study evaluating the effectiveness of PBD catheters. However, a study investigating the effectiveness of naso-biliary drainage found no significant difference in efficacy between 4F and 6F drainage catheters [10].

The duration for serum bilirubin values to recover after biliary drainage ranges from 4 days to 3 weeks Clark et al. conducted a study with 42 patients using an 8.3F bile drainage catheter. They observed an average daily decrease in total bilirubin of 1.4 mg/dl [11]. In our study, the average daily reduction in total bilirubin was 1.4 ± 0.8 mg /dl in the 10F group and 0.9 ± 08 mg /dl in the 8F group. The reduction in daily total bilirubin was lower in the 8F group compared to what was reported in the literature. Narrow catheters (8,3F) were reported to be more occlusive [12]. In our study, we observed no bending or occlusion during catheter controls in both groups. However, the lower decrease in bilirubin in the 8F group compared to the literature suggests that intermittent occlusions may be more common in the 8F group of cases. In our research, we observed a significant decrease in bilirubin levels in the 10F case group after the fourth day of intervention compared to the 8F case group. We believe that the 10F catheter has fewer intermittent occlusions and is more resistant to pressure. In a study conducted by Chen et al., bilirubin, AST, ALT, GGT, ALP levels were observed after the intervention, and a significant reduction was found in all levels except AST [13]. In our study, both groups showed a significant decrease in all values compared to the pre-procedure values. When comparing the rates of decline in liver function tests between the two groups, no significant difference was observed, except for bilirubin (p>0,05). We are confident that both catheters are effective in the improvement of liver function.

The literature reports that complications of pancreatitis are less than 12.5% after PBD procedure [14-18]. There are few studies in the literature investigating the impact of PBDs on amylase levels. Savader et al. monitored amylase levels in 50 cases using 8.3F and 8F catheters over a seven-day period following the intervention. Pre- and post-procedural amylase levels were within the normal range (40-220 U/L) in 28 patients. In 12 cases (24%), there was an asymptomatic increase in amylase after the procedure,

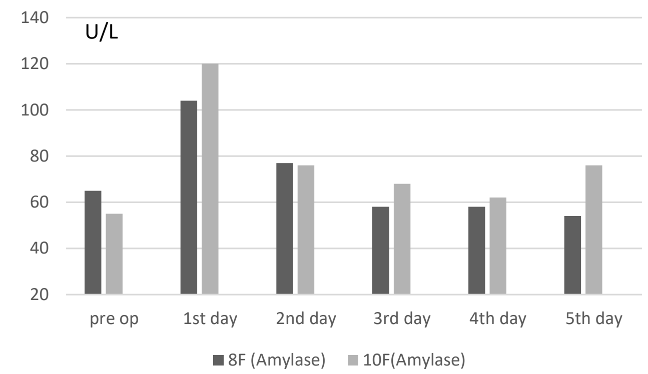

Figure 5: Diagram showing reduction in amylase values.

Table 1: Clinical characteristic of patients.

	8F	10F	Total
Average age	64.7±9	66.2+11	
Male	18	20	38
Female	9	7	16
Average total bilirubin before procedure	17±6 mg/dl	18±5 mg/dl	
Average direct bilirubin before procedure	12±4,5 mg/dl	12±4 mg/dl	
Mean diameter proximal of the stenosis	17,5±5 mm	18,1±4 mm	
PBD type			
External	3	3	6
External-internal	24	24	48
Stenosis level			
Proximal	9	11	20
Middle	12	8	20
Distal	6	8	14
Obstruction aetiologies			
Pancreatic cancer	12(%44)	10(%37)	22(%40)
Cholangiocarcinoma	7(%25)	8(%29)	15(%27)
Gastric carcinoma	5(%18)	3(%11)	8(%14)
Gallbladder cancer	1(%3)	2(%7)	3(%5)
Periampullary carcinoma	1(%3)	2(%7)	3(%5)
Colon cancer	1(%3)	0	1(%1)
Lymphoma	0	1(%3)	1(%1)
Neuroendocrine tumours	0	1 (%3)	1(%1)
Complications rate			
Reproduction in the catheter	9(%33,3)	6(%22)	15(%28)
Cholangitis	3(%11)	1(%3,7)	4(%7)
Infected biloma	1(%3,7)	1(%3,7)	2(%4)
Subcapsular hematoma	0(%0)	1(%3,7)	1(%2)
No complication	14(%52)	18(%66,7)	32(%59)

with a mean peak value of 420 U/L. An increase in levels of amylase (mean peak of 1556 U/L) with symptoms of pancreatitis were reported in 5(10%) cases after the procedure. In 5(10%) cases, the amylase levels were initially normal before the intervention. Although the levels were high (373-422 U/L) after the intervention, there was no evidence of pancreatitis [15]. In our study, based on Savader's reference values, we discovered that post-operative amylase levels were within normal limits in 37(68%) of the cases in both the 8F and 10F case groups. Furthermore, asymptomatic amylase elevations were observed in 17(32%) cases, and asymptomatic pre- and post-operative elevated amylase levels were seen in 5(9%) cases. We did not observe any cases of pancreatitis. This finding may be related to our study's small number of patients. However, post-procedure amylase levels indicated a significant increase in the 10F group compared to pre-procedure levels. This may be caused by increased pancreatic duct obstruction associated with catheter diameter.

Cholangitis complications have been observed in studies at a rate of 5-65% [19-23]. The risk increases with the duration of PBD. Nennstiel et al. discovered a 5% cholangitis complication rate following 939 PBD procedures in patients with malignant obstruction. However, the PBD catheter diameter was not stated in the study [21]. In a study of 105 cases without mention of prophylactic antibiotic therapy, Hansson et al. found a cholangitis rate of 25%. They observed cholangitis attacks in all cases of Percutaneous Biliary Drainage (PBD) procedures lasting longer than four months. The average drainage time was a median of 15 days (ranging from 1 to 150 days) in operated cases and a median of 2 months (ranging from 1 to 19 months) in non-operated cases [22]. In their study, Mueller et al. found cholangitis in 63% of cases when using internal-external drainage with a clamped drainage catheter. They also found an 11% rate of cholangitis when switching to larger diameter catheters (10F, 12F) [23].

Some authors stated that bile flow is low and complication rates are higher when PBD is performed with catheters smaller than 10 F [24]. Carrasco et al. found 107(63%) positive bile cultures and 75(37%) cholangitis in their study of 161 patients with malignant biliary obstruction using 8.3F and 10F catheters (mean follow-up 19 days, ranging from 3 to 180 days) [24]. Nomura et al. reported a 77% bile growth rate and a 28% cholangitis rate in 164 cases of malignant obstruction [25]. We found 9(33%) and 6(22%) positive bile cultures for 8F and 10 F catheters respectively, and cholangitis occurred in 3(11%) and 1(3.7%) patient in both groups. The short observation period and the use of prophylactic antibiotic treatment before and during intervention may explain the low number of infection-related complications in our study. There was no significant difference in infection-related complications between the two groups.

In the literature, a rate of 1% to 15% of bilomas have been reported due to bile leakage [12]. In their study of 188 cases, Mueller et al. found a biloma in 8 cases (4%) [23]. In our study, the rate of bilomas was 3.7% in both catheter groups, with a single case in each group, which is consistent with the literature. The trials reported a 6% rate of serious complications such as sepsis, death and life-threatening bleeding [23,26]. If the bile ducts are not dilated, the success rate of PBD is 70%, and if dilated, it rises to 98% [12]. Bleeding risk increases with ten or more parenchymal entries [27,28]. One case of non-life-threatening subcapsular haematoma was noted in the 10F case group in our study. It may be related to the wide tract of the 10F catheter. In our study, there were no major complications. We believe this is due to the fact that in all our cases there was significant dilatation due to malignant obstruction and that the procedures were carried out by two senior interventional radiologists.

Conclusion

Bilirubin values reduction is better with 10F compared to 8F catheters. Both 8F and 10F catheters can effectively improve other liver tests. On the first day after the procedure, amylase levels were statistically higher in the 10F group compared to the 8F group. There was no significant statistical difference between the two groups in terms of the rate of complications.

Conflict of interest: The authors declare no conflicts of interest associated with this manuscript.

Note: This study was presented as an oral presentation at the 8th International Hippocrates Congress (4-5 March 2022).

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