

Comparing percutaneous primary and secondary biliary stenting for malignant biliary obstruction: A retrospective clinical analysis

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Abstract

Purpose: Percutaneous transhepatic primary biliary stenting (PS) is an alternative to the widely used staged procedure (secondary biliary stenting, SS) for treating obstructive jaundice in cancer patients. To evaluate the efficacy and safety of PS and SS, a retrospective analysis was carried out. **Materials and Methods:** The percutaneous biliary stenting procedures performed between January 2000 and December 2007 at one hepatobiliary center were retrospectively analyzed, comparing the technical success rates, complications, and length of hospitalization of the two procedures. Of 61 patients (mean age 65.5 ± 13.1 years; range 31.1-92.7 years) suffering from obstructive jaundice caused by primary or metastatic tumors, 30 received PS and 31 received SS. The groups were comparable in the anatomical level of the obstruction, stent configuration, or the concurrent presence of cholangitis. Placement of metallic stents required one session for patients in the PS group and an average of 2.6 ± 1.1 sessions for patients in the SS group. **Results:** The overall technical success rate was 98.4% with 1 (1/61) failed approach to transcend the occlusion in the SS group. The rate of minor complications was 10% in the PS group and 6.5% in the SS group. The corresponding rates of major complications were 23.3% and 54.8%, respectively. SS patients had a higher rate of complications in general ($P < 0.05$), as well as a higher rate of severe complications in particular ($P < 0.05$). Procedural mortality was 0% for both the groups. The mean overall length of hospitalization was 7.7 ± 9.6 days for PS and 20.6 ± 19.6 days for SS ($P < 0.001$). **Conclusion:** Primary percutaneous biliary stenting of malignant biliary obstructions is as efficacious and safer than a staged procedure with secondary stenting. By virtue of requiring shorter hospital stays, primary stenting is likely to be more cost-effective.

Key words: Biliary drainage; malignant biliary obstruction; percutaneous biliary stenting; stents

Introduction

The long-term survival of patients with inoperable malignant

biliary obstruction is poor. These patients are often elderly and in poor general condition, with subclinical or frank cholangitis. Percutaneous biliary stenting is an established method to palliatively treat neoplastic obstructive jaundice.^[1,2] The intent of the therapy is to extend life, relieve symptoms of obstructive jaundice, improve quality of life, and prevent cholangitis with the aid of stenting.^[3] The median survival rate lies between 97 and 247 days.^[4-6] After major surgical procedures such as the Whipple operation or bilio-digestive anastomosis, the resulting strictures and anatomical changes can make it difficult or impossible to gain access to the biliary tree using an endoscopic retrograde approach. Relative to

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the retrograde endoscopic approach, biliary decompression in high obstructions can be achieved by the percutaneous transhepatic technique with a significantly higher success rate, without any higher risk of complications.^[7]

The percutaneous internal biliary drainage can be performed as a primary biliary stenting (PS) or as a staged percutaneous biliary stenting (secondary stenting, SS). In the one-step procedure, the stent is placed directly in the obstructed bile duct during the first and only session. Access tract embolization is not routinely performed. In the staged procedure, the first step is percutaneous external or external–internal transhepatic biliary drainage. The metallic biliary stent is then placed in the next session. Some interventionists then leave a biliary “safety” catheter in place for a few days to preserve access in case of malfunction. Currently, both protocols are utilized side by side at many institutions as patient-related factors, which may determine the complication rate and outcome, are not well defined.^[8]

Here, we present a retrospective analysis of 110 interventions in 61 patients, performed at our hepato-biliary referral hospital between January 2000 and December 2007. Patient population and the causes of obstructive jaundice were analyzed, and the two procedures, SS and PS, were compared regarding their technical success rates, complications, and length of hospitalization.

Materials and Methods

As this was a retrospective analysis of clinical data, approval by our institutional review board (IRB) was not required. Written informed consent was obtained before performing the intervention.

Case selection

We performed a full-text search of our Radiology Information System (RIS) from January 2000 until December 2007. The following key words were used in the search: Biliary stenting, biliary drainage, biliary metal endoprosthesis, and percutaneous transhepatic cholangiography. From the results of the full-text search, which yielded 529 interventions, we excluded the following: All control cholangiographies, causes for obstruction other than cancer, previously applied stents by retrograde endoscopic means, plastic stents and changes from external to internal drainage. From the remaining 166 interventions, we further excluded drain exchanges that did not have preceding or subsequent stenting in our clinic and all patients transferred to our hospital for selected treatments only.

Final patient group comprised 110 interventions in 61 patients. Mean age was 65.5 ± 13.1 years (range 31.1–92.7 years). All were suffering from obstructive jaundice caused by a primary malignancy or by its metastases and all were under palliative care.

The patients were divided into two groups: The PS and the SS groups. The PS group included 30 patients who underwent 30 procedures, while the SS group included 31 patients who underwent a total of 80 interventions. There was no statistical difference between the two groups in any of the following characteristics: Age ($P = 0.88$), gender ($P = 0.87$), previously failed ERCPs ($P = 0.91$), level of obstruction ($P = 0.67$), primary tumors ($P = 0.07$), status as an inpatient or an outpatient ($P = 0.21$), mono-, Y- or T-configured stentings ($P = 0.95$), previous treatments ($P = 0.07$), or concurrent cholangitis ($P = 0.42$). Patient characteristics are summarized in Table 1.

All patients received self-expanding uncovered metal stents. We compared the PS and the SS procedures in terms of their technical success, complications, length of hospitalization, and cost. Technical success was defined as percutaneous, transhepatic placement of a stent providing continuous drainage of bile.

Complications were classified as either minor or major^[9] according to the Standards of Practice Committee Classification of Complications by Outcome (SIR) [Table 2] and further according to whether they were short term or long term.^[8,10] These complications were classified

Table 1: Patient characteristics

	Primary stenting	Secondary stenting	P value
Patients/Interventions	30/30	31/80	
Demographics			
Average age in years (range)	65.8 (38.2-91)	65.3 (31.1-92.7)	0.88 (t-test)
Male/female	19/11	18/13	0.87
Former treatment			
Hepaticojejunostomy	6.7% (2/30)	9.7% (3/31)	0.07
Whipple operation	13.3% (4/30)	6.5% (2/31)	0.07
ERCP failed	43.3% (13/30)	42.0% (13/31)	0.91
Indication			
Primary malignancy	62.1% (18/30)	77.4% (24/31)	0.07
Pancreas	36.7% (11/30)	22.6% (7/31)	
Bile ducts	23.3% (7/30)	48.4% (15/31)	
Liver	0	6.5% (2/31)	
Metastasis	40% (12/30)	22.6% (7/31)	
Level of obstruction ^a	37 localizations	44 localizations	0.67
High (Liver hilum)	43.2% (16/37)	36.4% (16/44)	
Mid (Ductus hepatochol)	37.8% (14/37)	47.7% (21/44)	
Low (Pancreas)	18.9% (7/37)	15.9% (7/44)	
Cholangitis	23.3% (7/30)	29.0% (9/31)	0.42
Configuration of stentings	30 stentings	35 stentings	0.95
Mono ^b	25	31	
Y-/T-configuration ^c	2/3	2/3	

^aA patient may have multiple levels of obstruction, ^bStenting of only one lobe of the liver with single or multiple stent placement, ^cIncludes secondary procedures where a stent was placed in T- or Y-configuration, ERCP: Endoscopic Retrograde Cholangio-Pancreatography

Table 2: SIR standards of practice committee classification of complications by outcome

Minor complications
No therapy, no consequence
Nominal therapy, no consequence; includes overnight admission for observation only
Major complications
Therapy required, minor hospitalization (<48 hours)
Major therapy required, unplanned increase in level of care, prolonged hospitalization (>48 hours)
Permanent adverse sequelae
Death

SIR: Society of Interventional Radiology (U.S.A.)

into categories A and B for minor complications and categories C and D for major complications.

The main difference between minor and major complications was the length of hospitalization. A complication was identified as minor when it resulted in a stay for a maximum 24 h, requiring no more than conservative treatment or overnight observation. A complication was identified as major when it resulted in a stay exceeding 24 h and requiring therapy.

Short-term complications were considered to be those that occurred within the first 30 days after stenting, while long-term complications were those occurring after 30 days. In this study, all long-term complications required hospitalization with therapy, and we therefore categorized these as major complications.

The length of hospitalization was defined as the total number of hospitalization days required, both before and after the intervention. Outpatient treatments were not classified as hospitalizations. The costs associated with each procedure were roughly estimated based on the number of hospitalization days required. No detailed comparison of the cost of each procedure itself was made.

Protocol followed for biliary stenting

Antibiotic prophylaxis was not routinely used. If a biliary contamination was assumed and no antibiotic regimen had been given, 1 g ceftriaxone intravenously was administered before the procedure. Sedative analgesia with midazolam and fentanyl was provided as needed. If cross-sectional imaging had been performed, the initial percutaneous transhepatic access site was chosen in order to obtain maximal biliary drainage and to facilitate optimal instrumentation.

These biliary interventions were performed by one of two radiologists with an interventional experience of more than 2 Years (RP, TP). Both interventional radiologists were more comfortable using Fluoroscopy to guide the

punctures and Ultrasound was not used.

In the PS group, after gaining percutaneous biliary access, negotiating any stenosis or occlusion and balloon dilatation, the stent (predominantly Wallstent®, Boston Scientific, Watertown, MA, USA) was immediately placed mostly through 6-, 7-, or 8-French vascular sheaths. Balloon dilatation of the stents was performed if a diameter stenosis of more than 30% persisted after deployment. It was left to the discretion of the interventional radiologist whether or not to embolize the access tracts while the sheath was removed, and if so, whether macrocoils, gelatin sponge, or both were used. If possible, the patients were discharged after post-interventional monitoring in the outpatient holding area for 4-5 h.

In the SS group, percutaneous biliary access was obtained the same way with standard fluoroscopic technique. 8.5- or 10.2-French external-internal draining catheters with an enteral locking pigtail (Cook®, Bjaeverskov, Denmark) were placed after negotiating the obstruction. If Y-configuration stenting was planned, the second percutaneous drainage was performed within the next few days. After a drainage period of at least 5 days, balloon dilatation of the tumoral stenosis and biliary stenting was performed. Self-expandable metallic stents (essentially Wallstent) were placed in a tubular, Y-, or T-configuration through 7- or 10-French vascular sheaths [Figures 1-4]. If deemed necessary, post-placement stent balloon dilatation was performed. In some cases, coaxial placement of a straight "safety" 5-French catheter for 24-48 h to preserve the access was performed. Again, embolization of the transhepatic access tract as the safety catheter or the sheath was removed was left at the discretion of the interventional radiologist.

Statistical analysis

Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequencies and percentages. Differences with respect to categorical variables were assessed using the Chi-square test or Fisher's exact test, if appropriate. Categorical variables included: Number of interventions; gender; former treatments; primary tumors; level of obstruction; present cholangitis; mono-, Y-, or T-configured stentings; and inpatient versus outpatient status.

The mean age of both groups was compared using the unpaired *t*-test. Length of hospitalization was compared using the Mann-Whitney U test. Correlation analyses between length of hospitalization and either the number of interventions or the severity of complications were performed using Spearman rank order correlation coefficients. A *P* value less than 0.05 was considered statistically significant. All statistical analyses were

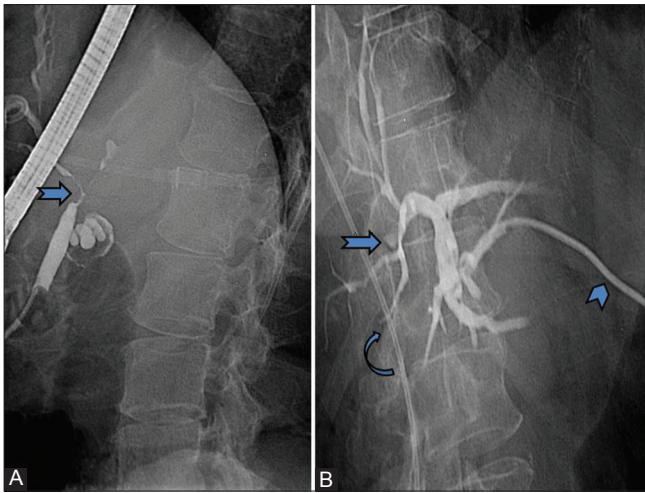


Figure 1 (A, B): A 52-year-old male with hilar cholangiocarcinoma (arrow) presented with liver abscess. Endoscopic drainage (curved arrow) was partially successful, draining only right side intrahepatic biliary ducts. We percutaneously accessed left side intrahepatic biliary duct with placement of external biliary drainage catheter (arrowhead)

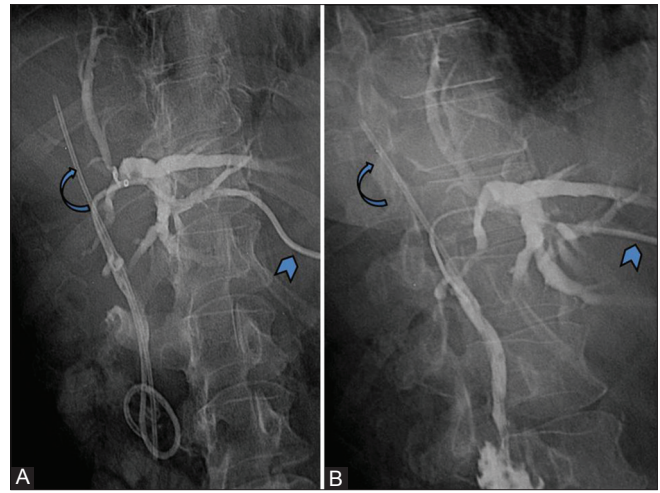


Figure 2 (A, B): Two days after the procedure, external-internal access was secured (arrowhead). Note the endoscopically placed plastic catheter (curved arrow) in right side intrahepatic biliary duct

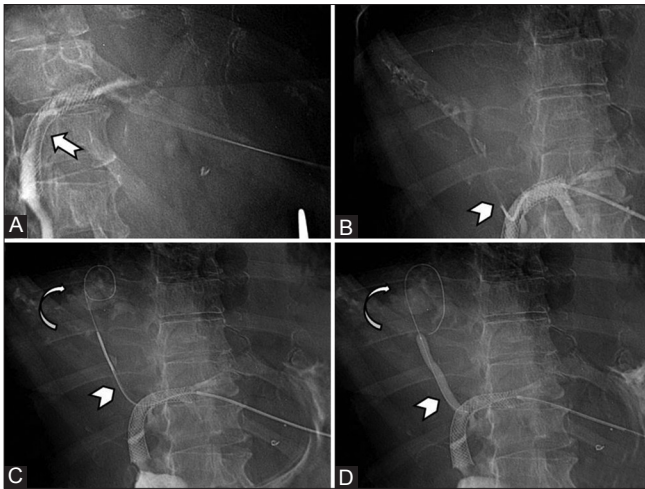


Figure 3 (A-D): (A) Placement of Wallstent (white arrow) draining left side intrahepatic biliary duct into duodenum. (B-D) Six weeks later, endoscopically placed plastic catheter was removed and access was secured to right side intrahepatic biliary duct through struts of Wallstent (white arrowhead), followed by dilatation of tract. Also note the relation of liver abscess (white curved arrow) with draining bile ducts



Figure 4 (A, B): Note the placement of second Wallstent through struts of previously placed Wallstent (black arrowhead) with final T-shaped configuration. Also note the relation of liver abscess (white curved arrow) with T-stent configuration

performed using commercially available software (SPSS, release 17.0, Chicago, IL, USA).

Results

Pre-interventional patient characteristics

Of the 30 interventions performed in the PS group, 25 were scheduled as inpatient procedures and 5 as outpatient procedures. In 76.6% (23/30) of the PS patients, there was no evidence of cholangitis. In 33% (10/30) of the interventions, prophylactic antibiotics were administered 1 h before or at the beginning of the intervention. Seven (23.3%) of the PS patients were already receiving antibiotics for concomitant

cholangitis. Thirteen (43.3%) of the PS patients had no documented antibiotic therapy, 13 (43.3%) had a history of an aborted or failed ERCP, and 4 (13.3%) had previously undergone a Whipple operation.

In the SS group, a total of 80 interventions were performed in 31 patients, including 29 as inpatient procedures and 2 as outpatient procedures. In 71.0% (22/31) of the SS patients, there was no evidence of cholangitis. In 25% (20/80) of the interventions, prophylactic antibiotics were administered 1 h before the procedure. Nine (29%) of the SS patients were, at the time of the procedure, already under therapeutic antibiotics for concomitant cholangitis, 13 (42%) had a

Table 3: Hospitalization

	PS	SS	P value
n patients	n=30	n=31	
Inpatients/outpatients	25/5	29/2	0.21
Hospitalization in days (range)	7.7±9.6 (2-41)	20.6±19.6 (3-90)	<0.001

SIR: Society of Interventional Radiology (U.S.A.), PS: Primary biliary stenting, SS: Secondary biliary stenting

Table 4: Short-term and long-term complications according to the SIR

	PS %	SS %	P value
30-day-morbidity ^a =short-term	20 (6/30)	48.4 (15/31)	<0.05
Short term minor complications	10 (3/30)	6.5 (2/31)	0.61
Short term major complications	10 (3/30)	41.9 (13/31) ^b	<0.01
Long-term major complications	13.3 (4/30)	12.9 (4/31)	0.96
Total minor and major complications	33.3 (10/30)	61.3 (19/31)	<0.05
Total major complications	23.3 (7/30)	54.8 (17/31)	<0.05

^aRepresents short-term minor and major complications, ^bFive patients developed cholangitis on average 8.8 days after first treatment, SIR: Society of Interventional Radiology (U.S.A.), PS: Primary biliary stenting, SS: Secondary biliary stenting

Table 5: Detailed complications according to the SIR

Complications ^a	PS	SS
Short term complications ^a (<30 days)	n=6	n=15
Minor		
Fever (A)	2	1
Lost coil (B)-stent dislocation (B)	1	1
Major		
Hemobilia (C)	1	2
Reobstruction (C)		4
Peritonitis (D)-pancreatitis (D)	1	1
Cholangitis (D)	1	2
Sepsis (D)		1
Drainage related		
Bile leakage (C)		1
Subcutaneous abscess (D)		1
Infected bilioma (D)		1
Long term complications (>30 days)	n=4	n=4
Reobstructions (C)	4	3
Stent kinking (C)		1

^aMultiple complications occurring in one patient were counted separately, e.g., stent dislocation and peritonitis, hemobilia and cholangitis as well as hemobilia and reobstruction within 30 days, ^bProcedure related, PS: Primary biliary stenting, SS: Secondary biliary stenting

history of an aborted or failed ERCP, and 2 (6.5%) had previously undergone a Whipple operation. There was no significant difference between the PS and the SS groups in inpatient versus outpatient status, concomitant cholangitis, or history of previously failed ERCP.

Technical variables

In 66.6% (20/30) of the PS cases, the access was through an intercostal space from the right side, and in 33.3% (10/30) of the cases, it was from the sub-xyphoidal approach. Thirty PS patients received Wallstents, which represented 89.5% of the stents used (34/38), whereas three standard vascular nitinol stents were placed in the remaining two patients. In one case,

a nitinol stent was placed simultaneously with two Wallstents.

The PS stents were applied in the following areas: 42.1% (16/38 stents) in the hilar region, 36.8% (14/38) in the mid-common bile duct (CBD), and 18.4% (7/38) in the distalCBD. Stents were placed in the Y configuration in two cases and in the T configuration in three cases. One case was a stent extension of a previous ERCP stenting, and one case was a stent-in-stent placement. Late reocclusion was the indication for the reintervention in both these cases.

In 71% (22/31) of the SS cases, access was through an intercostal space from the right side, in 22.6% (7/31) of the cases, it was from the left side epigastric region, and in 6.5% (2/31) of the cases, it was from both the sides. Compared to the PS group, the SS group received more multiple treatments. 67.7% of patients (21/31) required two interventional sessions, 19.4% of patients (6/31) required three, 6.5% (2/31 patients) required four, and 6.5% (2/31 patients) required even six interventions to achieve internal drainage through the metallic stents. 75.6% of the stents used were Wallstents (34/45 stents). The remaining 11 stents (24.4%) were all self-expanding nitinol stents from different manufacturers. In one case, a nitinol stent was placed simultaneously with a Wallstent. The SS stents were applied in the following areas: 36.4% (16/44 stents) in the hilar region, 47.7% (21/44) in the mid-CBD, and 15.9% (7/44 stents) in the distal CBD. Stents were placed in the Y configuration in two cases and in the T configuration in three cases; two cases represented stent extensions of a previously applied stent (stent-in-stent placement). An average of 2.6 ± 1.1 sessions were performed per patient in the SS group and 1 ± 0 session was performed in the PS group. Maximal sheath size was 8 French in the PS group and 10 French in the SS group; however, the median access size of the sheaths was the same for both the groups.

In the PS group, the accesses were embolized with coils in 10% of patients (3/30) and with gelatin sponge in 76.6% (23/30) of patients, while 4 patients (13.3%) underwent embolization both with a coil and a gelatin sponge plug. In the SS group, the accesses were embolized with coils in 12.9% of patients (4/31) and with gelatin sponge in 22.6% (7/31) of patients. The remaining 64.5% of patients in this group (20/31) had no documented embolization.

Patient outcomes

The overall technical success rate was 98.4% with 1 (1/61) failed approach to transcend the occlusion in the SS group. There were no deaths directly attributable to either procedure. The mean length of hospitalization was 7.7 ± 9.6 days (range 2-41 days) in the PS group and 20.6 ± 19.6 days (range 3-90 days) in the SS group [Table 1]. We found a correlation between the lengths of hospitalization and the number of interventions (P < 0.001; ρ=0.53).

The short-term minor complication rate was 10% in the PS group and 6.5% in the SS group ($P = 0.61$). The short-term major complication rate was 10% in the PS group and 41.9% in the SS group ($P < 0.01$). If we assumed long-term complications as the major complications, the overall major complication was 23.3% in the PS group and 54.8% in the SS group ($P < 0.05$). In the SS group, there were not only more complications in general ($P < 0.05$), but also significantly more severe complications ($P < 0.05$) [Table 3]. No patient in PS and SS group had permanent adverse effect or procedure related death [Tables 4 and 5].

Discussion

Since the introduction of percutaneous biliary stenting, a gradual shift has occurred from a staged procedure (SS), where biliary decompression is obtained first by plastic external or external-internal drains, followed days later by placement of one or more metal self-expanding stents, to a one-step intervention (PS), where the bile ducts are accessed and their obstruction is relieved by metal stents during the same session. Series published between 2003-2010 describe no clear criteria to choose between the two protocols.^[4,6,8,11] Some articles state that this decision was left to the discretion of the radiologist and that it depended on the presence or absence of hemobilia or on morphologic evaluation.^[11] Obviously in the staged procedure, there is more time to evaluate the need for additional percutaneous accesses or for the resectability assessment of tumors, taking into consideration the newly gained cholangiographic information.

Recent advances in computed tomography and magnetic resonance imaging technology, as well as the introduction of positron emission tomography are challenging this potential advantage of SS.^[12] Therefore, it is likely that individually tailored primary stenting strategies are established in advance in an increasing number of patients with malignant obstructive jaundice.

In a retrospective single-center analysis, which specifically addressed the question whether PS was superior to SS, no statistically significant difference between the two techniques was found in terms of stent patency and survival.^[8] In the same series, the initial biliary drain placement accounted for 57% of the early complications. Complications occurring during balloon dilatation pre- or post-stent deployment were less frequent (27% of early complications). No grading of the severity of the complications or statistical analysis of possible patient-related factors was performed. Based on their analysis, these authors recommend PS as it was safer and more cost-effective. Our results are in perfect agreement with study by Inal *et al.*^[8] We found primary percutaneous biliary stenting to be as efficacious and safer than a staged procedure with secondary stenting. By virtue of requiring shorter hospital stays, primary stenting is likely to be more

cost-effective.

The most common short-term complications^[13,14] reported in previous studies are infection, bleeding, and bile leakage. Recent studies^[4,8] including single and staged stenting procedures have reported overall early complication rates of 22.5% and 29%, respectively. Our short-term complication rates were 20% for the PS group and 48.4% for the SS group, the latter representing a twofold increase over the rates previously reported for that procedure. However, one has to keep in mind that the SIR complication grading system considers, for instance, a biliary tube dysfunction due to dislodgement or obstruction, as well as a minor hemobilia due to a benign porto-biliary fistula as a major complication, as they require a reintervention (tube change or readjustment). Actually, these two indications for a tube change represented 6 of the 13 major complications in the SS group. Interestingly, there was no statistical difference between the two protocols in those variables which might influence the immediate complication rate such as the presence of cholangitis or percutaneous stenting, immediately following a failed endoscopic decompression attempt. Unfortunately, a correlation between the type of early complication and single patient characteristics is not reliable in our study because of the small sample size. Based on our data, we strongly believe that infectious cholangitis or prior bile duct manipulation should not be regarded as a contraindication to PS.

Some authors consider primary biliary stenting followed by temporary placement of a "safety" biliary catheter still as a PS.^[8,15] This technique, although requiring an additional step (removal of the catheter days later), is believed to be justified by the preservation of access in case of early re-obstruction, due to debris, clots, or stent kinking. In this study, utilizing essentially woven metal stents, no external catheter was left after the stenting (the one kinked stent was a nitinol stent). With this true PS technique, which is similar to the endoscopic one, early re-obstruction was not seen.

Percutaneous biliary drainage should be carried out with antibiotic prophylaxis, as it is associated with a high incidence of bacterobilia and bacteremia, which can increase wound infection rates.^[16,17] Omitting the external drainage by using the PS technique might thus be expected to lead to a better outcome as a result of reduced bacteremia and wound infection. Infectious complications related to the procedure, although rare, were twice more frequent in the SS group in this study.

A number of authors have examined the survival rates of patients with malignant biliary strictures where metal stents were placed using preferentially the PS procedure.^[4,18,19] As in this study, stents were placed in tubular, T-, or Y-configuration, and their patient populations were comparable to ours, in terms of age, gender, and tumor

distribution. The immediate technical success rate reported in these studies was 100%, with no procedure-related deaths.^[4,15,18,20]

The most common long-term complication is re-obstruction due to tumor overgrowth.^[21,22] Meanwhile, the long-term complication rates^[22-24] lie between 7 and 26%. Our long-term complication rates were 13.3% for the PS group and 12.9% for the SS group. These values lie well within the previously reported range for the respective procedures.

In previous reports,^[4,10] the average length of hospitalization was between 4.5 and 5.4 days for PS and 12 days for SS. The mean post-procedure length of hospitalization was 6.5 days (range 4-10 days) in one study^[25] and a median of 16 days in another.^[26] It is difficult to directly compare the length of hospitalization in our study with that of other reports, many of which measured only the number of days in hospital following the procedure. In addition, because of several confounding variables, it is almost impossible in a retrospective study to exactly attribute the length of stay to a certain procedure. Among the PS patients in our study, two out of three stayed in hospital on average for 5.2 days. The overall average length of hospitalization increased to 7.7 ± 9.6 days with the inclusion of critically ill patients, one staying for 41 days and another staying for 28 days. Among the SS patients, two out of three stayed in hospital on average for 12.2 days, with the overall average length of hospitalization increasing to 20.6 ± 19.6 days, with the inclusion of two critically ill patients who remained in hospital for 90 and 79 days, respectively. The SS group had significantly longer hospitalizations. We found a correlation between the lengths of hospitalization and the number of interventions ($\rho = 0.53$; $P < 0.001$), suggesting that reinterventions might indeed be the main reason for prolonged hospital stays.

Although PS has been recommended^[10] only for patients who are both in good general condition and have Bismuth type 1 and 2, we used it in patients who are in poor condition too. This may be another factor explaining why we observed longer hospitalizations and more short-term complications compared to other studies.

The present study has limitations; the sample size of both groups is small, as nowadays at our center, most biliary stenting procedures are successfully performed by the endoscopic retrograde technique. Although both cohorts may be comparable in terms of several selected clinical and anatomical variables, important outcome determinants may have been missed in this retrospective study. Grading of complications according to the SIR scale may be disadvantageous for the SS group, as biliary draining tube problems, although rarely being harmful, often require minor reinterventions.

In summary, our results demonstrate significantly lower

complication rates with the PS procedure over the first 30 days. In addition, more severe complications occurred in the SS group. These were often associated with prolonged drainages. A shorter period of hospitalization may not only ease the patient's discomfort during the stay, but also aid in reducing the costs by decreasing room occupancy and the number of interventions.

The PS procedure thus appears to be a safe and reliable alternative to SS. We believe that PS should also be performed in patients in poor general condition because of its efficacious biliary decompression and fewer drain-related complications.

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