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The effect of a preoperative biliary prosthesis on the infectious complications of the pancreaticoduodenectomy

Pablo Sánchez Acedo, Cruz Zazpe Ripa, Inés Eguaras Córdoba, Javier Herrera Cabezón, Antonio Tarifa Castilla and Bruno Camarero Triana

Unit of Hepato-Biliary-Pancreatic Surgery. Complejo Hospitalario de Navarra. Pamplona, Navarra. Spain

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Correspondence: Pablo Sánchez. Unit of Hepato-Biliary-Pancreatic Surgery. Complejo Hospitalario de Navarra. C/ Irunlarrea, 3. 31008 Pamplona, Navarra. Spain
e-mail: pablosanchez_84@hotmail.com

ABSTRACT

Introduction: there is controversy about the effect of a preoperative biliary prosthesis (PBP) on complications of pancreaticoduodenectomy (PD). There are no recommendations for antibiotic prophylaxis in these patients. The objective of the study was to analyze the association of PBP, bacteriology and the development of complications after PD.

Methods: this was a retrospective observational study with 90 consecutive patients that underwent DP between 2015 and 2018. PBP was indicated in patients with total bilirubin levels > 12 mg/dl who could not be operated on within a reasonable time. Antibiotic prophylaxis with cefoxitin was administered in patients without PBP and a five-day treatment with piperacillin-tazobactam for PBP. A bile culture was systematically performed.

Results: the average age of the patient cohort was 69 years. Fifty-one patients suffered complications (56%), with a mortality rate of 3%. The average hospital stay was eleven days and PBP was placed in 51 patients (56%). Antibiotic prophylaxis was adequate in

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62 patients (69%). The most frequently isolated bacteria were *E. faecium* (30%), *E. coli* (20%) and *E. faecalis* (19%). Patients with PBP had a significantly higher percentage of positive cultures (98% *vs* 25%, p < 0.01), a higher number of bacteria (2.9 *vs* 0.5, p < 0.01) and perioperative sepsis (31% *vs* 12%, p = 0.03), but without an increased hospital stay or overall morbidity.

Conclusions: PBPs increase the risk of perioperative sepsis, the percentage of positive cultures and the average number of isolated bacteria. The protocol of prophylaxis with cefoxitin and the administration of pipercillin-tazobactan with PBP adequately treated 69% of patients. With this protocol, PBPs do not imply an increase in complications or hospital stay.

Key words: Pancreaticoduodenectomy. Endoscopy. Morbidity. Infection. Bacterobilia.

INTRODUCTION

Currently, pancreaticoduodenectomy (PD) performed by specialized teams is a safe technique, with a mortality rate of less than 5%. However, morbidity continues to be high, with an overall incidence of around 40-60% and one third are infectious complications (1-3).

There is controversy in the literature about the benefits and risks of endoscopic biliary prosthesis in patients with periampullary tumors. Although there are studies that indicate that preoperative biliary prostheses (PBP) are associated with an increase in morbidity and mortality (4,5). However, it is currently a widely used resource in jaundiced patients that require neoadjuvant treatment or due to a delayed surgery (6,7).

Likewise, there are no consensus recommendations or protocols for preoperative antibiotic prophylaxis in these patients. Although there are studies that suggest that this should be different in patients with PBP than in patients without drainage, as they have more bile contamination (8,9).

The main objective of the study was to analyze the association between the placement of PBP with the bacteriology of bile in our environment and the development of postoperative complications in patients undergoing PD. As a secondary objective, the

efficacy of the prophylaxis protocol used in our center was assessed.

MATERIAL AND METHODS

A retrospective observational analysis was performed using a prospective database, with 90 consecutive patients that underwent PD between 2015 and 2018 in a tertiary center. The study was performed in accordance with the ethical standards of our center.

Pre-operative care

The placement of preoperative biliary prosthesis was indicated in patients with total bilirubin level greater than 12 mg/dl at diagnosis or those that could not be operated on within a reasonable period of time (10-14 days). This also included candidates for neoadjuvant treatment. Biliary drainage was usually performed as an emergency, before a multidisciplinary committee had analyzed the case or a diagnosis was determined. Thus, the choice of the type of prosthesis used was made according to the technical criteria endoscopist.

Antibiotic prophylaxis was performed with cefoxitin (2 g iv) in patients without instrumentation of the bile duct or ciprofloxacin (400 mg iv) in patients with an allergy to β-lactams. PBP patients received prophylaxis and treatment for five days with piperacillin-tazobactam (4 g/6 h iv) or ciprofloxacin (400 mg iv) and gentamicin (240 mg iv) in patients with allergies.

Surgical technique

The standard surgical technique was PD with an initial approach of the superior mesenteric artery, as described by Pessaux and Marzano (10,11). Pancreatic reconstruction was performed by a pancreaticogastrostomy (PG) (type I-B S0) (12) following the Delcore technique (13). A standard lymphadenectomy with a total mesopha-pancreas extirpation was performed in patients with a tumor (14). An intraoperative sample was taken for bile culture in all cases.

Clinical protocol

Post-operative care was standardized in a clinical pathway that included the removal of the nasogastric tube after 24 hours and at the start of a liquid diet, provided that the clinical situation allowed. Enteral or parenteral nutrition was not used systematically. Amylase analysis was performed in the drains on the first and third day in order to assess their early withdrawal.

Variables

A prospective registry was kept in an anonymized database in the FileMaker® program during admission and discharge of the patient. The database included demographic data, American Association of Anesthesia (ASA) classification (15), instant nutritional assessment (INA) (16), diagnosis, surgical procedures, antibiotic prophylaxis used, date of surgery, surgical complications according to the Clavien-Dindo classifications (17) and the International Study Group on Pancreatic Surgery (ISGPS) for pancreatic fistula (PF) (18), delayed gastric emptying (19) and hemorrhages (20).

Perioperative sepsis was reported, which was defined as a potentially fatal organ dysfunction caused by a poorly regulated response of the host to the infection (21), which began during the first 24 hours after the intervention, without hemorrhagic complications. The time of onset, duration, the need for admission to the Intensive Care Unit and the clinical impact on the patient were also recorded. Furthermore, the results of the intraoperative biliary culture, the subsequent cultures and the antibiogram were recorded.

All complications within 30 days after surgery or until discharge from the hospital were included, as well as those detected during the consultation or hospital readmissions during the same period. Grades I and II Clavien-Dindo complications were considered as mild and ≥ III were considered as serious.

Statistical analysis

Descriptive statistics were used for the demographic and clinical characteristics of the patients, as well as the complications after PD. Qualitative variables were analyzed to compare the differences between patients with and without biliary prosthesis using the Chi-squared test or the Fisher's exact test. Quantitative variables were analyzed

with the Student's t test or the Mann-Whitney U test. The analysis of the data was performed with SPPS 15.0 and SPSS 22.0s. Statistical significance was considered as a p value ≤ 0.05.

RESULTS

Ninety patients who underwent surgery during the study period were included in the study and the mean age was 69 years (Table 1). These patients presented an anesthetic risk, mainly ASA II (46.7%) and ASA III (43%). Table 2 shows the complications recorded; 51 patients (56%) presented some type of postoperative complication that resulted in death in three patients (3.3%). A total of 14 patients (15%) had a pancreatic fistula. The average hospital stay of the patient series was eleven days.

PBP was placed in 51 patients (56.6%) and all the prostheses were placed by endoscopic retrograde cholangiopancreatography (ERCP), except for one patient that required transparietohepatic cholangiography (CTPH). Table 3 shows that 21 patients (16%) presented signs that were compatible with perioperative sepsis. The antibiotics used in the prophylaxis protocol were sensitive to the bacteria found in the cultures of the 62 patients (69%). Table 4 shows the bacteria registered in the bile cultures; there was a total of 38 different bacteria, the most frequently isolated being *E. faecium* (30%), *E. coli* (20%), *E. faecalis* (19%) and *S. anginosus* (14%).

Table 5 shows the analysis of the factors related to PBP. There were no significant differences in relation to the demographic variables listed in table 1 between the different patient groups. The patients with PBP had a significantly higher percentage of positive cultures (98% *vs* 25%, $p < 0.01$), a higher mean number of isolated bacteria (2.9 *vs* 0.5, $p < 0.01$) and perioperative sepsis (31% *vs* 12%, $p = 0.03$). However, this did not imply an increase in hospital stay or overall morbidity. Globally, there was a lower percentage of adequate prophylaxis for patients with a prostheses (55 *vs* 87%, $p = 0.01$). However, when only patients with positive culture were analyzed, the difference was not statistically significant (54 *vs* 80%, $p = 0.13$).

The type of prosthesis did not affect bile contamination (100% *vs* 96%). A greater number of bacteria were isolated from patients with metallic prostheses (3.6 *vs* 2.6, p

= 0.03) and there was a lower percentage of adequate prophylaxis (47% *vs* 64%, p = 0.24). Although this did not reach statistical significance. In contrast, patients with plastic prostheses had a higher percentage of perioperative sepsis (35.4% *vs* 17.6%, p = 0.19) but this was not statistically significant.

According to the indication for the prosthesis, this was used in 13 (25.5%) patients due to bilirubin levels > 12 ml/dl at diagnosis and 38 (74.5%) were due to a delay in the surgical intervention (> 10-14 days) or of the need for neoadjuvant treatment. Therefore, there is a significant difference in the mean time from the placement of the prosthesis to the intervention of 30 days (10-75) for patients with bilirubin levels > 12 ml/dl *versus* 70.7 days (20-200) in the other group. However, as shown in the table, there were no significant differences in relation to morbidity, mortality or hospital stay between the two groups.

Some patients were treated prior to the intervention with antibiotics, due to cholangitis at diagnosis or after biliary drainage. This group of patients received the same preoperative antibiotic scheme as the rest of patients and the rate of an adequate prophylaxis was significantly lower (45 *vs* 75%, p = 0.009). Despite this, none of these factors were clinically significant in relation to the overall morbidity or hospital stay.

DISCUSSION

There are numerous publications in the literature that argue in favor of and against the use of preoperative biliary drainage in patients undergoing PD. On the one hand, several clinical trials have shown that the systematic use of biliary drainage in these patients implies an increase in post-operative morbidity and infectious complications (4,22). On the other hand, there are studies that indicate that preoperative drainage in patients with obstructive jaundice due to a tumor have a lower rate of serious complications, mortality and hospital stay (6). Thus, it seems reasonable to assume that systematic biliary drainage in all patients is unnecessary. Therefore, the need for PD should be assessed in patients who could benefit from this procedure, such as those with an obstruction caused by a tumor that are unable to undergo surgery immediately due to the need for neoadjuvant treatment, further tests or the

availability of operating rooms (7).

The increase in the contamination of the bile duct with the use of PBP is one of the main complications described in the literature, although there are very few studies reported in our environment. In our study, 98% of patients with PBP had positive cultures compared to 25.6% without prostheses. In addition, the mean number of bacteria isolated from these patients was significantly higher, 2.9 compared to 0.5 bacteria. These results are very similar to previously reported studies that confirm that almost all patients with PBP have bile contamination.

There were no significant differences with regard to the type of prosthesis used. Both approaches increase the percentage of contamination and the number of isolated bacteria. Patients with metallic prostheses have a higher percentage of global complications and patients with plastic prosthesis have a greater incidence of postoperative sepsis. However, the differences were not significant and may be due to the fact that the groups are not comparable.

There were also no differences in the patients who had the prosthesis for a longer time period. Patients that require prosthesis placement for a prolonged time period until the intervention for an average of 70.7 days (over four weeks) did not have an increased postoperative morbidity and mortality or hospital stay. Furthermore, they even had a higher percentage of adequate prophylaxis and fewer isolated bacteria than patients with a prostheses due to bilirubin levels greater than 12 ml/dl. However, these results did not reach significance.

The main bacteria isolated in the studies were from the family of *Enterococcus, Klebsiella* and *Enterobacter* (9,23) and these are listed in table 4. The most frequently isolated bacteria were *E. faecium* (30%), *E. coli* (20%), *E. faecalis* (19%), followed by *S. anginosus* (14%) and *K. pneumoniae* (12.2%).

One of the possible limitations of this study is the use of different antibiotics in patients with biliary instrumentation as established in the protocol. Under ideal conditions, a prospective controlled study would be performed, in which all patients receive the same treatment. The decision to modify the standard antibiotic therapy (cefoxitin 2 g iv) received by patients with PBP was made in 2008, based on the available literature and our results show that patients with PBP had more infections.

Thus, treatment was performed for five days with piperacillin-tazobactam (4 g/6 h iv). In addition, the intraoperative bile culture was performed systematically and a register of these patients was established. With this protocol, 69% of patients had an adequate prophylaxis; 85% of patients without PBP and 55% of patients with PBP. Unfortunately, the results of patients prior to the introduction of the protocol were not available to be able to compare the results.

The remaining patients with an inadequate prophylaxis was mainly due to the presence of fungi, especially candida (15%) and bacteria resistant to piperacillin-tazobactan. Resistance may be favored by the prior use of antibiotics, as occurs in patients who presented with cholangitis after PBP placement. In fact, prophylaxis was adequate in only 45% of this group of patients. This data can be used to select the patients with the highest risk of resistance and to evaluate the use of antibiotics with a wider spectrum. However, since this was an observational study with a limited number of patients with preoperative cholangitis, it is not possible to draw conclusions in this regard. Therefore, it would be necessary to perform a controlled study aimed at this aspect in order to confirm the hypothesis. In our center, the substitution of the prophylaxis of the patients with a greater risk is being evaluated, due to the results of this study. This includes those with a prosthesis due to bilirubin levels higher than 12 ml/dl and/or those who had received antibiotic treatment previously (for cholangitis mainly).

A study in 2013 (24) concluded that piperacillin-tazobactan is an adequate antimicrobial agent in the prophylaxis of PD. This agent has a good coverage of *Enterococcus* and *Enterobacter*, which are two common species in intraoperative cultures, and reduces the occurrence of surgical site infections. Other studies presented similar results to ours, with a rate of adequate antibiotic prophylaxis of 71% when using two combined antibiotics (cefazolin and metronidazole). This, suggests that adding gentamicin could improve the results to close to 100% (25). Most of the literature are international publications and it is difficult to extrapolate the results of these studies to our environment, since they use different antibiotics and the resistance profile is different. In any case, they all seem to recommend the prophylaxis of patients without a prosthesis with at least one of the first or second generation

cephalosporin agents and to modify the prophylaxis in patients with biliary manipulation to a broad-spectrum antibiotic or a combination of antibiotics. Subsequently, they recommend adapting the antibiotic to the antibiogram once the result of the culture is obtained (8,9).

Finally, we analyzed the clinical effect that the prosthesis placement has on postoperative complications. In our study, 31.4% of patients with PBP presented clinical signs of sepsis during the first 24 hours postoperatively, compared to 12.8% patients without PBP.

These results are consistent with those of other classic studies that report a higher percentage of postoperative infections in these patients (4,26,27). This increase in postoperative infections has been one of the reasons why some authors do not recommend the placement of PBP before PD. However, this obviates the benefits of biliary drainage in patients with cholestasis, with a lower percentage of serious complications, mortality and hospital stay (6).

Another limitation of our study is the fact that it is not a randomized trial. The patients with PBP are selected patients, either because they have a high bilirubin level at diagnosis or for a long period until the intervention and theoretically could be in worse clinical condition. In any case, this reinforces the results of our study as the PBP placement does not mean that there is an increase in global morbidity and mortality. Furthermore, the average stay of both groups was also similar. Thus, the placement of PBP is a valid technical alternative in selected cases before the PD when the expected bacteriobilia is known and a suitable antibiotic protocol is applied.

CONCLUSIONS

The placement of PBP increases the risk of perioperative sepsis, the percentage of positive cultures and the average number of isolated bacteria. However, the use of a broad-spectrum antibiotic therapy and subsequent directed antibiotic therapy does not result in increased complications or hospital stay.

The most frequently isolated bacteria in our environment were *Enterococcus, Streptococcus* and *Klebsiella.*

The strategy of prophylaxis with cefotaxime in patients without PBP and piperacillin-tazobactan in patients with PBP means that 69% of patients are properly treated.

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Table 1. Demographic data and operative variables

Sex	
Male	55 (61%)
Female	35 (39%)
Age (range)	68.8 (45-84)
Average BMI (range)	25.74 (16-35)
ASA	
Lost	1
I	8 (8.9%)
II	42 (46.7%)
III	39 (43.3%)
IV	0
Malignant tumor	65 (72.2%)
Medium surgical time (range)	331 (235-540)

BMI: body mass index; ASA: American Association of Anesthesia.

Table 2. Complications according to the Clavien-Dindo and ISGPS classifications

Complication	
Yes	51 (56%)
No	39 (43%)
Clavien-Dindo	
Grade I	5 (5.5%)
Grade II	29 (32.2%)
Grade III	8 (8.9%)
Grade IV	6 (6.7%)
Grade V	3 (3.3%)
Clavien-Dindo grade ≥ III	17 (18.8%)
Delay of gastric emptying	22 (24%)
Pancreatic fistula	14 (15.5%)
Hemorrhage	16 (17.7%)
Reintervention	13 (14%)
Total transfusion	10 (11%)
Re-entry	15 (16.6%)
Average stay (range)	11.4 (5-38)

Table 3. Results of preoperative biliary prosthesis

Preoperative biliary prosthesis	51 (56.6%) (50 CPRE + 1 CPTH)
Type of prosthesis	
Plastic	31 (60%)
Metallic	17 (18.8%)
Not specified	3 (5.8%)
Reason prosthesis	
Bilirubin > 12 mg/dl	13 (25.5%)
Prolonged time until surgery	38 (74.5%)
Preoperative cholangitis	15 (16.6%)
Perioperative sepsis	21 (16.5%)
Inotropic < 24 h	13 (11.7%)
Inotropic > 24 h	5 (5.5%)
Intensive Care Unit	3 (3.3%)
Antibiotic prophylactic	
Cefoxitin	27 (30%)

Table 4. Isolated bacteria

E. faecium	27 (30%)
E. coli	18 (20%)
E. faecalis	17 (18.8%)
St. anguinosus	13 (14.4%)
E. cloacae	12 (13.3%)
K. pneumoniae	11 (12.2%)
K. oxytoca	11 (12.2%)
Candida albicans	10 (11.1%)
C. perfringens	10 (11.1%)
B. fragilis	3 (3.3%)
P. aeruginosa	3 (3.3%)
C. freundii	3 (3.3%)
M. organii	3 (3.3%)
E. casseliflavus	3 (3.3%)
Candida tropicalis	2 (2.2%)
E. gallinarum	2 (2.2%)
St. parasanguinis	2 (2.2%)
Others	21 (23.3%)

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Table 5. Analysis of factors related to preoperative biliary prosthesis

	Preoperative biliary prosthesis		*p value*
	Yes	*No*	
Complications	53%	60%	0.4
Average stay	10.6 days	12.5 days	0.13
Biliary positive culture	98%	25.6%	< 0.00
Isolated bacteria (mean)	2.9	0.5	< 0.00
Perioperative sepsis	31.4%	12.8%	0.03
Adequate prophylaxis (global)	55%	87%	0.01
Adequate prophylaxis (positive culture)	55%	80%	0.13
	Type of prosthesis		*p value*
	Metallic	*Plastic*	
Complications	70%	48.5%	0.14
Average stay	12 days	9.87 days	0.11
Biliary positive culture	100%	96%	0.45
Isolated bacteria (mean)	3.6	2.6	0.03
Perioperative sepsis	17.6%	35.4%	0.19
Adequate prophylaxis	47%	64%	0.24
Reason for the prosthesis			
	Bilirubin > 12 mg/dl	*Prolonged time until surgery*	*p value*
Average time until surgery (range)	30 days (10-75)	70.7 days (20-200)	< 0.00
Complications	61.5%	44.7%	0.29
Average stay	11.9 days	10.1 days	0.53
Biliary positive culture	100%	97.3%	0.55
No. of bacteria	3.2	2.8	0.92

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