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Delayed gastric emptying following pancreatoduodenectomy: a Roux-en-Y gastrojejunostomy vs Billroth II gastrojejunostomy randomized study

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ABSTRACT

Introduction: delayed gastric emptying (DGE) is the most common complication after pancreaticoduodenectomy (PD) and it occurs in 50% of cases.

Objectives: the endpoint was to determine if there were any differences in the incidence of DGE between Roux-en-Y gastrojejunostomy (ReY) and Billroth II gastrojejunostomy (BII) in PD with pancreaticogastrostomy (PG).

Methods: this was a case-control prospective randomized study of all PD cases between 2013 and 2016. Sixty-four patients were included, 32 in each group. An intention-to-treat statistical analysis was performed.

Results: no significant differences were found with regard to morbidity and mortality or hospital stay. DGE was present in 25% of the patients in the BII group in comparison to 15.6% in the ReY group, which was not statistically significant ($p = 0.35$). There was a higher percentage of patients with primary DGE in the BII group, 12.5% *versus* 6.2%, but this was not statistically significant ($p = 0.53$). No difference in DGE severity was observed. Male gender (OR 8.38 [1.1; 129]), abdominal complications (OR 15 [1.7;

396.9]), pre-operative malnutrition (OR 99.7 [3.3, 11,126]) and hemorrhage (OR 9.4 [1.37, 107.94]) were the main risk factors for DGE according to the multivariate analysis.

Conclusions: there were no significant differences in the incidence or severity of DGE between BII or ReY after PD with PG.

Key words: Pancreatic surgery. Delayed gastric emptying. Surgery complications. Randomized study.

INTRODUCTION

Pancreaticoduodenectomy (PD) is the procedure of choice for the removal of malignant and benign tumors that involve the periampullary region. The procedure-associated mortality is currently between 3-5% and may be even lower in high-volume centers, which is lower in comparison to previous decades. However, the incidence of complications is still high (50-70%). The most common complications are delayed gastric emptying (DGE) (1), postoperative hemorrhage (PPH) (2) and pancreatic fistula (PF) (3).

The development of DGE has been associated with the following reconstruction techniques: Billroth II gastrojejunostomy (BII) or Roux-en-Y gastrojejunostomy (ReY) and retrocolic or antecolic gastrojejunostomy (GJ) (4). Following PD, DGE (5) is the most common complication in recent series, with an incidence between 20 and 40%. This represents 50% of all possible complications including PF, PPH, intra-abdominal infection, or re-operation. DGE is considered to be secondary in cases associated with other complications, and primary (in 10 to 20% of the cases) when there are no related intra-abdominal complications.

A meta-analysis of DGE prevalence that explored BII reconstruction in comparison to ReY reconstruction showed that patients with non-standardized reconstruction techniques were included in most studies and heterogeneous definitions of DGE were also used. Furthermore, all studies were carried out in patients who underwent a pancreaticojejunostomy (PJ) (6,7).

In a study previously carried out by our group (8), 34.4% of 332 patients with PD developed DGE. Two hundred and twenty PD with pancreaticogastrostomy (PG) and 22

with PJ were performed between April 2008 and December 2016. To date, no prospective randomized studies of DGE have compared both digestive tract reconstruction techniques when a pancreatic anastomosis is performed to the stomach.

The International Study Group of Pancreatic Surgery (ISGPS) (1) standardized the definition of DGE and its severity, which allows a more precise comparison of series. Recently, some authors nuanced this classification, as grade A DGE could be an effect of the protocol for removing the nasogastric tube (NGT) or the feeding (9,10). The objective of this study was to analyze DGE incidence (as defined by the ISGPS) in ReY and BII reconstruction in patients who underwent PD. The secondary endpoint was to determine the risk factors for DGE.

PATIENTS AND METHODS

This was a single center, prospective, case-control randomized study (ClinicalTrials.gov Identifier: NCT01984216) and all consecutive patients who underwent PD between December 2013 and August 2016 were included. All patients were informed about the study and signed an informed consent approved by the ethics committee of the center.

Exclusion criteria

- Impossibility to perform the standard PD technique with PG and antecolic GJ.
- Resection associated with other organs, excluding the portal vein/superior mesenteric vein.
- Previous gastric surgery.
- Preoperative gastric or duodenal obstruction.
- Previous abdominal surgery of the inframesocolic compartment, excluding appendectomy and gynecological surgery.

Randomization

Study patients were randomly allocated to one of two possible reconstruction groups (BII or ReY) adopting a numbered sealed envelope system. The surgeon did not know which reconstruction technique was to be used until the envelope was opened. The

protocol distribution inside the envelopes was performed according to a computer-generated random list of numbers.

Surgical technique

The surgical technique used was the standard superior mesenteric artery first approach procedure, as described by Pessaux and Marzano (11,12). PG (I-B S0 type) was the method of choice for reconstruction (13) following Delcore's (14) technique, using two-layer sutures: an external one with interrupted stitches made of a non-absorbable material and an internal one with absorbable monofilament running sutures. Digestive reconstruction was performed based on the randomization, either ReY or a BII. Absorbable monofilament running manual suture was used in both cases. Standard lymphadenectomy of the stations (5, 6, 8a, 12b, 12c, 13a, 13b, 14, 17a, 17b) (15) with a total meso-pancreas excision was used (16) in cancer patients.

Postoperative care

Postoperative care was managed using a standardized clinical pathway, which included the removal of the nasogastric tube after 24 h and initiation of a liquid diet, provided that the clinical status allowed it. Enteral or parenteral nutrition were not systematically used. Patients who had undergone previous biliary tract surgery, had cholangitis or had a bile duct prosthesis received prophylactic antibiotics (piperacillin-tazobactam) until bile or prosthesis cultures were available. An alternative medication was provided if there were allergies to the previously mentioned drugs. Patients received prophylactic intravenous (iv) esomeprazole treatment (40 mg/12 h) for gastrointestinal bleeding. Preoperative subcutaneous octreotide (0.1 mg/8 h) was given during the first five days after the surgery in order to prevent PF and iv erythromycin lactobionate (100 mg/8 h) and cinitapride at the start of the oral feeding to prevent DGE.

An analysis of abdominal drain fluid amylase concentration was performed on postoperative day 1 and 3 (PDO1 and PDO3), according to the criteria of the International Study Group on Pancreatic Fistula. The drains were removed if the amylase levels reached ≤ 400 U/l. The procedure was repeated every 48 h for higher values, following the same criteria.

Study variables

A prospective registry was kept with a specific anonymous database using FileMaker® during patient admission. The database included: demographic data, ASA classification (17), body mass index (BMI kg/m²), instant nutritional assessment (INA) (well nourished, mildly malnourished, moderately malnourished and severely malnourished), diagnosis, surgical procedures, date of the surgery, surgeons and surgical complications according to the Clavien-Dindo (18) and the ISGPS classifications for PF, DGE, and PPH (1-3).

All complications within 30 days following surgery or until discharge were registered. Those detected during consultation or hospital readmissions within the same period were also recorded. Mortality included all deaths within 30 and 90 days after surgery, including readmission cases. Clavien-Dindo complications grades I and II were considered as mild and \geq III as severe.

Statistics and sample size determination

Descriptive statistics were used for patient sociodemographic and clinical characteristics, as well as the complications following PD. For example, the mean and standard deviation or frequencies and percentages were used, depending on the nature of the variable. Qualitative variables were analyzed in order to compare the differences between study groups, using the Chi-square test or Fisher's exact test. Quantitative variables were analyzed using the Student's t-test or the Mann-Whitney U test.

A bivariate assessment of the relationship between the variables and their association with the development of DGE was performed using binary regression logistic models. Risk measurements were generated as odds ratios (OR) with 95% confidence intervals (CI). Furthermore, a multivariate logistic regression model was fitted that included relevant variables that were potentially associated with the occurrence of complications in the original model and significant variables at 0.1 were maintained. The analysis of the data was performed with SPSS 15.0 and SPSS 22.0s. A p-value of \leq 0.05 was considered as statistically significant.

RESULTS

Pancreaticoduodenectomy (PD) was performed in 86 patients between December 1st 2013 and August 8th 2016 (32 months). Six cases were excluded as they were non-resectable and one was excluded as they underwent a total pancreatectomy. Therefore, 79 PD were performed during the period. One patient refused to participate in the study and sign the informed consent, thus 78 subjects were finally included in the study. Fourteen cases were subsequently excluded: nine due to a previous abdominal surgery (two colectomies, one total gastrectomy, one right hepatectomy, one radical cystectomy, one previous pancreaticojejunostomy, one splenectomy and one anterior resection of the rectum with ileostomy), three due to previous duodenal obstruction and two other cases as it was not possible to perform the PG (Fig. 1). Finally, 64 patients were randomly assigned to one of the study groups, 32 cases underwent ReY (experimental group) and 32 underwent BII (control group).

With regard to demographic variables, no significant differences were found between the study groups (Table 1). Tumors were malignant in 78.1% of the subjects and the primary diagnosis was pancreatic adenocarcinoma. Fifty per cent of the subjects had a certain degree of malnutrition according to the INA (19) in the DGE-BII group compared to 62.5% in the Roux-en-Y group; the difference was not significant.

Table 2 shows the observed complications according to the Clavien-Dindo classification. Of the 64 patients, 56.2% had some type of complication and 20.3% were classified as Clavien \geq 3. The overall mortality was 3.1%. One case was an 84-year-old patient with a hemorrhage caused by a gastroduodenal artery pseudoaneurysm that was treated with embolization; he developed heart failure and died on day 26 post-surgery. A 58-year-old patient with biliopancreatic fistula who underwent a second surgery died of a massive hemorrhage on day 10. Six patients (9.3%) underwent a second surgery, four due to digestive hemorrhage, one due to a superior mesenteric artery pseudoaneurysm and one case of peritonitis. There were seven PF (10.9%), three of six cases needed an additional surgery and this was linked to mortality in one of the cases.

No significant differences were found between the study groups with regard to total complications (56.4%) or major complications (Clavien \geq 3), 21.9% in comparison to 18.8%. No significant differences were found for repeat surgeries, PF and degree of PF.

The variables associated with DGE are shown in table 3. The overall percentage of DGE was 20.3%, 25% for BII and 15.6% for ReY; the difference was not statistically significant. No significant intergroup differences were found with regard to the degree of DGE or the time required to tolerate the diet. With regard to the type of DGE, 12.5% of patients in the BII group developed primary DGE in comparison to 6.2% in the ReY group, although the difference was not statistically significant.

A multivariate analysis of the various factors that affect DGE was performed (Table 4). The associated primary factors were severe preoperative malnutrition (OR 99.7, 95% CI: 3.3-11,126.01) and the presence of postoperative abdominal complications (OR 15, 95% CI: 1.73-395). There was also a significant association with hemorrhagic complications (OR 9.44, 95% CI: 1.37, 107.94) and male gender (OR 8.38, 95% CI: 1.11-129.14).

DISCUSSION

DGE is the most common complication following PD and represents around 50% of all the complications. The causes are unknown, although the factors with the most scientific evidence include hormonal (motilin), technical (pylorus-preserving pancreaticoduodenectomy PPPD, antecolic/transmesocolic gastrojejunostomy and BII/ReY), intra-abdominal complications (PF, abscess, collections and repeat surgery) and early rehabilitation programs (NGT, epidural analgesia without morphine, anti-nausea medication, prokinetic drugs and hydric balance). Some authors differentiate primary DGE from secondary DGE due to intra-abdominal processes (20). The differences between postoperative ileus and DGE are also unclear and computed tomography scans or digestive system contrast studies have not been performed in most series.

The incidence and factors associated with DGE development have been analyzed in many studies. However, there is scarce information about the effect of the type of digestive reconstruction following PD. In 2013, Shimoda et al. (21) published the only trial on this topic with 101 randomized patients; 49 underwent ReY and 52 BII. The results showed a significantly lower incidence of DGE with BII (5.7%), being this rate much lower than that reported by most studies that used this reconstruction method. In contrast, the incidence was similar to that reported in other studies (around 20.4%)

in the group of patients who underwent ReY. From a methodological view, this study most resembles our study, although their patients underwent PJ and not PG as in our study. Thus, conclusions cannot be extrapolated.

There are no randomized studies to date that compare these two techniques with PG patients. The most similar study was published by Glowka (22) in 2017. This was a prospective study with 168 patients who underwent PD with PG (78 BII and 90 ReY). Patients were not randomized, even though it was an experimental study. Furthermore, there is no mention of the criteria used for choosing the technique, which limits the analysis of the results. It should also be noted that a variation of BII was used in this study: a Braun enteroenterostomy was performed. The anastomosis reduces the volume of bile that may leak back into the stomach with a BII, which affects the comparison with ReY. The results of their study show that there were no significant differences in the incidence of DGE between the two techniques, which is in line with our results. However, DGE occurred in 30% of the patients who underwent ReY and 26% in the BII group in this series, whereas the incidence of DGE was lower for patients that underwent a ReY (15.6%) in our study. Glowka does not describe exclusion criteria used in the study and the higher percentage of DGE could be due to the inclusion of patients who developed postoperative ileus due to adherence of previous surgeries.

With regard to the factors linked to DGE, the presence of other abdominal complications was identified in our study. This is the primary factor associated with DGE in the literature (23,24). However, it is not clear if it really affects all types of DGE or if this association is only linked to a DGE secondary to intra-abdominal processes. This would explain why a decrease of postoperative complications lowers the incidence of DGE, although it is still unclear if this occurs with primary DGE.

In our study, as reported by Glowka (22), an association between DGE and hemorrhagic complications was observed. This relationship is not reflected in other studies with PY, thus our results could be due to PG. However, our outcomes show that 60% of postoperative hemorrhages following PG usually present as upper gastrointestinal bleeding during the first postoperative days. In general, they are self-limited but their treatment includes the placement of an NGT and bowel rest, which delays oral tolerance. The criteria are met in order to classify these patients as having

DGE but without actually having an emptying problem (25). The same occurs when a patient undergoes a second surgery due to hemorrhage.

Another factor identified in our study was severe preoperative malnutrition. Currently, the perioperative nutrition (26,27) and the nutritional status of patients who undergo PD is of great importance. Many observational studies have associated the lower number of postoperative complications and even an increased long-term survival with a better preoperative nutritional status. With regard to DGE, the nutritional status and fragility of the patient can affect the postoperative recovery of subjects that are unable to eat. This data can be biased because the percentage of complications is higher in these patients or they require postoperative NPT. Thus, this is similar to what was previously discussed for hemorrhagic complications, i.e., they meet the criteria without really being DGE.

Our study is limited by sample size and the few cases of primary DGE and thus there is insufficient strength to analyze this problem. Further studies should be designed to clearly identify the two subtypes, as their causes could be different and this could hinder results when analyzed together. The definition and classification of DGE by the ISGPS is important for the international standardization of criteria and facilitates the comparison between different groups. Untangling the differences between primary and secondary DGE would help to better understand its causes and patients who meet the criteria due to other postoperative complications that prevent oral tolerance can be included/excluded from the classification.

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Table 1. Demographic variables

	<i>BII group</i> (n 32)	<i>ReY group</i> (n 32)	<i>p-value</i>
<i>Sex</i>			
Male	18 (56.2%)	17 (53.1%)	1
<i>Age</i>	64.7 (± 14.9)	69 (± 11)	0.2
<i>ASA</i>			
I	4 (12.9%)	5 (15.6%)	0.66
II	12 (38.7%)	14 (43.8%)	
III	15 (48.4%)	12 (37.5%)	
IV	0	1 (31%)	
<i>Diagnosis</i>			
Pancreatic adenocarcinoma	13 (40.6%)	17 (53.1%)	0.31
Papillary adenocarcinoma	3 (9.4%)	3 (9.4%)	
Papillary adenoma	0	2 (6.2%)	
Cholangiocarcinoma	6 (18.8%)	4 (12.5%)	
Intraductal papillary mucinous neoplasia	5 (15.6%)	6 (18.8%)	
Neuroendocrine tumor	3 (9.4%)	0	
Pancreatitis	2 (6.2%)	0	
<i>History of pancreatitis</i>	5 (15.6%)	2 (6.2%)	0.42
<i>History of diabetes mellitus</i>	3 (9.4%)	1 (3.1%)	0.6
<i>Instant nutritional assessment</i>			
Well nourished (albumin > 3.5 and lymphocytes > 1,500)	16 (50%)	20 (62.5%)	0.6
Mildly malnourished (albumin > 3.5 and lymphocytes < 1,500)	10 (31.5%)	7 (21,8)	
Moderately malnourished (albumin < 3.5 and lymphocytes > 1,500)	4 (12.5%)	2 (6.2%)	

Severely malnourished (albumin < 3.5 and lymphocytes < 1,500)	2 (6.2%)	3 (9.3%)	
<i>Diameter of the pancreatic duct (of Wirsung) (mean)</i>	4.78 (2.06)	4.23 (2.52)	0.35

ASA: American Society of Anaesthesiologists score; BII: Billroth II gastrojejunostomy;

ReY: Roux-en-Y gastrojejunostomy.

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Table 2. Morbidity and mortality

	<i>BII group</i> (n 32)	<i>ReY group</i> (n 32)	<i>p-value</i>
<i>Complication</i>	18 (56.2%)	18 (56.2%)	1
<i>Clavien ≥ 3</i>	7 (21.9%)	6 (18.8%)	0.77
<i>Death</i>	0	2 (6.2%)	0.42
<i>Duration (minutes)</i> (mean - standard deviation)	320.6 (± 66.3)	331.5 (± 50.1)	0.45
<i>Hospital stay</i> (mean - standard deviation)	11.1 (± 6.5)	11.1 (± 6.1)	0.98
<i>Infection</i>	6 (18.7%)	8 (25%)	0.59
<i>Patient re-operated</i>	4 (12.4%)	2 (6.2%)	0.39
<i>Readmission</i>	6 (18.8%)	10 (31.2%)	0.25
<i>Pancreatic fistula</i>	3 (9.4%)	4 (12.5%)	0.45
<i>Transfusion (intra- or postoperative)</i>	14 (43%)	15 (46.8%)	0.8
<i>Degree of PF</i>			0.28
B	0	3 (9.4%)	
C	3 (9.4%)	1 (3.1%)	

PF: pancreatic fistula; BII: Billroth II gastrojejunostomy; ReY: Roux-en-Y gastrojejunostomy.

Table 3. Delayed gastric emptying (DGE)

	<i>BII group</i> (n 32)	<i>ReY group</i> (n 32)	<i>p-value</i>
<i>Tolerance to diet (days)</i>			
< 7	24 (75%)	26 (81.2%)	0.47
7-13	5 (15.6%)	3 (9.3%)	
14-20	2 (6.2%)	(6.2%)	
> 21	1 (3.1%)	0	
<i>DGE</i>			
Yes	8 (25%)	5 (15.6%)	0.35
No	24 (75%)	27 (84%)	
<i>Type of DGE</i>			
Primary	4 (12.5%)	2 (6.2%)	0.53
Secondary	4 (12.5%)	4 (12.5%)	
<i>Degree of DGE</i>			
A	5	1	0.06
B	1	5	
C	2		

BII: Billroth II gastrojejunostomy; ReY: Roux-en-Y gastrojejunostomy.

Table 4. Multivariate logistic regression for delayed gastric emptying

	<i>OR</i>	<i>CI (95%)</i>	<i>p-value</i>
Age	0.99	(0.93; 1.05)	Non-significant
Sex (male)	8.38	(1.11-129.14)	Significant
Severe malnutrition	99.7	(3.3-11,126.01)	Significant
Hemorrhage	9.44	(1.37, 107.94)	Significant
Patient re-operated	0.1	(0.0-1.4)	Non-significant
General complication	6.92	(0.18-895.72)	Non-significant
Abdominal complication	15	(1.73-395)	Significant

Fig. 1. Flow diagram of patients included in the study. PD: pancreaticoduodenectomy;
PG: pancreaticogastrostomy.