



Impact of pylorus preservation on delayed gastric emptying after pancreaticoduodenectomy – analysis of 5,000 patients based on the German StuDoQ|Pancreas-Registry

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Background: Delayed gastric emptying (DGE) is one of the most common complications after pancreatic head resection. It leads to increased length of hospital stay, high costs for healthcare systems and reduced quality of life. The primary aim of the study was to assess the impact of pylorus preservation, respectively resection on the occurrence of DGE in patients undergoing pancreaticoduodenectomy (PD).

Methods: All cases of pylorus-resecting PD (PRPD) and pylorus-preserving PD (PPPD) entered in the StuDoQ|Pancreas nationwide registry of the German Society of General and Visceral Surgery from 01/01/2014 until 31/12/2018 including demographics, surgical techniques, histopathological and perioperative data were retrospectively analyzed. This study was approved by the ethics committee of the Ruhr-University Bochum, Germany.

Results: Data of 5,080 patients were enrolled. PPPD was the method of choice (70.4%). Pylorus preservation had no impact on the occurrence of DGE (20.3% *vs.* 21.5%, $P=0.33$), but further risk factors could be identified. The comparison of PPPD and PRPD groups showed statistically significant differences in the surgical approach (primary open approach, 94.8% *vs.* 98.0%, $P<0.001$), duration of surgery (326.4 *vs.* 352.1 minutes, $P<0.001$), technique of pancreatic anastomosis (pancreaticojejunostomy *vs.* pancreaticojejunostomy), 78.6% *vs.* 85.2%, $P<0.001$).

Conclusions: Patient factors, intraoperative factors, duration of surgery and postoperative factors (postoperative pancreatic fistula, biliary leakage and other surgical complications) were identified as risk factors for DGE. Future research should focus on register-based, prospective, randomised-controlled studies such as the currently recruiting “PyloResPres trial”.

Keywords: Pancreatic head resection; registry; StuDoQ|Pancreas; pylorus preservation; delayed gastric emptying (DGE)

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Introduction

Mortality after pancreatic surgery has been reduced significantly over the past decades. Experienced centers report mortality rates ranging from 0–6% (1,2). However, postoperative morbidity remains at a high level (3). Delayed gastric emptying (DGE) is one of the most common complications after pancreatic head resections and occurs in up to 80% of cases (4). DGE leads to increased length of hospital stay, high costs for healthcare systems, reduced quality of life (5) and a delay in adjuvant cancer treatment.

The International Study Group for Pancreatic Surgery (ISGPF) defined DGE by the number of days a nasogastric tube is required and solid food can be digested (6).

Surgical techniques, postoperative pancreatic fistulas (POPF), higher age, sepsis or intraabdominal abscesses are seen as risk factors for DGE, although conflicting results have been reported (7-9). Due to a lack of a causal therapy, the prevention of DGE is of major importance.

There is scarce data about the impact of DGE after major pancreatic surgery. Large study populations have not been examined yet and there is an unmet need for further knowledge about this clinically highly important issue.

The German Society of General and Visceral Surgery (DGAV) initiated a national registry (Studien-, Dokumentations- und Qualitätszentrum, StuDoQ) for pancreatic surgery in 2013 (StuDoQ|Pancreas), providing extensive information from German and foreign pancreatic surgery centers (10). Data about demographics, indications, types of procedures and perioperative outcome after pancreatic head resections have been gathered, retrospectively analysed and are reported on behalf of the nationwide registry. The aim of the study was to assess the impact of pylorus preservation, respectively resection on the occurrence of DGE in a large cohort of patients undergoing pancreaticoduodenectomy (PD). We present the following article in accordance with the STROBE reporting checklist (available at <https://gs.amegroups.com/article/view/10.21037/gs-21-645/rc>).

Methods

The StuDoQ|Pancreas registry

The DGAV established the nationwide StuDoQ|Pancreas

registry for pancreatic diseases in order to assess the quality of pancreatic surgery in Germany. Data from more than 50 high volume pancreatic surgery centers are pseudonymized and retrospectively entered in an online tool. Written consent was given by all patients for evaluation in the registry. StuDoQ|Pancreas information was cross-checked with the hospitals' controlling data and annually certified. All cases of classic and pylorus-preserving PD entered in StuDoQ|Pancreas from 01/01/2014 until 31/12/2018 including demographics, surgical techniques, histopathological and perioperative data have been analyzed. Patients with an unknown DGE status or who underwent a surgical procedure other than PPPD or PRPD were excluded from evaluation.

Definitions

PD was defined either as pylorus-resecting (PRPD, Kausch-Whipple-procedure) or pylorus-preserving (PPPD, Traverso-Longmire). Lymphadenectomy (LAD), DGE, postoperative pancreatic fistula (POPF), postpancreatectomy hemorrhage (PPH) and chyle leakage were analyzed according to the grading system of the International Study Group for Pancreatic Surgery (ISGPS) (6,11-14). Complications and morbidity were assessed using the Clavien-Dindo-Classification (15).

Statistical analysis

Calculations were performed using SPSS V21.0 (IBM Corp. Released 2015, IBMStatistics for Windows, Version 23.0. Armonk, NY: IBM Corp.) and WinPepi (Pepi-for-Windows) (16). A two-sided significance level of 0.05 was applied. Scale variables were assessed by mean and range, categorical variables by absolute count and percentages.

Univariate analyses were performed using Student's *t*-test, Mann-Whitney-U, Kruskal-Wallis and χ^2 -test. Statistically significant associations with DGE were also assessed in a multivariate logistic regression model.

Ethical statement

The study was conducted in accordance with the

Table 1 Univariate analysis of patient characteristics of the PPPD and PRPD group; values are expressed by means and standard deviations

Characteristics	PPPD, n=3,577	PRPD, n=1,503	P value
Age, years	66.8±11.3	66.9±11.4	0.724
Sex			
Male	1,976 (55.2)	888 (59.1)	<0.01
Female	1,601 (44.8)	615 (40.9)	
BMI (kg/m ²)	25.56±5.41	25.77±10.1	0.312
ASA, n (%)			
I	158 (4.4)	46 (3.1)	<0.01
II	1,646 (46.0)	624 (41.5)	
III	1,712 (47.9)	803 (53.4)	
IV	60 (1.7)	30 (2.0)	
V	1 (0.0)		
Postoperative length of stay (days)	20.60±14.97	21.35±15.2	0.034
Preoperative biliary drainage, n (%)			
No	2,221 (62.1)	989 (65.8)	<0.01
Yes	1,356 (37.9)	514 (34.2)	
Leading symptoms, n (%)			
Pain	1,273 (35.6)	572 (38.1)	<0.01
Nausea	584 (16.3)	339 (22.6)	
Hypoglycemia	17 (0.5)	10 (0.7)	
Jaundice	1,336 (37.3)	452 (30.1)	

BMI, body mass index; ASA classification, American Society of Anesthesiologists; PRPD, pylorus-resecting pancreaticoduodenectomy; PPPD, pylorus-preserving pancreaticoduodenectomy.

Declaration of Helsinki (as revised in 2013). The study was approved by the ethics committee of the Ruhr-University Bochum, Germany (Reg. Nr. 20-7116-BR) and individual consent for this retrospective analysis was waived.

Results

Five thousand and eighty patients were enrolled. 2,864 (56.4%) patients were male whereas females accounted for 43.6% (n=2,216). The mean age was 66.78±11.35 years and the mean BMI 25.62±7.16 kg/m². The mean postoperative length of stay was 20.82±15.05 days. 2,515 (49.5%) patients were classified as ASA III or higher. Preoperative abdominal pain was the most common clinical symptom (n=1,845, 36.6%), followed by jaundice (n=1,788, 35.2%) and nausea (n=923, 18.2%). The high amount of cholestasis led to the application of biliary stents in 36.8% (n=1,870) of

patients. PPPD was the method of choice in the majority of patients (70.4%). 3,577 PPPD and 1,503 PRPD were performed. The mean postoperative length of stay in ICU was 5.09±8.91 days in the entire study population. *Table 1* presents the comparison of PPPD and PRPD groups. Pylorus resection was more common in males, those without biliary drainage and in patients with higher ASA class and those suffering pain. It led to a prolonged hospital stay and nausea.

In the entire study population a conventional/open approach was chosen in 4,864 (95.7%) of patients. Extended LADs were performed in 11.9% (n=605) and pancreaticojejunostomies (PJ) in 80.6% (n=4,093) of pancreatic head resections. Synchronous resections of liver metastases were performed 112 (2.2%) times. An overall 30-day-mortality of 4.1% (n=213) was reported. Most patients deceased within 30 days after surgery due

Table 2 Univariate analysis of operative data of the PPPD and PRPD group

Characteristics	PPPD, n=3,577, n (%)	PRPD, n=1,503, n (%)	P value
Approach			
Laparoscopic	36 (1.0)	5 (0.3)	<0.001
Laparoscopically assisted	89 (2.5)	14 (0.9)	
Primarily open	3,391 (94.8)	1,473 (98.0)	
Secondarily open	60 (1.7)	11 (0.7)	
Duration of surgery (minutes)	326.39±93.5	352.1±106.4	<0.001
Lymph node dissection			
Standard	2,822 (78.9)	1,278 (90.1)	<0.001
Extended	464 (13.0)	141 (9.4)	
Pancreatic duct			
<3 mm	1,431 (56.3)	609 (56.5)	1.0
>3 mm	1,109 (43.7)	468 (43.5)	
Pancreatic consistency			
Soft	1,566 (56.6)	620 (54.1)	0.691
Hard	1,203 (33.6)	527 (45.9)	
Pancreatic anastomosis			
Pancreaticojejunostomy	2,812 (78.6)	1,281 (85.2)	<0.001
Pancreaticogastrostomy	729 (20.4)	186 (12.4)	
Blind closure	18 (0.5)	17 (1.1)	
ICU stay (days)	5.06±9.11	5.15±8.34	0.739
30-day survival (number of patients)	3,424 (95.7)	1,443 (96.1)	0.643
Postoperative pancreatic fistula (grade)			
None	2,799 (78.2)	1,195 (79.5)	0.318
Biochemical leak	288 (8.1)	97 (6.55)	
B	273 (7.6)	134 (8.9)	
C	271 (6.1)	77 (5.1)	
Delayed gastric emptying (grade)			
None	2,854 (79.8)	1,181 (78.6)	0.330
A	374 (10.5)	162 (10.8)	
B	213 (6.0)	100 (6.7)	
C	136 (3.8)	60 (4.0)	
Bile leakage	210 (5.9)	73 (4.3)	0.150

Table 2 (continued)

Table 2 (continued)

Characteristics	PPPD, n=3,577, n (%)	PRPD, n=1,503, n (%)	P value
Postpancreatectomy hemorrhage			
None	3,317 (87.1)	1,340 (89.2)	<0.001
A	84 (2.3)	38 (2.5)	
B	166 (4.6)	57 (3.8)	
C	210 (5.9)	68 (4.5)	

ICU, intensive care unit; PRPD, pylorus-resecting pancreaticoduodenectomy; PPPD, pylorus-preserving pancreaticoduodenectomy.

Table 3 Univariate analysis of benign and malignant histopathological results

Characteristics	PPPD, n (%)	PRPD, n (%)	P value
Malignant	n=2,579	n=1,154	
Pancreatic ductal adenocarcinoma	1820 (70.6)	863 (74.8)	0.008
Ampullary carcinoma	344 (13.3)	94 (8.2)	<0.001
Bile duct carcinoma	330 (12.8)	115 (10.0)	0.014
Duodenal carcinoma	71 (2.8)	69 (6.0)	<0.001
Intraductal papillary mucinous neoplasm carcinoma	14 (0.5)	10 (0.9)	0.253
Cystadenocarcinoma	–	3/0.2	
Benign	n=983	n=283	
Intraductal papillary mucinous neoplasm	258 (26.3)	65 (23.0)	0.265
Mucinous cystic neoplasm	23 (2.3)	10 (3.5)	0.267
Serous cystic neoplasm	36 (3.7)	16 (5.6)	0.137
Pseudocyst	15 (1.5)	7 (2.5)	0.283
Cystic pancreatic neuroendocrine neoplasm	10 (1.0)	2 (0.7)	0.635
Benign tumours	116 (11.8)	19 (6.7)	0.015
Chronic pancreatitis	384 (39.1)	163 (57.6)	<0.001
Other	3 (0.3)	1 (0.3)	0.899
Pancreatic neuroendocrine neoplasm	138 (14.2)	–	

PRPD, pylorus-resecting pancreaticoduodenectomy; PPPD, pylorus-preserving pancreaticoduodenectomy.

to surgical complications (49.8%, n=103). *Table 2* indicates surgical data for the PPPD and PRPD group.

Pylorus preservation was more common with minimally invasive-approach and associated with shorter duration of surgery and more extended lymph node dissections. The majority of patients received a PJ.

The most common resected neoplasm was a pancreatic ductal adenocarcinoma (PDAC). *Table 3* demonstrates histopathological results: 3,436 malignant (67.3%) and

1,644 (32.7%) benign diagnoses were found.

PPPD was more common for ampullary and bile duct cancer, while it was less common for PDAC and duodenal cancer. A pylorus resection was more frequent in patients with chronic pancreatitis, while PPPD was the method of choice for benign tumours.

DGE occurred in 20.6% (n=1,045) of all patients. Patients suffering from DGE stayed for 28.98±20.4 postoperative days, whereas patients without DGE were discharged after

Table 4 Multivariate comparison of DGE and non-DGE group

Characteristics	DGE positive n=1,045, n (%)	DGE negative n=4,035, n (%)	P value
Sex			
Male	602 (57.6)	2,262 (56.1)	0.368
Female	443 (42.4)	1,773 (43.9)	
Surgical technique			
Pylorus-preserving pancreaticoduodenectomy	723 (69.2)	2,854 (70.7)	0.330
Pylorus-resecting pancreaticoduodenectomy	322 (30.8)	1,181 (29.3)	
Pancreatic anastomosis			
Pancreaticojejunostomy	760 (72.7)	3,333 (82.6)	<0.001
Pancreaticogastrostomy	263 (25.2)	652 (16.2)	
Postoperative pancreatic fistula			
None	658 (63.0)	3,336 (82.7)	<0.001
Biochemical leakage			
B	136 (13.0)	271 (6.7)	
C	131 (12.5)	163 (4.0)	
Postpancreatectomy hemorrhage			
None	820 (78.5)	3,637 (90.1)	<0.001
A	54 (5.2)	68 (1.7)	
B	72 (6.9)	151 (3.7)	
C	99 (9.5)	179 (4.4)	
Duration of operation (minutes)	347.9±107.7	330.4±95.3	<0.001
Age, years	67.8±10.9	66.5±11.4	0.01
Biliary leakage	101 (9.7)	182 (4.5)	<0.001
Other surgical complications	224 (21.4)	549 (13.6)	<0.001

Other surgical complications: chyle leakage, pancreatic leakage, anastomotic stenosis, gastrointestinal bleeding, pancreatitis in the remnant. DGE, delayed gastric emptying.

18.71±12.48 days ($P<0.001$). DGE grade A was found in 10.6% ($n=536$), grade B in 6.2% ($n=313$) and grade C in 3.9% ($n=196$) of patients. DGE grade A led to a postoperative stay of 23.14±13.67 days and grade B was associated with a stay of 28.82±26.88 days. Patients suffering from DGE grade C were discharged after 45.22±29.98 days ($P<0.001$). *Table 4* highlights characteristics of patients with DGE.

Higher age and longer duration of surgery were associated with DGE. DGE also was more common in PG than in the PJ group. Over 25% of DGE patients had POPF, whereas less than 11% suffered from POPF in the non-DGE group. DGE patients developed PPH more

often than non-DGE patients (21.5% *vs.* 9.9%). All types of postoperative complications were increased the DGE group: POPF, PPH, HJ leakage and others.

Univariate analysis revealed various characteristics that were associated with a statistically significant increase of the frequency of DGE. These characteristics were analysed in a multivariate logistic regression model. It revealed a statistically significant association with the occurrence of DGE for higher age ($P=0.006$), longer duration of surgery ($P<0.001$), reconstruction as PG ($P<0.001$), POPF ($P=0.001$), insufficiency of HJ ($P<0.001$) and other surgical complications ($P=0.009$). The results are found in *Figure 1*.

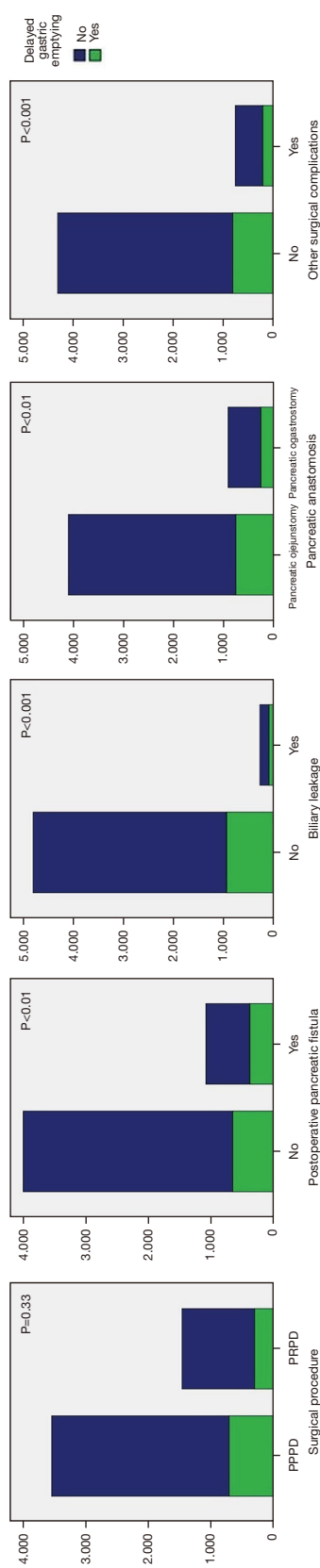


Figure 1 Stacked bar charts present frequencies resulting from the multivariate DGE-evaluation for operational procedure (DGE: 20.2% vs. 21.2%), pancreatic anastomosis (DGE: 18.6% vs. 28.7%), postoperative pancreatic fistula (DGE: 16.5% vs. 35%), biliary leakage (DGE: 19.7% vs. 35.7%) and other surgical complications (DGE: 18.9% vs. 28.8%). PPPD, pylorus-preserving pancreaticoduodenectomy; PRPD, pylorus-resecting pancreaticoduodenectomy.

Discussion

DGE occurs up to 80% of patients after pancreaticoduodenectomy and ranks as the most common complication (4,17). It is accompanied by an increased length of hospital stay, higher costs for healthcare systems and reduced quality of life (5). The initiation of an adjuvant chemotherapy might be delayed which possibly exercises a negative influence on survival. The pathophysiology of DGE is not completely understood, although various attempts have been made to elucidate the mechanism. Ischemia and denervation of the stomach due the mobilization or lymphadenectomy, reduced motilin levels after duodenectomy or intraabdominal complications have been suspected causes (18). Propulsive medication such as off label use of erythromycin might attenuate DGE (19).

Currently, PPPD is the procedure of choice in contrast to the classic, pylorus-resecting operation. According to the literature it leads to reduced length of surgery, blood loss and equal complication rates (20,21).

So far, literature data about DGE are mostly based on small numbers of patients or meta-analyses. In this study we are presenting data of 5,080 PD patients from the StuDoQ|Pancreas registry of the DGAV. All patients were enrolled in high volume centers for pancreatic surgery. Due to the outstanding number of patients, the statistical analysis leads to high validity of the data.

In our study, the majority of pancreaticoduodenectomies were performed as pylorus-preserving operations. DGE occurred in 20.6% of patients, a rate that has also been shown by other groups (8). Whereas in the literature, a wide range of DGE from 5% up to 81% are reported (4,17). In our study population, most cases showed a mild DGE (grade A, 10.6%), which correlates to results in the literature (7). Half of all cases showed a mild DGE underlining the use of a standardized definition for DGE such as the applied ISGPS definition.

After uni- and multivariate analyses higher age, a longer duration of surgery, reconstruction as PG, POPF, insufficiency of HJ and other surgical complications can be seen as risk factors for DGE. According to our data avoiding a reconstruction as PG and a longer duration of surgery could decrease the frequency of DGE, whereas a high patients' age or the occurrence of complications can scarcely be influenced in practice.

Parmar and coauthors stated only postoperative complications as POPF, sepsis and the need for reoperation to be associated with DGE (8). Mohammed *et al.* listed

intraabdominal abscesses as an additional risk factor, which was not validated in our study population. Histological results were not associated with higher DGE rates according to results in the literature (9). Hüttner *et al.* found a statistically significant association of PPPD and DGE in a meta-analysis (21). Klaiiber *et al.* described inconclusive results in their meta-analysis of randomized controlled trials, whereas the German PROPP-trial showed no advantage of PRPD in relation to DGE in a prospective single center study (22,23). The present data reveal no statistical difference in this context (20.2% *vs.* 21.4%, $P=0.330$). PG and PJ were shown to be associated with the same frequency of DGE in a large prospective randomized trial (2). Our registry data show a higher rate of DGE cases in the PG group. Werba *et al.* analyzed the registry of the NSQIP collaborative and also identified risk factors for DGE. Among others, they found concurrent adhesiolysis, feeding jejunostomy or a vascular reconstruction with vein graft to be associated with DGE. Age and postoperative complications were also enumerated (24). Inconsistent results might be caused by differing local operational techniques, enrolled patients or varying recorded variables in each registry. We do include a large number of patients in this registry study, however there are data, which the registry is not able to provide.

The reconstruction techniques using a single or double loop for the hepatojejunostomy, the addition of a Billroth II (BII) or Roux-en-Y technique for the gastrojejunostomy, antecolic or retrocolic reconstruction have not been specified in the registry. The pancreatic anastomosis technique has neither been tracked. Therefore an inclusion of these technical details was not feasible in our study, even though at other occasions these factors have shown to be of relevance for DGE. In Germany the duct-to-mucosa-pancreaticojejunostomy is widely spread, although various variations are used [Blumgart, Heidelberg technique (25,26)]. Hartwig *et al.* recommended an antecolic route to reduce the occurrence of DGE (27). Yang *et al.* found a lower frequency of DGE after a BII reconstruction (28). A Braun enterostomy should follow a BII reconstruction in order to attenuate DGE (29). In the registry rare complications (e.g., chyle leakage, pancreatic leakage, anastomotic stenosis, gastrointestinal bleeding or pancreatitis in the remnant) are summed up as “*other surgical complications*”, impeding a precise evaluation

Even though all data were included in the registry in a prospective fashion, all data have been evaluated retrospectively. Randomized controlled trials addressing

the impact of DGE are scarce (30). Therefore, the DGAV has already initiated a prospective, randomized controlled, multicenter, register-based study entitled “*PyloResPres-Trial*” (DRKS00018842). This registry based RCT trial might enable more insights into the mechanism of DGE, have impact on the technique of pancreatic head resections and offer a decrease of occurrence of this common complication after PD.

The StuDoQ-registry created the unique opportunity to analyze the data of more than 5,000 patients who underwent a pancreatic head resection. Higher age, longer duration of surgery, reconstruction as PG, POPF, insufficiency of HJ and other surgical complications were identified as risk factors leading to DGE. Future research should focus on large, register-based, prospective randomised-controlled trials. The PyloResPres trial is a promising attempt to gather more information about this important complication of pancreatic surgery and its results will be awaited with interest.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the ethics committee of the Ruhr-University Bochum, Germany (Reg. Nr. 20-7116-BR) and individual consent for this retrospective analysis was waived.

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