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# Proposal and Critical Appraisal of Exclusion Criteria to the International Study Group for Pancreatic Surgery Definition of Delayed Gastric Emptying



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- BACKGROUND:** The International Study Group for Pancreatic Surgery (ISGPS) defined criteria to objectively standardize delayed gastric emptying (DGE) after pancreaticoduodenectomy (PD). These criteria are inclusive by design, and may overestimate actual DGE incidence. This study critically examined individual DGE cases after PD to determine which patients are misclassified by these criteria, and for what reasons. Exclusion criteria designed to optimize the accepted DGE definition are proposed and evaluated.
- STUDY DESIGN:** We performed a retrospective review of prospectively collected data. We reviewed 357 consecutive patients undergoing PD by a single surgeon; included were 52 cases of ISGPS-defined DGE (14.6%). A detailed evaluation was conducted of cases using accepted and novel diagnostic criteria.
- RESULTS:** Of 52 ISGPS-defined DGE cases, 12 (23%) appeared not to represent genuine DGE on clinical review. Six required nasogastric tube placement for reoperation or management of emesis secondary to non-DGE conditions, 4 for reintubation without other evidence of DGE, and 2 remained NPO to treat non-DGE conditions. The proposed exclusion criteria use absence of gastric distention, passage of oral contrast, and presence of documented non-DGE conditions to determine genuine DGE. The incidence of true DGE was 11.2% in this cohort. The overall positive predictive value of the ISGPS criteria was 76.9%. Preoperative variables, DGE class, and incidence of disease-specific outcomes were similar with both definitions.
- CONCLUSIONS:** The ISGPS consensus guidelines promote a standardized, sensitive, and easily applicable definition of DGE, but may falsely classify DGE in approximately 23.1%. Introduction of the proposed exclusion criteria, which establish objective radiologic data as a component of the definition, could substantially limit this overestimation. (*J Am Coll Surg* 2015;220:1036–1043. © 2015 by the American College of Surgeons)
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Delayed gastric emptying (DGE) remains one of the most common complications after pancreaticoduodenectomy (PD), with a variably reported incidence between 7.9% and 57%.<sup>1-4</sup> Standardized evaluation of DGE has long been complicated by inconsistent definitions of the condition, usually characterized by days of postoperative nasogastric tube (NGT) decompression, days until tolerance of liquid or solid diet, and use of prokinetic agents postoperatively. Formerly, multiple institutions used these characteristics in different measures, and several definitions ensued.<sup>5</sup>

In 2007, the International Study Group of Pancreatic Surgery (ISGPS) proposed a consensus definition for DGE, based on severity of DGE and clinical significance.<sup>5</sup>

### Abbreviations and Acronyms

DGE	=	delayed gastric emptying
ISGPS	=	International Study Group of Pancreatic Surgery
NGT	=	nasogastric tube
PD	=	pancreaticoduodenectomy
PPPD	=	pylorus-preserving pancreatico-duodenectomy

These guidelines have quickly become indispensable for the classification of DGE after PD.

The ISGPS definition has been evaluated in a small number of studies, assessing the differences in outcomes between patients with ISGPS grades A through C,<sup>4,6-9</sup> and outcomes appear to correlate well with ISGPS grade. These studies have demonstrated that the criteria proposed by the ISGPS readily identify patients with DGE, but also questioned whether the inclusive design of these criteria may overestimate the incidence of genuine DGE.<sup>8</sup>

Our institution previously reported a comprehensive analysis of indicators of DGE, and suggested a modification to the ISGPS criteria that excluded patients who required relaparotomy during the same hospital stay, leading to NGT replacement, required mechanical ventilation (beyond postoperative day 2) and NGT placement, or who required prolonged NPO status for an objectively diagnosed non-DGE cause (ie, high-output pancreatic fistula).<sup>1</sup> Our previous findings suggested that the ISGPS criteria potentially overclassify numerous patients as having DGE when they actually require NGT placement for indications other than DGE.

In order to address these concerns, this study was designed to critically analyze every case of DGE identified by the ISGPS criteria in 357 consecutive PD patients, to determine which diagnoses of DGE were confounded by other conditions and potentially misclassified. This study attempted to characterize which non-DGE conditions most frequently result in diagnoses of DGE and which objective clinical data may help ascribe true positivity to the ISGPS criteria, with a goal of optimizing the definition of DGE.

## METHODS

### Patient selection

Between the years 2003 and 2013, a total of 357 patients underwent either classic Kausch-Whipple (PD) or pylorus-preserving pancreatico-duodenectomy (PPPD) by a single surgeon at Yale-New Haven Hospital. Perioperative characteristics were prospectively collected for all consecutive patients undergoing PD or PPPD for any indication. Data collection and analysis followed a

protocol approved by the Yale University School of Medicine Human Investigations Committee. Demographic characteristics, comorbid conditions, operative and perioperative variables, and complications were identified and evaluated for each patient. Perioperative complications were assessed within a 90-day follow-up period.

### Operative technique

When not precluded by oncologic or disease-specific considerations, PPPD was performed. In all other cases, a classic PD was performed. Pancreatico-jejunostomy was performed in a 2-layer end-to-side fashion using duct-to-mucosa reconstruction, while hepaticojejunostomy was performed in a single-layer end-to-side fashion. Gastro- or duodeno-jejunostomy was performed in an end-to-side (Billroth II) fashion. Early in the case series, these were performed in a retrocolic fashion, but our approach changed to antecolic positioning in 2008. Similarly, closed suction drainage of the peritoneum was routinely used early in the series, with placement of 2 drains adjacent to the hepatico- and pancreatico-jejunostomies, respectively. However, intraperitoneal drains were rarely used after 2005, as evidence suggesting they were unnecessary was integrated into our practice.<sup>10</sup>

### Definitions of delayed gastric emptying and exclusion criteria

The ISGPS criteria for DGE (Table 1) were applied to each patient, resulting in classification from grades A through C, or negative for DGE.<sup>5</sup> Patients with ISGPS-classified DGE underwent comprehensive chart review to determine the reason they were so classified. Patients were subcategorized based on the conditions leading to their need for nasogastric decompression, including genuine DGE, reintubation, relaparotomy, secondary to other postoperative complication, or “early clinical practice” (when patients were kept NPO or NGTs were routinely used for long enough to qualify a patient as having DGE by ISGPS criteria). Patients classified as early clinical practice (n = 3) were included in the analysis because they could not be excluded based on our criteria.

Review of each clinical course, the causes of reintubation or reoperation, and CT scans or x-rays demonstrating gastric distention and either failure or ready passage of contrast through to small bowel were evaluated to ensure that the classifications of primary DGE represented clinical reality. No standard radiographic definition of gastric distention after PD exists, so presence or absence of gastric distention was assessed subjectively, defined by an enlarged gastric pouch, often with a large amount of air or fluid within. For the purposes of this study, passage of contrast was most often assessed by analysis of CT

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