

# Clinical and Economic Validation of the International Study Group of Pancreatic Fistula (ISGPF) Classification Scheme

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**Objective:** The authors sought to validate the ISGPF classification scheme in a large cohort of patients following pancreaticoduodenectomy (PD) in a pancreaticobiliary surgical specialty unit.

**Summary Background Data:** Definitions of postoperative pancreatic fistula vary widely, precluding accurate comparisons of surgical techniques and experiences. The ISGPF has proposed a classification scheme for pancreatic fistula based on clinical parameters; yet it has not been rigorously tested or validated.

**Methods:** Between October 2001 and 2005, 176 consecutive patients underwent PD with a single drain placed. Pancreatic fistula was defined by ISGPF criteria. Cases were divided into four categories: no fistula; biochemical fistula without clinical sequelae (grade A), fistula requiring any therapeutic intervention (grade B), and fistula with severe clinical sequelae (grade C). Clinical and economic outcomes were analyzed across all grades.

**Results:** More than two thirds of all patients had no evidence of fistula. Grade A fistulas occurred 15% of the time, grade B 12%, and grade C 3%. All measurable outcomes were equivalent between the no fistula and grade A classes. Conversely, costs, duration of stay, ICU duration, and disposition acuity progressively increased from grade A to C. Resource utilization similarly escalated by grade.

**Conclusions:** Biochemical evidence of pancreatic fistula alone has no clinical consequence and does not result in increased resource utilization. Increasing fistula grades have negative clinical and economic impacts on patients and their healthcare resources. These findings validate the ISGPF classification scheme for pancreatic fistula.

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Pancreatic fistula is widely regarded as the most ominous of complications following pancreatic resection. Its clinical impact and sequelae have been previously described and

shown to contribute to the development of other morbid complications and high rates of mortality.<sup>1–4</sup> Despite refinements in operative technique and advancements in postoperative management, fistulas still occur with a frequency of 5% to 30%.<sup>5–12</sup> Efforts to mitigate this problem have included technical considerations (modification of the pancreaticojejunal anastomosis technique, reconstruction with pancreaticogastrostomy, and placement of pancreatic duct stents), perioperative infusion of somatostatin analogues, and use of adhesive sealants.<sup>9</sup> However, the successes of these various techniques and pharmacologic adjuvants is frequently challenged, and dissension exists as to which methods are optimal for prevention and management of fistulas.

The debate is further compounded by numerous and widely varying definitions of pancreatic fistula. Data from a recent analysis of 4 widely accepted definitions of fistula reported in the gastrointestinal surgical literature demonstrates that fistula rate depends largely upon the definition used.<sup>13</sup> The lack of a universal definition of pancreatic fistula, therefore, precludes objective comparisons of surgical experiences with this complication.

To address this problem and develop a consensus approach, an international consortium of 37 leading pancreatic surgeons from 15 countries, the International Study Group on Pancreatic Fistula (ISGPF), convened, reviewed the literature, and discussed their surgical experiences with fistulas.<sup>14</sup> The result was a universal and applicable definition of pancreatic fistula and a grading system for fistula severity based on clinical impact on the patient.

Appraisal of this grading system has yet to be accomplished, and to date, the ISGPF clinical classification scheme has not been rigorously tested or validated. The aims of this study, therefore, are: 1) to analyze our experience with pancreatic fistula by applying the ISGPF classification scheme in a high-volume pancreaticobiliary surgical specialty unit; 2) to demonstrate its value in examining outcomes in a large cohort of patients undergoing pancreaticoduodenectomy; and 3) to validate its application, clinically and economically, as a suitable alternative to current biochemical definitions of fistula.

## METHODS

### Patients

Two surgeons performed 176 pancreaticoduodenectomies from October 2001 to January 2006, with either

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