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## Is Acs Nsqip Organ Space Infection A Aurrogate for Aancreatic Fistula?

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### Structured Abstract

**Background**—In the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) pancreatic fistula has not been monitored, although organ space infection (OSI) data are collected. Therefore, the purpose of this analysis was to determine the relationship between ACS NSQIP organ space infection and pancreatic fistulas.

**Study Design**—From 2007-11, 976 pancreatic resection patients were monitored via ACS NSQIP at our institution. From this database, 250 patients were randomly chosen for further analysis. Four patients were excluded because they underwent total pancreatectomy. Data on OSI were gathered prospectively. Data on pancreatic fistulas and other intra-abdominal complications were determined retrospectively.

**Results**—Organ space infections (OSIs) were documented in 22 patients (8.9%). Grade B (n=26) and C (n=5) pancreatic fistulas occurred in 31 patients (12.4%) while Grade A fistulas were observed in 38 patients (15.2%). Bile leaks and gastrointestinal (GI) anastomotic leaks each developed in five (2.0%) patients. Only 17 of 31 Grade B and C pancreatic fistulas (55%), and none of 38 Grade A fistulas were classified as OSIs in ACS NSQIP. In addition, only two of five bile leaks (40%) and two of five GI anastomotic leaks (40%) were OSIs. Moreover, three OSIs were due to bacterial peritonitis, a chyle leak and an ischemic bowel.

**Conclusions**—This analysis suggests that the sensitivity (55%) and specificity (45%) of Organ Space Infection (OSI) in ACS NSQIP are too low for OSI to be a surrogate for Grade B and C pancreatic fistulas. We conclude that procedure-specific variables will be required for ACS NSQIP to improve outcomes following pancreatectomy.

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## Keywords

fistula; NSQIP; organ space infection; pancreas; pancreatectomy

In recent decades mortality for major elective surgical procedures has been greatly reduced. While overall morbidity has improved, the incidence of complications remains high following pancreatectomy (1-3). Reasons for reduction in mortality and morbidity include the development of aseptic techniques, the advent of antibiotics, the creation of blood banks as well as safe blood transfusion, and improved critical care. More recently, the systematic tracking of risk-adjusted outcomes has resulted in significant improvements in postoperative mortality and morbidity (4-7). This approach was first implemented by Veterans Affairs (VA) hospitals beginning in 1994 and is referred to as the National Surgical Quality Improvement Program (NSQIP)(8). Given the significant improvements made in postoperative outcomes at Veterans hospital as a result of NSQIP, the American College of Surgeons (ACS) developed the NSQIP program for civilian hospitals (4,9-11). ACS NSQIP has led to similar improvements in postoperative outcomes as seen with VA-NSQIP (1-7) and has since been used to evaluate outcomes in a variety surgical subspecialties (12-14).

A limitation of both VA-NSQIP and ACS NSQIP has been the lack of procedure-specific variables. As a result, key outcome measures for certain operations are not captured by ACS NSQIP (15-18). An example of this limitation is pancreatic fistula following pancreatectomy. Currently, the only variable that is collected by ACS NSQIP which may capture postoperative pancreatic fistula is organ space infection (OSI). However, the sensitivity and specificity of OSI for pancreatic fistula has not been established. Large institutional series report clinically relevant pancreatic fistula rates of 10-25%, whereas the rate of OSI following pancreatectomy has been 10% and has not changed over the last several years (19, 20). Given this difference, we hypothesize that the organ space infection (OSI) variable in ACS NSQIP is a poor surrogate for postoperative pancreatic fistula.

## Methods

Data for all patients undergoing pancreatectomy at Indiana University Hospital are prospectively collected and maintained in an Institution Review Board-approved database. Approximately 250 pancreatectomies are performed annually, 60% of which are proximal resections. Indications for pancreatoduodenectomy (PD) include pancreatic ductal adenocarcinoma in approximately 65% of proximal resections, followed by chronic pancreatitis in 25% and ampullary, duodenal and distal bile duct cancers in approximately 10% (20).

## Patient Population

Over a five-year period from 2007 to 2011, 976 patients underwent pancreatectomy at Indiana University Hospital. Two hundred fifty patients were randomly chosen from the database during this time period. Four patients who had undergone a total pancreatectomy were excluded because they did not have the possibility of developing a pancreatic fistula. Thus, a final cohort of 246 patients was available for analysis. Thirty-day postoperative

outcomes were prospectively monitored on all pancreatectomy patients via ACS NSQIP with data collected by a trained Surgical Clinical Reviewer. Data on pancreatic fistulas and other intra-abdominal complications were determined retrospectively by electronic chart review.

### ACS NSQIP

The American College of Surgeon National Surgical Quality Improvement Program (ACS NSQIP) is a national program in which over 500 North American hospitals, including Indiana University Hospital, participate. Trained Surgical Clinical Reviewers at each hospital collect data on over 135 variables for each patient undergoing major surgical procedures, including preoperative risk factors, intraoperative variables, and 30-day postoperative outcomes. To ensure inter-rater reliability, ACS NSQIP requires standard initial and ongoing reviewer training and conducts periodic audits of participating hospitals. Surgical procedures are cataloged in ACS NSQIP by International Classification of Disease (ICD-9-CM) codes. ACS NSQIP contains demographic data (for example, age, sex and race), information on medical comorbidities (for example, diabetes and hypertension), preoperative laboratory values, surgical and outcomes data (1-5). At Indiana University Hospital, the Surgical Clinical Reviewer collected data on 100% of pancreatectomies since 2006.

### Procedure-Specific Outcomes

Primary outcomes reviewed were pancreatic fistula rates, organ space infection rates, and rates of other intra-abdominal complications such as biliary leaks and gastrointestinal anastomotic leaks. Charts were reviewed for the incidence of pancreatic fistula and graded according to International Study Group for Pancreatic Fistula (ISGPF) definition (21). In addition, the incidence of biliary and gastrointestinal fistulas were determined. A diagnosis of a biliary fistula required documentation by the attending surgeon or a drain bilirubin level more than three times the upper limit of normal. Gastrointestinal fistulas also required documentation by the attending surgeon and included gastrojejunostomy and duodenojejunostomy leaks as well as colonic fistulas (from an ileocolonic or colocolonic leak following multivisceral resection or from an injury to the colon).

### Organ Space Infection (OSI)

The standard ACS NSQIP definition for organ space infection (OSI) was employed (1-5). ACS NSQIP defines OSI as an infection that involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation. The criteria for an OSI are an infection that occurs within 30 days after the principal operative procedure AND involves any of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during the operation AND at least ONE of the following:

- A. Purulent drainage from a drain that is placed through a stab wound into the organ/space. This does not apply to drains placed during the principal operative procedure, which are continually in place, with continual evidence of drainage/infection since the time of the principal operative procedure

- B. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
- C. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
- D. Diagnosis of an organ/space surgical site infection (SSI) by a surgeon or attending physician. The ACS NSQIP definition for a deep incisional SSI is an infection which

involves any tissues beneath the skin (e.g., immediate subcutaneous fat, fascial, and muscle layers). The criteria for a deep incisional SSI is an infection that occurs at the surgical site within 30 days after the principal operative procedure AND involves deep soft tissues AND at least ONE of the following:

- A. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
- B. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever ( $> 38^{\circ}\text{C}$ ), localized pain, or tenderness, unless the site is culture-negative.
- C. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
- D. Diagnosis of a deep incision SSI by a surgeon or attending physician.

Pancreatic fistulas which drained spontaneously via the incision were classified as deep SSIs, not organ space infections.

### Statistical Analysis

Data are presented as median with range or as percentages. Groups were compared by Chi squared analysis, Fisher's exact test or analysis of variance (ANOVA) as appropriate. P-values less than 0.05 were considered statistically significant. Data were analyzed using Microsoft® Excel (Irvine, CA).

## Results

### Patient Demographics

The median age of the patients was 63 years (Table 1). Of the 246 patients, 50.4% were men. The majority of patients were Caucasian (79.3%). The median body mass index (BMI) was 26 kg/m<sup>2</sup>. Overall, 26.1% of patients had diabetes, with 10.6% requiring insulin. Seventy-four patients were smokers (30.1%), ten of whom (4.1%) had chronic obstructive pulmonary disease. Median preoperative serum albumin levels were 3.6g/dL (range 1.6-4.8g/dL). Median preoperative bilirubin level was 0.8mg/dL (range 0.1-20.4mg/dL) and 78 patients (31.7%) underwent preoperative biliary drainage. Six patients (2.4%) underwent neoadjuvant therapy. Nearly two-thirds of patients (60.2%) underwent

pancreatoduodenectomy while 34.6% underwent distal pancreatectomy (both open and laparoscopic). The remaining 13 patients (5.2%) underwent central pancreatectomy or enucleation.

## Fistulas

The overall rate of pancreatic fistula was 28.0% with 15.4% having a Grade A fistula, 10.6% having a Grade B fistula, and 2.0% having a Grade C fistula (Table 2). Patients undergoing pancreatoduodenectomy had the lowest overall fistula rate at 25.0% followed by patients undergoing distal pancreatectomy at 30.6%. Patients undergoing enucleation or central pancreatectomy had the highest pancreatic fistula rate at 46.2%. Patient undergoing enucleation or central pancreatectomy had significantly more Grade C fistulas than those undergoing proximal or distal resection ( $p<0.03$ ). For patient undergoing pancreatoduodenectomy, 13.5% had a Grade A fistula, 9.5% had a Grade B fistula, and 2.0% had a Grade C fistula. For patients undergoing distal pancreatectomy, 17.6% suffered a Grade A fistula and 12.9% suffered a Grade B fistula. Bile leaks occurred in five patients (2.0%) and five (2.0%) had gastrointestinal fistulas. While all five of the biliary fistulas occurred in pancreatoduodenectomy patients, one of the gastrointestinal leaks (colonic fistula) occurred in a patient undergoing distal pancreatectomy.

## Organ Space Infections

Twenty-two patients (8.9%) had an organ space infection (Table 1). Patients who developed an OSI were similar to those who did not except that they were more likely ( $p<0.04$ ) to have chronic obstructive pulmonary disease. Seventeen of 22 (77.3%) patients who had an OSI also had a pancreatic fistula (Table 3). All of these pancreatic fistulas were either Grade B ( $n=13$ ) or C ( $n=4$ ). Pancreatic fistulas were more common in patients with an OSI (77.3 vs 23.2%,  $p<0.001$ ). None of the OSI patients had a Grade A fistula (0.0 vs. 17.0%,  $p<0.001$ ). Grade B (59.1 vs 6.3,  $p<0.03$ ) and C (18.2 vs. 0.4,  $p<0.03$ ) fistulas were more common in patients with an OSI. Thus, only 17 of 69 patients (24.6%) with a pancreatic fistula had an OSI. In summary, none of the 38 Grade A pancreatic fistulas (0%), had an OSI (Figure 1). Also, only 17 of the 31 Grade B and C pancreatic fistulas (55%) were classified as OSIs. Biliary, gastrointestinal and chyle fistulas also occurred more frequently in patients with an OSI, but these differences were not statistically significant. Only two of five bile leaks (40%) and two of five GI anastomotic leaks (40%) were OSIs. Three OSIs also were due to a chyle leak, ischemic cholangitis and bacterial peritonitis (Figure 1).

## Discussion

While the in-hospital mortality of pancreatic surgery has been significantly reduced over the past few decades, the morbidity of these operations is among the highest of any surgical procedure. This observation is true even at high volume hospitals where pancreatectomy is performed by high volume surgeons. Morbidity rates in these settings are reported to be as high as 40-50% (1-3, 19, 20, 22). Pancreatic fistula and infectious complications following pancreatectomy account for a significant portion of the morbidity and mortality after these high-risk procedures (23). Data from high-volume centers suggest that the rate of clinically significant pancreatic fistula following pancreatoduodenectomy ranges from 10-15%

(20,24). Similar institutional data for distal pancreatectomy report clinically significant fistula rates up to 20% (25-27). Accepted rates of biliary and gastrointestinal fistulas based on data from these institutions are 5% and 2%, respectively (28).

The implementation of ACS NSQIP has demonstrated that measuring surgical outcomes can improve the quality of care (1-4, 7). However, the central tenet of ACS NSQIP relies on the ability to capture and accurately catalogue complications from the medical record. To achieve an improvement in the rate of pancreatic fistula with the use of ACS NSQIP, this complication must first be accurately quantified. The purpose of this analysis was to determine the relationship between ACS NSQIP, organ space infection variable and the incidence of pancreatic and other gastrointestinal fistulas.

In the current analysis, 32% of patients had either a pancreatic, biliary, or gastrointestinal fistula. Yet, the organ space infection rate in this same cohort was 8.9% per ACS NSQIP. This discrepancy was largely a result of the inability of the OSI variable to identify clinically relevant pancreatic fistulas. Only 55% of Grade B and C fistulas and no Grade A fistulas were captured by ACS NSQIP OSI. Furthermore, when factoring in the false positives, the specificity of OSI for pancreatic fistula was only 45%.

The highest rate of pancreatic fistulas occurred in patients following enucleation or central pancreatectomy (46.2%). Patients undergoing pancreatoduodenectomy or distal pancreatectomy had fistula rates of 25% and 30.6%, respectively. When Grade A fistulas were excluded, pancreatic fistula rates were 11.5% in the pancreatoduodenectomy patients and 12.9% in the distal pancreatectomy group. A significantly higher rate of Grade C pancreatic fistulas occurred in patients undergoing enucleation or central pancreatectomy (15.4%). Although the sample size was small, this observation speaks to the risk of these procedures, as main duct injury may be difficult to appreciate during an enucleation, while central pancreatectomies have the potential to leak from two sites.

Poor overlap was observed between patients documented to have an OSI and those with pancreatic fistula. No patient with a Grade A fistula was documented as having an OSI. This finding is expected since Grade A fistulas are clinically silent. What was more concerning was that only 55% of patients with Grade B and C fistulas were noted to have an OSI. Similarly, only four of ten patients with a biliary or gastrointestinal fistula were also reported as having an OSI. This lack of capture may be the result of the strict criteria used to identify patients with OSI. For example, even if a deep space fluid collection is percutaneously drained, unless the fluid is sent for culture and is positive, that patient may not be identified as having an OSI.

This analysis indicates that ACS NSQIP OSI is a poor surrogate for pancreatic fistula. Nevertheless, several limitations must be discussed. First, this analysis is from a single institution, and the OSI rates were abstracted from the medical records by one Surgical Clinical Reviewer. A multi-institutional effort where multiple nurse abstractors contribute would be ideal to validate these findings. Similarly, the pancreatic and gastrointestinal fistulas were identified retrospectively. In addition, during the study period, all surgeons placed intraoperative drains, but drain management was not standardized. This variation in



practice may have influenced the results. If the fistula is controlled by the operative drain (Grade A), and does not require percutaneous drainage or reoperation, then it would not meet criteria for an OSI. To this end, surgeons who do not place intraoperative drains would require percutaneous drain placement or reoperation to meet criteria for an ACS NSQIP OSI.

While ACS NSQIP has enabled surgeons to improve outcomes after major surgical procedures, recent publications have questioned the adequacy of ACS NSQIP in evaluating procedure-specific complications. Glarner, et al. reported that wound complications rates after inguinal lymph node dissection for melanoma are much lower according to ACS NSQIP compared to single institution data because the ACS NSQIP definition of wound occurrences does not include seroma, hematoma, lymph leak or skin necrosis (15). Similarly, Eck and colleagues demonstrated that ACS NSQIP reports higher morbidity rates after breast conserving surgery compared to mastectomy because it includes reoperation for positive margins as a complication (16). When reoperation for positive margins is excluded, morbidity for breast conserving therapy falls far below that expected of all breast procedures.

More recently, Rickles et al. reported that only 25% of anastomotic leaks following colectomy were coded as having an organ space infection, leaving 75% of anastomotic leaks not captured by the NSQIP database ( $p < 0.001$ ) (17). With regards to the accuracy of event reporting specific to pancreatic surgery, Epelboym et al. reported a discordance of 27% when comparing the postoperative complications captured by ACS NSQIP abstraction and an independent retrospective chart review. Similar to our study, they found discordance in the rate of OSI and Grades B and C pancreatic fistula (7.6% OSI rate vs 10.4% fistula rate) (18). Taken together, these studies demonstrate the need for procedure-specific variables to improve the reliability of ACS NSQIP reporting.

In response to the need for procedure-specific variables for pancreatectomy, a multi-institutional group of researchers launched a Pancreatectomy Demonstration Project in 2012. A collaboration of 43 high- and low-volume ACS NSQIP hospitals collected pancreatectomy-specific variables for all pancreatectomies performed at their institutions. In 2013, 101 ACS NSQIP Pancreatectomy Procedure-Targeted hospitals also began collecting pancreatic fistula as a postoperative outcome. Analyses of these efforts will be required to validate the observations from this single institution study. Nevertheless, this analysis provides new information regarding the relationships between ACS NSQIP OSI and clinically relevant pancreatic fistulas and other gastrointestinal complications following pancreatic surgery.

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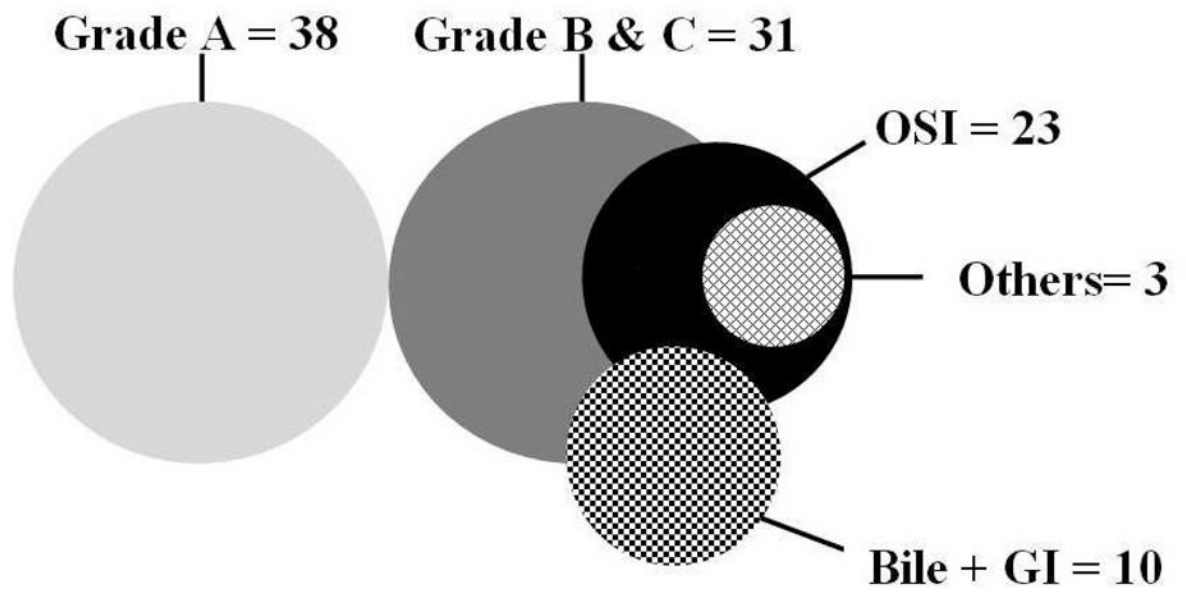
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## Abbreviations

<b>ACS</b>	American College of Surgeons
<b>BMI</b>	body mass index
<b>ICD</b>	International Classification of Disease
<b>IDDM</b>	insulin dependent diabetes mellitus
<b>ISGPF</b>	International Study Group for Pancreatic Fistula
<b>NSQIP</b>	National Surgical Quality Improvement Program
<b>OSI</b>	organ space infection
<b>PD</b>	pancreatoduodenectomy
<b>SSI</b>	surgical site infection
<b>VA</b>	Veterans Affairs



**Figure 1.** Relationship of organ space infections (OSI) to Grade A, B, and C pancreatic fistulas and other intra-abdominal complications. GI, gastrointestinal.

**Table 1**  
**Demographics of Patient Without and With Organ Space Infections (OSIs)**

<b>Demographic</b>	<b>No OSI n=224</b>	<b>OSI n= 22</b>	<b>All Patients n=246</b>
Age (y)	61 (23-91)	62 (24-81)	63 (23-93)
Male (%)	50.5	50.0	50.4
Caucasian (%)	79.5	77.3	79.3
BMI (kg/m <sup>2</sup> )	26	28	26
Diabetes (%)			
Non-IDDM	17.0	0.0*	15.5
IDDM	10.3	13.6	10.6
Smoker (%)	30.0	27.3	30.1
COPD (%)	3.1	13.6 <sup>†</sup>	4.1
Albumin (g/dl)	3.6 (1.6-4.8)	3.5 (1.7-4.6)	3.6 (1.6-4.8)
Bilirubin (mg/dl)	0.8 (0.1-20.4)	1.0 (0.2-14.2)	0.8 (0.1-20.4)
Biliary drainage (%)	31.3	36.4	31.7
Neoadjuvant therapy(%)	2.7	0.0	2.4

BMI= body mass index, IDDM = insulin dependent diabetes mellitus, COPD = chronic obstructive pulmonary disease

\* p = 0.06 vs No OSI,

<sup>†</sup> p<0.04 vs No OSI

**Table 2**  
**Fistulas by Operation**

Fistula type	Whipple n=148	Distal n=85	Enucleation/Central n=13	All Patients n=246
Pancreatic (%)	25.0	30.6	46.2	28.0
A (%)	13.5	17.6	23.1	15.4
B (%)	9.5	12.9	7.7	10.6
C (%)	2.0	0.0	15.4*	2.0
Biliary (%)	3.4	0.0	0.0	2.0
GI (%)	2.7	1.2	0.0	2.0
Chyle (%)	0.7	0.0	0.0	0.4

GI – gastrointestinal,

\* p<0.03 vs Whipple and Distal

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**Table 3**  
**Organ Space Infections (OSIs) and Fistulas**

<b>Fistula</b>	<b>No OSI n=224</b>	<b>OSI n=22</b>
Pancreatic (%)	23.2	77.3*
A (%)	17.0	0.0*
B (%)	5.8	59.1 <sup>†</sup>
C (%)	0.4	18.2 <sup>†</sup>
Biliary (%)	1.3	9.1
GI (%)	1.3	9.1
Chyle (%)	0.0	4.5

GI = gastrointestinal,

\*p<0.001 vs No OSI,

<sup>†</sup>p<0.03 vs No OSI

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