Perioperative Bundle to Reduce Surgical Site Infection after Pancreaticoduodenectomy: A Prospective Cohort Study

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BACKGROUND: Pancreaticoduodenectomy is historically associated with incisional surgical site infection (iSSI) rates between 15% and 20%. Prospective studies have been mixed with respect to the benefit of individual interventions directed at decreasing iSSI. We hypothesized that the application of a perioperative bundle during pancreaticoduodenectomy would decrease the rate of iSSIs significantly.

METHODS: An initial cohort of 150 consecutive post-pancreaticoduodenectomy patients were assessed within 2 to 4 weeks of operation to determine baseline iSSI rates. The CDC definition of iSSI was used. A 4-part perioperative bundle was then instituted for the second cohort of 150 patients. This bundle consisted of a double-ring wound protector, gown/glove and drape change before fascial closure, irrigation of the wound with bacitracin solution, and a negative-pressure wound dressing that was left in place until postoperative day 7 or day of discharge. Three-hundred patients provided 80% power to detect a 50% risk reduction in iSSIs.

RESULTS: Cohorts 1 and 2 were similar with respect to age (68 vs 69 years; p = 0.918), sex (male, 51% vs 55%; p = 0.644), BMI (26 vs 26 kg/m^2; p = 0.928), use of neoadjuvant therapy (21% vs 17%; p = 0.377), median operative time (222 vs 215 minutes; p = 0.366), and presence of a preoperative stent (53% vs 41%; p = 0.064). The iSSI rate was 22.3% in the initial cohort. This rate was higher than both our institutional database (13%) and NSQIP reporting (11%). Within the second cohort, the iSSI rate decreased significantly to 10.7% (n = 16; p = 0.012). All 4 components of the bundle were used in 91% of cohort 2 patients.

CONCLUSIONS: In this cohort study of 300 consecutive patients who underwent pancreaticoduodenectomy, the implementation of a 4-part bundle decreased iSSI rate from 22% to 11%. (J Am Coll Surg 2019;228:595−604. © 2019 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

Surgical site infections (SSI) account for approximately 20% of all hospital-acquired infections, and will occur in 2% to 5% of surgical patients each year.[1,2] Categorized as superficial incisional, deep incisional, and organ/space, based on the depth of the infection,[3] SSIs can increase hospital costs by approximately $20,000 per admission,[4] and add an average of 10 days to inpatient length of stay.[2] Given this effect on patient outcomes and healthcare costs, much work has been done to develop interventions that can decrease the rate of SSIs.[5] The most robust data have been produced in the fields of colorectal, gynecology, and urology, which involve manipulation of the gastrointestinal or genitourinary systems; or in fields such as

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orthopaedics, neurosurgery, and cardiothoracic, in which placement of prostheses require all efforts to reduce SSI.

Efforts at reducing SSI in patients undergoing pancreaticoduodenectomy (PD) might have received less attention because postoperative pancreatic fistula is a unique and challenging morbidity associated with this procedure. Previous data, however, have noted overall SSI rates in pancreatic surgery to be as high as 30%,[6,7] and specifically, incisional SSI (iSSI) rates as high as 20%.[7-9] A previously published retrospective study demonstrated that the implementation of a 12-part surgical care bundle led to a substantial decrease in the rate of wound infection in patients undergoing PD.[10] Earlier studies that have evaluated single interventions to lower iSSI rates in abdominal procedures have been mixed. For example, 2 separate prospective randomized trials have evaluated negative-pressure wound therapy. In a study by Shen and colleagues,[11] this intervention did not decrease wound infection rates in patients undergoing major abdominal operations (PD included), and a more recent trial from Johns Hopkins Hospital suggested a decrease in wound infection rates with this approach.[12]

We designed this study to evaluate the impact of a 4-part perioperative bundle aimed at reducing iSSIs after PD. Because the literature suggested that this would decrease iSSIs, we designed the trial as a prospective cohort study rather than a randomized trial. Additionally, we sought to define patient and operative variables that are associated with an increased risk of iSSIs in our cohort.

METHODS

Patient selection

Two consecutive cohorts of patients who underwent PD at Memorial Sloan Kettering between September 2016 and June 2018 were included. Approval for this study was obtained from Memorial Sloan Kettering's IRB. Patients underwent PD by 1 of 7 hepatopancreatobiliary surgeons in the department without any change in their standard practice between September 2016 and June 2017 (cohort 1), followed by implementation of a perioperative bundle between July 2017 and June 2018 (cohort 2).

All patients were prospectively identified from a weekly review of the operative schedule. Demographic, clinical, laboratory, and pathologic data were collected in a prospectively maintained database from the electronic medical record. Operative records were reviewed to ensure PD was completed in all patients, and patients were excluded if their PD was aborted or converted to another procedure.

The primary end point was development of a superficial or deep iSSI within 30 days of operation. Organ/space SSI and iSSIs that were associated with organ/space infections were not included in the final analysis. Secondary end points included the evaluation of clinical factors associated with iSSIs.

Evaluation of surgical site infections

A questionnaire was developed based on CDC and American College of Surgeons NSQIP guidelines for superficial and deep iSSIs.[13,14] This questionnaire was used by office staff and clinicians to evaluate all PD patients during outpatient visits in the 30 days after the operation, with day 1 being counted as the day of the operation per CDC and NSQIP. Incisional SSIs were also identified through review of the patient's postoperative inpatient progress notes. The same evaluation system was used to identify iSSIs both before and after implementation of the perioperative bundle.

The iSSI data obtained from our questionnaire were compared with the iSSI rates that are captured by larger national and institutional databases. To do this, data from the NSQIP database were obtained for patients who underwent PD at our institution between September 2016 and June 2017. Additionally, our departmental database was reviewed for documentation of iSSIs during this time period. Again, only iSSIs without associated organ/space infections were included in this analysis.

Development and implementation of the perioperative bundle

At the time of study design, review of the literature identified 3 interventions with varying levels of evidence supporting their role in reducing SSI rates individually in nonpancreatic procedures—use of a wound protector,[15-18] antibiotic irrigation,[19] and incisional negative-pressure dressing.[20,21] In addition, a fourth intervention, gown and glove change with new sterile instruments for fascial closure, was noted to be a common practice in SSI reduction bundles at both at our institution and in the literature.[10,22]

The perioperative bundle implemented consisted of the following 4 components: double-ring wound protector (Alexis Wound Protector/Retractor; Applied Medical); 500 mL bacitracin/saline irrigation of incision before skin closure; gown/glove change and sterile instruments for fascial and skin closure; negative-pressure incisional dressing (PICO System; Smith & Nephew) placed over the closed surgical wound until postoperative day 7 or the day of discharge, whichever occurred first. The size of the wound protector and PICO dressing varied based on incision size, and was left to the discretion of the operating surgeon. Of note, all patients received perioperative antibiotics per institutional protocol, and our standard approach to operative fluid management and blood sugar control was used as published previously.[23]

This 4-step perioperative bundle was implemented by all attending surgeons as a change of practice for all patients who underwent PD on or after July 2017. Before implementation, in-service presentations were provided to all physicians, nurse practitioners, operating room and ward nurses, and research study assistants within the hepatopancreatobiliary division. All patients who had at least half of the bundle were included as an intention to treat analysis.

Statistical analysis

Sample size was calculated to provide 80% power to detect a 50% reduction in iSSIs. It was determined that the study population should consist of 300 patients, and there would be 150 patients in each of the pre- and post-bundle cohorts.

Continuous data were expressed as median and range, and categorical variables were expressed as frequency and percentage. Fisher's exact test and Wilcoxon rank-sum test were used to compare differences in parameters between bundle and SSI groupings. All tests were 2-sided and $p < 0.05$ was considered significant. Multivariable logistic regression was used to build a model to control for covariates that were significant at $p < 0.05$ in the univariate analysis. SAS, version 9.4 (SAS Institute) was used for all analysis.

RESULTS

This study included a total of 300 patients who underwent PD; the first cohort consisted of 150 patients before implementation of the bundle and the second cohort was composed of 150 patients who received the perioperative bundle (Fig. 1). Demographic, clinical, and operative characteristics of the study cohort are listed in Table 1. Of note, approximately half of patients were jaundiced at presentation (52%, n = 156) and 47% (n = 141) received a preoperative biliary stent. Of all patients included, 19% (n = 57) received neoadjuvant therapy. Final pathologic diagnosis was: pancreatic ductal adenocarcinoma in 60% (n = 180), ampullary or duodenal adenocarcinoma in 10% (n = 31), noninvasive intraductal papillary mucinous neoplasm in 10% (n = 31) and pancreatic neuroendocrine tumors in 5% (n = 16). The remainder of pathologic diagnoses varied at a frequency <5%.

The rates of iSSIs before implementation of the bundle were captured using the questionnaire developed for the study, and subsequently compared with the rates of iSSI as noted by NSQIP and institutional data. Using our questionnaire, the incidence of iSSI was 22% in the first cohort of patients. In contrast, the iSSI rate for this cohort was calculated to be 11% using NSQIP data and 13% based on the information recorded in our departmental database.

Patients in both cohorts were similar with regard to baseline demographic and clinical variables (Table 1). Additionally, operative variables, including pylorus-preserving PD, length of operation and estimated blood loss were similar between the 2 groups. The incidence of iSSIs before use of the perioperative bundle was 22% (n = 33), and was reduced to 11% (n = 16) after bundle implementation ($p = 0.012$). Time between operation and development of iSSIs was similar in both groups (pre-bundle median 12 days; range 4 to 29 days and post-bundle median 12.5 days; range 7 to 24 days; $p = 0.429$).

Table 2 lists demographic and clinical variables based on the presence or absence of iSSI. Neoadjuvant therapy (31% vs 17%; $p = 0.029$), jaundice (74% vs 48%; $p < 0.001$), and preoperative biliary stent placement (76% vs 41%; $p < 0.001$) were more common in patients with iSSIs. In addition, patients with iSSI were more likely to have a longer operation (238 vs 214 minutes; $p = 0.028$) and greater estimated blood loss (300 vs 250 mL; $p = 0.017$). Body mass index, weight loss, smoking history, and diabetes were not significantly different between those who did and did not have an iSSI.

Univariate analysis of these variables demonstrated a significant association between development of iSSI and receiving neoadjuvant therapy, jaundice at presentation, preoperative biliary stent placement, longer operative time, and increased blood loss (Table 3). Use of the perioperative bundle was associated with a decreased rate of iSSIs on univariate analysis (odds ratio 0.42; 95% CI 0.22 to 0.81; $p = 0.009$). Using multivariate logistic regression to control for confounding variables, use of the perioperative bundle was found to be independently associated with the rate of iSSIs (odds ratio 0.50; 95% CI 0.25 to 0.99; $p = 0.046$). Conversely, the presence of a preoperative biliary stent was independently associated with an increased rate of iSSI (odds ratio 3.13; 95% CI 1.05 to 9.34; $p = 0.041$).

In the pre-bundle cohort, the complete bundle was never used, however, individual components were used based on the preference of the operating surgeon. A wound protector was used in 14% (n = 21) of cases, bacitracin irrigation in 13% (n = 19), and gown/glove and instrument change for fascial closure in 8% (n = 12). Negative pressure incisional therapy was not used. In the second cohort, all 4 components of the bundle were used 91% of the time.

DISCUSSION

Surgical site infections are seen in 2% to 5% of all surgical patients,[1] and can significantly contribute to postoperative

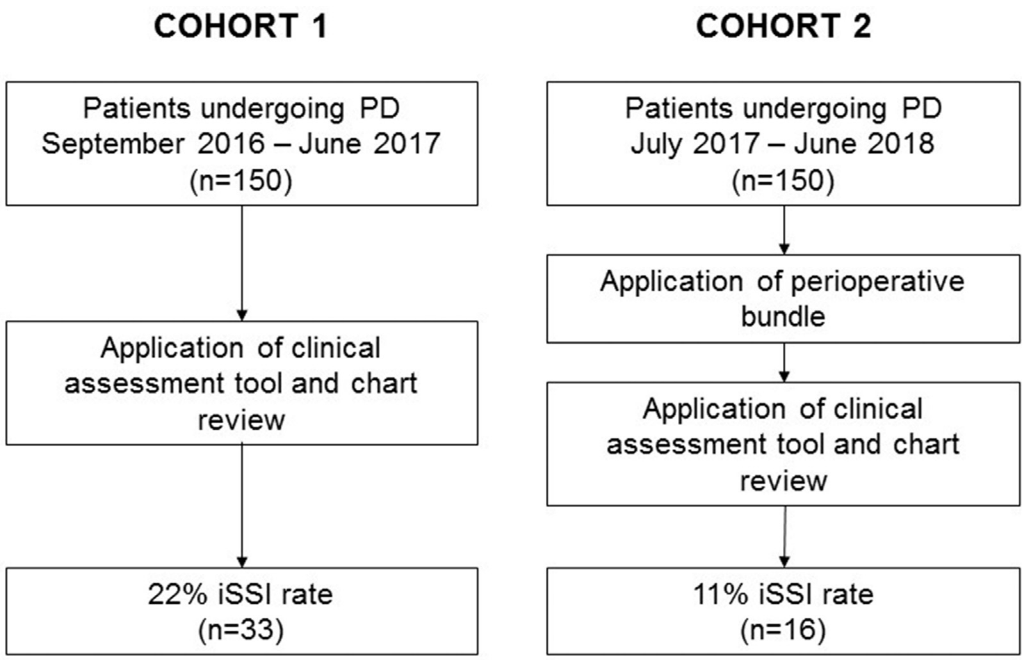

Figure 1. Study workflow.

morbidity and increased healthcare costs. Multiple studies have evaluated the use of perioperative interventions that decrease iSSI rates in clean-contaminated cases, including PD. An earlier retrospective cohort study by Lavu and colleagues[10] demonstrated that use of a 12-part perioperative bundle for patients undergoing PD significantly reduced the incidence of wound infection.

In this prospective cohort study, we demonstrate that the implementation of a 4-part bundle, consisting of a plastic wound protector, antibiotic irrigation, gown/glove and instrument change for facial closure, and negative-pressure incisional dressing, significantly reduced the incidence of iSSI after PD. The perioperative bundle was chosen from review of available literature at the time of study design, which supported the use of wound protectors, antibiotic irrigation, and negative-pressure incisional dressings in clean-contaminated cases. The rationale for these interventions include physical barrier to contamination of the abdominal wall provided by the wound protector, reduction in bacterial load with the use of antibiotic irrigation, and negative-pressure wound therapy to remove dead space and suction fluid. Changing of gown/gloves and the use of new sterile instruments were included in our bundle, as they are affordable interventions and have been components of successful

Table 1. Patient Demographic, Clinical, and Operative Characteristics in the Pre- and Post-Bundle Cohorts

Variable	All patients (n = 300)	Pre-bundle (n =150)	Post-bundle (n = 150)	p Value
Male sex, n (%)	159 (53)	77 (51)	82 (55)	0.644
Age, y, median (range)	68 (19–94)	68 (24–90)	69 (19–94)	0.918
BMI, kg/m^2, median (range)	26 (17–47)	26 (18–41)	26 (17–47)	0.928
Weight loss, n (%)	118 (39)	64 (43)	54 (36)	0.287
Smoking history, n (%)	164 (55)	89 (59)	75 (50)	0.131
Diabetes, n (%)	65 (22)	38 (25)	27 (18)	0.161
Immunosuppressed, n (%)	10 (3)	3 (2)	7 (5)	0.335
Preoperative stent, n (%)	141 (47)	79 (53)	62 (41)	0.064
Preoperative jaundice, n (%)	156 (52)	82 (55)	74 (49)	0.419
Neoadjuvant therapy, n (%)	57 (19)	32 (21)	25 (17)	0.377
Pylorus preserving, n (%)	100 (33)	52 (35)	48 (32)	0.713
Operative time, min, median (range)	216 (100–640)	222 (112–480)	215 (100–640)	0.366
Estimated blood loss, mL, median (range)	250 (10–4,600)	250 (25–4,600)	200 (10–2,000)	0.086

Table 2. Patient Demographic, Clinical, and Operative Characteristics in Patients Who Did and Not Develop Incisional Surgical Site Infection

Variable	All patients (n =300)	iSSI absent (n = 251)	iSSI present (n = 49)	p Value
Male sex, n (%)	159 (53)	127 (51)	32 (65)	0.062
Age, y, median (range)	68 (19–94)	69 (19–94)	67 (35–89)	0.691
BMI, kg/m^2, median (range)	26 (17–47)	26 (17–47)	27 (19–38)	0.086
Weight loss, n (%)	118 (39)	93 (37)	25 (51)	0.079
Smoking history, n (%)	164 (55)	134 (53)	30 (61)	0.349
Diabetes, n (%)	65 (22)	53 (21)	12 (25)	0.575
Immunosuppressed, n (%)	10 (3)	10 (4)	0 (0)	0.376
Preoperative stent, n (%)	141 (47)	104 (41)	37 (76)	<0.001*
Preoperative jaundice, n (%)	156 (52)	120 (48)	36 (74)	<0.001*
Neoadjuvant therapy, n (%)	57 (19)	42 (17)	15 (31)	0.029*
Pylorus preserving, n (%)	100 (33)	80 (32)	20 (41)	0.248
Operative time, min, median (range)	216 (100–640)	214 (100–480)	238 (128–640)	0.028*
Estimated blood loss, mL, median (range)	250 (10–4,600)	250 (10–3,500)	300 (50–4,600)	0.017*

*Significant.
iSSI, incisional surgical site infection.

perioperative bundles, although there was a lack of specific data supporting their use.

Subsequent to the start of our study, multiple studies have been published that report on the use of individual interventions for reduction of iSSIs specifically in patients undergoing pancreatic resection. Several studies demonstrated a decrease in iSSI rates with the use of incisional negative-pressure therapy.[12,24,25] Additionally, 2 separate studies have demonstrated that the use of wound protectors in PD is associated with fewer iSSIs.[26,27] One of these studies was a randomized controlled trial that included only patients with preoperative biliary stents, a high-risk population.[26] Finally, a single study demonstrated a lower iSSI rate with instrument and drape change in all pancreatic resections.[28] However, not all studies have shown a benefit. A randomized controlled trial by Shen and colleagues[11] noted no difference in iSSI after pancreatic resection, however, this study included both proximal and distal pancreatectomies, as well as other major abdominal operations. Given the totality of the literature, we believe that all of these interventions have a degree of

Table 3. Univariate and Multivariate Analysis of Demographic, Clinical, and Operative Variables Based on Presence of Surgical Site Infection

	Univariate analysis			Multivariate analysis		
Variable	OR	95% CI	p Value	OR	95% CI	p Value
Male sex	1.84	0.97–3.48	0.062	—	—	—
Age	1.00	0.97–1.03	>0.95	—	—	—
BMI	1.02	0.98–1.07	0.320	—	—	—
Weight loss	1.77	0.96–3.28	0.069	—	—	—
Smoking history	1.38	0.74–2.58	0.315	—	—	—
Diabetes	1.21	0.59–2.48	0.600	—	—	—
Immunosuppressed	0.00	0.00	>0.95	—	—	—
Preoperative stent	4.36	2.17–8.76	<0.001*	3.13	1.05–9.34	0.041*
Preoperative jaundice	3.02	1.53–5.97	0.001*	1.24	0.42–3.71	0.698
Neoadjuvant therapy	2.20	1.10–4.39	0.026*	1.76	0.81–3.82	0.152
Pylorus preserving	1.47	0.79–2.76	0.226	—	—	—
Operative time	2.33	1.13–4.80	0.022*	1.16	0.89–1.52	0.258
Estimated blood loss	1.40	1.09–1.78	0.007*	—	—	—
Use of perioperative bundle	0.42	0.22–0.81	0.009*	0.50	0.25–0.99	0.046*

*Significant.
OR, odds ratio.

protective benefit, and that application of multiple interventions (perioperative bundle) is justified.

The data from the current study also confirm that neoadjuvant therapy, preoperative biliary stenting, increased operative time, and greater blood loss are factors associated with iSSIs. The strongest of these was preoperative biliary stenting, as it was independently associated with an approximate 3-fold risk in iSSI. This is consistent with previous studies that have evaluated risk factors for postoperative wound infection after pancreatic resection.[7,8,29-31] Although some of these factors are recognized before operation, and interventions for reductions in iSSIs could target high-risk patients, we would favor routine use of a perioperative bundle, given that operative variables can be unpredictable.

In addition, our proposed interventions should be viewed as affordable, and do not increase operative time in a clinically meaningful manner. Estimating costs with readily available data, total cost of the perioperative bundle is less than $600 (retail cost of the Alexis wound protector is approximately $200, bacitracin irrigation $30, surgical gown/gloves $10, and PICO system $320). These estimates are retail, and we anticipate the true cost to be even lower, given the significant discount received through hospital contracts. The estimated reported cost of a single iSSI is generally approximated at $10,000 in recent studies.[6,32] Therefore, for this bundle to be "cost-neutral" the number needed to treat to prevent 1 wound infection would be approximately 17. The data from our study suggest that only 9 patients need to be treated with the bundle to prevent 1 SSI.

The true incidence of SSIs can be difficult to capture through conventional methods, including evaluation of ICD-9 codes and NSQIP reporting. We calculated the incidence of iSSIs to be 11% to 13% in the first cohort of patients using NSQIP and institutional databases. However, after implementing a more structured tool for prospectively evaluating iSSI in postoperative patients, the measured rate was higher at 22%. This suggests that conventional methods might underestimate true iSSI rates, and that the magnitude of the problem might be larger than has been generally reported.

There are several limitations to this study. One is the inconsistent use of the perioperative bundle in cohort 2, and the limited use of the individual components in cohort 1. During the time period of cohort 2, components of the bundle were occasionally omitted secondary to operating room and patient factors. All patients who had at least half of the bundle were included as an intention to treat analysis, as these variations in practice are to be expected in a standard surgical practice. With 91% compliance, we were able to demonstrate a 50% reduction in iSSIs during the study time. Another limitation of this study is our inability to pinpoint which aspect of the bundle provides the greatest amount of protection against SSI. Although we believe that in comparison with the cost of management of SSI, the cost of the bundle is acceptable, it would be valuable to know which components are most important, and in which patients. Finally, as this was not a randomized trial, our attention to the problem of SSIs increased with time, and our reported decrease in SSIs might be secondary to a Hawthorne effect rather than a true causal relationship with the implementation of a perioperative bundle. The randomized trials noted here, however, do demonstrate a causal relationship and we should assume that there is a true protective effect of perioperative bundle implementation.

CONCLUSIONS

In this study, the implementation of a 4-part bundle was associated with a decrease in the rate of iSSIs from 22% to 11% in patients undergoing PD. In addition, after controlling for neoadjuvant therapy, preoperative biliary stent, operative time, and estimated blood loss, perioperative bundle use was independently associated with improved outcomes for iSSI. Patients who received the perioperative bundle had a 50% decreased risk of iSSI compared with those who did not. Additional randomized studies should evaluate this bundle in other clean-contaminated cases to validate its use for reduction of iSSIs.

Author Contributions

Study conception and design: Lawrence, McIntyre, Pulvirenti, Seier, Chou, Gonen, Balachandran, Kingham, D'Angelica, Drebin, Jarnagin, Allen

Acquisition of data: Lawrence, McIntyre, Pulvirenti, Chou

Analysis and interpretation of data: Lawrence, McIntyre, Pulvirenti, Seier, Chou, Gonen, Balachandran, Kingham, D'Angelica, Drebin, Jarnagin, Allen

Drafting of manuscript: Lawrence, McIntyre, Seier, Allen

Critical revision: Lawrence, McIntyre, Pulvirenti, Seier, Chou, Gonen, Balachandran, Kingham, D'Angelica, Drebin, Jarnagin, Allen

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Discussion

DR REID B ADAMS (Charlottesville, VA): Dr Allen and colleagues have addressed a vexing and important problem for all of us in surgery, particularly with procedures that have significant potential for gastrointestinal contamination.

It is interesting to see the evolution of approaches to this issue. Because we were an early NSQIP institution, we realized in 2003 we had a surgical site infection (SSI) rate of almost 20% after