Closed incision negative pressure wound therapy following pancreaticoduodenectomy for prevention of surgical site infections in high-risk patients

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Background: Surgical site infection (SSI) is one of the most common sources of morbidity after pancreaticoduodenectomy. Surgical site infections are associated with readmissions, prolonged length of stay, delayed initiation of adjuvant chemotherapy and negative effects on quality of life. Incisional vacuum-assisted closure (iVAC) devices applied on closed incisions may reduce SSI rates. The objective of this retrospective review is to evaluate the impact of iVAC on SSI rate after pancreaticoduodenectomy.

Methods: A cohort of patients undergoing pancreaticoduodenectomy at a single institution who had at least 1 risk factor for SSI and who received an iVAC were compared with a historical cohort of high-risk patients who received conventional dressings after pancreaticoduodenectomy. The primary outcome was incidence of SSI within 30 days, abstracted from chart review. Secondary outcomes were 30-day readmission, 90-day mortality, rate of postoperative pancreatic fistula and rate of delayed gastric emptying.

Results: In total, 175 patients were included, of whom 61 received an iVAC. The incidence of SSI was 13% (8 of 61 patients) and 16% (18 of 114 patients) in the iVAC and conventional dressing groups, respectively (odds ratio 0.81, 95% confidence interval 0.33–1.98). Preoperative biliary drainage was the most frequent SSI risk factor. Binary logistic regression using SSI as the outcome demonstrated no significant association with iVAC use when adjusted for SSI risk factors. There were no differences in rates of postoperative pancreatic fistula, delayed gastric emptying or 90-day mortality.

Conclusion: This report describes the outcomes of the integration of iVAC devices into routine clinical practice at a high-volume institution. Application of this device after pancreaticoduodenectomy for patients at elevated risk of SSI was not associated with a reduction in the rate of SSI.

Contexte : L’infection de la plaie opératoire (IPO) est l’une des principales causes de morbidité après la pancréatoduodénectomie. Les IPO sont associées à des réadmissions, au prolongement des séjours hospitaliers et au report de la chimiothérapie adjuvante, en plus de nuire à la qualité de vie. Le traitement des plaies par pression négative (TPN) appliqué sur des incisions refermées pourrait réduire les taux d’IPO. Cette étude rétrospective avait pour objectif de mesurer l’impact du TPN sur le taux d’IPO après la pancréatoduodénectomie.

Méthodes : Dans un seul et même établissement, une cohorte de malades soumis à une pancréatoduodénectomie présentant au moins 1 facteur de risque d’IPO et ayant bénéficié du TPN a été comparée à une cohorte historique de cas à risque élevé chez qui on a appliqué des pansements classiques après la pancréatoduodénectomie. Le paramètre principal était l’incidence des IPO dans les 30 jours suivant l’intervention, selon la revue des dossiers. Les paramètres secondaires étaient les réadmissions dans les 30 jours, la mortalité dans les 90 jours, et les taux de fistules postopératoires et de retards de la vidange gastrique.

Résultats : En tout, 175 malades ont été inclus, dont 61 ont reçu le TPN. L’incidence des IPO a été de 13 % (8 malades sur 61) et de 16 % (18 malades sur 114) dans les groupes ayant reçu le TPN et les pansements classiques, respectivement (rapport des cotes 0,81, intervalle de confiance de 95 % 0,33–1,98). Le drainage biliaire préopératoire était le facteur de risque d’IPO le plus fréquent. La régression logistique binaire avec l’IPO comme paramètre n’a permis d’établir aucun lien significatif avec le TPN après ajustement pour tenir compte des
Surgical site infection (SSI) is one of the most common causes of morbidity after pancreaticoduodenectomy, affecting 10%–30% of patients. Preoperative risk factors, such as biliary stenting and neoadjuvant chemotherapy, may increase the likelihood of SSI to as high as 68% after pancreaticoduodenectomy. Surgical site infection is associated with wound and fascial dehiscence, readmissions to hospital, prolonged length of stay and negative effects on quality of life. An SSI can delay patients’ receipt of chemotherapy and may be associated with worse cancer-specific survival. Given these major sequelae, it is a priority to reduce rates of SSI after pancreaticoduodenectomy.

Negative pressure wound therapy devices applied to closed incisions, also known as incisional vacuum-assisted closure devices (iVAC), consist of a foam sponge with a semi-occlusive adhesive barrier and a suction pump applying subatmospheric pressure. In theory, the devices may decrease tension on the wound and promote lymphatic drainage. Devices designed to be portable and to be used once have made the technology more accessible. The iVAC may help decrease rates of SSIs. A recent meta-analysis of 32 randomized trials across all surgical specialties demonstrated a 40% reduction in risk compared with conventional dressings.

The impact of iVAC on the rate of SSIs after pancreatic surgery in trial settings has been evaluated in a systematic review and meta-analysis, which identified 4 randomized trials with 309 patients and found no significant difference in the SSI rate. There was substantial heterogeneity in study populations and the majority of the trials were industry funded. Additional analyses of experiences with iVAC after pancreaticoduodenectomy that are free from industry funding and performed at high-volume centres may help to resolve remaining equipoise. The primary objective of this study was to assess whether iVAC reduces the risk of infection in patients at high risk of SSI after pancreaticoduodenectomy, compared with conventional dressing. The hypothesis was that iVAC reduces the rate of SSIs after pancreaticoduodenectomy in patients who are at high risk.

**Methods**

**Study design**

This was a retrospective cohort study with a historical control group (pre–post design) of patients who underwent pancreaticoduodenectomy and were deemed to be at high risk of SSI. Consecutive patients who underwent pancreaticoduodenectomy in the study period were identified through a local administrative database and screened for the presence of SSI risk factors for inclusion in the cohort. The study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement guidelines for reporting.

**Setting**

All patients in the study underwent a pancreaticoduodenectomy at a single community teaching hospital between June 1, 2018, and Feb. 1, 2021. The hospital is a designated centre of excellence for hepatobiliary surgical oncology in Ontario, Canada. Hepatobiliary surgical oncology is formally regionalized into 10 centres across the province, each of which must meet a minimum set of standards for operative volumes and relevant ancillary services. All pancreaticoduodenectomies were performed by 1 of the 2 fellowship-trained hepatobiliary surgeons at the hospital. Incisional vacuum-assisted closure dressings were introduced into clinical practice at the hospital on June 1, 2019. No patients received iVAC before June 2019 and patients deemed to be at high risk for SSI had an iVAC applied after June 1, 2019. Routine institutional practices for SSI prevention were maintained throughout the study period, including administration of preoperative antibiotics, skin preparation with chlorhexidine, use of an Alexis wound protector (Applied Medical), avoidance of intraoperative hypothermia and tight perioperative glycemic control. Cefazolin and metronidazole were used as the prophylactic antibiotics of choice, unless the biliary tree had previously been instrumented, in which case piperacillin and tazobactam were used, with first dosage before skin incision and redosage at appropriate time intervals throughout the surgical procedure. Surgical drains were placed adjacent to the pancreaticojejunostomy in all patients and connected to bile bags for gravity drainage.

**Participants**

All adult patients (age > 18 yr) who underwent pancreaticoduodenectomy between June 1, 2018, and Feb. 1, 2021, were screened for study inclusion. Patients were included if they had any risk factor for SSI. Patients were deemed to be at high risk of SSI if they had 1 or...
was removed, daily while the patient remained in hospital and at postoperative clinic visits. Patients were routinely evaluated in clinic approximately 2 weeks after discharge from hospital and again at 6 weeks. An SSI was deemed to be present if it met the Centers for Disease Control and Prevention (CDC) definition of superficial or deep incisional SSI occurring within 30 days of the operative procedure. The CDC defines superficial incisional SSI as infection involving skin or subcutaneous tissue with at least 1 of the following: purulent drainage; positive fluid or tissue culture; signs or symptoms such as tenderness, redness or warmth; or diagnosis of SSI by the surgeon. A deep incisional SSI is defined as involving fascial and muscle layers with at least 1 of the following: purulent drainage, dehiscence or deliberate opening with a sign or symptom of infection, abscess on imaging or direct examination, or diagnosis by the surgeon. The secondary outcomes were readmissions within 30 days postoperatively, 90-day mortality, rate of postoperative pancreatic fistula (POPF) and rate of delayed gastric emptying. Pancreatic fistula was defined in accordance with the International Study Group of Pancreatic Surgery’s 2016 update as drain output with fluid amylase level greater than 3 times the upper normal serum amylase level and an associated clinically relevant condition related to the fistula (grade B/C).

Intervention

Laparotomy wounds were closed in the standard fashion with running absorbable no. 1 monofilament sutures for the fascia, and the skin was approximated with staples spaced 5- to 10-mm apart. Before June 1, 2019, incisions were dressed with a conventional pad film dressing and a nonadherent pad that was sterile, waterproof and absorbent. The conventional dressings were removed by the clinician on the second postoperative day and the incision was subsequently left open to air. After June 1, 2019, incisions were dressed with an iVAC, namely the Prevena Incision Management System from Acelity. The Prevena Peel and Place device was used for incisions up to 20 cm in length, and the Prevena Customizable device was used for longer incisions. The dressings connected to the Prevena 125 Therapy Unit, which delivered a negative pressure of 125 mm Hg to the surgical field. The device was left in place for the first 7 days postoperatively as per the manufacturer’s instructions. After device removal, the incision was left open to air. If clinical concern arose, the device could be removed earlier at the clinician’s discretion to facilitate inspection of the incision, such as because of signs of SSI or drainage of frank blood or enteric contents.

Outcome measures

Data were collected through review of electronic health records. Patient characteristics including age, sex, BMI and comorbidities were abstracted from the chart. Clinical data including indication for pancreaticoduodenectomy, preoperative interventions, intraoperative events and postoperative outcomes were also abstracted. The primary outcome was incidence of SSI. Wound assessment for SSI occurred after the dressing was removed, daily while the patient remained in the historical control group, while those who had surgery after June 1, 2019, were included in the iVAC group. The study was approved by the Unity Health Toronto Research Ethics Board (REB No. 21-163) and a waiver of consent was granted.

Statistical analysis

Descriptive statistics were used to characterize the cohort of patients. Incidence of SSI was reported. The Fisher exact test was used to compare the iVAC cohort with the historical control cohort. Univariable and multivariable logistic regression was used to determine associations between clinical factors and SSI. Findings were reported as odds ratios with \( p \) values; \( p \) values less than 0.05 were considered statistically significant. Statistical analysis was performed using Stata version 15. A post hoc power calculation was performed using G*Power version 3.1. With a sample size of 175 patients, a 2-tailed hypothesis, \( \alpha \) of 0.05 and an estimated effect size of a 50% reduction in the SSI rate, the estimated power was 40%.

Results

A total of 220 patients underwent a pancreaticoduodenectomy between June 1, 2018, and Feb. 1, 2021. Among these patients, 175 with at least 1 high-risk feature for SSI underwent a pancreaticoduodenectomy, of whom 61 (35%) received an iVAC. Forty-two patients did not meet the inclusion criteria for entry into the study because they did not have any SSI risk factors, and an additional 3 patients were excluded because an iVAC was placed even though they did not have any SSI risk factors. The characteristics of patients in the iVAC (intervention) and conventional dressing (control) groups are described.
in Table 1. Preoperative biliary drainage was the most common risk factor for SSI in the iVAC cohort (79% v. 53%, \( p = 0.006 \)), while smoking was more common in the conventional dressing cohort (54% v. 34%, \( p = 0.005 \)). Pancreatic ductal adenocarcinoma was the most common indication for resection in both cohorts and accounted for 50% of the total study population, followed by cholangiocarcinoma and ampullary carcinoma. Intraductal papillary mucinous neoplasm was a more common indication for surgery in the conventional dressing cohort (15% v. 2%, \( p = 0.004 \)).

The incidence of SSI was compared across the iVAC and conventional dressing groups. Eight SSIs were diagnosed in the iVAC group (13%) compared with 18 in the conventional dressing group (16%). The difference in the incidence of SSI was not statistically significant (\( p = 0.64 \)).

In the unadjusted and adjusted logistic regression models (Table 2), the primary predictor, iVAC use, was not significantly associated with a reduction in SSI within 30 days postoperatively (unadjusted odds ratio [OR] 0.805, 95% confidence interval [CI] 0.328–1.976; adjusted OR 1.056, 95% CI 0.196–5.694). Other independent variables in the adjusted model included age, sex, BMI, diabetes, smoking and preoperative biliary drainage.

For the secondary outcome of readmissions, unadjusted logistic regression modelling revealed there was no association of iVAC use with readmissions (OR 1.869, 95% CI 0.654–5.342). In the adjusted model, variables included SSI, age, sex and preoperative biliary drainage. With that model, iVAC use was not associated with a reduction in readmissions (Table 3; adjusted OR 1.508, 95% CI 0.567–4.011). There was a statistically significant association between SSIs and readmissions (OR 3.892, 95% CI 1.391–10.890, \( p = 0.01 \)).

There were 10 instances of delayed gastric emptying in the iVAC group (16%) compared with 26 in the conventional dressing group (23%). The difference in the rate of delayed gastric emptying was not statistically significant (OR 0.664, 95% CI 0.296–1.487). There were 10 clinically relevant POPF in the iVAC group (16%) and 26 in the conventional dressing group (14%). The difference in the rate of POPF was not statistically significant (OR 1.2, 95% CI 0.508–2.837). There were 2 deaths within 90 days of surgery in the iVAC group (3%) and 4 deaths in the conventional dressing group (4%). The difference in 90-day mortality was not statistically significant (OR 0.932, 95% CI 0.165–5.240).

### Discussion

The results of this observational study suggest that in our experience, the use of iVAC does not reduce the incidence of SSI in patients at high risk after pancreateicoduodenectomy. When we conducted analyses across individual risk factors and adjusted the results for potential confounders in regression modelling, there remained no apparent association between iVAC use and lower rates of SSI.

#### Table 1. Characteristics of study population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%) of patients*</th>
<th>( \text{iVAC} ) ( n = 61 )</th>
<th>( \text{Conventional dressing} ) ( n = 114 )</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr, mean</td>
<td></td>
<td>66</td>
<td>65</td>
<td>0.53</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td>24 (39)</td>
<td>44 (39)</td>
<td>0.46</td>
</tr>
<tr>
<td>High-risk characteristic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td>24 (39)</td>
<td>43 (38)</td>
<td>0.58</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td>21 (34)</td>
<td>62 (54)</td>
<td>0.005</td>
</tr>
<tr>
<td>Preoperative biliary drainage</td>
<td></td>
<td>48 (79)</td>
<td>60 (53)</td>
<td>0.006</td>
</tr>
<tr>
<td>Neoadjuvant chemotherapy</td>
<td></td>
<td>14 (23)</td>
<td>11 (9.6)</td>
<td>0.99</td>
</tr>
<tr>
<td>Immunosuppression</td>
<td></td>
<td>2 (3.2)</td>
<td>4 (3.5)</td>
<td>0.94</td>
</tr>
<tr>
<td>Preoperative radiotherapy</td>
<td></td>
<td>1 (2)</td>
<td>1 (1)</td>
<td>1.00</td>
</tr>
<tr>
<td>Indication for surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pancreatic ductal adenocarcinoma</td>
<td></td>
<td>34 (56)</td>
<td>53 (48)</td>
<td>0.27</td>
</tr>
<tr>
<td>Cholangiocarcinoma</td>
<td></td>
<td>15 (24)</td>
<td>15 (13)</td>
<td>0.06</td>
</tr>
<tr>
<td>Ampullary carcinoma</td>
<td></td>
<td>10 (16)</td>
<td>12 (10)</td>
<td>0.34</td>
</tr>
<tr>
<td>IPMN</td>
<td></td>
<td>1 (2)</td>
<td>17 (15)</td>
<td>0.004</td>
</tr>
<tr>
<td>Pancreatic neuroendocrine tumour</td>
<td></td>
<td>0</td>
<td>5 (4)</td>
<td>0.16</td>
</tr>
<tr>
<td>Duodenal adenocarcinoma</td>
<td></td>
<td>0</td>
<td>4 (3)</td>
<td>0.30</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>1 (2)</td>
<td>8 (7)</td>
<td>0.16</td>
</tr>
<tr>
<td>Estimated blood loss, mL, median</td>
<td></td>
<td>600</td>
<td>400</td>
<td>0.024</td>
</tr>
</tbody>
</table>

IPMN = intraductal papillary mucinous neoplasm; iVAC = incisional vacuum-assisted closure.
*Unless indicated otherwise.

#### Table 2. Adjusted binary logistic regression model for association of use of incisional vacuum-assisted closure and surgical site infection

<table>
<thead>
<tr>
<th>Variable</th>
<th>Adjusted OR (95% CI)</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>iVAC use</td>
<td>1.056 (0.196–5.694)</td>
<td>0.95</td>
</tr>
<tr>
<td>Age, yr</td>
<td>1.003 (0.936–1.074)</td>
<td>0.94</td>
</tr>
<tr>
<td>Sex</td>
<td>1.567 (0.273–8.979)</td>
<td>0.61</td>
</tr>
<tr>
<td>BMI</td>
<td>0.999 (0.870–1.148)</td>
<td>1.00</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1.089 (0.221–5.357)</td>
<td>0.92</td>
</tr>
<tr>
<td>Smoking</td>
<td>3.129 (0.523–18.702)</td>
<td>0.21</td>
</tr>
<tr>
<td>Preoperative biliary drainage</td>
<td>1.143 (0.229–5.707)</td>
<td>0.87</td>
</tr>
</tbody>
</table>

BMI = body mass index; CI = confidence interval; iVAC = incisional vacuum-assisted closure; OR = odds ratio.

#### Table 3. Adjusted logistic regression model for association of use of incisional vacuum-assisted closure and readmissions

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR (95% CI)</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>iVAC use</td>
<td>1.508 (0.567–4.011)</td>
<td>0.41</td>
</tr>
<tr>
<td>SSI</td>
<td>3.892 (1.391–10.890)</td>
<td>0.010</td>
</tr>
<tr>
<td>Age</td>
<td>1.042 (0.996–1.091)</td>
<td>0.08</td>
</tr>
<tr>
<td>Sex</td>
<td>1.806 (0.650–5.019)</td>
<td>0.26</td>
</tr>
<tr>
<td>Preoperative biliary drainage</td>
<td>0.480 (0.182–1.265)</td>
<td>0.14</td>
</tr>
</tbody>
</table>

CI = confidence interval; iVAC = incisional vacuum-assisted closure; OR = odds ratio; SSI = surgical site infection.
There were some baseline differences in the 2 groups with respect to the prevalence of individual SSI risk factors: in the conventional dressing group, there was a higher proportion of patients who smoked and a lower proportion of patients who had preoperative biliary drainage. This may reflect population trends, with lower rates of smoking in recent years, and local practice changes, with increased preoperative biliary stenting. Research on risk factors for SSI after pancreaticoduodenectomy by Poruk and colleagues suggested that preoperative biliary drainage and neoadjuvant chemotherapy are the strongest predictors of increased SSI risk. It is possible that these differences may have resulted in the conventional dressing group having a lower risk of SSI than the iVAC group. While the analysis suggested that there was no significant difference in SSI rates between the groups, a lower than anticipated SSI risk in the conventional dressing group may have muted a signal toward benefit from iVAC. However, the adjusted model presented in Table 2 evaluated smoking and biliary drainage and suggested there was still no significant difference in the rate of SSI between the groups. Small sample sizes for individual risk factors may have contributed to the finding that none of the variables evaluated in the regression influenced SSI.

Two other observational studies have evaluated iVAC in the context of pancreatic surgery. Burkhart and colleagues evaluated a cohort of 394 patients who underwent pancreaticoduodenectomy. Application of iVAC was at the surgeon’s discretion and appeared to be associated with a lower rate of SSI (23.1% in the standard dressing group v. 11.7% in the iVAC group, OR 0.45, \( p = 0.008 \)). Gupta and colleagues described a cohort of 61 patients who underwent pancreaticoduodenectomy and reported a decrease in the rate of SSI with iVAC (41% v. 12%, adjusted OR 0.15, \( p = 0.036 \)). The rationale for group assignment was not specified. Compared with these studies, our group allocation was probably subject to less selection bias, as all patients who met the inclusion criteria received an iVAC after the specified introduction date.

Additionally, our findings are in keeping with those of Lenet and colleagues’ meta-analysis of randomized trials. Javed and colleagues conducted a single-centre, unblinded trial with 123 patients who underwent a pancreaticoduodenectomy. Notably, patients were eligible only if they had an elevated risk of SSI, which was defined as having preoperative biliary stent placement or neoadjuvant chemotherapy or both. They reported a reduction in the rate of SSI (31.1% v. 9.7%, relative risk 0.31, \( p = 0.003 \)). Similarly, Andrianello and colleagues evaluated a high-risk population of 100 patients undergoing pancreaticoduodenectomy at 1 institution in Italy. The baseline SSI rate was low (10.9% and 12.2%) and there was no significant difference with iVAC. Kuncewitch and colleagues reported findings for a subset of 73 patients from a larger trial. This was also a single-centre and unblinded study; however, it included patients who underwent pancreaticoduodenectomy, total pancreatectomy and distal pancreatectomy as well as some laparoscopic procedures. There were no stipulations concerning the presence of risk factors for SSI as criteria for eligibility. The rates of SSI were identical at 22% in the group that received standard surgical dressings and the group that received negative pressure wound therapy. O’Neill and Martin randomly assigned patients undergoing hepatectomy and pancreatectomy (18 patients underwent the latter procedure) to receive incisional negative pressure wound therapy or sterile island dressing; they reported no significant difference in SSI rates.

Our study builds on existing literature by describing results from real-world experience with iVAC after pancreaticoduodenectomy, with minimal selection bias, following a change in practice pattern at our institution. The results of the study may help inform others who are considering integrating iVAC into their clinical practice. The devices are costly but have the potential to decrease overall health care expenses if they indeed reduce SSI rates. In the future, a multi-centred randomized trial, ideally with stratification based on SSI risk profile and blinding of outcome adjudicators, would improve the quality of the current evidence base for iVAC use after pancreaticoduodenectomy as a strategy to prevent SSI.

**Limitations**

There are several limitations related to the design of our study. It is possible that some SSIs may have gone unreported in the electronic health record, particularly if a patient presented to a different hospital, which may occur as the delivery of pancreatic surgery is formally regionalized in Ontario. Patients often travel long distances for their operation and may have some postoperative issues managed closer to home. However, these events most likely would be captured and described in outpatient follow-up notes, which were reviewed, as patients were evaluated around 4 weeks postoperatively in clinic, even if they lived far from the centre. There may be detection bias related to differences in wound assessments, as the wounds of patients with conventional dressings were assessed more frequently during the index admission because those dressings were removed earlier than the iVACs. There are limitations related to the retrospective nature of data collection, including the presence of ambiguous data in the medical record, potential for inaccuracies owing to the use of templates, and the lack of blinding of data abstractors. Data for some potential confounders, such as operative duration, could not reliably be extracted from the electronic medical record and thus were not evaluated. It is unlikely that those factors would affect the study’s results as there is no reason that those factors would differ between groups.
CONCLUSION

In this cohort study the use of iVAC after pancreaticoduodenectomy for patients at elevated risk of SSI was not associated with a reduction in the rate of SSI compared with historical controls. This report contributes to the existing body of literature by analyzing outcomes following integration of the devices into routine clinical practice at a high-volume centre.

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Competing interests: None declared.

Contributors: B. Greene and S. Jayaraman designed the study. A. Lagrotteria and M. Tsang analyzed the data. B. Greene, A. Lagrotteria and S. Jayaraman wrote the article, which M. Tsang critically revised. All authors gave approval of the final version to be published.

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