Clinical impact of developing better practices at the institutional level on surgical outcomes after distal pancreatectomy in 1515 patients: Domestic audit of the Japanese Society of Pancreatic Surgery

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Funding information
The Japanese Society for Critical Pathway

Abstract
Background and Aim: Institutional standardization in the perioperative management of distal pancreatectomy (DP) has not been evaluated in a multicenter setting. The aim of the present study was to assess the influence of institutional standardization on the development of postoperative complications after DP.

Methods: Data were collected from 1515 patients who underwent DP in 2006, 2010, and 2014 at 53 institutions in Japan. A standardized institution (SI) was defined as one that implemented ≥6 of 11 quality initiatives according to departmental policy. There were 541 patients in the SI group and 974 in the non-SI group. Clinical parameters were compared between groups. Risk factors for morbidity and mortality were assessed by logistic regression analysis with a mixed-effects model.

Results: Proportion of patients who underwent DP in SI increased from 16.5% in 2006 to 46.4% in 2014. The SI group experienced an improved process of care and a lower frequency of severe complications vs the non-SI group (grade III/IV Clavien-Dindo; 22% vs 29%, respectively, clinically relevant postoperative pancreatic fistula; 22% vs 31%, respectively, P < .05 for both). Duration of in-hospital stay in the SI group was significantly shorter than that in the non-SI group (16 [5-183] vs 20 postoperative days [5-204], respectively; P = .002). Multivariate analysis with a mixed-effects model showed that soft pancreas, late drain removal, excess blood loss and long surgical time were risk factors for post-DP complications (P < .05). Pancreatic texture, drain management and surgical factors, but not standardization of care, were associated with a lower incidence of post-DP complications.

Keywords
distal pancreatectomy, morbidity, mortality, process of care, standardization

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Ann Gastroenterol Surg. 2018;2:212–219.
1 | INTRODUCTION

Distal pancreatectomy (DP) is the standard procedure for various diseases located in the pancreas body or tail. Although high-volume centers report low mortality rates ranging from 0% to 2%, the morbidity rate is still high, ranging from 24% to 56%. The most common complication after DP is postoperative pancreatic fistula (POPF), which ranges from 0% to 61%. POPF may lead to the development of severe complications, such as intra-abdominal abscesses, delayed gastric emptying (DGE), post-pancreatectomy hemorrhage (PPH), respiratory failure, sepsis, or death. The surgical procedure of DP can be categorized as technically simple relative to pancreaticoduodenectomy (PD). Effective closure of the pancreatic remnant is important and remains challenging for reducing clinically relevant (CR) POPF. However, well-defined management strategies for improving surgical outcomes are also lacking for DP.

Impact of a well-managed process of care on clinical outcomes has been assessed in a limited, single-institution method only, whereas the effects of standardized care on morbidity and mortality after DP have never been assessed in a multicenter setting. In the present study, we evaluated trends in clinical demographics, processes of care and postoperative complications after DP in patients in 53 Japanese institutions that participated in the Japanese Society of Pancreatic Surgery in 2006, 2010 and 2014. Next, we tested the hypothesis that the deliberate use of a process of care at an institutional level can improve morbidity and mortality after DP in relatively specialized institutions for pancreatectomy.

2 | PATIENTS AND METHODS

The questionnaire audits consisted of two parts. The first determined institutional characteristics, and the second was the perioperative data of 1515 patients who underwent DP in 2006, 2010 and 2014 at a total of 53 institutions in the Japanese Society of Pancreatic Surgery. The audit for PD was done simultaneously and is already published.

The first part of the questionnaire audit consisted of clinical questions concerning hospital volume, surgeon volume, and the 11 quality initiatives defined for the current study according to departmental policy at an institutional level, as shown in Table 1. Implementation of the quality initiatives was ranked according to levels of decision-making authority from A to C (A, full dependence on departmental policy; B, surgeon’s decision in part; C, surgeon’s decision). Based on this ranking, a standardized institution was defined as one in which ≥6 of 11 quality initiatives were ranked as “A” in each year (2006, 2010 and 2014). Quality initiatives in perioperative management were determined in accordance with the presence or lack of institutional criteria for perioperative management. Hospital volume was defined as low (0-24 PD per year), intermediate (25-49 PD per year), and high (50 or more PD per year). Surgeon volume (number of PD/year per surgeon) was defined as low (0-11 PD in a year) and high (12 or more PD in a year).

The second part of the questionnaire audit comprised data collected from 1515 patients who underwent DP in 2006, 2010, and 2014, including patient demographics, surgical parameters, clinical outcomes, and trends examined over time. Clinical backgrounds and outcomes were compared between patients who underwent DP in standardized institutions (SI group) and in non-standardized institutions (non-SI group) in 2006, 2010 and 2014. Moreover, risk factors for postoperative complications and mortality were investigated. Postoperative complications were defined based on the international criteria for postoperative pancreatic fistula (POPF), delayed gastric emptying (DGE), incisional surgical site infection (SSI), and Clavien-Dindo classification. This study was approved and overseen by the Institutional Review Board of Kansai Medical University (No. H1403101) and each participating hospital.

2.1 | Statistical analysis

The database was investigated by biostatisticians at Statcom Co. Ltd (Tokyo, Japan), as already reported. The first questionnaire audit was common, as the data were previously reported. Continuous variables were expressed as median and range. Nominal data were compared with χ² tests and continuous variables with analysis of variance. Mixed-effect models (SAS PROC MIXED) were used to account for clustering hospitals for continuous variables. Models were constructed with manual variable selection methods. Volume and quality measures were entered manually, and additional covariates previously reported to be associated with the occurrence of postoperative complications were also selected for inclusion. Clinical impacts of standardization of perioperative management, surgeon or hospital volume, and general clinical indicators on postoperative complications were assessed by logistic regression analysis with a mixed-effects model. P value <.05 was considered statistically significant. All analyses were carried out with SAS version 9.4 (SAS Institute, Inc., Cary, NC, USA).

| TABLE 1 | Eleven quality initiatives defined for the current study according to departmental policy at an institutional level |
| --- | --- |
| Surgical site infection precaution |
| Rehabilitation program |
| Pulmonary embolism prophylaxis |
| Duration of prophylactic antibiotic use |
| High-risk patient program |
| Type of intraperitoneal drainage |
| Criteria for nasogastric tube |
| Criteria for drain removal |
| Criteria for intraperitoneal drainage |
| Criteria for oral intake initiation |
| Criteria for hospital discharge |
| Parameter                                                                 | 2006 n = 308 | 2010 n = 515 | 2014 n = 692 |
|---------------------------------------------------------------------------|---------------|---------------|---------------|
| **Background, n (%)**                                                     |               |               |               |
| Diabetes mellitus                                                         | 88 (29%)      | 159 (31%)     | 204 (30%)     |
| Liver cirrhosis                                                           | 8 (2.6%)      | 19 (3.7%)     | 8 (1.2%)      |
| Chronic obstructive pulmonary disease                                     | 8 (2.6%)      | 28 (5.4%)     | 26 (3.8%)     |
| Chronic renal failure requiring hemodialysis                              | 1 (0.3%)      | 6 (1.2%)      | 12 (1.7%)     |
| Steroid use                                                               | 4 (1.3%)      | 16 (3.1%)     | 16 (2.3%)     |
| Anticoagulant therapy                                                     | 20 (6.5%)     | 50 (9.7%)     | 84 (12.1%)    |
| ASA 3-5                                                                   | 19 (6.2%)     | 29 (5.6%)     | 52 (7.5%)     |
| **Pathological diagnosis**                                               |               |               |               |
| PDAC                                                                      | 171 (56%)     | 274 (53%)     | 346 (50%)     |
| Cystic disease                                                            | 68 (22%)      | 122 (24%)     | 153 (22%)     |
| Chronic pancreatitis                                                      | 17 (5.5%)     | 10 (1.9%)     | 36 (5.2%)     |
| Neuroendocrine neoplasm                                                   | 18 (5.8%)     | 48 (9.3%)     | 72 (10%)      |
| Other or unknown                                                          | 34 (11%)      | 61 (12%)      | 85 (13%)      |
| Malignancy                                                                | 195 (63%)     | 325 (63%)     | 429 (62%)     |
| NAC(R)T                                                                  | 3 (1.0%)      | 50 (9.7%)     | 95 (14%)      |
| **Surgical factor**                                                       |               |               |               |
| Portal vein resection, n (%)                                              | 5 (1.6%)      | 16 (3.1%)     | 20 (2.9%)     |
| Arterial resection, n (%)                                                 | 15 (4.9%)     | 39 (7.6%)     | 68 (9.9%)     |
| Soft pancreas, n (%)                                                      | 206 (67%)     | 373 (72%)     | 538 (78%)     |
| Operative time, median (min-max), min                                     | 270 (79-677)  | 295 (89-846)  | 300 (90-780)  |
| Extent of blood loss, median (min-max), mL                                 | 552 (0-6303)  | 400 (0-9730)  | 303 (0-10270) |
| Means of pancreatic transection, n (%)                                     |               |               |               |
| Stapler                                                                   | 65 (21%)      | 236 (46%)     | 368 (53%)     |
| Scalpel                                                                   | 154 (50%)     | 177 (34%)     | 103 (15%)     |
| Ultrasonic activated device                                               | 30 (10%)      | 51 (10%)      | 110 (16%)     |
| Other                                                                     | 59 (19%)      | 51 (10%)      | 111 (16%)     |
| Laparoscopic surgery                                                      | 16 (5.2%)     | 85 (17%)      | 184 (27%)     |
| **Type of intraperitoneal drainage, n (%)**                               |               |               |               |
| Closed-suction type                                                       | 138 (45%)     | 307 (60%)     | 447 (65%)     |
| Single-drain use                                                          | 83 (28%)      | 166 (32%)     | 330 (48%)     |
| Days to removal (postoperative) of drain; median (min-max)                | 8.0 (0-95)    | 7.0 (1-103)   | 5.0 (1-154)   |
| Blood transfusion, n (%)                                                  | 55 (18%)      | 72 (14%)      | 87 (13%)      |
| Duration of prophylactic antibiotic; median (min-max), d                  | 3.0 (1-14)    | 3.0 (1-11)    | 3.0 (12-19)   |
| Days to removal (post-operative) of NG tube; median (min-max), d          | 1.0 (0-15)    | 1.0 (0-57)    | 1.0 (0-14)    |
| Days to initiation (post-operative) of oral intake; median (min-max), d   | 5.0 (2-28)    | 4.0 (1-55)    | 4.0 (1-53)    |
| **Postoperative complications**                                           |               |               |               |
| Overall complications, n (%)                                              | 176 (57%)     | 293 (57%)     | 447 (65%)     |
| In-hospital mortality, n (%)                                              | 6 (1.9%)      | 6 (1.2%)      | 5 (0.7%)      |
| Clavien-Dindo grading, I-IIa/IIBa/IIVa/IIVb/v                              | 28:28:0.3:2.6% | 33:22:1.4:1.0% | 43:24:1:5:0.6% |
| POPF grading, A/B/C                                                       | 12%:33%       | 18%:26%       | 24%:26%       |
| DGE grading, A/B/C                                                        | 2.6%:2.6%     | 3.1%:2.2%     | 2.2%:2.4%     |
| PPH grading, A/B/C                                                        | 0.6%:1.9%     | 1.2%:1.8%     | 0.6%:2.6%     |
| Incisional SSI, n (%)                                                     | 16 (5.2%)     | 20 (3.9%)     | 27 (3.9%)     |
| Organ/Space SSI, n (%)                                                    | 73 (24%)      | 102 (20%)     | 133 (19%)     |

(Continues)
3 | RESULTS

3.1 | First questionnaire audit

As reported previously,9 in 2014, 94% of institutions participating in this audit carried out a standardized surgical procedure of PD, 74% had a pancreatic team, 85% accrued a pancreatic database, and 90% collected surgical outcome measures. Among 53 institutions, the number of standardized institutions increased from seven in 2006 to 17 in 2010 and to 28 in 2014. Among 11 quality initiatives, in 2014, half or more of the institutions were ranked as "A" in the category of SSI precaution, rehabilitation program, pulmonary embolism prophylaxis, duration of prophylactic antibiotic use, type of biliary drainage and intraperitoneal drainage, and criteria for nasogastric tube, biliary drainage, and intraperitoneal drainage. However, the categories of high-risk patient program, criteria for drain removal, oral intake initiation, and hospital discharge were not standardized in many institutions, even in 2014.

3.2 | Trends of DP in 2006, 2010, and 2014

Proportion of patients who underwent DP at a SI increased from 17% in 2006 to 37% in 2010 to 46% in 2014.9 As shown in Table 2, number of DP carried out in these centers dramatically increased from 308 in 2006 to 515 in 2010 and to 692 in 2014. In terms of comorbidities, the proportion of patients who received anticoagulant therapy gradually increased from 6.5% in 2006 and 9.7% in 2010 to 12.1% in 2014. Although the majority of pathological diagnoses including pancreatic ductal adenocarcinoma did not change, the frequency of neuroendocrine tumors increased from 5.8% in 2006 to 10.0% in 2014.

In terms of surgical parameters, frequency of neoadjuvant therapy, arterial resection and use of a laparoscopic approach increased over time (Table 2). Although operative time increased, extent of blood loss decreased over time. Cut and closure type of pancreatic remnant changed from the use of a scalpel to a stapler. Use of closed suction drainage systems increased, whereas that of open drainage systems decreased. Drain removal occurred at a median of 25 postoperative days (POD) in 2006, which decreased to a median of 5 POD in 2014. Although overall postoperative complication rates decreased over time, and the effect of streamlining and standardizing processes of care at the institutional level on patient outcomes using the data of 1515 patients from 53 relatively specialized institutions for

3.3 | Standardized group vs non-standardized group

Distal pancreatectomy was carried out for 541 patients in the SI group and for 974 patients in the non-SI group. As shown in Table 3, the SI group contained a higher proportion of high-surgeon volume centers relative to the non-SI group (38% vs 26%, respectively; P < .001). In terms of drain management, a higher rate of closed suction drainage use was found in the SI group relative to the non-SI group (71% vs 52%, respectively; P < .001). Moreover, the median time to drain removal in the SI group (POD-5) was shorter than that in the non-SI group (POD-7; P < .001). In comparisons of postoperative complications, a lower incidence of overall complications (54% vs 64%), grade III/IV Clavien-Dindo classification (22% vs 29%), CR-POPF (22% vs 31%), and SSI (incisional, 2.6% vs 5.0%; organ/space, 17% vs 23%) was found in the SI group relative to the non-SI group, respectively (P < .05 for all). Median duration of hospital stay in the SI group was also shorter than that in the non-SI group (POD-16 vs POD-20, P = .002).

3.4 | Multivariate analysis of postoperative complications

Tables 4-7 show the results of multivariate logistic regression analyses to detect risk factors for each complication. Risk factors for overall complications were being a patient in a high-hospital-volume center and late drain removal (P < .05). Soft pancreas, open surgery, longer operative time and late drain removal were significantly associated with development of CR-POPF (P < .05). Development of post-pancreatectomy hemorrhage was significantly associated with the presence of vascular resection, excess blood loss, and late drain removal (P < .05). A significant association was found between higher American Society of Anesthesiologists (ASA) scores or presence of vascular resection and in-hospital mortality (P < .05). Deliberate use of a process of care at an institutional level was not associated with improvement of morbidity and mortality after DP.

4 | DISCUSSION

The present study evaluated trends in the clinical practice of DP over time, and the effect of streamlining and standardizing processes of care at the institutional level on patient outcomes using the data of 1515 patients from 53 relatively specialized institutions for

| Parameter | 2006 n = 308 | 2010 n = 515 | 2014 n = 692 |
|-----------|-------------|-------------|-------------|
| Readmission (within 30 d after discharge), n (%) | 6 (1.9%) | 20 (3.9%) | 21 (3.0%) |
| Reoperation, n (%) | 9 (2.9%) | 12 (2.3%) | 16 (2.3%) |
| Duration of in-hospital stay; median (min-max), d | 25 (6-122) | 19 (5-183) | 17 (5-204) |

ASA, American Society of Anesthesiology; DGE, delayed gastric emptying; NAC(R)T, neoadjuvant chemo(radiation)therapy; NG, nasogastric; PDAC, pancreatic ductal adenocarcinoma; POPF, postoperative pancreatic fistula; PPH, post-pancreatectomy hemorrhage; SSI, surgical site infection.
pancreatectomy in Japan, which is one of the biggest cohorts. As expected, our data showed that the number of SI has increased, and early drain removal, use of closed suction drainage and early hospital discharge were achieved more frequently over time. Laparoscopic approaches and DP with arterial resection, such as DP with celiac axis resection, have been more frequently carried out in a wider patient population, including patients with anticoagulant medication, and a longer operative time was needed, but the extent of blood loss decreased dramatically over time. Moreover, the SI group had the standardized process of care in terms of use of closed suction drainage, a higher proportion of early drain removal, and a shorter duration of antimicrobial therapy. In addition, the SI group was associated with lower rates of overall complications, severe complications (Clavien-Dindo III-V), CR-POPF, and SSI. However, multivariate analyses with a mixed-effects model showed that the SI group did not have a lower incidence of postoperative complications. Development of CR-POPF was significantly associated with pancreas texture, type of surgery, operative time and time to drain removal. In particular, time to drain removal was one of the risk factors for overall complications.

Several authors have reported that high-volume and specialized centers achieve better surgical outcomes after pancreatectomy. However, Riall et al suggested that there is still significant variability in the outcomes of pancreatic resection. Lucas and Pawlik have proposed that quality improvement efforts should focus not only on who is operating or where the operation occurs (surgeon or hospital volume), but also on how the process occurs. Therefore, improving quality measures beyond morbidity and mortality may better reflect quality in DP? These measures include traditional clinical

### TABLE 3 Clinical backgrounds and outcomes: SI group vs non-SI group

| Parameter (n = 1290) | Estimate | SE  | P- value |
|----------------------|----------|-----|----------|
| Case volume          |          |     |          |
| Low (0-24)           | 175 (18%) | 122 (23%) | .091    |
| Intermediate (25-49) | 450 (46%) | 231 (43%) |          |
| High (50+)           | 349 (36%) | 188 (34%) |          |
| Surgeon volume       | 722 (74%) | 333 (62%) | <.001   |
| Low (0-11)           | 252 (26%) | 208 (38%) |          |
| High (12+)           | 292 (79-780) | 292 (104-846) | .287 |
| Operative time, min  |          |     |          |
| Duration of prophylactic antibiotic | 3.0 (1-29) | 3.0 (1-13) | <.001 |
| Days to N/G removal (POD) | 1.0 (0-51) | 1.0 (0-72) | .009 |
| Days to initiation of oral intake (POD) | 1.0 (0-57) | 1.0 (0-28) | .204 |
| Morbidity, n (%)     | 622 (64%) | 294 (54%) | <.001 |
| Mortality n (%)      | 3 (0.3%) | 1 (0.2%) | .638 |
| Clavien-Dindo grading |          |     |          |
| III/IV/V, n (%)      | 280 (29%) | 117 (22%) | .002 |
| Delayed gastric emptying, n (%) | 60 (5.5%) | 34 (6.2%) | .671 |
| Clinically relevant POPF, n (%) | 298 (31%) | 121 (22%) | <.001 |
| Incisional SSI, n (%) | 49 (5.0%) | 14 (2.6%) | .022 |
| Organ/Space SSI, n (%) | 219 (23%) | 89 (17%) | .006 |
| Readmission, n (%)   | 35 (3.6%) | 12 (2.2%) | .139 |
| Reoperation, n (%)   | 24 (2.5%) | 13 (2.4%) | .932 |
| Duration of in-hospital stay, d | 20 (5-204) | 16 (5-183) | .002 |

### TABLE 4 Multivariate analysis with mixed-effects model: Risk factors for overall complications

| Parameter (n = 1290) | Estimate | SE  | P- value |
|----------------------|----------|-----|----------|
| Case volume          |          |     |          |
| Low (0-24)           | -0.008   | 0.191 | .967    |
| Intermediate (25-49) | 0.748    | 0.225 | <.001   |
| High (50+)           |          |     |          |
| Surgeon volume       | -0.196   | 0.184 | .287    |
| Standardization      | -0.095   | 0.160 | .554    |
| Body mass index      | 0.306    | 0.165 | .063    |
| Liver cirrhosis      | -0.787   | 0.400 | .050    |
| ASA                  | -0.127   | 0.253 | .616    |
| Malignancy           | -0.171   | 0.146 | .241    |
| Vascular resection   | 0.269    | 0.218 | .218    |
| Soft pancreas        | 0.287    | 0.159 | .072    |
| Laparoscopic surgery | 0.312    | 0.190 | .101    |
| Operative time, min  | 0.255    | 0.143 | .074    |
| Extent of blood loss, mL | 0.281   | 0.145 | .052    |
| Date of drain removal | 1.510  | 0.141 | <.001   |

ASA, American Society of Anesthesiologists; SE, standard error; SI, standardized institution.
outcomes, as well as processes of care and structural elements of care. Among them, the "process of care" can be under the control of surgeons and the medical staff. Vollmer et al proposed that improved process management can mitigate the impact of preoperative risk and effectively deliver quality advances, despite traditional outcomes that may already meet or exceed benchmark outcomes for a given major surgical procedure. Implementation of a clinical pathway as a tool for introducing a well-established process of care has been reported to be effective in delivering quality advances, despite traditional outcomes that may already meet or exceed benchmark outcomes for a given major surgical procedure. In this study, the occurrence of overall complications, including CR-POPF, was associated with a reduction in post-PD hospital stay in single institutional studies. In contrast, the surgical procedure of DP can be categorized as technically simple relative to PD. Perioperative management of patients who undergo PD is also simple in terms of the absence of pancreatico-jejunal anastomosis. In this study, the occurrence of perioperative care process at the institutional level did not affect the occurrence of post-DP complications including CR-POPF. The international multi-institutional distal pancreatectomy study group analyzed data from 2026 patients who underwent DP. Although they failed to predict CR-POPF occurrence reliably, seven risk factors (age, body mass index [BMI], serum albumin level, pathology, epidural use, splenectomy, and vascular resection) were identified. They suggested the existence of two possibilities: (i) fistula after distal pancreatectomy is a stochastic process that cannot be predicted; or (ii) despite the extensive data accrual by each collaborating institution, important risk factors were not accounted for. Unlike PD, risk factors for post-DP complications seem to have diversity. In the present study, a standardized institution was defined as one in which ≥6 of 11 quality initiatives (as shown in Table 1) were managed according to full dependence on departmental policy. Among them, the criteria of drain removal and hospital discharge and a high-risk patient program had not been standardized in half or more institutions. Therefore, standardization of the surgical technique and perioperative management is greatly required, and can be a critical indicator for assessing the clinical outcomes of PD. In contrast, the surgical procedure of DP can be categorized as technically simple relative to PD. Perioperative management of patients who undergo PD is also simple in terms of the absence of pancreatico-jejunal anastomosis. In this study, standardization of the perioperative care process at the institutional level did not affect the occurrence of post-DP complications.

### TABLE 5 Multivariate analysis with mixed-effects model: Risk factors for clinically relevant postoperative pancreatic fistula

| Parameter (n = 1286)                  | Estimate | SE   | p-value |
|--------------------------------------|----------|------|---------|
| Case volume 25-49 intermediate vs 0-24 low | -0.307   | 0.216 | .154    |
| 50 or more high vs 0-24 low           | 0.142    | 0.256 | .579    |
| Surgeon volume 12 or more high vs 0-11 low | -0.082   | 0.236 | .730    |
| Standardization SI vs non-SI          | -0.171   | 0.200 | .391    |
| Body mass index ≥25 vs <25           | 0.303    | 0.171 | .077    |
| Liver cirrhosis Present vs none      | -0.354   | 0.441 | .422    |
| ASA 3-5 vs 1-2                        | 0.251    | 0.276 | .362    |
| Malignancy Yes vs no                  | -0.154   | 0.162 | .341    |
| Vascular resection Present vs none    | 0.373    | 0.228 | .102    |
| Soft pancreas Yes vs no               | 0.403    | 0.185 | .030    |
| Laparoscopic surgery Yes vs no        | -0.508   | 0.220 | .021    |
| Operative time, min ≥500 vs <500     | 0.574    | 0.158 | <.001   |
| Extent of blood loss, mL ≥1000 vs <1000 | 0.066    | 0.158 | .678    |
| Date of drain removal ≥6 vs <6        | 1.793    | 0.183 | <.001   |

ASA, American Society of Anesthesiologists; SE, standard error; SI, standardized institution.

### TABLE 6 Multivariate analysis with mixed-effects model: Risk factors for postoperative pancreatic hemorrhage

| Parameter (n = 1289)                  | Estimate | SE   | p-value |
|--------------------------------------|----------|------|---------|
| Case volume 25-49 intermediate vs 0-24 low | 0.404    | 0.544 | .458    |
| 50 or more high vs 0-24 low           | 0.651    | 0.591 | .271    |
| Surgeon volume 12 or more high vs 0-11 low | 0.157    | 0.469 | .738    |
| Standardization SI vs non-SI          | -0.427   | 0.433 | .324    |
| Body mass index ≥25 vs <25           | 0.143    | 0.398 | .719    |
| Liver cirrhosis Present vs none      | -0.188   | 1.084 | .862    |
| ASA 3-5 vs 1-2                        | 0.167    | 0.647 | .797    |
| Malignancy Yes vs no                  | 0.475    | 0.432 | .272    |
| Vascular resection Present vs none    | 1.083    | 0.431 | .012    |
| Soft pancreas Yes vs no               | 0.252    | 0.383 | .511    |
| Laparoscopic surgery Yes vs no        | 0.298    | 0.558 | .594    |
| Operative time, min ≥500 vs <500     | -0.333   | 0.366 | .362    |
| Extent of blood loss, mL ≥1000 vs <1000 | 1.063    | 0.398 | .008    |
| Date of drain removal ≥6 vs <6        | 1.008    | 0.427 | .019    |

ASA, American Society of Anesthesiologists; SE, standard error; SI, standardized institution.
We would like to express our sincere appreciation to the surgeons and institutions that participated in this study, and to Drs S Yamaki, S Hirooka, and H Yanagimoto for their significant contribution to this study. Names of the institutions are listed in Table S1.

DISCLOSURE
Funding: This study was financially supported by the Japanese Society for Clinical Pathway.

Conflicts of Interest: Dr Satoi was supported by a grant from the Japanese Society of Clinical Pathway. Professor Unno is supported by grants from the Taiho, Takeda, Chugai, Novartis, Astellas, Yakult, and Toyama Chemical Pharmaceutical Companies. Other authors declare no conflicts of interest for this article.

Author Contributions: SS and TY contributed to all aspects of this study and article. FM, IM, HY, RA, MT, YM, HA, SH, MS, HR, MO, MU, YT, and HY contributed to study conception, collection of data and critical revision of the article. All authors approved the final draft of the article.

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### TABLE 7 Multivariate analysis with mixed-effects model: Risk factors for in-hospital mortality

| Parameter (n = 1293) | Estimate | SE  | p-value |
|----------------------|----------|-----|---------|
| Case volume          |          |     |         |
| 25-49 intermediate vs 0-24 low | −0.760 | 1.090 | .486    |
| 50 or more high vs 0-24 low | −0.568 | 1.243 | .648    |
| Surgeon volume       |          |     |         |
| 12 or more high vs 0-11 low | 0.701 | 1.107 | .527    |
| Standardization      |          |     |         |
| SI vs non-SI          | 1.415    | 0.911 | .121    |
| Body mass index       |          |     |         |
| ≥25 vs <25            | 1.043    | 0.756 | .168    |
| Liver cirrhosis       |          |     |         |
| Present vs none       | 1.013    | 1.376 | .462    |
| ASA                   |          |     |         |
| 3–5 vs 1–2            | 3.135    | 0.857 | <.001   |
| Malignancy            |          |     |         |
| Yes vs no             | 0.745    | 1.171 | .525    |
| Vascular resection    |          |     |         |
| Present vs none       | 2.552    | 0.863 | .003    |
| Soft pancreas         |          |     |         |
| Yes vs no             | −0.104   | 0.816 | .899    |
| Operative time, min   |          |     |         |
| ≥500 vs <500          | 0.485    | 0.835 | .561    |
| Days of drain removal |          |     |         |
| ≥6 vs <6              | 1.724    | 0.977 | .078    |

ASA, American Society of Anesthesiologists; SE, standard error; SI, standardized institution.

Institution and to use the definition of SI consistently, other important indicators or methods for assessing “standardization” might exist. Second, we assessed the fact that a conscious attempt was made to improve the process of care in each institution, but we could not evaluate that the actual processes were applied more frequently or more regularly. Thus, perioperative management strategies varied across institutions. However, this provides a realistic picture, reflecting inherent variability in the clinical practice of DP. Third, institutions participating in this study are specialized centers for pancreatectomy (or include at least one surgeon certified by the Japanese Society of Hepatobiliary Pancreatic Surgery) and, therefore, the findings may not be generalizable to all hospitals.

5 | CONCLUSIONS
Standardized adoption of a well-organized process of care for DP at the institutional level did not reduce post-DP complications. Traditional factors such as pancreatic texture, drain management and surgical factors were associated with a lower incidence of post-DP complications. Sustainable efforts will be required to reduce post-DP complications.

ACKNOWLEDGEMENTS
We would like to express our sincere appreciation to the surgeons and institutions that participated in this study, and to Drs S Yamaki, S Hirooka, and H Yanagimoto for their significant contribution to this study. Names of the institutions are listed in Table S1.

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How to cite this article: Satoi S, Yamamoto T, Motoi F, et al. Clinical impact of developing better practices at the institutional level on surgical outcomes after distal pancreatectomy in 1515 patients: Domestic audit of the Japanese Society of Pancreatic Surgery. Ann Gastroenterol Surg. 2018;2:212–219. https://doi.org/10.1002/ags3.12066