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ORIGINAL ARTICLE

A Critical Appraisal of the July Effect: Evaluating Complications Following Pancreaticoduodenectomy

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Abstract

Background Reports of higher rates of medical errors in the month of July have generated concern regarding major surgery at academic institutions early in the yearly promotion cycle. This study was designed to evaluate perioperative outcomes in patients undergoing pancreaticoduodenectomy (PD) at different times of the year.

Materials and Methods Outcomes were retrospectively evaluated for patients treated in July versus the rest of the year and in the first quarter (July–September) versus the remaining quarters. The primary outcome was operative morbidity as measured by Clavien-Dindo grade, a classification system of surgical complications. Secondary outcomes included mortality, operative blood loss, pancreatic fistula formation, delayed gastric emptying, intraabdominal abscess, anastomotic leak, reoperation, and other variables of interest.

Results From January 2003 to September 2015, 472 patients underwent PD by a single academic surgeon. Overall, 77.1% of PDs were performed for malignancy. The number of patients did not significantly vary by month or by quarter. The incidence of major morbidity (Clavien-Dindo grade ≥ III) in patients who had a PD was 12.2% in July and 17.5% in all other months ($P = 0.79$). The rate of pancreatic fistula, intraabdominal abscess, reoperation, readmission, and mortality did not differ significantly by month or by quarter ($P > 0.05$ for all).

Conclusions The current study does not find any correlation between time of year and operative morbidity or mortality, suggesting that PD can be safely performed irrespective of timing.

Keywords July effect · Complications · Pancreaticoduodenectomy · Whipple procedure · Clavien-Dindo

Introduction

Public awareness of the potential decline in the quality of care at teaching hospitals early in the academic year has intensified over the past two decades. The primary cause of concern is the large number of inexperienced physicians entering the workforce simultaneously, estimated at over 18,000 graduates a year from American medical schools.[1] In addition, resident responsibilities are increased at all levels after the yearly promotion cycle. These annual changes are thought to disrupt established care teams and may have a deleterious effect on patient care. The perceived increase in medical errors during this period of transition is popularly termed the *July effect*.[2] Current reports vary on whether there are care discrepancies due to academic seasonality. In those studies that conclude that the July effect does exist, the magnitude of its impact and the degree of hazard it creates for patients is disputed.[3–5]

Examining the overall quality of perioperative services is complex as surgery is multi-disciplinary by nature. While superior outcomes have been demonstrated within centers with greater hospital volume and surgeon experience, quality improvement efforts focused on graduate medical education—such as duty hour restrictions—have shown limited benefit to surgical patients.[6–9] Graduate medical education in surgery is unique in that it tends to be more hierarchical, includes more technical training, and lasts longer than non-surgical specialties. Due to these factors, research on the presence of a July effect in surgical patients is difficult to interpret. In contrast to studies evaluating all hospitalized patients,[3,10] poorer outcomes specifically in surgical patients have not been routinely

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described.[11–13] Surgical database studies have been contradictory, with some reports suggesting an increase in operative morbidity and mortality, while others have found no change.[14,15] Multiple studies of subspecialties such as orthopedic, cardiothoracic, and transplant surgery have not demonstrated a significant difference in patient outcomes when stratified by time of year.[16–18]

The objective of the current study is to evaluate the quality of care in patients undergoing pancreaticoduodenectomy (PD) at different intervals of the academic year. PD is regularly performed at major teaching institutions, and operative mortality in such centers is generally superior to that of non-teaching urban or rural hospitals.[19] While postoperative mortality is uncommon, complications remain regular occurrences.[20] Procedural intervention, prolonged lengths of stay, and intensive care unit (ICU) admissions are not unusual for patients following PD. Accordingly, trainees at all postgraduate levels and from different specialties are involved in caring for such patients. Furthermore, PD is often regarded as an index operation for residents in training and a particularly noteworthy teaching case by faculty.[21,22] Due to these considerations, we hypothesized that a detailed examination of patients undergoing PD based on the time of year would allow for an accurate assessment of the impact of the July effect on surgical outcomes at a tertiary academic center. These data could provide reassurance regarding major abdominal surgery early in the teaching year or highlight areas for potential improvement in the future.

Materials and Methods

Patient Selection and Cohort Creation

All patients undergoing PD for any indication at Yale New Haven Hospital between January 2003 and December 2015 were considered for study. Overall, 472 consecutive patients were evaluated via retrospective review of a prospectively maintained database of comprehensive surgical outcomes. No patients were excluded. Surgery was performed by a single academic surgical oncologist accompanied by a general surgery resident. The attending surgeon was present for the entire procedure other than for closing of the abdominal incision. Autonomy was provided commensurate with the resident's surgical abilities.

The academic year in the Department of Surgery at the Yale School of Medicine begins in the last week of June, with the initial week of July being the first complete week of the academic calendar. Two separate analyses were performed, each with all 472 patients. The first divided patients into four cohorts by their date of surgery defined by 3-month quarters (first quarter, July 1–September 30; second, October 1–December 31; third, January 1–March 31; fourth, April 1–June 30). The second analysis divided patients into two cohorts by date of surgery—the first included those undergoing surgery in July and the second was composed of all other months combined. Data collection for this study was approved by the Yale University Human Investigation Committee.

Structure of Care Team

All patients were managed on the surgical oncology service at the Yale New Haven Hospital. This team, under the direction of faculty, is led by a chief resident who is universally in their fifth postgraduate year (PGY) supported by a PGY-2 or PGY-3 resident, an intern, and a non-physician practitioner. While in the ICU, patients are managed by an intensivist who leads a team of PGY-2 or PGY-3 resident physicians in surgery, anesthesia, or emergency medicine and may be assisted by a surgical fellow training in critical care medicine. There is no fellowship-level training in complex general surgical oncology or hepatobiliary surgery at the Yale New Haven Hospital. The average number of pancreatoduodenectomies performed by Yale general surgery trainees is 7.5 per resident. The vast majority of these cases are performed in the chief (PGY-5) year. The Yale general surgery residency is an ACGME-accredited training program.

Operative Technique and Postoperative Care

All PDs were performed in an open fashion. Pylorus-preserving PD was carried out when not precluded by oncologic or disease-specific considerations. In all other cases, a classic (Kausch-Whipple) PD was performed. The gastro-/duodenojejunostomy was performed in an end-to-side (Billroth II) fashion in the retrocolic position early in the study. Later in the study, we transitioned to antecolic positioning as supportive data accumulated.[23] The pancreaticojejunostomy was performed in a two-layer, end-to-side fashion utilizing duct-to-mucosa reconstruction, while the hepaticojejunostomy was performed in a single-layer, end-to-side fashion. Stents were not used in the pancreatic or biliary anastomoses. During the course of the study, we transitioned from routine utilization of a nasogastric tube (NGT) postoperatively for gastric decompression to selective usage.[24] Similarly, we transitioned from routine closed suction drainage of the peritoneum to selective usage. Intraoperative drain placement was rarely carried out and performed predominately for concern for the integrity of the biliary anastomosis. We did not identify any detriment to selective drain placement in a comprehensive review of this cohort.[25]

All patients were admitted to the surgical ICU postoperatively and transferred to a surgical ward on postoperative day (POD) one or two in routine cases. A liquid diet was instituted once the NGT was removed or on POD 2–3 and then advanced to a regular diet as tolerated. Postoperative replacement of NGTs, percutaneous drain placement, or repeat laparotomy were performed as dictated by individual clinical circumstance. Metoclopramide and octreotide were not routinely used but readily administered when clinically indicated. Final dietary tolerance was classified by POD when lasting tolerance of solid intake occurred (i.e., no further need to return to NPO status). In patients with an operative drain, serum and drain amylase concentrations were assessed prior to drain discontinuation.

Defining Adverse Events

Postoperative morbidity was defined by standardized criteria when available. The International Study Group for Pancreatic Surgery definitions of fistula formation and delayed gastric emptying were employed when relevant.[26,27] Fluid drained from the abdomen with positive microbial cultures with minimal amylase content was considered an intraabdominal abscess. Gastro-/duodenojejunostomy or hepaticojejunostomy leak was defined as radiologic or operative identification of anastomotic disruption. Overall morbidity was quantified utilizing the revised Clavien-Dindo classification, with grades ≥ III considered a major complication.[28] Other complications were defined clinically, e.g., need for re-intubation and transfusion. Need for readmission or re-operation up to 60 days after the initial date of surgery was incorporated into grading complication severity. Preoperative patient health was approximated using the American Society of Anesthesiologists (ASA) physical status classification system.

Statistical Analysis

Data were independently evaluated by quarter and by month. For categorical variables, Pearson's χ^2 test was employed, except in cases of any variable count < 5, in which case Fisher's exact test was utilized. For continuous variables, a two-tailed *t* test was employed for normally distributed variables and the Wilcoxon rank-sum test was utilized for non-normally distributed variables. For all analyses, a P value < 0.05 was considered significant. A power calculation was performed to determine the sample size required to detect a 20% difference between the two groups. Using a standard type I error rate of 5% and type II error rate of 20%, a sample size of 452 would be adequate to detect a difference. Statistical analyses were performed using SPSS v. 21.0 (IBM Corp., Armonk, NY).

Results

Patient and Operative Characteristics

From 2003 to 2015, 472 consecutive patients who underwent PD were evaluated. The number treated was not significantly different when stratified by month ($P = 0.11$) or by quarter ($P = 0.59$). Mean patient age for the entire cohort was 64.3 ± 11.5 years, and the gender distribution was relatively balanced, with 220 females (46.6%) and 252 males (53.4%). Patients who were treated in the month of July were significantly older (67.5 ± 10.9 years) compared with the remaining months (64.0 ± 11.5 years; $P = 0.04$). The majority of patients (68.2%; 322/472) were ASA class III, broadly defined as severe systematic disease. Among all patients, 52.1% (246/472) had a history of hypertension, 24.8% (117/472) had diabetes mellitus, 15.5% (73/472) had at least one episode of pancreatitis preoperatively, and 15.5% (73/472) had a history of coronary artery disease. There was no significant difference in the rate of any comorbidity by month or by quarter. Surgery was performed for malignancy in 77.1% (364/472) of cases. At operation, the majority of patients underwent pylorus-preserving PD (56.4%; 266/472), compared with classic PD (43.6%; 206/472; Tables 1 and 2).

Complication Rate and Perioperative Outcomes

A 30-day Clavien-Dindo classification, a comprehensive measure of complications, was the primary outcome measure for the study. Patients with a Clavien-Dindo grade ≥ III, required additional procedures or experienced a life-threatening event. Overall, 16.9% (80/472) of patients had a grade III–V complication. Major complications occurred at a rate of 12.2% (6/49) in July and 17.5% (74/423) in all other months ($P = 0.79$; Table 1). Similarly, there was no difference in the rate of any secondary outcome measure by month or by quarter. The overall mortality rate was 1.7% (8/472) with no deaths occurring in patients treated in the month of July. To determine if patients had improved outcomes during the latter part of the study, a secondary analysis was performed. There was not found to be any significant directional association between major complications and the year ($R^2 = 0.038$; $P = 0.9$).

Multiple intraoperative and postoperative variables were comprehensively examined to assess surgical morbidity in July and in the 1st quarter (July–September) compared with the remainder of the year. Operative blood loss was similar throughout the academic year, with a mean of 543 mL in first quarter compared with 491 mL for October–June ($P = 0.5$; Table 2). The overall incidence of biliary/enteric anastomotic leak and abscess was 2.1% (10/472) and 2.8% (13/472), respectively, with neither complication occurring in patients who had an operation in July throughout the entire study period. Mean length of stay for the July cohort was 8.1 ± 8.1 days while the average for other months was 8.0 ± 7.2 days ($P = 0.87$). The reoperation rate was 2.0% in July (1/49), slightly lower than all other months combined (6.2%; 26/423; $P = 0.21$; Table 1).

Table 1 Patient characteristics and outcome measures in July and in all other months

	No. (%)			
Patient characteristics	All patients	July	Other months	*P* value
Overall number	472	49	423	
Age, mean ± SD (year)	64.3 ± 11.5	67.5 ± 10.9	64.0 ± 11.5	0.038
Sex, no. (%)				
Male	252 (53.4)	29 (59.2)	223 (52.7)	0.390
Female	220 (46.6)	20 (40.8)	200 (47.3)	
ASA classification				
II	132 (28.0)	15 (30.6)	117 (27.7)	0.743
III	322 (68.2)	33 (67.3)	289 (68.3)	
IV	18 (3.8)	1 (2.0)	17 (4.0)	
Patient comorbidities				
Hypertension	246 (52.1)	24 (49.0)	222 (52.5)	0.642
Diabetes (type II)	117 (24.8)	15 (30.6)	102 (24.1)	0.319
Pancreatitis	73 (15.5)	7 (14.3)	66 (15.6)	0.809
Coronary artery disease	73 (15.5)	8 (16.3)	65 (15.4)	0.860
Renal dysfunction[a]	37 (7.8)	4 (8.2)	33 (7.8)	0.551
Malignant disease	364 (77.1)	38 (77.6)	326 (77.1)	0.939
Operation				
Pylorus-preserving pancreaticoduodenectomy	266 (56.4)	25 (51.0)	241 (57.0)	0.462
Pancreaticoduodenectomy	206 (43.6)	24 (49.0)	182 (43.0)	
Outcome measures	All patients	July	Other months	*P* value
Operative blood loss, mean ± SD (ml)	505 ± 498	525 ± 440	502 ± 504	0.455
Return to ICU	47 (10.0)	5 (10.2)	42 (9.9)	0.555
Operative complication				
Delayed gastric emptying	74 (15.7)	6 (12.2)	68 (16.1)	0.485
Pancreatic fistula	51 (10.8)	3 (6.1)	48 (11.3)	0.265
Abscess	13 (2.8)	0 (0)	13 (3.1)	0.236
Anastomotic leak	10 (2.1)	0 (0)	10 (2.4)	0.059
Mortality	8 (1.7)	0 (0)	8 (1.9)	0.413
Clavien-Dindo grade ≥ III, 30 days	80 (16.9)	6 (12.2)	74 (17.5)	0.789
Length of stay, mean ± SD (days)	8.0 ± 7.3	8.1 ± 8.1	8.0 ± 7.2	0.873
Reoperation	27 (5.7)	1 (2.0)	26 (6.2)	0.205
Readmission	101 (21.4)	12 (24.5)	90 (21.3)	0.605

SD, standard deviation; *ASA*, American Society of Anesthesiologists; *ICU*, intensive care unit

[a] Renal dysfunction defined as preoperative creatinine > 1.2 mg/dl

Discussion

Medical errors are a common, yet avoidable aspect of health care. Reports estimate the number of annual preventable deaths at greater than 40,000; however, an increased emphasis on quality of care is combating this trend.[29,30] Select national studies focusing on cause-of-death have cited an increased mortality rate in July.[10,14] As this trend was enriched in regions with teaching hospitals, these data could be interpreted to suggest that the observed 10% increase in fatal medication errors in July was caused by the arrival of new physicians.[10] While the contribution of medication errors to the July effect is commonly cited, the impact of academic seasonality on surgical care is debated. Investigations of the National Surgical Quality Improvement Program (NSQIP) database revealed a 41% increase in surgical mortality from early July to late August.[14] The authors subsequently performed a larger follow-up analysis where only specific operations were studied—eliminating seasonal changes in the type of procedure performed—and did not find a difference in perioperative mortality.[11] Similarly, early studies reported a higher rate of surgical site infections in the month of July,[31] but subsequent studies found similar infection

Table 2 Patient characteristics and outcome measures stratified by quarter

	No. (%)					
Patient characteristics	All patients	July–September	October–December	January–March	April–August	*P* value
Overall number	472	126	115	116	115	
Age, mean ± SD (year)	64.3 ± 11.5	65.7 ± 11.8	65.2 ± 9.9	63.0 ± 12.0	63.3 ± 11.9	0.178
Sex, no. (%)						
Male	252 (53.4)	71 (56.4)	62 (53.9)	58 (50.0)	61 (53.0)	0.802
Female	220 (46.6)	55 (43.7)	53 (46.1)	58 (50.0)	54 (47.0)	
ASA classification						
II	132 (28.0)	41 (32.5)	27 (23.5)	30 (25.9)	34 (29.6)	0.704
III	322 (70.3)	81 (64.3)	82 (71.3)	81 (69.8)	78 (67.8)	
IV	18 (3.8)	4 (3.2)	6 (5.2)	5 (4.3)	3 (2.6)	
Patient comorbidities						
Hypertension	246 (52.1)	63 (50.0)	57 (49.6)	63 (54.3)	63 (54.8)	0.783
Diabetes (type II)	117 (24.8)	32 (25.4)	27 (23.5)	29 (25.0)	29 (25.2)	0.986
Pancreatitis	73 (15.5)	20 (15.9)	18 (15.7)	22 (19.0)	13 (11.3)	0.452
Coronary artery disease	73 (15.5)	22 (17.5)	19 (16.5)	14 (12.1)	18 (15.7)	0.680
Renal dysfunction[a]	37 (7.8)	11 (8.7)	13 (11.3)	6 (5.2)	7 (6.1)	0.298
Malignant disease	364 (77.1)	96 (76.2)	91 (79.1)	85 (73.3)	92 (80.0)	0.607
Operation						
Pylorus-preserving pancreaticoduodenectomy	266 (56.4)	71 (56.3)	62 (53.9)	70 (60.3)	63 (54.8)	0.766
Pancreaticoduodenectomy	206 (43.6)	55 (43.7)	53 (46.1)	46 (39.7)	52 (45.2)	
Outcome measures	All patients	July–September	October–December	January–March	April–August	*P* value
Operative blood loss, mean ± SD (ml)	505 ± 498	543 ± 627	508 ± 492	516 ± 467	449.1 ± 354	0.495
Return to ICU	47 (10.0)	12 (9.5)	14 (12.2)	9 (7.8)	12 (10.4)	0.849
Operative complication						
Delayed gastric emptying	74 (15.7)	19 (15.1)	16 (13.9)	19 (16.4)	20 (17.4)	0.829
Pancreatic fistula	51 (10.8)	10 (7.9)	10 (8.7)	15 (12.9)	16 (13.9)	0.226
Abscess	13 (2.8)	1 (0.8)	2 (1.7)	6 (5.2)	4 (3.5)	0.098
Anastomotic leak	10 (2.1)	0 (0)	5 (4.3)	3 (2.6)	2 (1.7)	0.059
Mortality	8 (1.7)	2 (1.6)	2 (1.1)	2 (1.7)	2 (1.7)	0.913
Clavien-Dindo grade ≥ III, 30 days	80 (16.9)	14 (11.1)	20 (17.4)	20 (17.2)	26 (22.6)	0.242
Length of stay, mean ± SD (days)	8.0 ± 7.3	7.6 ± 6.5	9.2 ± 10.6	7.3 ± 4.6	8.0 ± 6.2	0.374
Reoperation	27 (5.7)	4 (3.2)	8 (7.0)	8 (6.9)	7 (6.1)	0.151
Readmission	101 (21.4)	25 (19.8)	23 (20.0)	24 (20.7)	29 (25.2)	0.756

SD, standard deviation; *ASA*, American Society of Anesthesiologists; *ICU*, intensive care unit

[a] Renal dysfunction defined as preoperative creatinine > 1.2 mg/dl

rates in non-teaching community hospitals, citing potential environmental factors instead of resident experience as the causative factor.[32]

In the current study, we reviewed patient characteristics, perioperative care, and outcome measures of 472 individuals who had undergone PD over a 13-year period. Recruiting patients from a single institution provided a more comprehensive assessment of surgery-specific outcomes of interest including delayed gastric emptying, pancreatic fistula, and readmission than is typically possible in database-driven studies. Further, PD is an ideal operation to investigate seasonal changes in quality as care is multidisciplinary by nature and requires the involvement of the departments of surgery, anesthesia, critical care, and radiology spanning multiple postgraduate levels. As postoperative complications are not uncommon in PD,[20] the high event rate improves the detection of significant differences in even a small dataset. As only the data from a single attending surgeon was used, there was no potential for inter-operator variability.

Seasonal differences in overall severity of complications, as measured by the Clavien-Dindo grade, were not statistically significant regardless of when surgery was performed. However, there was a trend toward a decreased rate of complications early in the academic year. Major complications, defined as Clavien-Dindo grade ≥ III, occurred at a rate of 12.2% in the month of July and 17.5%

for all other months. Similarly, complications for the first quarter of the year (July–September) occurred at a rate of 11.1% versus 19.1% for the rest of the year. While the trend toward improved outcomes in the first quarter may be driven by greater attending physician supervision, increased senior resident involvement in care, or by unmeasured differences in patient populations, this difference was not statistically significant and, thus, may simply be due to random chance. In contrast, mean blood loss tended to be higher from July to September, but again, the difference was not statistically significant ($P = 0.50$; Table 2).

The study populations were relatively similar when stratified by month and by quarter. The difference in mean age between patients treated in July (67.5 years) versus all other months (64.0 years), was the only variable noted to be significantly different ($P = 0.04$; Table 1). As increasing patient age is generally correlated with worse outcomes, the advanced age noted in the month of July may strengthen the case for equal quality of care regardless of the time of year, as the older group would be expected to do worse overall.

A potentially confounding variable in this investigation was the inability to objectively quantify the amount of resident involvement in each operation. Seasonal outcomes would likely be consistent if the majority of the operation, or at least the essential components of the procedure, were performed by the attending surgeon. Factors that typically influence resident participation include difficulty of the procedure and individual trainee experience, neither of which were able to be captured in this study. While this study focused on patient outcomes and not resident education, this report serves as evidence that, despite individual differences in trainee experience, appropriately supervised residents can provide a consistent quality of patient care.

The data presented here agree with the majority of the literature concerning the July effect in surgery. Although some of the uncertainty likely relates to the diversity of surgical procedures and severity of patient comorbidities, the data do not generally support a season-dependent increase in surgical morbidity and mortality.[11,13,15,17]

In this study, we present outcomes data collected over a 13-year period for patients that had a PD and found no objective measures that indicate a reduction in the quality of care early in the academic year. While the sample size is relatively robust for a single-surgeon, single-operation study, the statistical power could be improved with the inclusion of additional patients. A larger sample size may enhance detection of subtle seasonal discrepancies in morbidity or mortality, but there does not appear to be a trend toward worse outcomes in July. Lastly, while the teaching model employed at our residency program is similar to that of many other teaching hospitals, a multi-institutional study would need to be conducted to confirm that the results presented are externally valid.

Conclusions

Although concern exists regarding outcomes of major surgery in July, this study indicates that PD can be safely performed irrespective of the time of year.

Author Contributions R.S. conceived the study. T.M., J.K, and J.M. developed the theory and performed the computations. All authors had a role in writing and editing the final manuscript.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

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