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ORIGINAL ARTICLE

Association between Preoperative Steroids and Outcomes in Patients Undergoing Pancreaticoduodenectomy using the National Surgical Quality Improvement Program

Hassan Aziz[1] · Zubair Ahmed[1] · Mohamed Abdimajid[1] · Yurie Sekigami[1] · Martin Hertl[1] · Martin D. Goodman[1]

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Abstract

Background A national study analyzing the association between preoperative steroid use and outcomes after pancreatic resections is lacking. The purpose of this study is to evaluate the association between preoperative steroids and outcomes after pancreaticoduodenectomy using a national database.

Materials and Methods A retrospective analysis of patients undergoing pancreaticoduodenectomy was performed using the National Surgical Quality Improvement Program (NSQIP) database (2014–2019). In addition, we utilized propensity score matching to compare patients on preoperative steroids to those who were not. Outcomes measured included 30-day complications and mortality, need for readmission, a prolonged hospital length of stay, delayed gastric emptying, and pancreatic fistula.

Results After propensity score matching, there were 438 patients in the steroid group and 876 patients in the no steroid group. There was no difference in pancreatic fistula (23.8% vs. 21.7%; *p*-0.3), delayed gastric emptying (21.1% vs.20.1%; *p*-0.06), major complications (31.8% vs. 30.1%; *p*-0.1), and mortality (3.5% vs. 3.2%; *p*-0.6) between the two groups.

Conclusion Glucocorticoids did not reduce the incidence of overall complications, postoperative fistula, and delayed gastric emptying following pancreaticoduodenectomy.

Keywords Glucocorticoids · Pancreatic surgery · Complications · Pancreatic fistula

Introduction

Pancreatic resection remains the most effective curative plan for pancreatic tumors.[1] Unfortunately, despite the recent advances, the occurrence rate of complications in pancreatic surgery is very high.[2] The occurrence of postoperative pancreatic fistula (POPF) may be as high as 50%.[3] POPF results in more significant patient morbidity and increases hospital stay.[4] POPF itself may lead to additional complications like postoperative bleeding, pseudocyst formation, and postoperative hemorrhage.[5,6] Other complications, like delayed gastric emptying (DGE), occur in 17% of the cases.[7,8] Both post pancreatectomy hemorrhage (PPH) and DGE pose significant risks to pancreatic surgery patients, and reducing their incidence would improve outcomes for many patients.[9,10]

Improved patient selection and improvement in pre- and postoperative care are associated with better patient survival but do not necessarily reduce the risk of complications.[11,12] Glucocorticoids, whose effectiveness has been debated in the literature, are steroids synthesized in the body and released by the adrenal glands.[13,14] They reduce inflammatory responses when they bind to the body's glucocorticoid receptors.[15,16] Glucocorticoids like hydrocortisone, dexamethasone, and corticosteroids have been employed perioperatively and intra-operatively to investigate their impact on reducing postoperative complications following various pancreatic procedures.[17] Dexamethasone is a commonly prescribed anti-inflammatory medication to mitigate the impacts of inflammatory diseases and cancers.[18-22]

The association between preoperative steroid use and outcomes after pancreatic surgery is an area of active research. Kelly and colleagues have proposed a preoperative risk scoring system for morbidity after distal pancreatectomy that includes male sex, high BMI, smoking and chronic steroid

✉ Hassan Aziz
haziz@tuftsmedicalcenter.org

[1] Tufts Medical Center, Tufts University School of Medicine, South Building, Floor 4, 860 Washington St, Boston, MA 02111, USA

use.[23] However, the effect of preoperative steroid use in patients undergoing PD remains unknown. Our study aimed to understand the association between preoperative steroids and clinical outcomes in patients undergoing pancreaticoduodenectomy (PD) using a national database.

Materials and Methods

Data Source

The American College of Surgeons National Surgical Quality Improvement Program (ASC-NSQIP) collects preoperative and 30-day postoperative data on patients undergoing surgical procedures.[24] A retrospective review was conducted using the NSQIP Procedure Targeted Participant Use Data File (PUF) for pancreatectomy for the available years 2014–2019. The NSQIP pancreatectomy-targeted dataset participant use file (PUF) includes cases accrued since 2014 and tracks defined pancreatectomy-specific variables and outcomes. Patients who underwent Whipple (pancreaticoduodenectomy) were included in the analysis. This study was deemed exempt from review by the Institutional Review Board through Tufts University.

Inclusion and Exclusion Criteria

Patients of age 18 and above who underwent pancreaticoduodenectomy for benign or malignancy disease of the pancreas were included. Patients who underwent distal pancreatectomy or total pancreatectomy were excluded from the study. Patients who had PD for benign etiologies were excluded. Patients who had missing data regarding demographics, operative characteristics, or use of steroids were excluded. Similarly, patients with missing data regarding complications, mortality, development of pancreatic fistula, or delayed gastric emptying were also excluded. Patients undergoing total pancreatectomy, or distal pancreatectomy — operations which are different from PD in terms of patient population, management, use of minimally invasive approach, drain and overall management were excluded in order to have a homogenous patient population.

Patient Characteristics

Patient demographics collected by NSQIP included age, gender, and race (classified as Black/African American, Asian, Native Hawaiian, and White). Pre-surgery characteristics included body mass index (BMI), current smoking status, severe COPD, dialysis dependency, American Society of Anesthesiologists (ASA) classification (> ASA III), preoperative weight loss, functional status, and use of neoadjuvant chemotherapy or radiation therapy. Operative findings included: Mean OR time, need for venous reconstruction, blood transfusions, multi-visceral resections, operative drains, gland texture, and duct size. NSQIP provides a variable "STEROID" to identify patients on steroids, defined as steroid use for chronic conditions. To classify as being on steroids, patients must have received regular doses of corticosteroids for at least 30 days before surgery. Patients were then categorized into two groups based on absence or presence of steroid use.[25]

Outcomes

Outcomes measured include 30-day complications and mortality, need for readmission, prolonged hospital length of stay, delayed gastric emptying, and development of POPF.

NSQIP defined pancreatic fistula as persistent drainage (a drain output of any measurable volume of fluid on or after postoperative day 3) of amylase-rich fluid (an amylase content greater than 3 times the serum amylase activity) and 1 of the following three criteria: drain continued longer than 7 days; percutaneous drainage performed, or reoperation performed. Alternatively, the pancreatic fistula was also present if a clinical diagnosis of the pancreatic fistula was made by an attending surgeon and 1 of the following 4 criteria: drain continued longer than 7 days; spontaneous wound drainage; percutaneous drainage performed; reoperation. In 2016, the pancreatic fistula's definition was slightly modified to include any patients with persistent drainage of amylase-rich fluid or an attending diagnosis of pancreatic fistula in the setting of patients being made NPO with total parenteral nutrition.[19]Clinically relevant pancreatic fistula was defined as the presence of a fistula in addition to 1 of the following: a drain in place longer than 21 days, a hospital length of stay of at least 14 days, organ space SSI, postoperative percutaneous drain placement, reoperation, sepsis, shock, or single and multisystem organ failure (respiratory or renal failure), as has been done previously using this database.

Minor complications included at least one of NSQIP's defined complications: superficial surgical site infection, pneumonia, pulmonary embolism not requiring intubation, urinary tract infection, bleeding requiring transfusion, deep vein thrombosis, and sepsis. Major complications included at least one of NSQIP's defined complications: septic shock, reoperation, cardiac arrest, myocardial infarction, cerebrovascular accident, acute renal failure, reintubation, prolonged ventilation, wound dehiscence, deep incisional surgical site infection, and organ space surgical site infection. Prolonged length of stay was defined by a hospital stay greater than the 75th percentile.[26]

Analysis

Categorical variables were analyzed using chi-squared and Fisher's exact tests for univariable analysis, while continuous variables were analyzed using the Kruskal–Wallis test. In addition, we utilized propensity score matching in a 1:2 manner before comparing the two groups for differences in outcomes. Factors utilized for matching included: age, gender, race, body mass index (BMI), preoperative weight loss, functional status, neoadjuvant therapy, comorbidities (Chronic obstructive pulmonary disease (COPD), heart failure, diabetes, and hypertension), and functional status. We also matched operating findings, including operative time, need for blood transfusion, duct size, gland texture, drains, and venous reconstruction.

Results

Five-thousand-nine-hundred-seventy-six patients underwent pancreaticoduodenectomy during the study period after we excluded patients with missing data regarding the demographics, type of surgery, and specific outcomes. Among these patients, 623 were on preoperative steroids. Figure 1 highlights patient selection criteria. After propensity score matching in a 1:2 ratio, there were 438 patients in the steroid group and 876 patients in the no steroid group. The two

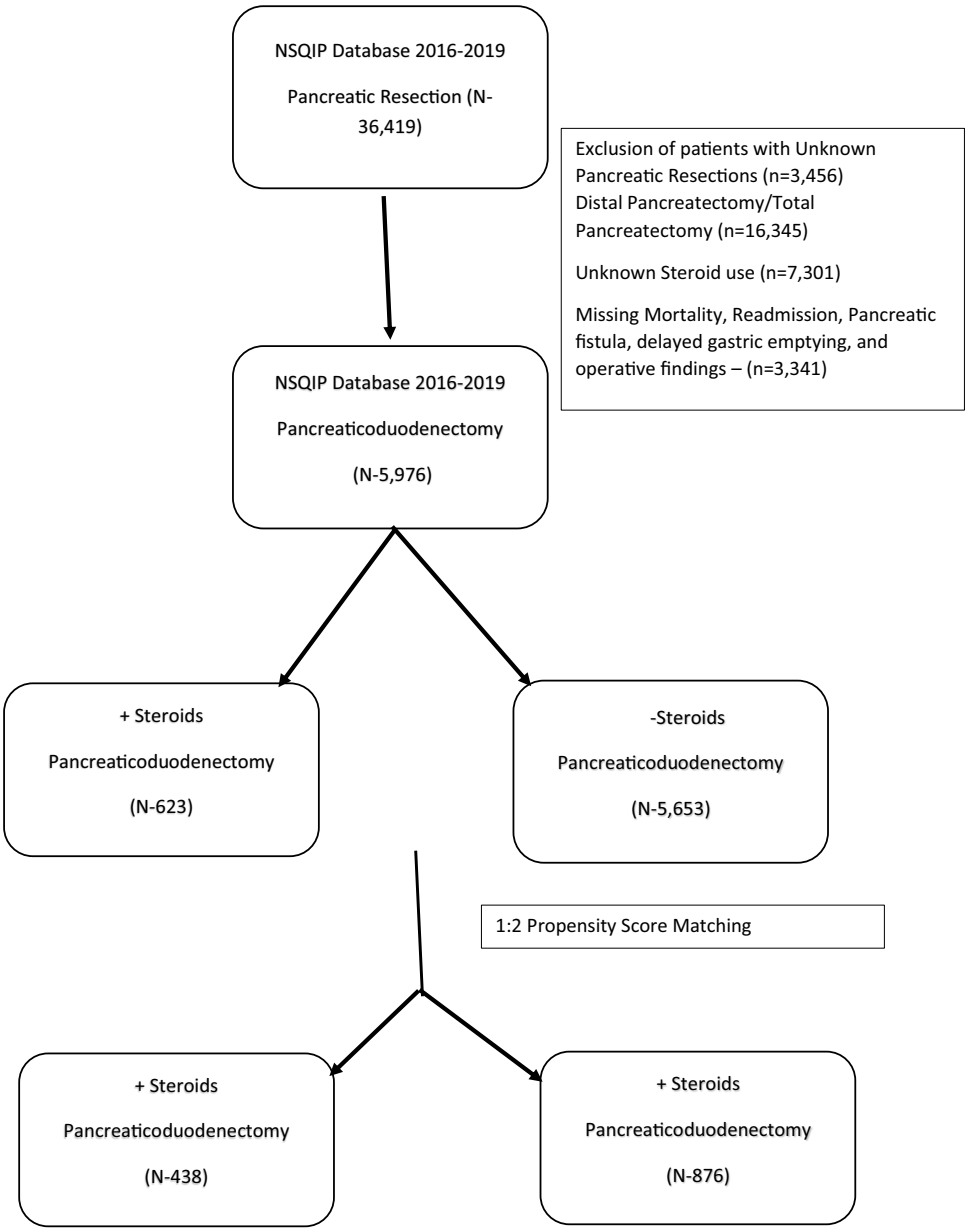

Fig. 1 Flow diagram

groups were similar in demographics, comorbidities, neoadjuvant therapy, and operative findings, including pancreatic duct size and gland texture. Table 1 highlights the patients' clinicodemographic findings after propensity score matching. The two groups were similar in age, gender, comorbidities, and operative details.

There was no difference in minor complications between the two groups (42.3% vs. 41.6%; *p*-0.7). The rate of superficial surgical site infection (8.5% vs. 9.1%); *p*-0.6), pneumonia (4.1% vs. 3.8%; *p*-0.3), and sepsis (10.1% vs. 11.2%; *p*-0.6) was similar between the two groups. Table 2 highlights the minor complications between the two groups. There was no difference in pancreatic fistula (23.8% vs. 21.7%; *p*-0.3), delayed gastric emptying (21.1% vs.20.1%; *p*-0.06),

Table 2 Minor complications

Outcomes	Steroids	No steroids	p-value
Minor complications	42.3%	41.6%	0.6
Superficial surgical site infection	8.5%	9.1%	0.3
Pneumonia	4.1%	3.8%	0.5
Pulmonary embolism not requiring intubation	1.3%	1.4%	0.3
Urinary tract infection	3.8%	3.9%	0.5
Bleeding requiring transfusion	4.2%	3.8%	0.6
Deep vein thrombosis	2.3%	2.5%	0.8
Sepsis	10.1%	11.2%	0.6

Table 1 Demographics and operative characteristics after propensity score matching

Demographics	Steroids ($n=438$)	No steroids ($n=876$)	p—value
Age, y, mean (SD)	65.4 + / − 21.2	67.8 + / − 20.2	0.6
Sex, n (%)			0.8
Female	209 (47.8%)	422 (48.2%)	
Male	229 (52.1%)	453 (51.8%)	
Race, n (%)			0.7
White	289 (66%)	581 (66.3%)	
Black	34 (7.9%)	71 (8.1%)	
BMI ≥ 35, n (%)	47 (10.8%)	98 (11.2%)	
Comorbidity, n (%)			
Severe COPD	31 (7.2%)	66 (7.6%)	0.6
CHF	3 (0.7%)	8 (0.9%)	0.7
Dialysis	3 (0.7%)	8 (0.9%)	0.6
Smoking	82 (18.8%)	181 (20.6%)	0.5
Hypertension	250 (57.2%)	507 (57.9%)	0.6
Obstructive jaundice	149 (34%)	317 (36.2%)	0.5
Preop-Weight loss	50 (11.5%)	120 (13.7%)	0.5
ASA class ≥ 3	358 (81.8%)	698 (79.7%)	0.6
Independent functional status	209 (47.8%)	421 (48.1%)	0.8
Neoadjuvant therapy			
Chemo/radiation	60 (13.7%)	126 (14.4%)	0.5
OR findings			
Mean OR Time, Min	350.4 + / − 49.3	340.8 + / − 51.2	0.6
Venous reconstruction	19 (4.3%)	41(4.7%)	0.8
Blood transfusion	23 (5.3%)	47 (5.4%)	0.6
Multivisceral resection	6 (1.4%)	12 (1.4%)	0.8
Operative drain	406 (92.7%)	792 (90.5%)	0.8
Gland texture, n (%)			0.6
Soft	200 (45.6%)	405 (46.3%)	
Intermediate	50 (11.5%)	110 (12.6%)	
Hard	92 (21%)	171 (19.6%)	
Pancreatic duct size, n (%)			0.6
≤ 3 mm	117 (26.8%)	253 (28.9%)	
4–6 mm	189 (46.3%)	385 (44.0%)	
≥ 7 mm	34 (7.9%)	72 (8.3%)	

CHF, Congestive heart failure; *OR*, operating room; *BMI*, Body mass index

Table 3 Major complications

Major complications	Steroids	No steroids	*p*-value
Septic shock	3.7%	3.1%	0.7
Reoperation	6.6%	6.9%	0.8
Cardiac arrest	1.6%	1.9%	0.5
Myocardial infarction	0.9%	1.1%	0.7
Cerebrovascular accident	0.4%	0.3%	0.6
Acute renal failure	0.8%	0.7%	0.5
Reintubation	4.3%	4.1%	0.8
Prolonged ventilation	2.5%	2.6%	0.9
Wound dehiscence	1.8%	2.1%	0.8
Deep incisional surgical site infection	2.3%	2.5%	0.8
Organ space surgical site infection	14.3%	15.1%	0.3

Table 4 Pancreas specific complications

	Steroids	No steroids	*p*-value
Complications			
Mortality	3.5%	3.2%	0.6
Readmission	15.8%	14.7%	0.3
prolonged LOS	11.5%	10.5%	0.5
Pancreatic Fistula	23.8%	21.7%	0.3
Reoperation	6.3%	5.9%	0.5
Delayed Gastric Emptying	21.1%	20.1%	0.6

reoperation rates (6.3% vs. 5.9%; *p*-0.5), wound dehiscence (1.8% vs 2.1%; *p*-0.8), organ space surgical site infections (14.3% vs. 15.1%; *p*-0.3) major complications (31.8% vs. 30.1%; *p*-0.1), and mortality (3.5% vs. 3.2%; *p*-0.6) between the two groups. Table 3 highlights the major complications.

Similarly, there was no difference in mortality (3.5% vs 3.2%; *p*-0.6), pancreatic fistula rates (23.8% vs. 21.7%; *p*-0.3), delayed gastric emptying (21.1% vs. 20.1%; *p*-0.6) between the two groups. Table 4 highlights complications related to pancreatic resection.

Discussion

The data analysis revealed that overall, glucocorticoids did not have a significant effect on the reduction and thus prevention of postoperative pancreatic complications. In addition, there was no difference in mortality, complications, delayed gastric emptying, or pancreatic fistula rates between the two groups.

This topic of perioperative steroids and associated outcomes has been studied before in literature.[27-30] Preoperative steroids did not reduce the rates of pancreatic fistula in this study. This is similar to studies by Laaninen et al.; Newhook et al., and Sandini et al.; in which steroids did not reduce the development of postoperative fistula.[27,28,30] However, Antilia et al. had a significant reduction in the rate of pancreatic fistula in both Grade B and C and overall, using hydrocortisone compared to placebo, both used intra-operatively (6% and 43%: Grade B 29% and Grade C 14%, $p=0.02$).[29]

We found no difference in postoperative septic or infectious complications between the two groups. In a study by Newhook et al.; dexamethasone failed to prevent postoperative complications or improve survival.[28] However, Sandini et al. saw an improvement in infectious complications between those who received dexamethasone intraoperatively compared to placebo (18.8% vs. 28.8%, $p=0.032$).[31] In addition, Sandini et al. saw significant improvement in length of survival with dexamethasone (46 vs. 22 months, $p=0.017$). Although the control and experimental groups were randomly selected, the experimental group was significantly younger and more likely to be female than the control, which could have contributed to the longer survival length.[27] Laaninen et al. had a significant reduction in Clavien-Dindo III-IV in the experimental group compared to control (18% vs. 41%, $p<0.05$). Other significant hydrocortisone interactions were reducing overall morbidity using the comprehensive complication index and reducing C-reactive protein values in postoperative days 2–3.[30]

The association between chronic steroid use and outcomes after PD has been sparsely studied in the literature. In a study by Okano et al.; chronic steroid use was not associated with increased infectious complications after PD.[31] The authors identified male sex, older age, high BMI, other previous malignancy, liver disease, bile contamination, prolonged duration of surgery, intraoperative blood transfusion, and soft pancreas as risk factors for increased postoperative complications after PD. Greenblatt et al. in an NSQIP study (2005–2009), found that patients who had any morbidity after PD were more likely to be older, males, with a higher mean BMI, and a higher frequency of dependent functional status and each of the following comorbid conditions: dyspnea, COPD, coronary artery disease, hypertension, peripheral vascular disease, neurologic disease, steroid use, and bleeding disorders.[32]

This study showed no difference in delayed gastric emptying in either group. Dexamethasone has been recommended in the ERAS pathway to prevent anesthesia-related postoperative nausea and vomiting (PONV), which is recommended in the ERAS pathway for PD. This finding is like studies by Sandini et al. and Laaninen et al., which showed no improvement in DGE in patients who received preoperative steroids.[27,30]

Inherent limitations arise from using the ACS-NSQIP database. First, ACS-NSQIP only reports events 30 days post-surgery and, thus, ACS-NSQIP may underestimate the exact rate of all postoperative events, many of which occur

after 30 days. Secondly, while ACS-NSQIP provides thousands of cases and hundreds of thousands of data points, it has limited oncologic metrics and lacks surgeon/hospital volume and patient geographic location. Thirdly, the indication, exact dose and type of steroid given, and the time of its administration is not recorded in the database. NSQIP codes for "Steroid use for chronic condition"; therefore, patients who received steroids only in the preoperative phase cannot be differentiated from other patients who have been on steroids chronically. This limits the ability to generalize the effect of steroid pretreatment between patients. Another limitation is the lack of data regarding the volume of DP procedures performed at each participating center. Furthermore, ACS-NSQIP tends to over-represent quaternary and tertiary care centers and may not apply to all hospitals. However, it is not easy to analyze the trends in care over the past decade on a national level. Finally, the strength of this study is in having accurate and validated clinical details coupled with outcomes data available for a large number of patients.

Conclusion

Preoperative steroid use did not reduce the incidence of overall complications, postoperative fistula, and delayed gastric emptying following pancreaticoduodenectomy.

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