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Geriatric Assessment Improves Prediction of Surgical Outcomes in Older Adults Undergoing Pancreaticoduodenectomy:

A Prospective Cohort Study

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Abstract

Objective—To prospectively evaluate the additional value of geriatric assessment (GA) for predicting surgical outcomes in a cohort of older patients undergoing a pancreaticoduodenectomy (PD) for pancreatic tumors.

Background—Older patients are less often referred for possible PD. Standard preoperative assessments may underestimate the likelihood of significant adverse outcomes. The prospective utility of validated GA has not been studied in this group.

Methods—PD-eligible patients were enrolled in a prospective outcome study. Standard preoperative assessments were recorded. Elements of validated GA were also measured, including components of Fried's model of frailty, the Vulnerable Elders Survey (VES-13), and the Short Physical Performance Battery (SPPB). All postoperative adverse events were recorded, systematically reviewed, and graded using the Clavien-Dindo system by a surgeon blinded to the GA results. Multivariate regression analyses were conducted.

Results—Seventy-six older patients underwent a PD. Significant unrecognized vulnerability was identified at the baseline: Fried's "exhaustion" (37.3%), SPPB <10 (28.5%), and VES-13 >3 (15.4%). Within 30 days of PD, 46% experienced a severe complication (Clavien-Dindo

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grade ≥III). In regression analyses controlling for age, the body mass index, the American Society of Anesthesiologists score, and comorbidity burden, Fried's "exhaustion" predicted major complications [odds ratio (OR) = 4.06; $P = 0.01$], longer hospital stays ($\beta = 0.27$; $P = 0.02$), and surgical intensive care unit admissions (OR = 4.30; $P = 0.01$). Both SPPB (OR = 0.61; $P = 0.04$) and older age predicted discharge to a rehabilitation facility (OR = 1.1; $P < 0.05$) and age correlated with a lower likelihood of hospital readmission (OR = 0.94; $P = 0.02$).

Conclusions—Controlling for standard preoperative assessments, worse scores on GA prospectively and independently predicted important adverse outcomes. Geriatric assessment may help identify older patients at high risk for complications from PD.

Keywords

decision making; geriatric assessment; pancreas cancer; pancreaticoduodenectomy; prospective

As the percentage of US citizens older than 65 years increases, there is expected to be a proportional increase in the incidence of age-related malignancies,[1] including pancreatic cancer.[2] Pancreaticoduodenectomy (PD) is the only available potentially curative treatment for pancreatic cancer. Although perioperative mortality rates after PD have decreased dramatically when performed by experienced surgeons within high-volume medical centers, older patients remain at high risk for complications and death.[3] This is likely related to a proportional increase in associated multimorbidity, cognitive losses, functional impairments, and frailty syndromes in older patients.[4] Surgeons have traditionally relied on standard assessments of patient performance status and their own clinical judgment to select patients for major cancer operations. Available risk stratification scoring systems that have been used to guide decision making and treatment planning include the American Society of Anesthesiologists (ASA) classification system [5] and Karnofsky performance status (KPS).[6] Geriatric assessments (GAs) are multidisciplinary evaluations that may be used to identify individuals who are frail and therefore at the highest risk for poor outcomes.[7] Despite their potential predictive value, GAs have not been prospectively used by members of the surgical community to risk stratify patients before cancer surgery.

Surgical decision making for older cancer patients is challenging and requires a balance between equity of access for older adults and avoiding overtreatment in a higher-risk population. Wide variations still exist in the patterns of care for older patients with cancer and related conditions.[8] Although *fit* older patients with cancer seem to derive similar benefits to younger patients from standard treatments, *frail* older patients are at higher risk for worse surgical and cancer-related outcomes.[8] The domains of GA include assessments of self-care (eg, activities of daily living), self-sufficiency (instrumental activities of daily living), cognitive status (eg, Blessed memory), disease burden (eg, Charlson comorbidity), physical performance [eg, frailty, Short Physical Performance Battery (SPPB) tests], and "geriatric syndromes" (eg, falls, delirium, and incontinence). Direct comparison of GA to performance status measures (ie, Eastern Cooperative Oncology Group-Performance Status (ECOG-PS)) suggests that ECOG-PS underestimates the loss of activities of daily living, instrumental activities of daily living, and impaired cognition of many older adults.[9] GAs may identify reversible conditions that can be addressed to improve patients' fitness before

surgery. They might also help clinicians anticipate complications by predictably identifying needs for extra support during and after surgery.

We prospectively conducted a GA of older adults undergoing PD. First, we measured the frequency of the underlying vulnerability/frailty at the baseline in surgical patients that had already been deemed acceptable risk and selected for PD. Second, we assessed the independent predictive value of 5 validated GA measures to detect the likelihood of significant postoperative adverse events including the risk of major surgical complications, presence of a surgical site infection, length of hospital stay, frequency of discharge to a "nonhome" environment (ie, skilled nursing facility, nursing home, and rehabilitation center), and 30-day hospital readmission rates. We hypothesized that these GA elements would identify patients belonging in clinically relevant elevated risk categories, independent of the application of standard surgical risk assessments.

METHODS

Recruitment

Patients older than 18 years were recruited between October 2007 and July 2011 at the University of Chicago Medical Center. They were eligible for the study on the basis of the following inclusion criteria: (1) being referred for surgical evaluation for PD; (2) being able to read English and provide informed consent; (3) having no history of a neurologic or musculoskeletal condition that caused significant muscle-related toxicity or mobility impairment (ie, Parkinson disease and severe osteoarthritis); and (4) having no documented diagnosis of dementia.

Qualified patients having a PD were told about the study by the treating surgeon, registered nurse, or other member of the research team, with the treating surgeon's approval, during a preoperative visit. Those agreeing to participate completed the informed consent process approved by the Biological Sciences Division's Institutional Review Board at the University of Chicago. Of the 117 patients consented, 10 patients were excluded later because of ineligibility for surgery and 31 were determined to have an unresectable tumor, metastatic disease, or later declined surgery, leaving 76 for evaluation.

Materials

Preoperative GA Measurements—Patients had GA completed preoperatively by trained research assistants to ensure consistent data collection. Geriatric assessment included the following specific testing, 4 (of 5) components of Fried's frailty[7]: (1) self-reported unintentional weight loss of 10 lb or more in the previous 12 months; (2) height-adjusted slow gait speed; (3) muscular weakness as measured by a gender-adjusted grip strength pressure on a hand dynamometer (lowest 20%); and (4) self-reported patient exhaustion measured by 2 survey questions. Self-reported exhaustion consisted of agreement with at least one of the 2 following items when considering feelings over the past week: "I felt that everything I did was an effort," and "I could not get going." The Vulnerable Elders Survey (VES-13) is a function-based tool for screening community-dwelling populations to identify older persons at risk for impending health deterioration. The VES-13 accounts

for age, self-rated health, and limitations in physical function, and functional disabilities in a summed score. Scores of 3 or more are considered at risk for poor outcomes. The SPPB is an objective assessment tool for evaluating physical functioning in older persons. It includes evaluations of gait speed, timed chair stands, and timed balance measures. Scores of less than 10 are deemed to be functionally impaired, with lower scores indicating worse physiological performance. The Blessed memory test is a screening measure of cognitive functioning. All surgeons and the hospital care team members were blinded to the results of the GA.

Inpatient Monitoring—A record of the perioperative events that consisted of details about the surgical procedure (eg, type of procedure, length of time, blood loss, postoperative admission, and discharge site) was collected. Data for the length of procedure, administration of anesthesia, and surgical estimated blood loss were systematically collected on a predetermined surgical report form. Before each participant's surgery, the anesthesiologist provided the ASA preoperative assessment score[5] and the surgeon provided the KPS[6] rating.

Postoperative Complications—Complications were graded according to the Clavien-Dindo guideline, which classifies complications into 5 classes.[10] "Major complication" was defined as Clavien-Dindo grade III or greater. A separate form was used for prospective, blinded data collection on the occurrence of surgical complications in several categories: cardiac, constitutional, gastrointestinal, infectious, pulmonary, renal, and surgical miscellaneous. The form also details the severity of any anastomotic leak and delayed gastric emptying. Postoperative outcomes were recorded every second day by an experienced physician's assistant throughout the patient's hospitalization. All outcomes were entered into a password-protected database and reviewed monthly by the study team.

Statistical Analyses

Descriptive statistics were computed for the patient sample for the sociodemographic and clinical variables; these are expressed as percentages or means and standard deviations. Assuming an effect size of 0.15, a power of 0.80, and $\alpha = 0.05$, multivariate logistic and linear regression models were used to assess the predictive value of the GA while controlling for hypothesized important covariates from the literature.[11] The primary outcomes of interest included Clavien-Dindo system major complications (grade ≥III),[12] admission to the intensive care unit (ICU), discharge to rehabilitation, length of hospital stay, and 30-day readmissions to the hospital. Given the sample size, we limited the models to 5 prespecified potential predictor variables[13]—4 covariates for a preselected "base model" with the serial addition of each GA predictor, giving 5 independent variables for each model. In choosing variables for our base model, we focused on clinically relevant, preoperative predictors of outcomes rather than perioperative ones as we wanted to identify factors most helpful for clinicians before surgery. The base model included patient age, body mass index (BMI),[14,15] ASA preoperative assessment score,[5] and co-morbidity burden. After controlling for all of the base model variables, each GA predictor was tested individually. A logistic regression was performed for the dichotomous outcomes of major complications, admission to the ICU, discharge to rehabilitation, and 30-day readmissions. A linear regression was used for the

outcome of length of hospital stay. A predictor with a β-coefficient or odds ratio (OR) with a $P < 0.05$ was considered statistically significant. All statistical analyses were performed using the STATA SE Version 11 (College Station, TX).

RESULTS

Baseline Sociodemographics and Clinical Characteristics (Table 1)

The mean age of participating patients was 67 years—nearly 80% were older than 60 years; 81% identified themselves as white, and approximately 40% had a high school education or less. The majority of the sample had a BMI that was either overweight (40%) or normal (33%). More than 95% of the participants had a KPS of 80 or greater; 80% had an ASA score of 3 to 4, and about 60% had 2 or less comorbidities.

GA Characteristics (Table 2)

The preoperative GA showed that 15% of the sample scored 3 or more on the VES-13 screening test for significant deficits, and 29% scored below 10 on the SPPB, the criteria for objective performance deficits. Patients were found to meet criteria for Fried's frailty by individual items as follows: (1) unintentional weight loss, 56%; (2) slow gait, 11%; (3) self-reported exhaustion, 37%; and (4) grip strength weakness, 42%. The positive screening score for possible dementia on screening on the Blessed memory test was 5%.

Surgical Characteristics (Table 3)

Seventy-five percent of patients had a standard PD, whereas the rest had a pylorus-preserving PD. The majority of patients had preoperative internal biliary stents (63%), and 50 patients (65%) had one or more closed-suction drains placed within the surgical field during their operation. More than 70% of patients had malignant tumors, and the remaining diagnoses were benign, including pancreatic cystic neoplasms, adenomas, and pancreatitis.

Outcomes (Table 4)

Postoperatively, about one third of the patients were admitted to the surgical intensive care unit. Almost 80% of patients had at least one complication, including 46% who suffered a major complication (Clavien-Dindo score ≥III) and 60% who had some type of infectious complication. Other common complications included altered gastrointestinal motility (ie, delayed gastric emptying, gastroparesis, ileus, and small bowel obstruction; 26%), acute renal injury/failure (16%), and delirium (9%). The median length of stay was 10 days, which was higher for those with complications (15 days). Most patients were discharged to home (89%), with the remaining 11% discharged to a rehabilitation or skilled nursing facility. The 30-day readmission rate was 29%.

Preoperative Predictors of Surgical Outcomes (Table 5)

Base Model—We tested the 4-predictor base model (age, BMI, ASA score, and comorbidities) before independent consideration of GA measures, entering the group as a predetermined "block" for each outcome. *Older* age was associated with discharge to a rehabilitation facility (OR = 1.10; $P = 0.04$) and *decreased* likelihood of 30-day

readmission to the hospital (OR = 0.94; $P = 0.02$). The BMI was associated with greater total postoperative hospital days ($\beta = 0.30$; $P = 0.01$).

GA Measures—Controlling for the base model variables, *self-reported exhaustion* from Fried's frailty measures was positively associated with experiencing major complications (OR = 4.06; $P = 0.01$), being admitted to the surgical intensive care unit (OR = 4.30; $P = 0.01$), and the number of days in the hospital ($\beta = 0.27$; $P = 0.02$). Higher scores on the SPPB, indicating better physical performance, were associated with a lower likelihood of being discharged to rehabilitation (OR = 0.67; $P = 0.04$). No other measures were statistically associated with the outcomes.

DISCUSSION

Both single-institution and population-based studies have shown that advanced age is associated with higher rates of morbidity and mortality, and decreased survival after PD.[16–21] Finlayson et al[17] reviewed 23,518 pancreatic resections in the Nationwide In-patient Sample Database and showed that mortality increased from 6.7% in patients 65 to 69 years of age to 9.3% in the 70 to 79 years old cohort, and 15.5% in octogenarians. Riall et al[20] reported a striking age-dependent decrease in long-term survival after PD from 9553 geriatric patients in the Surveillance Epidemiology and End Results database who had a pancreatic resection.

To our knowledge, this is the first study demonstrating the utility of prospective, preoperative GA on the prediction of surgical outcomes for older adults, otherwise considered appropriate candidates for PD. We found that, even among older adults with high KPS scores, there was significant unidentified vulnerability, ranging from 15% (for VES-13) to 56% (for unintentional weight loss). We also found that *self-reported exhaustion* (an element of Fried's frailty) and the SPPB independently predicted important outcomes after PD, including major complications, admission to the ICU, and length of hospital stay, even after controlling for the preoperative assessments of age, BMI, ASA score, and comorbidity burden. These findings provide initial support for further investigation of these measures as independent preoperative assessments for older adults otherwise appropriate for PD.

The most informative GA predictor of important outcomes—self-reported exhaustion—is also among the easiest to administer. It predicts several important surgical outcomes, such as major complications, necessity of ICU stay, and length of hospital stay. The specific physical mechanism by which it does so is unknown. It is possible that it reflects patient energy reserves not easily accounted for in traditional preoperative evaluation. It is also possible that patients' global assessment of their own health is captured in the exhaustion questions. Another important predictor was the SPPB, which identified those who were most likely to be discharged to a rehabilitation facility rather than to home. Again, this well-established GA tool is easily administered by trained personnel in 10 minutes or less.[22] It would be helpful to know, before surgery, which patients are most likely in need of rehabilitation services so that they will be able to plan ahead.

Unexpectedly, older patients were less likely to be readmitted to the hospital within 30 days than their younger counterparts. Perhaps the younger patients were discharged earlier, assuming they would be better able to recover at home, although our data do not show this ($r = 0.12$; $P = 0.29$). Alternatively, older adults in our study were more frequently discharged to rehabilitation facilities ($r = 0.24$; $P = 0.01$), and perhaps that allowed them to recover under professional supervision, thereby hastening recovery and preventing readmissions. With increasing attention to preventable readmissions to the hospital, understanding this process is essential.[23]

Others have found GA helpful in assessing cancer patients[24] and in those undergoing surgery.[25] Some elements of GA have been found to predict outcomes such as length of stay in cancer patients undergoing thoracic surgery.[26] They have also been shown to predict mortality in older surgical patients admitted to the ICU.[27] To our knowledge, ours is the first study to prospectively demonstrate that GA measures can predict important clinical outcomes in older pancreatic cancer patients undergoing PD.

There were limitations to this study. The sample size, although excellent for a single surgical center, is still small, limiting the strength of statistical inferences. We chose our base model carefully, given the statistical limitations because of sample size, focusing on preoperative predictors of clinical outcomes and limiting ourselves to 5 independent variables. We did examine whether certain other potential predictors were important; for example, preoperative stenting was not found to be predictive or to change the findings (data not shown). This is an observational, single-armed, study without a control arm, so we are unable to fully account for unobserved characteristics. However, it is a prospective design and outcome ascertainment, and statistical analysts were blinded to outcomes, which strengthen the likelihood of the associations we did find. We were unable to include all the desired elements of the GA, such as the weekly energy expenditure component of Fried's frailty, because of time and resource constraints. A more complete assessment awaits a larger prospective study. Finally, the patients enrolled were at the discretion of the treating surgeons, and we cannot assess how representative this sample is of all those older patients with pancreatic cancer.

CONCLUSIONS

For older patients with pancreatic tumors who are considered appropriate for PD—the only current curative option for this disease—a significant proportion, up to half in our study, still have potentially important, unrecognized GA deficits. In particular, knowing in advance that a patient is exhausted or has physical performance deficits can help predict clinically relevant outcomes, such as the likelihood of surgical complications, ICU admissions, or longer hospital stays. The identification of GA deficits preoperatively provides surgeons with a window of opportunity to refer patients to a geriatrician for a full evaluation and possible interventions to reduce the operative risk. By selecting older patients who are at higher risk for such outcomes, we can better mitigate the morbidity associated with this curative therapy and optimize the care plan for older patients who are good candidates for surgery.

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TABLE 1

Patient Characteristics, Preoperative (n = 76)

Variables	% or Mean
Sociodemographics	
Age, yr: mean ± SD	67.3 ± 1.3
Age, yr	
<60	21.0
60–69	36.8
70–79	32.9
≥80	9.2
Female	44.7
Ethnicity	
White	81.6
African American	10.5
Hispanic	6.6
Asian	1.3
Education	
Less than high school	10.3
High school graduate (grade 12)	30.9
Some college or junior college	35.3
College graduate	11.8
Postgraduate	11.8
Income, US$	
≤35,000	38.3
35,001–50,000	18.3
50,001–100,000	16.7
100,001–200,000	18.3
>200,000	5.0
Don’t know	3.3
Marital status	
Single	7.9
Engaged/married	71.0
Separated/divorced	3.9
Widowed	17.1
Surgical risk factors	
BMI	
Underweight (<18.5)	2.6
Normal (18.5–24.9)	32.9
Overweight (25.0–29.9)	39.5
Obese I (30.0–34.9)	17.1
Obese II (35.0–39.9)	5.3
Obese III (≥40.0)	2.6

Variables	% or Mean
Karnofsky performance status	
100	34.2
90	44.7
80	18.4
≤70	2.6
ASA classification system	
4	5.3
3	75.0
2	17.1
1	2.6
Comorbidities	
0	11.1
1	25.0
2	23.6
3	13.9
4	9.7
5	8.3
6	6.9
7	0.0
8	1.4

SD indicates standard deviation.

TABLE 2

GA Characteristics (n = 76)

Measure	Score	%
VES-13	0	60.6
Possible range: 0 – 13	1	21.1
	2	2.8
	3	7.0
	4	2.8
	5	1.4
	6	0.0
	7	4.2
VES-13, score ≥3	Abnormal	15.4
Short Physical Performance Battery	12	38.6
Possible range: 0 – 12	11	17.1
	10	15.7
	9	11.4
	8	1.4
	7	2.9
	6	5.7
	5	2.9
	4	1.4
	3	1.4
	2	0.0
	1	0.0
	0	1.4
SPPB <10	Abnormal	28.5
Chair stand points	0	12.4
	1	8.6
	2	14.8
	3	22.2
	4	42.0
15-ft walk time: Mean ± SD (n = 45)		4.6 ± 1.4
Fried's frailty components		
Weight loss		56.0
Slow walk		11.1
Exhaustion		37.3
Weakness		42.5
BM test	28	10.7
	27	0.0
	26	21.3
	25	1.3
	24	14.7

Measure	Score	%
	23	1.3
	22	13.3
	21	0.0
	20	12.0
	19	4.0
	18	16.0
	17	0.0
BM <17	Abnormal	5.3

BM indicates Blessed memory; SD, standard deviation.

TABLE 3

Peri- and Postoperative Characteristics (n = 76)

Characteristics	N (%) or mean (±SD)
Preoperative biliary stent	48 (63.2)
Operation performed	
Pancreaticoduodenectomy	57 (75.0)
Pylorus-preserving PD	19 (25.0)
Estimated blood loss, mL	614.9 (±429.1)
Operative time, min	404.8 (±99.9)
Postoperative drain placed	50 (65.8)
Pathology	
Benign	21 (27.7)
Malignant (49 R0/6 R1)	55 (72.3)
Benign diagnoses	
Pancreatic cystic neoplasm	13 (17.1)
Adenoma	4 (5.3)
Pancreatitis	4 (5.3)
Malignant diagnoses	
Ampullary	15 (19.7)
Bile duct	7 (9.2)
Duodenal/intestinal	2 (2.6)
Pancreatic exocrine	29 (38.2)
Pancreatic Endocrine/neuroendocrine	2 (2.6)

R0, negative resection margins; R1, presence of microscopic tumor cells at the surface of the resection margin; SD, standard deviation.

TABLE 4

Postoperative Outcomes

Outcome	N (%)
Intended postoperative location	
Surgical intensive care unit	24 (31.6)
Surgical floor	52 (68.4)
Any complications	60 (78.9)
Major complications (Clavien grade III or higher)	35 (46.1)
Highest grade complication	
None	16 (21.1)
I	7 (9.2)
II	18 (23.7)
IIIa	15 (19.7)
IIIb	3 (3.9)
IVa	8 (10.5)
IVb	5 (6.6)
V	4 (5.3)
Infection-related complications	
All	50 (65.8)
SSI	43 (56.6)
Superficial SSI	18 (23.8)
Peritoneal SSI (abscess + leaks)	25 (32.9)
Confirmed pancreatic fistula	12 (15.7)
Bacteremia/sepsis	7 (9.2)
Urinary tract infection	7 (9.2)
Clostridium difficile colitis	6 (7.9)
Other complications	
Delirium	7 (9.2)
Gastrointestinal (delayed gastric emptying/gastroparesis/ileus/small bowel obstruction)	20 (26.3)
Acute renal injury/failure	12 (15.7)
Cardiac (congestive heart failure/arrhythmias)	8 (10.5)
Ventral hernia/fascial dehiscence	8 (10.5)
Hospital length of stay, d	
Median	Median, 10; range, 6–47
Patients with major complications	Median, 15; range, 7–47
Patients without major complications	Median, 9; range, 6–17
Discharge location	
Home with or without physical therapy	65 (89.0)
Acute rehabilitation facility/skilled nursing facility	8 (11.0)
Death in hospital (within 30 d)	3 (3.9)
Any death within 30 d	4 (5.3)
30-d readmission	

Outcome	N (%)
Any readmission after discharge	21 (28.8)

SSI indicates surgical site infection.

TABLE 5

Regression Predictors of Outcomes by Base Model (Age, BMI, ASA, Comorbidities) and Individual Predictors

	Major Complications		Surgical ICU Admission		Days in Hospital		Rehabilitation Discharge		30-d Readmission	
	OR	*P*	OR	*P*	*β*	*P*	OR	*P*	OR	*P*
Base model										
Age	1.03	0.22	1.04	0.22	0.22	0.07	1.10	0.04	0.94	0.02
BMI	1.10	0.07	0.96	0.39	0.30	0.01	1.08	0.21	1.02	0.74
ASA	0.68	0.43	2.41	0.16	− 0.10	0.41	1.53	0.70	1.78	0.28
Comorbidities	0.90	0.50	1.16	0.36	0.00	0.97	1.09	0.71	1.00	0.99
Individual predictors										
Weight loss	0.81	0.70	2.17	0.23	0.08	0.55	2.47	0.38	1.25	0.73
Exhaustion	4.06	0.01	4.30	0.01	0.27	0.02	2.39	0.32	1.98	0.25
Weakness	0.70	0.51	1.70	0.37	− 0.09	0.50	0.92	0.93	1.45	0.56
Walk time	− 0.02	0.96	0.82	0.57	− 0.07	0.95	1.33	0.59	1.06	0.90
Chair stands	0.82	0.34	0.74	0.20	− 0.01	0.99	0.50	0.06	0.76	0.28
SPPB	1.06	0.62	0.93	0.55	0.12	0.43	0.67	0.04	1.02	0.87
VES-13	1.05	0.80	1.16	0.47	0.13	0.38	0.55	0.29	0.78	0.32
Memory score	0.97	0.65	1.06	0.45	0.07	0.58	1.11	0.47	1.04	0.60

ASA indicates the American Society of Anesthesiologists preoperative assessment score; SPPB, Short Physical Performance Battery, 0 to 12 with higher scores indicating better function; VES-13, 0 to 13 with higher scores indicating higher burden.