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Factors Influencing Survival in Patients Undergoing Palliative Bypass for Pancreatic Adenocarcinoma

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Abstract

Purpose—The purpose of this study is to identify factors predictive of early mortality following palliative bypass in patients with previously unsuspected advanced pancreatic adenocarcinoma to provide a basis for the selection of appropriate therapies.

Methods—All patients with pancreatic adenocarcinoma who underwent a bypass procedure at our institution between 9/30/1994 and 1/31/2006 were reviewed. Patients with peri-operative mortality were excluded from the analysis. Univariate analysis was performed on peri-operative data to identify factors associated with early mortality (death within 6 months of surgery). Patients having multiple risk factors were assigned an overall prognostic score based on the sum of these factors.

Results—Of the 397 patients with pancreatic adenocarcinoma analyzed, four factors were found to predict early mortality following palliative bypass: Presence of distant metastatic disease (HR 2.59, $P < 0.0001$), poor tumor differentiation (HR 1.71, $P = 0.009$), severe pre-operative nausea and vomiting (HR 1.48, $P = 0.013$), and lack of previous placement of a biliary stent (HR 1.36, $P = 0.048$). Patients with a prognostic score of 0 were significantly more likely to survive past 6 months than patients with a prognostic score of 1 (HR 2.71, $P < 0.0001$), 2 (HR 3.70, $P < 0.0001$), or 3 (HR 5.63, $P < 0.0001$).

Conclusions—In a cohort of patients undergoing a palliative bypass procedure, specific peri-operative factors can be used to identify patients who are at risk of early mortality. These factors may be helpful in selecting appropriate interventions for this group of patients.

Keywords

pancreatic cancer; palliative bypass; prognostic score

INTRODUCTION

Pancreatic cancer remains the fourth leading cause of death among men and women in the United States [1]. The 5-year survival rate for patients diagnosed with pancreatic cancer remains less than 5%. Complete surgical resection is the only curative option for patients presenting with pancreatic cancer; however, only 15–20% of patients present with resectable disease [2]. Many patients are taken to surgery for planned resection only to be found to have previously unsuspected metastatic disease or vascular encasement precluding curative resection. If deemed unresectable at the time of laparotomy, surgical double palliative bypass followed by chemotherapy and/or radiation may be an option for some patients. Other patients with known unresectable disease can be treated non-operatively with a bile duct stent and/or the placement of a duodenal stent prior to initiation of chemotherapy and/or radiation for palliation of symptoms. Clear pre-operative evidence of distant metastatic disease or uncontrolled jaundice is often considered contraindications to aggressive surgical palliation [3].

Surgical bypass procedures may be associated with negative outcomes with reported surgical morbidity and mortality rates of up to 30 and 2%, respectively [45]. The increased use of modern CT imaging has recently reduced the number of unplanned palliative bypasses; however, the decision to proceed with a surgical bypass is still often made intraoperatively when the pancreatic carcinoma is found to be unresectable or metastatic. Clinical trials have not been performed to evaluate the survival of patients undergoing surgical bypass as compared to closure and the rapid initiation of endoscopic, non-operative palliative procedures followed by chemotherapy and/or radiotherapy. While surgical palliation may be more durable than non-operative palliative approaches, a subset of patients who undergo surgical bypass have a dismal survival outlook and may have been better suited for non-operative approaches. Identification of risk factors associated with early mortality in this setting may help guide surgeons in the use of surgical versus non-surgical bypass, thereby avoiding any associated morbidity and allowing them to proceed directly to neoadjuvant or definitive therapy.

As such, we sought to identify clinical factors predictive of early mortality in a large cohort of patients who were found to have unresectable or metastatic pancreatic cancer at the time of surgery. Utilizing these factors, we define an overall prognostic scoring system composed of factors independently predictive of early mortality. Using these factors and a prognostic score we provide data for clinicians regarding expected outcomes based on specific patient presentations. While the majority of past studies have reported various prognostic factors in heterogeneous populations of unresectable and/or resected patients [6–13], we herein present one of the largest studies specifically evaluating outcomes of patients who underwent a surgical bypass procedure.

METHODS

Patients and Procedures

Between 9/30/1994 and 1/31/2006, 574 patients underwent a palliative bypass procedure at the Johns Hopkins Hospital. Patients diagnosed with diseases other than biopsy-proven pancreatic adenocarcinoma ($N = 160$, 27.9%) or who had peri-operative mortality ($N = 17$, 3.0%), defined as death within 30 days of surgery from any cause, were excluded leaving 397 patients for analysis. Information on peri-operative factors potentially associated with mortality was collected from available electronic medical records and cross-referenced with available paper chart records. Pathologic analysis of specimens was overseen by a single senior pathologist for this study (RHH).

The study was approved by the Johns Hopkins University institutional review board (IRB). All data were prospectively collected as part of an IRB-approved hepatobiliary database. Survival was determined and cross-checked by review of clinical follow-up information, cancer center abstracting services, and the social security death index.

Statistical Analysis

Statistical analyses were performed using STATA, version 10. Tests of differences were performed using *t*-tests and χ^2 tests. For patients with missing data for a particular factor, χ^2 tests were performed including only those with known status. The primary outcome variable was early mortality, defined as death within 6 months of surgery excluding peri-operative deaths within the first 30 days. Surviving patients were censored at 180 days. Survival curves were estimated using the Kaplan–Meier technique. Comparisons of survival between groups were made using the log-rank test.

A Cox proportional hazards model was used to examine the association with early mortality and the defined patient characteristics. Univariate analyses were used to examine individual risk factors and associations with early mortality. Each significant risk factor was assigned one point and the points were then summed to create a prognostic score, with a maximum score of 4. Other scoring systems were tested using scores weighted by HR for each factor; however, such scores did not differ significantly from a non-weighted prognostic score (data not shown). Multivariate Cox regression analysis was used to analyze the validity of the prognostic score using the covariates of sex, age, surgery type, post-op complications, and surgical intent. The multivariate model was used to demonstrate the association of the prognostic score with mortality at 6, 9, and 12 months.

RESULTS

Patients underwent a palliative hepaticojejunostomy, gastrojejunostomy, or a combined procedure as noted in Table I. A majority of patients (88%) also received an ethanol celiac plexus block at the time of surgery.

Demographics

Of the 574 patients at our institution who underwent a palliative bypass operation 397 had biopsy-proven pancreatic adenocarcinoma. The median age of the 397 patients was 67 years with a range of 36–97. Two-hundred thirty four (59%) patients underwent a double bypass operation while the remainder underwent either a hepaticojejunostomy alone (9%) or a gastrojejunostomy alone (29%). Median hospital stay was 7 days. Based on pre-operative clinical notes, 342 (86%) patients were taken to surgery with purely curative intent but were subsequently found to have occult metastasis or unresectable disease at time of exploration. The remainder had borderline resectable disease but were taken for attempted resection with planned possible conversion to palliative bypass (Table I).

Prognostic Factors

The median survival of the cohort was 6.0 months with a 1 and 2-year survival rate of 21 and 5%, respectively (Fig. 1). Univariate analysis was performed on peri-operative factors associated with mortality within 6 months of surgery and are displayed in Table II. Age, sex, tumor size, presence of jaundice, abdominal pain, weight loss >10 lbs, CA 19-9 >90, and presence of co-morbidities (defined as at least one diagnosis of diabetes mellitus, coronary artery disease, chronic obstructive pulmonary disease, or hypertension) were not associated with early mortality. Carcinomas originating in the body or tail of the pancreas trended toward association with early mortality but did not reach statistical significance likely due to low numbers ($P = 0.057$). Four factors on univariate analysis were found to be associated

with mortality within 6 months of surgery (Table II). These factors included the presence of distant metastases (HR 2.59, $P < 0.0001$), poor tumor differentiation (HR 1.71, $P = 0.009$), presence of pre-operative nausea and vomiting (HR 1.48, $P = 0.013$), and lack of previous biliary stent placement (HR 1.36, $P = 0.048$, Fig. 2).

Creation of a Prognostic Score for Patients Undergoing a Palliative Bypass Procedure

Given the associations demonstrated on univariate analysis, a prognostic score was constructed using the four variables which were found to be significantly associated with early mortality. Each factor associated with early mortality was assigned 1 point and the sum for each patient was totaled to create a prognostic score. The distribution of scores in our patient population was: Score = 0, $N = 84$ (21%), score = 1, $N = 134$ (34%), score = 2, $N = 136$ (34%), score = 3 or greater, $N = 43$ (11%). The prognostic score predicted for early mortality at 6 months. Compared to patients with a prognostic score of 0, the HR for early mortality in patients with prognostic score of 1 was 2.71 ($P < 0.0001$), 3.70 ($P < 0.0001$) for patients with a prognostic score of 2 and 5.63 ($P < 0.0001$) for patients with a score of 3 or greater (Fig. 3).

Multivariate analysis of the prognostic score was performed using a model containing the covariates of sex, age, type of bypass operation, surgical intent (pure curative intent vs. suspected unresectable disease), and post-operative complications and is shown in Table III. A prognostic score of 1, 2, or >3 was associated with a significant increase in mortality at 6, 9, and 12 months using this model. The hazard ratios among the scores were similar and no significant linear trend was noted.

DISCUSSION

Even in carefully selected patients, the range of post-operative survival after a palliative bypass procedure is wide [5,14], with a subgroup of patients dying within a short time after the bypass procedure. While immediate palliative bypass is necessary to relieve impending obstructions in some of these patients, some patients might potentially be better served with stent placement and rapid initiation of alternative therapy (chemotherapy and/or radiation) [15,16]. Furthermore, our data suggest that some patients are at such high risk of early mortality that they may not benefit from upfront surgical exploration. Such patients may be better treated with non-operative palliation (bile duct and/or duodenal stent) and rapid initiation of alternative therapies such as chemotherapy, chemoradiation, or best supportive care.

The advent of advanced 3D imaging techniques has greatly improved the detection of occult metastatic disease and unresectable disease before planned surgical intervention [17]. As such there has been a recent decline in the number of patients found to be unresectable at time of surgery at our institution. All patients considered for potentially curative surgery at our institution now undergo advanced CT surgical planning. The decision to proceed with surgery is based on a multidisciplinary review of these thin-slice images. These techniques, however, were not readily available or utilized during the early part of our study cohort. Furthermore, advanced imaging technologies are costly and may not be available at all centers.

To provide further useful clinical data to assist with decision-making we have analyzed our database to identify factors which may predict for poor post-operative outcome if an upfront surgery is attempted as primary therapy. Previous studies have searched for factors predictive of poor survival following surgical procedures for pancreatic adenocarcinoma [6–13]. Of these, two contain significant data relating to the outcomes of patients undergoing palliative bypass. The first in a study reported from the Netherlands in 2003 which involved

183 patients who underwent palliative bypass for pancreatic cancer [9]. In their retrospective analysis they identified the presence of metastatic disease and tumor size as correlating with worse long-term survival. The contribution of metastatic disease with early mortality correlates closely with our data; however, tumor size was not found to contribute significantly in our study. This may be in part due to the fact that exact tumor size data were not recorded intraoperatively for two-thirds of our patient cohort. During palliative bypass procedures such data are often not felt to be relevant, however, future studies including these data may indeed reveal a connection.

A second recent study performed in Germany looked at prognostic factors in 136 patients who underwent planned palliative bypass for known metastatic or locally advanced pancreatic cancer [13]. In their analysis American Society of Anesthesiologists (ASA) score, presence of liver metastases, daily pain, CA 19-9 >100 U/ml, and CEA >10 U/ml were found to be associated with early mortality. ASA score was not readily available on review of our electronic medical records and so was not analyzed in our study. Presence or absence of severe abdominal pain was analyzed in our study, however, was not found to be significantly associated with survival. Due to the subjective nature of pain the difference in grading and recording pain between our two institutions could be responsible for this discrepancy. CEA levels were not routinely obtained preoperatively in our cohort.

In the present study we identified clinical variables from a unique cohort of 397 patients with biopsy-proven pancreatic adenocarcinoma who all underwent a bypass procedure at a single institution. Our purpose was to determine if there are specific factors which can predict for poor outcomes following palliative bypass surgery. Unlike previous studies, we found CA19-9 level (using the cutoff of 90 U/ml) was not significantly associated with early mortality. This finding is cutoff dependent, however, and raising the cutoff to a level >1,500 does correlate with early mortality in our population. Given, however, that this level has never been validated in other patient cohorts, we retained the cutoff of 90 which has been shown in other reports to be associated with poor prognosis [18]. Not surprisingly the presence of occult metastases was found to be predictive of increased mortality at 6 months following a palliative bypass operation. We further demonstrate that pre-operative nausea and vomiting, poor tumor differentiation, as well as lack of pre-operative biliary stenting can serve as additional poor prognostic markers for survival.

These findings have a number of implications. The presence of distant metastases as predictive of early mortality suggests the importance of aggressive staging of patients before surgical exploration to increase the chance of detecting low-volume metastatic disease. This could perhaps include laparoscopy at centers without advanced imaging [19]. From our results, the presence of nausea/vomiting is an easily determinable clinical factor, and as such may be a useful clinical screening tool for detecting more advanced or locally invasive disease (i.e., into the stomach or duodenum), thereby suggesting that perhaps further investigation is needed before proceeding directly to surgery or proceeding with bypass if resection is deemed inappropriate intraoperatively. Tumor differentiation has not been consistently studied in other bypass cohorts but our data would imply that tumor biopsy or other tissue sampling should be an early step in determining a proper treatment course for patients who may be considered borderline resectable. Biopsy, however, may be subject to sampling error and may under or over-report the final level of differentiation within the entire tumor. Finally, the finding of stent placement as a potential protective factor may suggest that patients with obstructive symptoms tend to present earlier than those who remain asymptomatic; this would also be consistent with the fact that location of the tumor in the body/tail of the pancreas trended toward a poorer prognosis than patients with tumors in the head of the pancreas (which is more likely to lead to the development of obstructive symptoms). Alternatively patients who have stent placement may have some other factor

which reduces their morality (better control of bilirubin levels, less incidence of obstructive cholangitis, etc.) [20].

Following identification of these prognostic factors, we constructed a prognostic score, which predicts for early mortality at 6 months using a univariate analysis. Multivariate analysis of the score while controlling for sex, age, surgical intent, bypass type, and post-operative complications showed that any score greater than 0 was significantly associated with early mortality at 6, 9, and 12 months. There was no linear trend in the multivariate model suggesting that the presence of any one factor was significant enough to affect morality and potential interaction among the factors. As such, careful consideration before surgery should be undertaken for any patient who has any of these factors identified preoperatively.

Our analysis is primarily limited by its retrospective design (though data were derived from a prospective database) and lack of complete patient data for all of the factors analyzed. While there is no evidence that the missing data were associated with any particular prognostic factor this cannot be fully proven. Our analysis would indicate that collecting full data including CA 19-9 and other factors would likely be beneficial and could aid in designing optimal treatment strategies even in patients with advanced disease.

CONCLUSIONS

In conclusion, the results of this large study demonstrate additional clinical predictors of poor outcome for patients with advanced pancreatic adenocarcinoma undergoing palliative bypass surgery. These factors can help identify candidates who are unlikely to benefit from upfront surgical resection and subsequent bypass procedures and thus would assist the decision making process both prior to any attempted surgical procedure or intraoperatively when the patient is found to have unresectable pancreatic cancer.

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Fig. 1.
Overall survival of 397 patients with pancreatic adenocarcinoma undergoing a palliative bypass procedure.

Fig. 2. Survival of 397 patients with pancreatic adenocarcinoma undergoing a palliative bypass procedure. [Color figure can be seen in the online version of this article, available at <http://wileyonlinelibrary.com/journal/jso>]

Fig. 3. Survival of 397 patients undergoing palliative bypass procedure for pancreatic adenocarcinoma according to Prognostic Score. [Color figure can be seen in the online version of this article, available at <http://wileyonlinelibrary.com/journal/jso>]

TABLE I

Characteristics of 397 Patients With Unresectable Pancreatic Adenocarcinoma Undergoing a Palliative Bypass Procedure

Variable	
No.	397
Median age (y)	67 (Range 36–97)
Gender	
Male	213 (54%)
Female	184 (46%)
Race	
White	359 (90%)
Black	33 (8%)
Other	5 (2%)
Pre-operative symptoms	
Nausea and vomiting	103 (26%)
Jaundice	277 (70%)
Abdominal pain	209 (53%)
Weight loss >10 lbs	147 (37%)
Metastatic disease	232 (58%)
Isolated to lymph nodes	14 (4%)
Isolated to liver	150 (38%)
Pre-operative biliary stent	257 (65%)
Pre-operative CA19-9 level	
0–90	180 (45%)
>90	55 (14%)
Unknown	162 (41%)
Tumor location	
Head/neck	355 (89%)
Body/tail	34 (9%)
Unknown	8 (2%)
Co-morbidities	
Coronary artery disease	48 (12%)
Hypertension	165 (42%)
Diabetes	110 (28%)
COPD	22 (6%)
At least one of above	224 (56%)
Surgical procedure	
Double bypass	234 (59%)
Hepaticojejunostomy only	37 (9%)
Gastrojejunostomy only	116 (29%)
EtOH celiac plexus block	338 (85%)
Median hospital stay (days)	7 (Range 3–46)

Variable	
Tumor differentiation	
Poor/poor-moderate	97 (25%)
Moderate/well	100 (25%)
Unknown	200 (50%)
Initial curative surgical intent	342 (86%)

COPD, Chronic obstructive pulmonary disease; EtOH, ethanol.

TABLE II

Univariate Analysis of Prognostic Factors Associated With Early Mortality in 397 Patients Undergoing Palliative Bypass Procedure for Pancreatic Adenocarcinoma

Variable	N	HR	95% CI	log-rank <i>P</i> -value
Age (y)				
<60	96	1		
60–75	218	0.994	0.698–1.42	0.975
>75	83	1.25	0.820–1.89	0.304
Sex				
Male	213	1		
Female	184	1.24	0.930–1.64	0.145
Tumor size				
0–3 cm	54	1		
>3 cm	79	1.6	0.917–2.78	0.098
Tumor location				
Head/neck	163	1		
Body/tail	34	1.54	0.988–2.41	0.057
Jaundice				
No	109	1		
Yes	277	0.788	0.576–1.08	0.135
Abdominal pain				
No	174	1		
Yes	209	1.13	0.840–1.51	0.426
Weight loss > 10 lbs				
No	88	1		
Yes	150	1.16	0.773–1.74	0.476
Co-morbidities				
No	94	1		
Yes	224	1.19	0.828–1.70	0.35
Pre-op CA19-9				
0–90	55	1		
>90	180	1.48	0.927–2.39	0.1
Distant metastases				
No	179	1		
Yes	218	2.59	1.89–3.53	<0.0001
Tumor differentiation				
Moderate-well	100	1		
Poor/poor-moderate	97	1.71	1.14–2.57	0.009
Nausea/vomiting				
No	280	1		
Yes	103	1.48	1.08–2.02	0.013
Pre-op stent				

Variable	N	HR	95% CI	log-rank <i>P</i> -value
Yes	257	1		
No	122	1.36	1.01–1.84	0.048

TABLE III

Results of the Multivariate Analysis of the Prognostic Score Associated With Overall Survival, Using Covariates of Sex, Age, Post-Operative Complications and Surgical Intent

Prognostic score	Multivariate hazard ratios (95% CI)		
	6-month survival	9-month survival	12-month survival
Score = 0	Ref. 1.00	Ref. 1.00	Ref. 1.00
Score = 1	2.61 (1.55–4.41)	1.83 (1.24–2.71)	1.63 (1.17–2.31)
Score = 2	2.05 (1.59–2.66)	1.66 (1.36–2.02)	1.52 (1.28–1.81)
Score = 3+	1.87 (1.50–2.34)	1.65(1.38–1.97)	1.62 (1.38–1.90)