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Referrals for Surgical Evaluation in Patients with Pancreatic Cancer: Is There A Difference Between Minority and Non-Minority Patients?

A. Study Purpose and Rationale

Pancreatic cancer is the fourth leading cause of cancer death for both men and women in the United States despite being only the tenth most common cause of cancer (1,2). Annually, there are an estimated 43,000 diagnoses and 36,800 deaths (1). The low 5-year survival of 6% is largely attributable to the late stage of pancreatic cancer at the time of diagnosis (1). Surgical resection is the only potentially curative treatment. Unfortunately, because of the late presentation of the disease, only 15% to 20% of patients are candidates for pancreatectomy (3). Although previously associated with high morbidity and mortality rates, modern series show that in experienced hands, the standard Whipple procedure is associated with a five-year survival of 20% to 30% in completely resected patients, and a perioperative mortality rate of less than 4 percent (4-8). This relatively low perioperative mortality rate represents a decline from over 15% in the 1970s, making the Whipple procedure a much more attractive option now than it has been at any time in its long history.

African-Americans are at higher risk of developing pancreatic cancer. A population-based retrospective analysis conducted in California showed that African Americans had a higher incidence of pancreatic adenocarcinoma than non-Hispanic whites and all races/ethnicities combined (9). They also have a slightly higher risk of presenting with advanced disease and with non-resectable tumors (9). In addition, differences in patterns of care exist among African American, Hispanic and non-Hispanic white patients with pancreatic adenocarcinoma. A population-based study using the National Cancer Institute's (NCI) Surveillance Epidemiology and End Results (SEER) and the NCI Patterns of Care/Quality of Care (POC/QOC) studies showed that differences in primary tumor size, stage and insurance status contributed to racial/ethnic differences in the receipt of cancer-directed surgery (defined as a surgery that included resection of the primary tumor) (10). Despite these observations, there is very limited data on the clinical characteristics of pancreatic adenocarcinoma in African Americans or in other racial/ethnic minorities that could potentially explain these observations.

Preliminary data from our tertiary academic institution shows that over the past 8 years, 22.1% of patients with pancreatic cancer belonged to a racial/ethnic minority group (defined as Black/Non-Hispanic, Black-Hispanic or White-Hispanic). The points of care at Columbia University Medical Center (CUMC) accessed by patients appears to vary by race/ethnicity, as minority patients had a greater number of visits to the Emergency Department and inpatient

services but significantly fewer surgical visits when compared to White/Non-Hispanic patients.

Considering the disparities in care seen in other areas of the country and the observed difference in surgical visits seen at CUMC, we plan to examine the surgery referral patterns of both minority and non-minority patients in our institution. Specifically, the study would determine if there is a difference in referral rates between the two groups due to ethnicity. Given that surgery is the only potential curative treatment for pancreatic cancer, identifying differences in patterns of referral for surgical evaluation may lead to further understanding and improvement of the management of minority patients afflicted by this disease.

B. Study Design and Statistical Procedures

The primary aim of the study will be to compare the proportion of patients referred for surgical evaluation when demographic data about the subject is available with the proportion of patients referred when the physicians are blinded to the subjects' demographics.

The study will consist of a retrospective chart review to be done by independent medical oncologists, defined as medical oncologists who are not associated with CUMC and who have never been involved in the subjects' medical care.

Prior to the independent reviews, a research assistant will review each chart to extract information regarding the subject's ethnicity, insurance status and clinical setting of initial evaluation (private faculty practice or fellows clinics), and to determine if referral for surgical evaluation occurred. The presence of a referral to surgery will be defined as clear documentation of referral for surgical evaluation in medical provider notes or as a surgical evaluation note in the electronic medical record (EMR). The charts will then be assigned a unique identification number, and a database will be created using this number and containing the above information. Information relating to the subject's name, ethnicity, primary language, country of origin, employment status, insurance status or actual referral for surgical evaluation will be removed prior to giving the charts to the independent reviewers; they will only be able to identify each subject by the unique identification number given to each chart by the research assistant at the beginning of the study.

The independent reviewers will be asked to evaluate each of the patient's clinical history (including age, stage of disease at the time of presentation, and other medical comorbidities) and any available imaging studies related to the diagnosis of pancreatic cancer. They will then be asked to determine if, based on the available information, they would refer the patient for surgical evaluation as part of the treatment for their disease. Four medical oncologists will review all available charts. If they are in disagreement over a certain case, the case will be further discussed with a fifth medical oncologist to reach an agreement.

Once all charts have been reviewed and a unanimous decision regarding referral has been made, the answers will be entered into the previously created database. The proportion of patients actually referred for surgical evaluation will be compared to the proportion of patients who would have been referred for surgical evaluation by the independent reviewers using Chi Square analysis to determine statistical significance.

The study population will consist of minority (defined as Black/Non-Hispanic, Black-Hispanic or White-Hispanic) and non-minority (defined as White/Non-Hispanic) patients with pancreatic cancer seen at CUMC from 2002 to 2010 as determined by the CUMC Clinical Data Warehouse. Diagnosis will be confirmed with imaging studies present in the EMR that suggest a diagnosis of pancreatic cancer (CT scans, MRIs, EUS) and/or clear documentation of pancreatic cancer in medical provider notes.

The number of charts to be reviewed in this study is estimated at 2,310, approximately 660 charts belonging to minority patients and 1650 charts belonging to non-minority patients. This estimate is based on data collected by the CUMC Clinical Data Warehouse in September 2010. Power analysis to determine effect in this population shows that to be considered significant, the proportion of non-minority patients referred for surgical evaluation must be <0.15 or >0.26 for a p-value of 0.05, a power of 80%, and an assumed proportion of referral for surgical evaluation equal to 0.2 among the non-minority group (determined by prior studies evaluating the proportion of surgical candidates among patients with pancreatic cancer). Thus, based on the size of the study population, referral for surgical evaluation among minority patients will be statistically different from non-minority patients if less than 15% or greater than 26% of minority patients are referred for surgical evaluation.

C. Study Procedures

Non-applicable

D. Study Drugs

Non-applicable

E. Medical Devices

Non-applicable

F. Study Questionnaires

Non-applicable

G. Study Subjects

The study population will consist of minority (defined as Black/Non-Hispanic, Black-Hispanic or White-Hispanic) and non-minority (defined as White/Non-Hispanic) patients with pancreatic cancer seen at CUMC from 2002 to 2010 as determined by the CUMC Clinical Data Warehouse.

Inclusion criteria includes: confirmed diagnosis of pancreatic cancer, and patients' ethnicity

identified as Black/Non-Hispanic, Black-Hispanic, White-Hispanic or White/Non-Hispanic.

Exclusion criteria includes: inability to confirm the diagnosis of pancreatic cancer, inability to determine the subject's ethnicity, inability to determine subjects' age, stage of disease or presence of other medical comorbidities, and inability to determine if referral for surgical evaluation occurred.

H. Recruitment of Subjects

Non-applicable

I. Confidentiality of Study Data

Patients' charts will be assigned a unique identification number at the beginning the study. The clinical information pertinent to the independent review will be printed from the EMR and any information related the patients' demographics will be removed; independent reviewers will keep track of the charts using the unique identification number previously assigned. Packages containing the de-identified clinical information will be mailed to the independent reviewers; they will be asked to discard it after their recommendations have been made. All information collected prior to and during the study will be maintained in a computerized database accessible only to the research assistant and investigators. The results of the study will be presented as an analysis of the entire study population and not as an individual participant.

J. Potential Conflicts of Interest

There are no potential conflicts of interest associated with this study.

K. Location of the Study

Determination of study participants and initial chart screening will be done at CUMC. The independent chart reviews will be done in different academic medical centers.

L. Potential Risks

There are no risks to patients are associated with this study.

M. Potential Benefits

There is no direct benefit to the study participants included in this observational analysis. The study may benefit future patients with pancreatic cancer by improving the management of patients affected by this disease through improved recognition of different patterns of care.

N. Alternative Therapies

Non-Applicable

P. Costs to Subjects

Non-Applicable

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