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HOSPITAL AND MEDICAL CARE DAYS IN PANCREATIC CANCER

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Dedication

To my fiancé, Jeff Duncan, for his unending support and encouragement in my pursuit of this degree and success in my career.

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HOSPITAL AND MEDICAL CARE DAYS IN PANCREATIC CANCER

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Abstract:

Background: Little is known about resource utilization (number of days in the hospital or medical care) between diagnosis and death in patients with pancreatic cancer.

Methods: Using Surveillance, Epidemiology, and End Results (SEER)-Medicare linked data, we identified 25,476 patients with pancreatic cancer (1992-2005). Hospital and medical care days per person-month from the time of diagnosis were described, stratified by stage, treatment, and survival duration.

Results: Hospital/medical care days vary by length of survival and treatment strategy in patients with pancreatic cancer. For all stages, patients were in the hospital a mean of 6.4 days and received medical care a total of 9.0 days in the first month after diagnosis, decreasing to 1.7 and 3.7 days per month, respectively, by the end of the first year. Hospital/medical care days per month of life were higher in patients with shorter survival but increased sharply at the end of life in all patients, regardless of duration of survival. In patients with locoregional disease, resection was associated with a higher number of hospital/medical care days during the first 4 months after diagnosis, but fewer at the end of the first year. For distant disease, hospital days were similar but days in medical care were higher for patients receiving chemotherapy, increasing especially at the end of life.

Conclusions: This study is the first to quantify hospital/medical care days in patients with pancreatic cancer by stage, treatment, and survival. This information will provide realistic expectations and allow for treatment decisions based on patient preferences.

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Chapter 1: Introduction

Pancreatic cancer is the 4th leading cause of cancer deaths in the United States. An estimated 43,140 new cases and 36,800 deaths from pancreatic cancer were reported in 2010.^{1, 2} Depending on the stage, physicians and patients have a variety of treatment options, including chemotherapy, radiation, and surgery. Although many patients receive aggressive therapy, the 5-year survival for patients with pancreatic cancer remains less than 5%.³ Surgical resection for locoregional disease has been shown to improve median survival from 6 months to approximately 13-19 months and long-term survival from less than 5% to 15-20% in population-based studies.⁴⁻⁶

Patients with metastatic disease rarely survive longer than one year. There are multiple randomized phase II and III trials comparing a variety of gemcitabine- or 5-fluorouracil-based chemotherapy regimens for metastatic disease. These regimens show nearly equal efficacy and improve median survival from 3-4 months to 5-7 months.^{7, 8}

Available treatments have significant risks in the setting of modest improvements in survival. Resulting toxicities such as pain, nausea, vomiting, and weight loss from chemotherapy or radiation, along with surgical complications such as wound infection, pancreatic fistula, and delayed gastric emptying⁹ may outweigh the benefit of any increased survival. Previous studies have focused almost entirely on survival. Resource utilization with regard to days in the hospital or days in medical care (seeing a physician, getting a test, or in the hospital) has not been well described and patients do not have clear expectations. Information regarding expected hospital and medical care days may help patients and physicians when making treatment decisions.

In this study, we describe the total number of days in the hospital and days receiving medical care in the first year after diagnosis in patients with adenocarcinoma of the pancreas. We use Surveillance, Epidemiology, and End Results (SEER) data and linked Medicare claims to examine these outcomes as a function of stage, treatment, and duration of survival.

Chapter 2: Methods

This study was approved by the Institutional Review Board at the University of Texas Medical Branch.

Data Source

We used data from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) tumor registry and linked Medicare claims data collected by the Center for Medicare and Medicaid Services.¹⁰ The Medicare data include all claims for covered health care services, including inpatient and outpatient care, for all Medicare patients. The study included patients aged 66 years and older who were diagnosed from 1992 through 2005 and their Medicare claims through 2007.

Patients

Our cohort included patients with a primary diagnosis of adenocarcinoma of the pancreas. International Classification of Disease for Oncology 3rd edition (ICD-O-3) morphology codes were used for adenocarcinoma (8000/3, 8010/3, 8020/3, 8021/3, 8022/3, 8140/3, 8141/3, 8211/3, 8230/3, 8500/3, 8521/3, 8050/3, 8260/3, 8441/3, 8450/3, 8453/3, 8470/3, 8471/3, 8472/3, 8473/3, 8480/3, 8481/3, 8503/3). We included patients aged 66 years or older at the date of diagnosis in order to examine comorbidities in the Medicare database in the year prior to diagnosis. Patients must have been enrolled in Medicare Part A and Part B without HMO for 12 months before and 24 months after diagnosis or until death. Patients diagnosed at autopsy or by death certificate only were excluded.

Staging

The SEER program did not use AJCC TNM staging for pancreatic cancer before 2004. Therefore, tumor stage was analyzed using SEER historic stage. The SEER historic stages were:

1) localized disease (AJCC 0, IA, IB), 2) regional disease (AJCC IIA, IIB, III), or 3) distant disease (AJCC IV). Initial SEER staging is derived from the best available information obtained within four months of diagnosis, including information from inpatient and outpatient hospital records.³ In patients undergoing resection, full pathologic staging is available, with presumed local disease often being upstaged to regional disease. For this reason, locoregional disease is evaluated together.

In 19.6% of patients, the stage was unknown. The numbers and trends in hospital and medical care days for the group of patients with distant disease were similar to those of the combined group of patients with distant and unknown stages. Therefore, the patients with distant disease and unknown stage disease were analyzed together with regards to hospital days and total days receiving medical care.

For many patients, complete pathologic staging and information about tumor differentiation, lymph node status, and tumor size were not available. For these variables, the percentages are based on the denominator of patients with data available.

Hospital and Medical Care Days

We evaluated the entire period of time from diagnosis to death in patients with adenocarcinoma of the pancreas. Within the first year after diagnosis, we describe hospital days and medical care days in detail, as this period accounts for a significant proportion of remaining life for most patients with pancreatic cancer. For those with locoregional disease we evaluate the time period beyond the first year.

Both hospital days and total days receiving medical care were assessed for each patient from the date of diagnosis to one year after diagnosis by month. Only the month and year of diagnosis were available in SEER. The date of diagnosis was defined as the first day of the

documented diagnosis month. This was done in order to avoid missing any days of observation for each patient. Patients who died or were admitted to hospice within one year after diagnosis were censored in their last month of follow-up. Patients who entered hospice were able to contribute information up until the point they entered hospice. Once these patients entered hospice, they were no longer able to contribute information regarding hospital days or days in medical care, and were censored at that time.

Hospital days at each month of follow-up were calculated by dividing the total number of hospital days incurred by the cohort by the total number of observation days contributed by the cohort in a month. This number was multiplied by 30 to determine the days per person-month. Total days receiving any kind of medical care encompassed any days the patient had a physician visit (primary care physician, gastroenterologist, medical/radiation oncologist, surgeon), was hospitalized, or underwent diagnostic or therapeutic procedures (CT, MRI, ERCP, ultrasound, biopsy, chemotherapy, radiation). If a patient had more than one type of medical encounter on a given day, the day was counted as only one day in medical care.

Statistical Analysis

SAS version 9.2 (SAS Institute, Cary, NC) was used for all statistical analyses. Summary statistics were calculated for the entire cohort, including gender, race, marital status, age at diagnosis, income, education, tumor size (in centimeters), lymph node status, SEER historic stage (locoregional/distant), and first course of treatment. The proportion of patients receiving treatment (surgery, chemotherapy) in each month from date of diagnosis was examined to determine if treatment should be analyzed as a time-dependent covariate. Since the majority of patients received treatment in the first two months after diagnosis, it was analyzed as a fixed covariate.

The analysis is primarily descriptive. Patients were stratified by stage (locoregional vs distant), treatment strategy (surgery vs. no for locoregional disease, chemotherapy vs. no for distant disease), and by duration of survival (0-3 months, 3-6 months, 6-12 months, ≥ 12 months). Stratification was done to create homogeneous groups with respect to tumor biology and functional status.

For the overall cohort and within each strata and combinations of strata, hospital and medical care days were calculated by person-month of life for the first year after diagnosis. Results are depicted as bar graphs with the months since diagnosis on the x-axis and the total number of medical care days per person-month on the y-axis.

Chapter 3: Results

The characteristics of the final cohort of 25,476 patients with carcinoma of the pancreas are presented in Table 1. The mean age at diagnosis was 77.6 ± 7.3 years. Thirty-two percent (32.0%) of patients had locoregional disease (n=8,152) and 48.4% had distant disease (n=12,331) at diagnosis. In 19.6% of patients the stage was unknown. Of the patients with locoregional disease, 24.5% underwent surgical resection (n=1,999). Twenty-four percent of patients with distant or unknown stage disease (n=4,143) received chemotherapy.

In the overall cohort, 49.7% of patients survived 3 months or less, 18.3% survived 3-6 months, 16.7% survived 6-12 months, and 15.4% survived ≥ 12 months. Of those with locoregional disease (n=8,152), 29.2% of patients survived 3 months or less. In the cohort of patients with metastatic disease (n=12,331), 63.2% of patients died within 3 months of diagnosis. Of the patients with unknown stage disease (n=4,993), 49.6% of patients survived 3 months or less.

Table 1: Patient Demographics, Tumor Characteristics, and Treatment (N=25,476)

Patient Demographics	
Age (y), mean \pm SD	77.6 \pm 7.3
Female gender	14,841 (58.3%)
Race (white)	21,007 (82.5%)
Marital Status (married)	12,161 (47.7%)
% Census Tract Below Poverty Line, mean \pm SD	11.3% \pm 10.1%
Median Income of Census Tract (\$), mean	47,548
% Census Tract with <12 years Education, mean \pm SD	19.4% \pm 13.5%
Tumor Characteristics	
Size (cm), mean \pm SD	4.3 \pm 2.5
Tumor Stage	
Locoregional	8,152 (32.0%)
Distant	12,331 (48.4%)
Unknown	4,993 (19.6%)
Treatment	
Surgical Resection	
Overall (N=25,476)	2,328 (9.1%)
Locoregional (N=8,152)	1,999 (24.5%)
Distant/Unknown (N=17,324)	329 (1.9%)
Chemotherapy	
Overall (N=25,476)	8,075 (31.7%)
Locoregional (N=8,152)	3,932 (48.2%)
Distant/Unknown (N=17,324)	4,143 (23.9%)

Hospital and Medical Care Days (Table 2)

Table 2 shows the total days spent in the hospital and medical care per month after diagnosis in the overall cohort. Total days receiving medical care included any days in which a patient was hospitalized, had a physician visit, or received any diagnostic test or therapeutic treatment. In the first month after diagnosis, patients with pancreatic cancer were in the hospital a mean of 6.4 days and had a total of 9.0 medical care days. This number progressively decreased, with surviving patients having a mean of 1.7 days in the hospital and 3.7 days in medical care in the 12th month after diagnosis.

Table 2: Hospital and Medical Care Days vs. Observation Days in the Overall Cohort

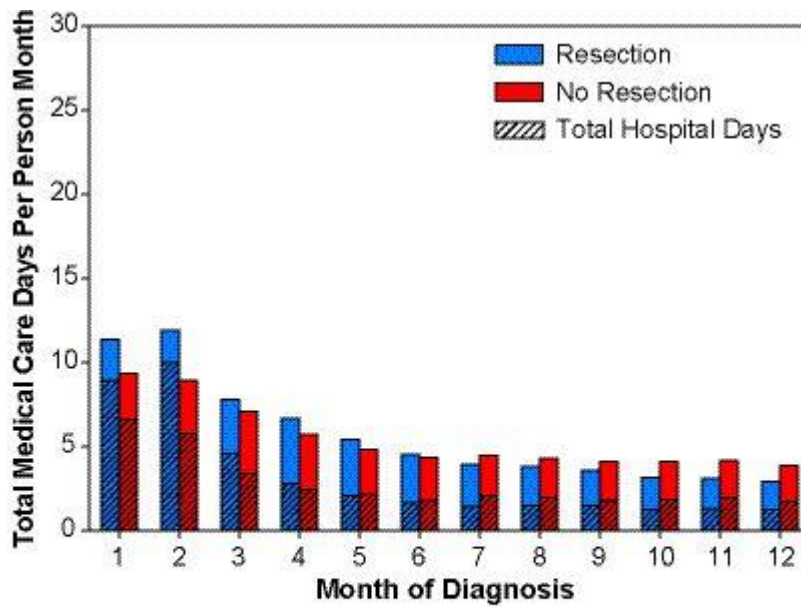
(N=25,476) The proportion of patients at risk in each observation month varies due to censoring due to death or entry into hospice. Total days spent in medical care included any days the patient had a hospitalization, physician visit, underwent a diagnostic procedure or received therapeutic treatment.

Month of Diagnosis	Number Censored	Number at Risk	Observation Days	Total Hospital Days	Total Medical Care Days	Hospital Days Per Person-Month	Medical Care Days Per Person-Month
1	4,825	20,651	715,163	153,176	213,985	6.43	8.98
2	5,717	14,934	524,620	110,950	159,245	6.34	9.10
3	3,000	11,934	399,641	49,780	92,109	3.73	6.91
4	1,919	10,015	327,802	30,711	64,921	2.81	5.94
5	1,396	8,619	278,921	21,046	46,955	2.26	5.05
6	1,108	7,511	241,293	15,939	37,273	1.98	4.63
7	923	6,588	211,390	14,088	31,671	2.00	4.49
8	837	5,751	185,063	11,712	26,533	1.90	4.30
9	660	5,091	162,843	9,734	22,232	1.79	4.10
10	561	4,530	144,435	8,373	18,960	1.74	3.94
11	453	4,077	129,088	7,611	16,782	1.77	3.90
12	413	3,664	116,165	6,395	14,216	1.65	3.67

We next examined hospital days as a function of treatment received. Figure 1 presents the hospital and medical care days in the first 12 months of diagnosis for patients with locoregional pancreatic cancer, stratified by resection status. Also shown in the figure is the number of patients surviving to the beginning of each observation month. Two patterns are apparent. First, patients who underwent surgical resection had a higher number of hospital and medical care days during the first 4 months after diagnosis compared to those who did not undergo surgical resection, but were in the hospital less and required fewer days in medical care toward the end of the first year. As expected, patients who underwent surgical resection had a substantially longer survival, based on the numbers surviving to each observation period. At the

beginning of the 12th month of diagnosis, 60.8% of resected patients were alive, compared to 20.4% of unresected patients.

Figure 1: Hospital Days and Medical Care Days for Patients with Locoregional Disease by Resection Status. Total days spent in medical care included any days the patient had a hospitalization, physician visit, underwent a diagnostic procedure or received therapeutic treatment. Hospital days are embedded within medical care days. The number of patients surviving to the beginning of each month is reported.



Number Surviving to the Beginning of Each Month

Month of Diagnosis	1	2	3	4	5	6	7	8	9	10	11	12
Resection	1999	1939	1831	1770	1707	1642	1561	1502	1424	1339	1269	1216
Non-resection	6153	5340	4276	3577	3121	2737	2410	2112	1833	1622	1414	1256

Because of the differences in survival, we stratified by survival duration of 0-3 months, 3-6 months, 6-12 months, and ≥ 12 months (Figure 2A-D). These represent mutually exclusive groups of patients. Hospital and medical care days per month of life were higher in patients with shorter survival. In each of the survival subgroups, patients were in the hospital more often immediately after diagnosis and again immediately prior to death. Again, patients with locoregional pancreatic cancer who underwent surgical resection had more hospital and medical care days immediately after diagnosis when compared to unresected patients. For example, patients who underwent surgical resection for locoregional disease and survived greater than 12 months had a mean of 2.4 days in the hospital per month for the first year, compared to 1.6 days for unresected patients.

Figure 2: Hospital Days and Medical Care Days for Patients with Locoregional Disease by Resection Status and by Duration of Survival (A: 0-3 months, B: 3-6 months, C: 6-12 months, ≥ 12 months). Total days spent in medical care included any days the patient had a hospitalization, physician visit, underwent a diagnostic procedure or received therapeutic treatment. Hospital days are embedded within medical care days.

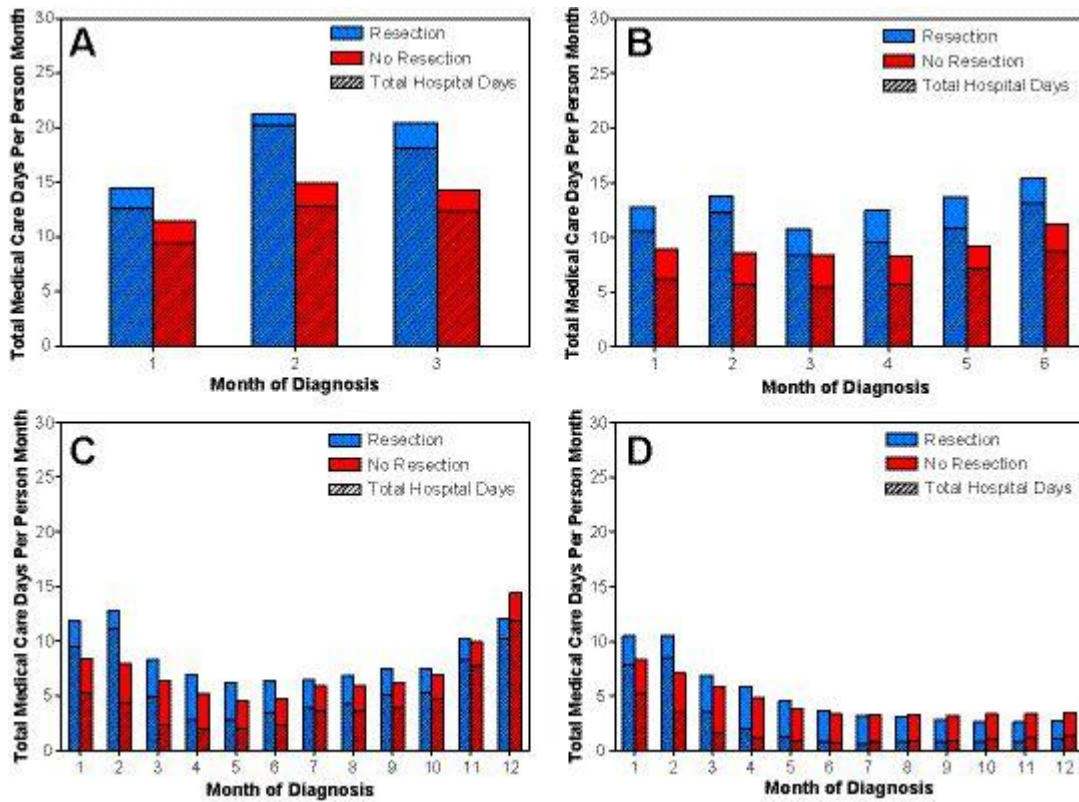
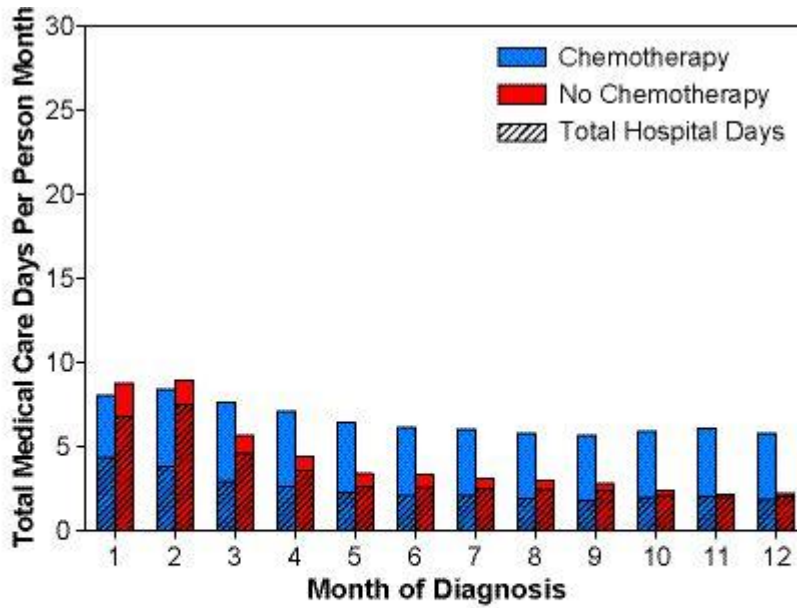


Figure 3 presents the hospital and medical care days in the 12 months after diagnosis for patients with distant and unknown stage pancreatic cancer, stratified by chemotherapy status. Again, the number of patients surviving to the beginning of each observation month is reported. At the beginning of the 12th month of diagnosis, 20.0% of patients who received chemotherapy were alive, compared to 5.1% of patients who did not receive chemotherapy. Hospital and medical care days per month for these patients decreased modestly until the 5th month after diagnosis. As the time from diagnosis increased for the group of patients with distant and unknown stage disease, days in the hospital decreased to approximately 2 per month regardless of chemotherapy status. However, days in medical care remained significantly higher for patients undergoing chemotherapy. In all survival subgroups hospital and medical care days were more frequent immediately prior to death (Figure 4A-D). Total days in medical care increased throughout the duration of survival and especially at the end of life in those receiving chemotherapy.

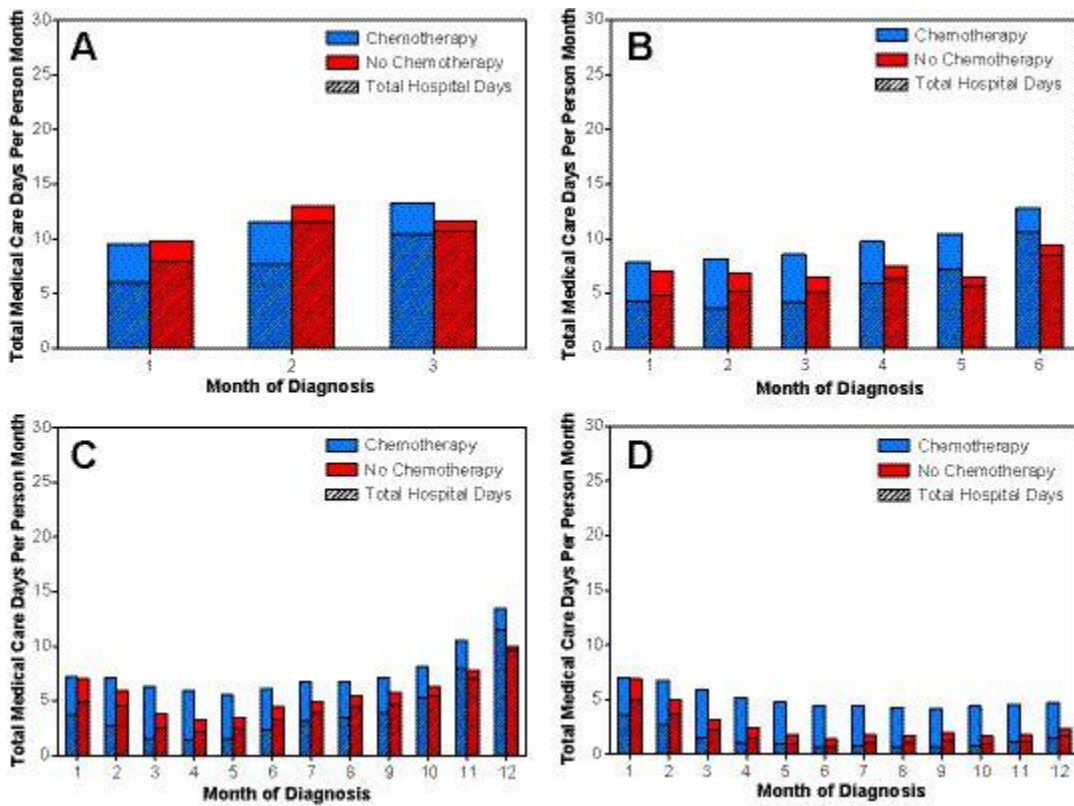
Figure 3: Hospital Days and Medical Care Days for Patients with Distant/Unknown Stage Disease by Chemotherapy Status. Total days spent in medical care included any days the patient had a hospitalization, physician visit, underwent a diagnostic procedure or received therapeutic treatment. Hospital days are embedded within medical care days. The number of patients surviving to the beginning of each month is reported.



Number Surviving to the Beginning of Each Month

Month of Diagnosis	1	2	3	4	5	6	7	8	9	10	11	12
Chemotherapy	4871	4736	4163	3498	2937	2456	2118	1799	1524	1300	1125	976
Non-chemo	12453	8636	4664	3089	2250	1784	1422	1175	970	830	722	629

Figure 4: Hospital Days and Medical Care Days for Patients with Distant/Unknown Stage Disease by Receipt of Chemotherapy and by Duration of Survival (A: 0-3 months, B: 3-6 months, C: 6-12 months, ≥ 12 months). Total days spent in medical care included any days the patient had a hospitalization, physician visit, underwent a diagnostic procedure or received therapeutic treatment. Hospital days are embedded within medical care days.



Chapter 4: Discussion

Our study is the first to use population-based data to comprehensively describe and quantify hospital and medical care days in patients with pancreatic cancer, stratified by stage, treatment, and duration of survival. Previous studies have focused almost entirely on the survival benefit of various treatment strategies. Our study attempts to examine two factors that impact patients' lives after a diagnosis of pancreatic cancer: hospital days and days spent in medical care. Such information may be useful in decision-making regarding various treatment strategies.

For the overall cohort with pancreatic cancer, patients were in the hospital an average of 6.4 days in the first month after diagnosis. The longer a patient survived, the fewer days he or she spent in the hospital. This was evidenced by a decline in hospital days per person-month over the first year, and, in particular, the first three months. In all cases hospital and medical care days increase at the end of life.

For patients with locoregional disease, those who underwent curative-intent resection experienced more hospital and medical care days during the first four months after diagnosis compared to patients who did not undergo resection. This is likely a result of their hospital admission for surgery, postoperative care, and possible complications. In those who survived more than 6 months, unresected patients were admitted more often at the end of life when symptoms of pain and biliary and enteric obstruction are at their worst. Bao et al. have developed a prediction rule based on preoperative tumor characteristics to predict patients who are likely to benefit from surgical resection.¹¹ Using this information, those patients who are expected to survive long-term after surgical resection should be offered surgery, whereas patients who might not survive longer than a few months should perhaps be spared a morbid surgery and a high number of hospital and medical care days during their survivorship experience.

For distant and unknown stage disease, patients receiving chemotherapy were in the hospital less often over the first three months, with an increase in hospital and medical care days at the end of life. These findings are in concordance with our previous results, which noted an increase over time in the use of ICU care and chemotherapy at the end of life in Medicare beneficiaries dying of pancreatic cancer, with a concomitant decrease in early hospice enrollment (≥ 4 weeks prior to death).¹²

Previous studies analyzed three main quality of life measurements (health status, functional status, symptoms) for patients with pancreatic cancer using the EORTC QLQ-C30 questionnaire.¹³⁻¹⁵ Other studies have used similar scales (physical, social, psychological, emotional) when mailing a quality of life questionnaire to survivors of pancreatic cancer who had undergone pancreaticoduodenectomy.^{9, 16, 17} In general, these studies demonstrated that quality of life was similar for patients after completion of treatment compared to patients without cancer. However, these studies were limited to long-term survivors, had small sample sizes, and excluded a large portion of patients who survive only a few months, when quality of life may be at its worst. In addition, comparisons are to healthy controls rather than to patients with pancreatic cancer undergoing alternative treatments.

Currently, there are no decision-making tools available for physicians and patients with pancreatic cancer. For breast, colon, and lung cancer, physicians may access Adjuvant! Online for assistance in making treatment decisions (<http://adjuvantonline.com/index.jsp>). This website allows physicians to enter information regarding age, sex, comorbidities, tumor size and differentiation, and lymph node status. As a result, information is given regarding stage, 5-year mortality, and risk reduction with various treatment modalities.¹⁸

The information obtained in our study is not unexpected. For example, we would expect that patients who undergo surgical resection would be in the hospital more often than those who do not have surgery in the months after diagnosis, or that the longer the duration of survival, the less time would be spent in the hospital. However, our study is the first to quantify hospital days and days in medical care experienced by patients with pancreatic cancer. In addition to information regarding long-term survival, patients can now understand the potential impact of treatment on their experience and expectations may be more realistic. Providing information on hospital and medical care days based on a patient's stage and treatment options can help patients and treating physicians make decisions regarding management that are based on personal preferences.

Our study has several limitations. In our analysis, patients were censored when they died or entered hospice, as these patients would no longer contribute any information about hospital and medical care days. We did not take into account patients who entered hospice and subsequently withdrew. In addition, we designated the day of diagnosis as the first day of the month, as SEER does not provide the exact day of diagnosis. This was done so that we would not miss any hospital admissions. This would overestimate the number of observed days and underestimate the number of hospital days in the first month. For every period thereafter, this is not an issue.

We did not attempt to control for selection bias in our study. For example, patients who undergo surgical resection for locoregional disease have improved survival, but this is likely due to a combination of the benefit of resection and the better health status of patients who are offered surgery. Similarly, patients who did not receive chemotherapy for distant disease were in the hospital more often; this may be a result of disease progression without chemotherapy or

poorer performance status in patients who were not offered chemotherapy. However, this descriptive study likely accurately reflects real-life decision-making, with patients who are more fit for aggressive therapy being more likely to be offered such therapy.

Chapter 5: Conclusion

The goal in the treatment of pancreatic cancer should be to balance the quantity and quality of life according to individual preferences. Our study is the first to use national, administrative data to quantify hospital and medical care days in patients with pancreatic cancer and to assemble this information in a useful format. This information, in combination with specific patient preferences and predicted survival, can help patients with pancreatic cancer and their physicians make the best treatment decisions. Having realistic expectations after a diagnosis of pancreatic cancer will allow patients to make decisions based on personal preferences that will maximize both their quality and quantity of life.

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Vita

Dr. Boyd was born on August 29, 1983 in Austin, Texas to parents Robert and Patricia Boyd. She completed her Bachelor of Science degree at the University of Illinois at Urbana-Champaign, where she was a 4-year member of the Varsity Women's swim team. During her time at Illinois, Dr. Boyd was a 2-time winner of the Illini Spirit Award, Allen B. Klingel Academic Award winner, and Outstanding Female Scholar Athlete Award winner (given to the senior athlete with the highest GPA). Upon graduating, she returned to Ohio and received her Medical Degree from The Ohio State University College of Medicine. During medical school, Dr. Boyd was a member of the Inter-Professional Council, the Gold Humanism Honor Society, and Honor and Professionalism Council. Dr. Boyd then matched into a general surgery residency at the University of Texas Medical Branch, and has completed two years of clinical residency. She is now in her second of two years of dedicated research time in the surgery department under Dr. Taylor Riall. So far during her research time, Dr. Boyd has authored or co-authored one book chapter and four published manuscripts, with several others in progress. She has become a member of the American College of Surgeons, Association for Academic Surgery, American Hepato-Pancreato-Biliary Association, Society for Surgery of the Alimentary Tract, and UTMB Translational Research Scholars Program. In February 2011, Dr. Boyd presented her manuscript entitled "415 Patients with Adenosquamous Carcinoma of the Pancreas: A Population-Based Analysis of Prognosis and Survival" at the Academic Surgical Congress (ASC). Shortly after, she presented at the annual American Hepato-Pancreato-Biliary Association meeting. She is planning on presenting at the ASC for the second time in February 2012. In June 2011, Dr. Boyd was awarded second place in the Singleton Surgical Society

Clinical Research competition. Dr. Boyd will return to her clinical residency in July 2012 and hopes to eventually pursue a fellowship in Surgical Oncology.

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