



Patterns of care, predictors, and outcomes of chemotherapy in elderly women with early-stage uterine carcinosarcoma: A population-based analysis



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HIGHLIGHTS

- Few patients with early-stage uterine carcinosarcoma received adjuvant chemotherapy.
- Patterns of treatment did not change over the duration of the study period.
- Chemotherapy was not associated with an improved overall survival.

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ABSTRACT

Objective. To examine the patterns of care, predictors, and impact of chemotherapy on survival in elderly women diagnosed with early-stage uterine carcinosarcoma.

Methods. The Surveillance, Epidemiology, and End Results (SEER)-Medicare database was used to identify women 65 years or older diagnosed with stage I–II uterine carcinosarcomas from 1991 through 2007. Multivariable logistic regression and Cox-proportional hazards models were used for statistical analysis.

Results. A total of 462 women met the eligibility criteria; 374 had stage I, and 88 had stage II uterine carcinosarcomas. There were no appreciable differences over time in the percentages of women administered chemotherapy for early stage uterine carcinosarcoma (14.7% in 1991–1995, 14.9% in 1996–2000, and 17.9% in 2001–2007, $P = 0.67$). On multivariable analysis, the factors positively associated with receipt of chemotherapy were younger age at diagnosis, higher disease stage, residence in the eastern part of the United States, and lack of administration of external beam radiation ($P < 0.05$). In the adjusted Cox-proportional hazards regression models, administration of three or more cycles of chemotherapy did not reduce the risk of death in stage I patients (HR: 1.45, 95% CI: 0.83–2.39) but was associated with non-significant decreased mortality in stage II patients (HR: 0.83, 95% CI: 0.32–1.95).

Conclusions. Approximately 15–18% of elderly patients diagnosed with early-stage uterine carcinosarcoma were treated with chemotherapy. This trend remained stable over time, and chemotherapy was not associated with any significant survival benefit in this patient population.

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Introduction

Uterine carcinosarcoma is a rare gynecologic malignancy, with incidence of fewer than three per 100,000 women per year [1]. Although carcinosarcoma used to be considered a type of uterine sarcoma, this malignancy has recently been reclassified as a dedifferentiated or

metaplastic form of endometrial carcinoma [2]. However, carcinosarcomas behave more aggressively than the most undifferentiated of the ordinary type of endometrial carcinoma [3]. Compared to endometrial adenocarcinoma, carcinosarcomas are more likely to present with advanced stage disease at the time of diagnosis [4]. Furthermore, recurrence rates for carcinosarcoma are approximately 50%, and survival is poor even when the tumor is limited to the uterine corpus [5].

Because most patients' recurrences are distant, the National Comprehensive Cancer Network guidelines recommend adjuvant chemotherapy as a treatment option in patients diagnosed with early-stage uterine carcinosarcoma [6]. The Gynecologic Oncology Group (GOG)

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150 study showed that chemotherapy was associated with better survival than whole abdominal irradiation, but this difference was not statistically significant, and the study included all stages of uterine carcinosarcoma [7]. Moreover, given that women over the age of 65 account for nearly 50% of diagnosed uterine carcinosarcoma in the United States [5] and that often such patients have medical comorbidities and poor performance status, many patients may be at high risk for chemotherapy-related toxicity [5]. Thus, the objectives of this study were to determine the frequency of use of chemotherapy for treatment of elderly women diagnosed with early-stage uterine carcinosarcoma, assess changes in treatment over time, and determine the predictors and outcomes of chemotherapy. To accomplish these goals, we used a large cohort derived from the Surveillance, Epidemiology, and End Results (SEER)-Medicare database of the National Cancer Institute.

Methods

Study cohort

SEER is a population-based cancer registry that collects information on all incident cancers. The Medicare database includes data on patients with Medicare part A (inpatient) and part B (outpatient), including billed claims and services [8]. Eligible patients for this study were those diagnosed at the age of 65 years and older with primary uterine carcinosarcoma between January 1, 1991 and December 31, 2007. Only patients diagnosed with stage I or stage II uterine carcinosarcoma who underwent a cancer-directed surgery (hysterectomy) were included in the analysis. We excluded patients who were members of a Health Maintenance Organization at any point in the 12-month period before and after their cancer diagnosis, those enrolled in Medicare because of end-stage renal disease and dialysis, and patients with other primary tumors. This study was exempted from review by the Institutional Review Boards of Washington University School of Medicine and Wayne State University School of Medicine.

Data extraction

Age at diagnosis was classified into five-year intervals. Stage was assigned from the recorded extent-of-disease codes according to the revised 2009 International Federation of Gynecology and Obstetrics staging criteria for endometrial cancer. Surgical procedure data were derived from site-specific surgery codes. Data concerning the performance of lymph node dissection and lymph node metastasis were derived from pathology codes. Information on use of adjuvant external beam radiation therapy and vaginal brachytherapy was collected. Medicare claims files (physician [NCH], outpatient [OUTPAT], and hospital [MEDPAR]) were used to identify receipt of chemotherapy within six months of cancer diagnosis. Receipt of fewer than three months and three or more months of chemotherapy was separately recorded for purposes of stratification. We used the Healthcare Common Procedure Coding System (HCPCS) codes to identify patients who had received a specified chemotherapeutic drug within 180 days after their cancer diagnosis. For patients who did not have specific chemotherapy HCPCS codes, we used HCPCS codes (J8510, J9999, 964XX, 965XX, Q0083–85, Q0163–Q0185, G0355–G0363), ICD-9-CM diagnostic codes (V581, V662, V672), procedure or surgery codes (9925), and codes from the 2005 Medicare oncology demonstration project to capture any evidence that an unspecified chemotherapeutic drug was administered. Socio-economic status of each patient was evaluated by describing the education and income level of the census tract in which the patient resided at the time of diagnosis. We included a modified version of the Charlson comorbidity index, which was based on the ICD-9 diagnostic and procedure codes as well as on the HCPCS codes for ten conditions, captured in the 12-month period before cancer diagnosis [9,10]. Area of residence was categorized as urban or rural, and the registry in which each patient was recorded was noted. Each patient's vital status (alive vs. dead) was

recorded. Because of Medicare confidentiality rules, we could not show data in which cells contained fewer than 11 patients (denoted by * in Table 1). In cases where a number less than 11 could be deduced by providing a related number, data were suppressed (denoted by ** in Table 1).

Statistical analyses

The distribution of demographic and clinical characteristics between patients diagnosed with stage I and stage II uterine carcinosarcomas was compared by using Chi-square tests. Multivariable logistic regression models were developed to examine the predictors of chemotherapy, external beam radiation, and vaginal brachytherapy. The Kaplan-Meier method was used to compute survival probability data, and the log-rank test was used to compare differences between groups. Cox proportional hazards regression models were developed to examine overall survival while controlling for other clinical and demographic characteristics. SAS 9.3 (SAS Institute Inc., Cary, North Carolina) was used for all statistical analyses. All *P*-values reported are two-tailed, and a *P*-value of less than 0.05 was considered to be statistically significant.

Results

Patients

A total of 462 women met the eligibility criteria. Of these, 374 had stage I, and 88 had stage II uterine carcinosarcomas (Table 1). The mean age of the patients was 76 years (range: 66 years–93 years). The majority of the patients were white and resided in urban areas. The geographic distributions of the patients were as follows: 19% from the northeast, 25% from the midwest, 41% from the west, and 14% from the south. A large portion (31%) of the patients had comorbidities as determined by a modified Charlson co-morbidity index score equal to or greater than one. Lymphadenectomy was performed in 66% of the patients. Adjuvant external beam radiation was administered in 41% of the patients. Only 16% of the patients received adjuvant chemotherapy; 40 of these 76 patients received a platinum agent either alone or in combination with other cytotoxic agents. Most patients who received platinum agents were treated with a doublet ($n = 29$), the most common of which was platinum in combination with taxanes such as paclitaxel or docetaxel. The type of chemotherapy administered in the remaining 36 patients was either unspecified or included a non-platinum based regimen.

Clinical and demographic characteristics were compared between stage I and stage II patients (Table 1). More patients with stage II than with stage I uterine carcinosarcoma underwent a lymphadenectomy or received adjuvant treatment with chemotherapy, vaginal brachytherapy, or external beam radiation. Overall, the use of chemotherapy for patients with early stage uterine carcinosarcoma did not change significantly over time (14.7% in 1991–1995; 14.9% in 1996–2000; and 17.9% in 2001–2007; $P = 0.67$). Similarly, the rates of administration of external beam radiation did not differ over time for these patients (40.5% in 1991–1995; 37.2% in 1996–2000; and 42.1% in 2001–2007; $P = 0.72$). In contrast, the use of vaginal brachytherapy increased over time (11.2% in 1991–1995; 19.2% in 1996–2000; and 21.8% in 2001–2007; $P = 0.05$), but this change was not statistically significant.

Predictors of use of adjuvant therapy

We used multivariable logistic regression to analyze the predictors of receipt of adjuvant chemotherapy (Table 2). Age, location of SEER registry, stage, and receipt of adjuvant external beam radiation emerged as significant independent predictors. Women ≥ 75 years of age were less likely to be treated with chemotherapy, as were those who received external beam radiation for treatment of their uterine carcinosarcoma.

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