



The impact of adjuvant vaginal brachytherapy in women with Stage II uterine endometrioid carcinoma: Results of a National Cancer Database analysis

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ABSTRACT

PURPOSE: To report survival outcomes in women with Stage II uterine endometrioid carcinoma who received adjuvant radiation therapy (RT) without chemotherapy using the National Cancer Database.

METHODS AND MATERIALS: The National Cancer Database was queried for women with International Federation of Gynecology and Obstetrics Stage II uterine endometrioid carcinoma who underwent hysterectomy followed by adjuvant RT without chemotherapy. The χ^2 tests were performed to compare differences in outcome by type of adjuvant RT (external beam radiation therapy [EBRT] alone, vaginal brachytherapy [VBT] alone, or combination of EBRT and VBT). Overall survival (OS) was assessed by Kaplan–Meier and log-rank tests. Univariate and multivariate analyses were performed to identify predictors of OS.

RESULTS: We identified 2681 women. Simple hysterectomy was performed on 2261 women (84%). Adjuvant EBRT, VBT, and combination RT were administered to 27%, 36%, and 37%, respectively. There was a statistically significant difference in OS by modality of adjuvant RT ($p = 0.01$) favoring women who received VBT alone or in combination with EBRT. The 5-year OS was 80%, 87%, and 83% for women who received EBRT, VBT, and combination RT, respectively ($p = 0.001$). On multivariate analysis, old age, African-American race, no or fewer number of examined lymph nodes, and higher tumor grade were independent predictors of worse OS. RT modality did not sustain its independent prognostic significance as a predictor of OS.

CONCLUSIONS: In this nationwide hospital-based study of women with International Federation of Gynecology and Obstetrics Stage II uterine endometrioid carcinoma, adjuvant VBT alone provided excellent survival outcomes and may be a reasonable adjuvant RT modality for properly selected women with adequate lymph node dissection and low-grade tumors. © 2017 American Brachytherapy Society. Published by Elsevier Inc. All rights reserved.

Keywords:

Endometrial carcinoma; Stage II; NCDB; Brachytherapy; Hysterectomy; Prognosis; Survival

Introduction

The most common gynecologic malignancy in the United States is endometrial carcinoma (EC) with an

estimated incidence in 2016 of 60,050 new cases and 10,470 deaths (1). Most women are diagnosed with early-stage disease with endometrioid histology representing over 85% of these cases (2).

Prognostic factors and survival outcomes in women with International Federation of Gynecology and Obstetrics (FIGO) Stage II EC have often been analyzed together with Stage I disease in previous studies due to its low incidence (3, 4). Although useful, previous studies for women with Stage II EC also included women with nonendometrioid histologies (5, 6) and women with endocervical glandular

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involvement without cervical stromal involvement (5, 7–9), which is no longer considered Stage II based on the revised FIGO staging system, which restricts the diagnosis of Stage II EC to invasion of the cervical stroma (10).

Because of its efficacy in reducing vaginal cuff recurrence together with its associated favorable quality of life, multiple studies including American Brachytherapy Society Surveys have found an increasing trend for the use of adjuvant vaginal brachytherapy (VBT) in women with early-stage EC (11–13).

A multiinstitutional study of women with strictly 2009 FIGO Stage II disease, solely of endometrioid histology, showed similar survival outcomes with adjuvant VBT compared with those who received pelvic external beam radiation therapy (EBRT) (14). Other smaller studies similarly showed that adjuvant VBT alone may be an adequate treatment in women with Stage II EC (8, 15–17).

We sought to further examine the impact of adjuvant VBT in a larger cohort of women using a nationwide hospital-based registry. Specifically, our aim was to investigate the impact of adjuvant RT modality on overall survival (OS) in women with EC, solely of endometrioid histology.

Methods and materials

The National Cancer Database (NCDB) is a nationally recognized clinical oncology database jointly sponsored by the American College of Surgeons and the American Cancer Society and serves as a powerful surveillance and quality improvement mechanism for participating cancer programs (18). Hospital registry data are collected from more than 1500 Commission on Cancer–accredited facilities, and approximately 70% of de novo cancer diagnoses in the United States are captured.

We only included women aged 18 years or older with a single primary diagnosis of 2009 FIGO Stage II uterine EC between 2004 and 2012 in our study, after converting all historical versions of the American Joint Committee on Cancer stages to the revised FIGO staging system (10). Only endometrioid histology was included with the following primary sites codes (C54–C55.9): 8050, 8070, 8140, 8255, 8260, 8380–8383, 8480–8481, 8560, and 8570.

All women underwent surgical staging with different types of hysterectomies. Women who underwent subtotal hysterectomy or those who had positive margins (macroscopic or microscopic) were excluded.

Adjuvant RT (pelvic EBRT, VBT, or combination RT) was administered to all women included in our study. We defined adequate adjuvant RT as treatment received within a maximum of 6 months postoperatively within a total treatment duration not exceeding 8 weeks and with pelvic EBRT dose range of 40–54 Gy.

Other exclusion criteria included women with multiple primary malignancies, those who received neoadjuvant or intraoperative RT, those who received neoadjuvant or

adjuvant chemotherapy (CT), and those without known vital status or missing disease tumor grade.

The overall demographic and clinical characteristics included for analysis were as follows: age, race (white, black, or other), comorbidity score grouping (0, 1, 2), type of hysterectomy performed (simple, radical/modified radical, or hysterectomy not otherwise specified), lymph node (LN) dissection status (yes or no), total number of LNs examined (including pelvic and paraaortic LNs) as a continuous variable or dichotomized to 10 or less LNs or > 10 LNs, tumor grade (1, 2, 3, or 4), lymphovascular space invasion (LVSI) (negative, positive, or unknown), and modality of adjuvant RT (pelvic EBRT, VBT, or combination RT). Per NCDB definition of tumor grade, Grades 1–4 are defined as well-differentiated, moderately differentiated, poorly differentiated, and undifferentiated histology, respectively. OS was calculated for all cases from the date of diagnosis until death.

All statistical analyses were performed using Statistical Analysis Software, version 9.4 (SAS Institute, Inc., Cary, NC). The χ^2 tests were performed to analyze differences in distribution of variables by modality of adjuvant RT and type of hysterectomy and with the generation of two-sided *p*-values. Statistical significance was defined at an α value of ≤ 0.05 . Survival outcomes were assessed by Kaplan–Meier and log-rank tests. Univariate and multivariate analyses (MVA) were performed to identify statistically significant predictors of OS. Only variables with a *p*-value of < 0.2 on univariate analysis were selected for MVA.

Results

We identified 2681 women who met our inclusion criteria. The median followup time was 60 months (range, 47.7–62.2). Simple hysterectomy was the most commonly used type of hysterectomy in our study cohort (84%) compared with only 8% of patients who underwent radical or modified radical hysterectomy. VBT alone or in combination with pelvic EBRT was the most commonly used RT modality (36% and 37%, respectively). There were more patients in the VBT group who underwent LN dissection with a higher number of LNs examined compared with patients in the other two RT groups. In addition, patients in the VBT group were significantly associated with low-grade tumors and tumors with negative LVSI. Table 1 summarizes the patient demographics and clinical characteristics by RT modality.

There was a statistically significant difference in OS by modality of adjuvant RT in favor of patients who received VBT ($p = 0.010$) but not by type of hysterectomy ($p = 0.85$). The 5-year OS for women who received pelvic EBRT, VBT, or combination RT was 80% (95% confidence interval [CI] [82, 85]), 87% (95% CI [84, 90]), and 83% (95% CI [80, 86]), respectively ($p = 0.001$), as shown in Fig. 1. Looking at the OS difference between the different RT modality groups in patients who underwent LN

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