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Postoperative Radiotherapy for Endometrial Cancer: Treatment Results and Prognostic Factors

Öztun Temelli[1], Şimay Gürocak[1], Ersoy Kekilli[2], Kemal Ekici[1]

[1]Inonu University, Faculty of Medicine, Department of Radiation Oncology, Malatya, Turkey
[2]Inonu University, Faculty of Medicine, Department of Nuclear Medicine, Malatya, Turkey

Abstract

Introduction and Purpose: In this study, we aim to investigate the effects of the prognostic factors related to tumour, treatment, local and regional controls, overall survival, and disease free survival in postoperative radiotherapy patients.

Materials and Methods: Sixty-one patients admitted to suffering from adenocarcinom of endometrium were analyzed retrospectively following surgical operation, adjuvant radiotherapy, and brachytherapy. We evaluated the patients in trems of age, tumour differentiations, tumour stage, lymphovascular invasion, serosal invasion, myometrial invasion, endocervical invasion, adnex involvement, lymph node involvement, menopausal age, hypertension, diabetes mellitus, smoking history, parity, hormone replacement therapy, chemotherapy process, vaginal brachitherapy, the type and doses of radiotherapy and local relapses. Throughout our research, we studied how overall survival and disease-free survival are influenced by factors like age, stage, tumour differentiation, histological type, lymph node involvement, lymphovascular invasion (LVI), endocervical invasion, serosal invasion, menopausal age, hypertension, diabetes mellitus, smoking history, parity, hormone replacement therapy (HRT), operation type, depth of myometrial invasion, and adnexal involvement.

Results: Fifty three patiens (87%) were exposed to total abdominal hysterectomy+bilateral saphingo oohporectomy+bilateral pelvic lymp node dissection (TAH+BSO+BPLND), while 8 patients (13%) were exposed to TAH-BSO. Thirty patients were treated by conventional methods, 23 patients were treated by conformal methods. Eight patients were treated only by brachytherapy. The five-year overall survival rate was 80.3% and disease-free survival rate was found to be 77%. Two year overall survival rate was 93.4% and disease-free survival rate was 85.2%. It was noticed that serosal invasion (p=0.034) affect overall survival.

Conclusion: Postoperative radiation therapy is an effective and safe treatment option in endometrium cancer.

Key Words: Radiotherapy; Endometrium Cancer; Overall Survival; Disease Free Survival.

Endometrium Kanserinde Postoperatif Radyoterapi: Tedavi Sonuçları ve Prognostik Faktörler

Özet

Amaç: Bu çalışmayla postoperatif radyoterapi uygulanan hastalarda, tümöre ve tedaviye bağlı prognostik faktörlerin, lokal ve bölgesel kontrol, genel sağkalım ve hastalıksız sağkalım üzerindeki etkisinin araştırılması amaçlanmıştır.

Gereç ve Yöntemler: Adjuvan eksternal radyoterapi ve brakiterapi uygulanan 61 endometrium kanserli hasta retrospektif olarak değerlendirilmiştir. Hastaların yaşı, tümör diferansiasyonu, tümör evresi, lenfovasküler invazyon, seroza invazyonu, myometrial invazyon, endoservikal tutulum, adneks tutulumu, lenf nodu tutulumu, sigara kullanımı, hipertansiyon ve diyabet hastalığı, hormon replasman tedavisi alıp almaması, doğum sayısı, menopoz yaşı, kemoterapi durumu, vajinal brakiterapi, radyoterapi şekli ve dozları, lokal nüks değerlendirilmiştir.

Bulgular: Altmış bir hastanın 53'ü (%87) endometrioid adenokarsinom, 8'i (%13) ise diğer adenokarsinom (seröz, müsinöz, clear cell, mikst tip) histolojisine sahipti. Hastaların 53'üne (%87) Total abdominal histerektomi+ bilateral salfingooferektomi + bilateral pelvik lenf nodu diseksiyonu (TAH+BSO+BPLND), 8 hastaya (%13) sadece TAH+BSO yapılmış. Otuz hastaya konvansiyonel, 23 hastaya ise konformal radyoterapi uygulanmıştır. Sekiz hastaya ise eksternal radyoterapi uygulanmamış sadece brakiterapi uygulaması yapılmıştır. İki yıllık genel sağkalım %93.4; 5 yıllık genel sağkalım %80.3 olarak bulunmuştur. Ortalama sağkalım 51 aydır. Hastalıksız sağkalım 2 yıllık ve 5 yıllık sırasıyla %85.2 ve %77 olarak tespit edildi. Genel sağkalım üzerine, serozal invazyon olması (p=0.034) anlamlı bulundu.

Sonuç: Endometrium kanserinde postoperatif radyoterapi efektif ve güvenli bir yöntemdir.

Anahtar Kelimeler: Radyoterapi; Endometrium Kanseri; Genel Sağkalım; Hastalıksız Sağkalım.

INTRODUCTION

Endometrial cancer is the most common gynecologic malignancy in the United States and Europe. In Turkey, too, it is the most frequently seen gynecologic malignancy according to the 2009 data from the Department of Cancer. 75% of endometrial cancer is limited to the uterus at the time of diagnosis. Early recognition and good response to treatment have enabled an 84% of average 5-year survival in all cases (1). The real cause of endometrial cancer is unknown though unopposed oestrogen is often regarded as the main reason. Early menarche, late menopause, obesity, nulliparity, infertility, estrogen-secreting tumours, use of animal fat, family history, diabetes mellitus, exogenous oestrogen, and tamoxifen are among the known risk factors for hypertension. Surgery is the main treatment approach. In addition, adjuvant radiotherapy is a method that has been in use for many years. But adjuvant radiotherapy has not proved to be quite efficacious in preventing development of distant metastases and

providing satisfactory overall survival results though it is a successful method in locoregional control (2).
The aim of this study is to retrospectively examine the prognostic factors that influence the survival rates and results of adjuvant treatment of patients with endometrial cancer who underwent radiotherapy.

MATERIALS AND METHODS

Throughout the study, we had a retrospective evaluation of a total of 61 patients who, following their surgeries for endometrial carcinoma, had been admitted to Inonu University, Faculty of Medicine, Department of Radiation Oncology between December 2003 and December 2003 and received adjuvant external radiotherapy and brachytherapy. The ages of the patients ranged from 36 to 82 (median age: 59). Twenty-nine patients had stage 1, 6 had stage 2, and 26 patients had stage 3 cancer. We evaluated the patients in terms of prognostic factors like hypertension, diabetes, smoking, hormone replacement therapy, menopause age, parity etc. Table 1 shows the detailed data about the patients.

Table 1. Patient characteristics.

Characteristics of tumours		n=61 (%)
Stage	1	29 (47.5)
	2	6 (9.8)
	3	26 (42.6)
Grade	1	7 (11.5)
	2	25 (41)
	3-4	27 (44.3)
	Unknown	2 (3.3)
Types of pathology	Endometrioid	53 (86.3)
	Other (serous, mucinous, clear cell, mixed type)	8 (13.1)
Lymph node involvement	None	41 (67.2)
	Pelvic lymph node	16 (26.2)
	Para-aortic lymph node	14 (23)
Histopathology	Endoservical invasion	24 (39.3)
	Lymphovascular invasion	27 (44.3)
	Serosal invasion	4 (6.6)
	Myometrial invasion	15 (24.6)
	-<%50	46 (75.4)
	-≥%50	
	Adnex involvement	5 (8.2)
Menopausal age	Premenopausal	9 (14.8)
	Early ≤52	26 (42.6)
	Late ≥53	7 (11.5)
	Unknown	19 (31.1)
Hypertension	No	32 (52.5)
	Yes	21 (34.4)
	Unknown	8 (13.1)
Diabetes	No	38 (62.3)
	Yes	15 (24.6)
	Unknown	8 (13.1)
Smoking history	No	51 (83.6)
	Yes	4 (6.6)
	Unknown	6 (9.8)
Parity	≤1	13 (23.3)
	2-4	20 (32.8)
	≥5	20 (32.8)
	Unknown	8 (13.1)
Hormone replacement treatment	No	52 (85.2)
	Yes	2 (3.3)
	Unknown	7 (11.5)

Fifty-three of the 61 patients had radiotherapy after which 44 of these patients underwent intracavitary brachytherapy while only 8 patients needed vaginal intracavitary brachytherapy. External beam radiotherapy was performed with LINAC and Cobalt-60 devices. All patients were treated in the supine position. Throughout the process, the patients underwent conventional or conformal radiotherapy. The conventional radiotherapy area covered all the pelvis from below the L5-S1 level to the bottom of the obturator foramen and 1-2 cm outward from the bone structures, including the regional lymphatics on the sides. In patients with vaginal involvement, we needed go down below the level of tuberositas ischium. The area we worked on was limited to the front of the symphysis pubis and the back of mid sacrum. We regarded the vaginal cuff, paravaginal and parametrial tissues, proximal vagina, and regional lymphatics as CTV in patients to whom we applied

conformal radiotherapy. PTV was defined as CTV+1cm.The radiotherapy dose was between 4500cGy and 5040cGy (average: 4760). The fraction dose was 180cGy and 200cGy. The upper area limit started from the bottom of the T12-L1 vertebral junction in patients who underwent paraaortic radiotherapy. The paraaortic radiotherapy dose was limited to 4500-4600cGy. The spinal cord dose was limited to 4600cGy in the patients taking paraaortic radiotherapy. The brachytherapy application was performed after the external beam radiotherapy. The brachytherapy sessions were carried out by using HDR-afterloading that contained ridium 192 source. The brachytherapy therapy had 3-6 fractions, each fraction having set at 600cGy.

To calculate the overall survival time, we estimated the time between admittance to hospital and the exitus. For the patients we could not reach, we tried to contact them by phone calls or get information about them from the hospital data system. To calculate the disease-free survival time, we considered the recurrence date in patients with recurrence due to local and regional reasons; the metastasis development date in patients who developed metastasis; date of death for the patients who died throughout the process; and the date of the last follow-up in the patients the latest situation of whose we could not retrieve. We used the Radiation Therapy Oncology Group (RTOG) scale to evaluate the adverse effects. To perform the statistical evaluation of the obtained findings, we used SPSS for Windows (Statistical Package for Social Sciences) 13.0 software. To assess the findings, we made use of mean, standard deviation, and frequency values as descriptive statistical measures and the Log Rank test for Kaplan-Meier survival analysis and comparisons. P<0.05 value was considered statistically significant.

RESULTS

The median follow-up time of our study was 36 months (6-107 months). In all the cases, the 1-year overall survival rate was 100%; 2-year overall survival rate was 93.4%; and 5-year overall survival rate was 80.3% (Figure 1). The survival times ranged from 7 months to 108 months. The median survival was 51.1±28 months. The disease-free survival time was 85.2% and 77% for 2 years and 5 years, respectively (Figure 2) while the mean disease-free survival was calculated as 36.5 months (4 - 107 months). The five-year overall survival times were 82.8%, 100%, and 73% in stages 1, 2 ,and 3, respectively (p=0.129). The five-year disease-free survival rates were 82%, 100%, and 65%, respectively.

Throughout our research, we studied how overall survival and disease-free survival are influenced by factors like age, stage, tumour differentiation, histological type, lymph node involvement, lymphovascular invasion (LVI), endocervical invasion, serosal invasion, menopausal age, hypertension, diabetes mellitus, smoking history, parity, hormone replacement therapy (HRT), operation type, depth of myometrial invasion, and adnexal involvement. The presence serosal invasion was the only statistically significant value in terms of overall survival (p=0.034). In terms of disease-free survival, we could not observe any notable results. In terms of factors affecting local control, we have found vaginal brachytherapy to be effective in preventing local recurrence.

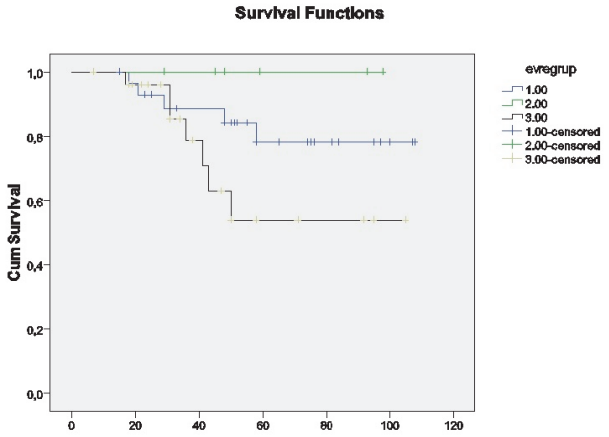

Figure 1. The stage-wise 5-year overall survival curve

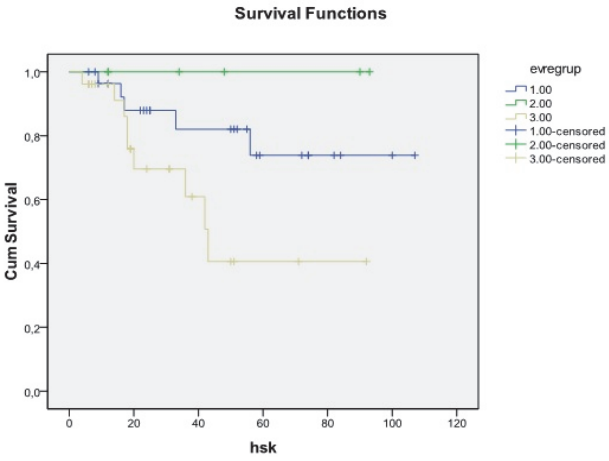

Figure 2. The stage-wise 5-year disease-free survival curve

The local recurrence rate of the patients undergoing brachytherapy was 7.7% while the same value for those who did not take the therapy was 22%. After the treatment, we have found local recurrence in 4 patients, locoregional recurrence in 2 patients, and pancreatic cancer as second primary cancer in 1 patient (1.6%). Thirteen of our patients developed distant metastases while 2 of these patients had additional local recurrence. The most common areas of metastasis were lung, bone, and soft tissues. 20 patients had post-operative adjuvant chemotherapy while for 7 patients we administered chemotherapy upon recurrence/metastasis. One of the patients who developed para-aortic lymph node metastases had to take paraaortic radiotherapy. After the treatment we lost a patient due to obstructive pulmonary disease, another patient due to liver cirrhosis, 13 other patients due to local-regional recurrence of endometrial cancer or distant metastasis, and 4 patients

as a result of cardiac causes. We used the Radiation Therapy Oncology Group (RTOG) scale to evaluate the side effects. Throughout the radiotherapy 12 patients had grade 1-2 gastrointestinal complaints (weight loss not exceeding 15%, inappetence, nausea and vomiting with that could be cured with antiemetics) and 8 patients had grade 1-2 genitourinary side effects like dysuria, haematuria, and incontinence. We did not observe any grade 3-4 adverse effects (necrosis, ulceration, haematuria requiring transfusion, or bladder obstruction). We recorded late side effects in four patients. Two of these patients had rectal bleeding while the other two had dysuria and haematuria.

DISCUSSION

Endometrial cancer is the most common gynecologic malignancy in the United States and Europe. In women, after breast, lung, and colorectal cancers, it is the 4th most common type of cancer. In Turkey, it is the 4th most frequently seen cancer in women according to the 2009 data from the Department of Cancer. It is the 8th most life-claiming cancer. Although it is seen in postmenopausal women between the ages of fifty and eighty-five, it is more common among people between 65 and 69.

The primary treatment method of endometrial cancer is surgery. The TAH-BSO surgery is the preferred method. The use of lymphadenectomy is controversial. Lymphadenectomy is valued in grade 3 diseases, advanced stages of the disease, or inappropriate histologic types (2, 3). A multidisciplinary approach is required in the treatment and other ways of treatment like adjuvant radiotherapy and chemotherapy may be necessary in reducing local and distant recurrence. The two big randomised studies, Gynecological Oncology Group (GOG-99) and Postoperative Radiation Therapy in Endometrial Cancer (PORTEC-1), have shown that radiotherapy is useful in local control though it does not provide overall survival benefits (4). Including 715 stage 1 endometrial cancer patients, PORTEC-1 have worked on two randomly organised groups: TAH+BSO and TAH+BSO+radiotherapy to show that the local recurrence rate in the radiotherapy group was 4% while the same rate was 14% in the other group. However, it was stated that there was no difference in overall survival rates between the two groups. Being over 60 years, grade 3 histology, and more than 50% of myometrium involvement were determined as high-risk factors. The presence of 2 of these 3 factors have been identified as high-risk groups. Among these patients, the 5-year local-regional recurrence rate was 5% in the radiotherapy group and 23% in the group that did not undergo radiotherapy (5).

GOG-99 has focused on 392 patients in stages 1B, 1C, and 2A patients. The patients have been divided into two random groups after TAH-BSO+BPLND+radiotherapy and TAH-BSO+BPLND operations. The study shows that there is less recurrence in the radiotherapy group (p=0.007) even though there were no statistically significant differences in terms of survival. This study defines two sets of risk groups: high and low. The risk factors include age, grade (2-3), stromal lymphovascular invasion, and deep myometrial invasion (more than 2/3). Patients over seventy with one of the risk factors, patients over fifty with two risk factors, and patients, free of age, with three independent risk factors are considered in high-risk group. The isolated vaginal recurrence rate in patients treated with radiotherapy was 1.6% while the same value was 7.4% in the control group (6).

In the ASTEC meta-analysis, 905 intermediate-risk and high-risk early-stage patients have been divided into surgery and surgery+adjuvant radiotherapy groups. The 5-year overall survival rate in both groups was 84%. It is clear that the adjuvant radiotherapy in this study did not have any effects on survival though it contributed to local control ($p<0.005$) (7). Even in two large studies like PORTEC 1 and GOG 99, the most common area for local recurrence is the vagina. This demonstrates the need to use vaginal brachytherapy alone and/or for an incorporation of vaginal brachytherapy with external irradiation.

PORTEC-2 study conducted among medium-high risk phases 1 and 2 endometrial cancer patients (over 60 years stage 1C grade 1-2 patients, stage 1B grade 3 patients, and stage 2A patients) compares brachytherapy alone to pelvic radiotherapy and states that both modalities provide perfect vaginal and pelvic control. The study shows no differences between the groups in terms of overall survival and disease-free survival. But the study also shows that grade 1-2 gastrointestinal side effects are greater in the external radiotherapy group (8). Vaginal brachytherapy, due to the fact that it causes less side effects than pelvic radiotherapy, is a good alternative for pelvic radiation therapy in patients requiring adjuvant radiotherapy.

The local recurrence rate in patients undergoing brachytherapy was 7.7% whereas the patients who could not take the therapy for various reasons shared a recurrence rate of 22.2%. Therefore, it can be said that brachytherapy is an effective treatment method for local control ($p<0.001$). The 5-year overall survival rate was 80.3% and the 5-year disease-free survival rate was 77% in our study. The median overall survival time was 51 months; the same parameter for disease-free survival was 36.5 months.

The stage of the tumour is the most important prognostic factor. As the stage increases, the survival decreases. In their study through which they performed postoperative adjuvant radiotherapy, Choi et al. have observed an 81.8% of 5-year survival in stage 1 patients, 62.9% of in stage 2 patients and 37% in stage 3 patients, respectively.

Buldanlı et al.'s study on 174 endometrial cancer patients reports 91.2%, 75.2%, and 17.4% 5-year survival rates in stage 1, 2 and 3-4 patients, respectively (1).

In our study, the 5-year survival rates were 82.8%, 100%, and 73.1% for stage 1, 2, and 3, respectively. It is clear that survival rate reduces in stage 3 patients. Meanwhile the percentage result for stage 2 patients is not reliable due to the fact that there were only 6 patients in this group (p=0.129).

Distant metastases, as it has been in many other studies, has been the most important failure pattern in our study. Indeed, it is he most common cause of death in endometrial cancer. The overall failure in this particular pattern has brought to mind other treatment modalities including chemotherapy (9).

In a meta-analysis conducted by Park et al., 1208 endometrial cancer patients were divided into adjuvant radiotherapy and adjuvant radiotherapy+chemotherapy groups. The study reveals that adding chemotherapy to adjuvant radiotherapy has had a positive impact on overall survival and disease-free survival in advanced stage patients (with a hazard ratio of 0.54 for overall survival, and 0.53 for disease-free survival) though this combination has not been effective on early stage patients (stages 1 and 2) (10).

Randall et al's study (GOG 122 study) compares 396 stage 3 and non-metastatic stage 4 patients through application of abdominopelvic radiation and doxorubicin-cisplatin-based chemotherapy. They have seen significant improvement in chemotherapy group in terms of progression-free survival and overall survival. However, they have reported increased toxicity along with increased pelvic failure rates. Sixty-month follow-up results of this study show 55% of patients alive in the chemotherapy group while this rate was 42% in the other group (11).

EORTC-55991 study including 372 phase 1, 2, 3A, and 3C patients has compared the patients in two groups: solely radiotherapy group and radiotherapy+adjuvant chemotherapy (pre-postradiotherapy) group. The chemotherapy in this study, however, was not set to a single standard; it was organised in four different ways. These were doxorubicin/cisplatin, paclitaxel/doxorubicin/cisplatin, paclitaxel/platinum, and paclitaxel/cisplatin/epirubicin. At the end of the study, they have observed an improvement of 7% in the chemotherapy group in terms of progression-free survival (79% vs. 72% after a 5-year follow-up, p=03) but no significant difference has been demonstrated in overall survival (82% vs. 74%; p=08) (12).

Chemotherapy improves progression-free survival and can be useful in advanced stage endometrial cancer patients in terms of progression-free survival and overall survival. But there is a need for new studies related to chemotherapy.

In our study, we have investigated the prognostic factors like stage, menopause age, age, type of operation, histological type, tumour differentiation grade, lymph node involvement, serosal invasion, lymphovascular invasion, myometrial involvement, adnexal involvement, and radiotherapy doses and administration methods. Only serosal invasion was found to be statistically significant. The studies in the literature reports the survival rate of patients with serosal invasion as 33.3% while the same rate for those without the invasion is 68.9%. In our study, these rates were 82.5% (without the invasion) and 50% (with the invasion), respectively, which is statistically significant (p=0,034).

Postoperative radiotherapy is an effective and safe method in endometrial cancer. Adjuvant therapy should be used to reduce local recurrence and distant metastasis. However, chemotherapy modalities should be developed for distant metastases. Lymph node dissection in surgery is controversial. There is certainly a need for more multicenter studies that should determine the location of lymphadenectomy, particularly in early stage endometrial cancer, in a well-designed (for example, researchers may work on specially designed - for each patient - standard para-aortic lymphadenectomy reaching down to the renal vein) manner in standardised centres.

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Correspondence/İletişim

Öztun TEMELLİ
Inonu University, Faculty of Medicine, Department of Radiation Oncology, MALATYA, TURKEY
E-mail: droztun@gmail.com

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