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Cervical cancer radiation therapy compliance rates based on location of radiation therapy

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HIGHLIGHTS

- Patients who underwent portions of their radiation therapy at different locations had protracted treatment courses.
- Patients who underwent all of their RT at one location finished their therapy an average of 16.4 days sooner.
- Patients with prolonged treatment courses who underwent RT at multiple locations had poorer overall survival.

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ABSTRACT

Objective. Completion of radiation therapy (RT) within 60 days has been proposed as a national quality measure for patients with carcinoma of the cervix as protracted RT has been associated with worse oncologic outcomes. The objective of this study was to compare compliance rates based on location of RT administration.

Methods. This was a retrospective chart review of patients diagnosed with cervical cancer between January of 2000 to December of 2016 who were planned to undergo primary treatment with sensitizing chemotherapy and RT. Patients who completed both external beam radiation therapy (EBRT) and brachytherapy (BT) at the primary institution were compared to patients who completed a portion or all of their RT elsewhere. The primary outcome measured was completion of RT within 60 days. Secondary outcomes included compliance with sensitizing chemotherapy, total radiation dose, recurrence rate, progression free survival (PFS) and overall survival (OS). The groups were compared using standard statistical analysis.

Results. This study included 100 patients, 75 of which received all of their RT at the primary institution. These patients were more likely to complete RT within 60 days when compared to patients who underwent RT at different facilities (58.7% vs 24%, respectively; $p = 0.005$). Patients who underwent all of their RT at the primary institution completed their therapy an average of 16.4 days sooner (75.1 ± 21.3 days versus 58.7 ± 13.2 days; $p = 0.001$). Overall survival was significantly improved in this group ($p = 0.03$).

Conclusion. Women who complete EBRT and BT at different institutions are more likely to have a protracted RT course (>60 days). These patients should be identified at diagnosis and efforts made to coordinate their care to avoid delays in treatment.

1. Introduction

The current treatment for locally advanced cervical cancer (Stage IB1-IVA) involves curative external beam radiation therapy (EBRT) with concurrent chemotherapy, followed by intracavitary brachytherapy (BT). Higher survival rates and local control are achieved when several quality indicators are applied. These quality indicators are endorsed by the Society of Gynecologic Oncology (SGO). The mainstay of these quality indicators include adequate radiation tumor dose and volume [1–3], limitation of overall treatment time to less than approximately 56–60 days [2,4,5], the use of brachytherapy [5,6], and administration of concurrent chemotherapy [5,7]. It has been demonstrated that patients treated according to specific clinical practice guidelines, regardless of stage, have a higher cancer-specific survival after five years when compared to nonadherence to these guidelines (88% vs 56%; $P < 0.001$) [8].

In our practice, many patients undergo external beam radiation (EBRT) and brachytherapy (BT) at different locations. Our objective was to compare rates of completion of radiation within 60 days (the suggested metric of the Commission on Cancer, [4]) among patients receiving treatment at one institution to those receiving treatment at multiple institutions. Secondary outcomes included compliance with

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sensitizing chemotherapy, completion of brachytherapy, total radiation dose, recurrence rate, and overall survival.

2. Materials and methods

A retrospective chart review was performed that included patients diagnosed with cervical cancer between January of 2000 to December of 2016 who were planned to undergo primary treatment with sensitizing chemotherapy, EBRT and BT at the primary institution (PI). Patients with locally advanced stage IB1-IVA cervical cancer who had established care with a gynecologic oncologist at the PI were included in this study. While the patients were seen at the PI they were often given the choice of several locations to undergo their radiation therapy and several patients opted to receive a portion of their RT at an outlying facility (OLF).

Eligible patients were identified by using the Oncology Registry Database. This database identifies reportable cancers using both national and state standards. Patients with cervical cancer were identified by using ICD-10 codes as well as pathology reports. Each case was then individually reviewed by certified tumor registrars to determine if these were new diagnoses. Patients who met criteria were then added to the database and followed for the duration of their life. Follow-up information was obtained from medical record review, coordination with the Columbus oncology associates database, and letters sent to primary physicians when necessary. Information regarding death was obtained from review of monthly death certificates for the state of Ohio. If information was not available, local obituary searches were performed as needed.

For patients who met inclusion criteria, a thorough chart review of histology, imaging, clinic notes, chemotherapy summaries, and radiation therapy summaries was performed. The distance to treatment facility was calculated using Google maps [9] with the patient's home address listed on their clinic chart at initial visit and the respective treatment facility. The distance in miles was recorded for the route with the shortest duration, regardless of the mileage.

Exclusion criteria included an incomplete record of radiation therapy, no available histologic diagnosis, histology other than squamous or adenocarcinoma, transfers of care, use of palliative radiation therapy rather than curative, previous hysterectomy or hysterectomy for initial cancer treatment with use of adjuvant therapy, and patients who did not complete or initiate RT due to medical complications or limitations.

Overall 209 charts were reviewed. Of these patients, 99 were excluded based on exclusion criteria. An additional ten patients were excluded as BT was not completed due to medical complications or limitations, indicating that completion of therapy was not related to compliance. BT was not completed in these ten patients for various reasons including difficulty with smit sleeve placement ($n = 3$), necrotizing fasciitis of the perineum ($n = 1$), debilitating stroke ($n = 2$), declining overall clinical status (n = 3), and sudden death (n = 1). The 100 patients that met inclusion criteria were divided into two groups for data analysis (Fig. 1).

The two groups consisted of those patients that had all of their radiation therapy (EBRT and BT) at the PI ($n = 75$) and those who had all or part of their radiation therapy (RT) at another institution ($n = 25$). All of the patients who underwent a portion of their RT outside of the PI completed their EBRT and BT at separate facilities.

Descriptive information on the study sample was tabulated using means, medians, standard deviations and ranges for numeric variables and percentages for nominal (categorical) variables. Univariate comparisons of demographic and clinical factors for the two groups (patients who received EBRT and BT at the PI and patients who received EBRT and/or BT at an OLF) were made using independent samples *t*-tests for continuous variables and chi-square tests for categorical data. For data that was not normally distributed (based on the Levene's test), independent samples *t*-tests not assuming equal variances or Wilcoxon rank sum tests were conducted. Statistical significance was based on traditional two-sided tests with the alpha error set at 5%. Statistical analyses were conducted using IBM SPSS Statistics version 19.0 (Armonk, NY).

Progression free survival (PFS) and overall survival (OS) were calculated using Kaplan Meier curves and *p* values estimated using log-rank tests. PFS and OS were calculated from the date of diagnosis.

3. Results

Demographic analysis of the two groups was performed. A significant difference in age was noted between the two groups with patients receiving all or part of their RT at an OLF being significantly older (59.1 $\pm$ 12.5 years versus 53.0 $\pm$ 13.6 years; $p = 0.047$). No statistically significant differences in marital status ($p = 0.545$), insurance coverage ($p = 0.537$), race/ethnicity ($p = 0.786$), or BMI ($p = 0.357$) were noted. See Table 1 for complete demographic data.

Tumor characteristics and stage were also similar between the two subgroups. A majority of tumors were squamous cell histology accounting for 80% ($n = 20$) of patients in the group who received part of their RT at an OLF and 84.0% ($n = 63$) of patients who received all of their RT at the PI. Tumor grade was also similar between the two groups ($p = 0.929$) with most tumors falling into the category of moderately to poorly-differentiated. The rate of concern for lymph node involvement

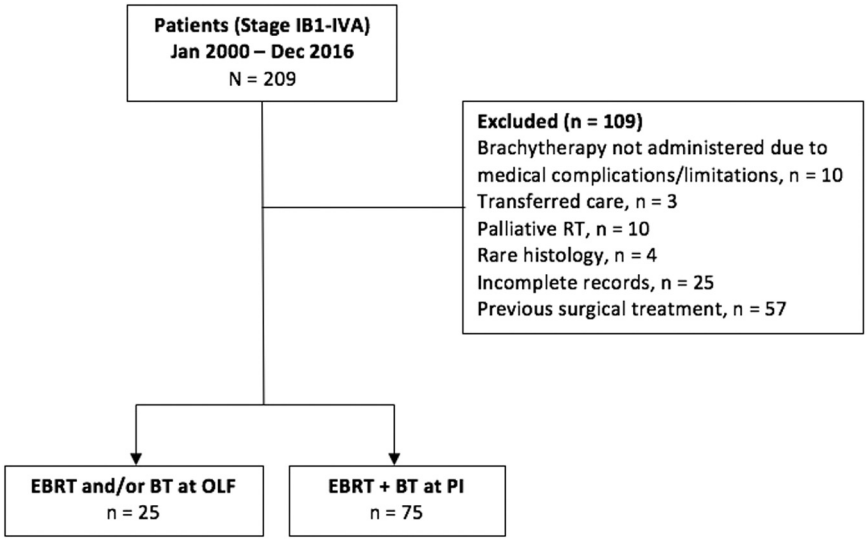

Fig. 1. Study Flowchart.

Table 1
Patient demographics and tumor characteristics.

	EBRT and/or BT at OLF (n = 25)	EBRT + BT at PI (n = 75)	p-value
Demographics			
Age, mean ± sd	59.1 ± 12.5	53.0 ± 13.6	0.047
Marital status, n (%)			0.545
Married	13 (52.0)	39 (52.0)	
Single	4(16.0)	15 (20.0)	
Divorced	6 (24.0)	10 (13.3)	
Widowed	2 (8.0)	11 (14.7)	
Race/ethnicity, n (%)			0.786
Hispanic/Latino	0 (0)	1 (1.3)	
Black/African American	2 (8.0)	5 (6.7)	
White/Caucasian	23 (92.0)	67 (89.3)	
Other	0 (0)	2 (2.7)	
Insurance coverage at diagnosis, n (%)			0.537
Medicaid	4 (16.0)	9 (12.0)	
Medicare	9 (36.0)	16 (21.3)	
Private insurance	10 (40.0)	39 (52.0)	
Uninsured	1 (4.0)	7 (9.3)	
Unknown/not specified	1 (4.0)	4 (5.3)	
BMI, mean ± sd	29.0 ± 8.6	30.9 ± 9.0	0.357
Tumor characteristics			
Histology, n (%)			0.704
Squamous cell	20 (80.0)	63 (84.0)	
Adenocarcinoma	5 (20.0)	11 (14.7)	
Carcinoma, NOS	0 (0)	1 (1.3)	
Grade, n (%)			0.929
Well-differentiated	2 (8.0)	5 (6.7)	
Moderately differentiated	8 (32.0)	25 (33.3)	
Poorly differentiated	7 (28.0)	25 (33.3)	
Undifferentiated	0 (0)	1 (1.3)	
Unknown	8 (32.0)	19 (25.3)	
Stage, n (%)			0.304
I	6 (24.0)	19 (25.3)	
II	7 (28.0)	32 (42.7)	
III–IV	12 (48.0)	24 (32.0)	
Lymph node involvement on imaging, n (%)	12 (48.0)	20 (27.0)	0.082
Lymph node involvement confirmed biopsy/surgery, n (%)	3 (12.5)	9 (12.2)	1.000

on imaging was higher in patients who received all or part of their radiation therapy at an OLF (48% versus 27%), however, this did not reach statistical significance ($p = 0.082$). Patients who received all or part of their RT at an OLF did have predominantly more advanced stage disease with 48% of patients having Stage III-Stage IVA disease compared to 32% of patients who received all of their RT at the PI. These differences did not meet statistical significance.

Patients who underwent all or part of their RT at an OLF lived significantly closer (mean of 13 ± 11.4 miles compared to 25.8 ± 22.9 miles; $p \leq 0.001$) to the facility providing EBRT but significantly further (mean of 53.9 ± 24.2 miles compared to 25.8 ± 23.1 miles; $p \leq 0.001$) from the BT facility when compared to patients who received all of their RT at the PI. The total mean dose of EBRT was similar between the two groups (45.5 ± 3.3 vs 45.1 ± 2.8; $p = 0.539$). The total mean dose of BT administered was also similar between the two groups (30.8 ± 5.2 vs 32.2 ± 4.7; $p = 0.278$). The administration of concurrent chemotherapy was also similar between both groups with a rate of approximately 92.3% in the group who received all or part of their RT at an OLF and a rate of 92.4% in patients receiving all of their RT at the PI ($p = 1.000$). Patients were more likely to receive intensity modulated radiation therapy if they received all or part of their RT at an OLF compared to patients who received all of their RT at the PI (24.0% vs 1.3%; $p = 0.001$). Pelvic wall boost RT rates were similar between groups ($p = 0.460$). See Table 2.

Patients who underwent all of their radiation therapy at the PI were more likely to complete their radiation therapy within the recommended 60 days than patients who had all or part of their radiation therapy at an OLF (58.7% vs 24%, respectively; $p = 0.005$). Patients who underwent all of their RT at the PI also completed their course of radiation therapy an average of 16.4 days sooner than patients who received all or part of their RT elsewhere (75.1 ± 21.3 days versus 58.7 ± 13.2 days; $p = 0.001$). While five year survival was increased in the group that received all of their RT at the PI (39.4% versus 28%), this difference did not meet statistical significance ($p = 0.344$). See Table 3.

Table 2
Treatment/facility.

Characteristic	EBRT and/or BT at OLF (n = 25)	EBRT + BT at PI (n = 75)	p-value
EBRT			
Distance to EBRT facility in miles, mean ± sd	13.0 ± 11.4	25.8 ± 22.9	<0.001
Total dose, mean ± sd	45.5 ± 3.3	45.1 ± 2.8	0.539
BT			
Distance to VBT facility in miles, mean ± sd	53.9 ± 24.2	25.8 ± 23.1	<0.001
Total dose, mean ± sd	30.8 ± 5.2	32.2 ± 4.7	0.278
Concurrent chemotherapy, n (%)	24 (92.3)	73 (92.4)	1.000
Cisplatin, n (%)	21 (91.3)	66 (97.1)	0.264
Total number of doses, mean ± sd	5.4 ± 0.9	5.5 ± 0.8	0.620
Use of IMRT, n (%)	6 (24.0)	1 (1.3)	0.001
Pelvic wall boost radiation therapy, n (%)	4 (16.0)	7 (9.3)	0.460

Progression free survival (PFS) was improved in patients who underwent all of their RT at the PI, however, this difference was not statistically significant ($p = 0.14$). See Fig. 2.

Overall survival (OS) was significantly improved in patients who received all of their RT at the PI ($p = 0.03$). See Fig. 3.

Median follow-up times were similar between the two groups with a median follow-up of 1099 days for patients who received a portion of their therapy at an OLF compared to a median follow up of 1573 days for patients who received all of their therapy at the PI ($p = 0.106$). See Table 3.

4. Discussion

This study demonstrated that patients who received all of their RT at one facility had a higher compliance rate (completion of radiation therapy in ≤60 days) than patients who received all or part of their radiation therapy at an OLF. Overall, patients who received all of their RT at the PI finished their therapy an average of 16.4 days sooner than patients who received RT elsewhere. All patients treated at the primary facility completed radiation in <10 weeks whereas patients who had treatment at outside facilities took up to 13 weeks.

Several studies have demonstrated that toxicity-related delays are the most common reason for a delay in treatment accounting for 20–57.4% of delayed therapy. However, the second most common

Table 3
Patient outcomes.

Characteristic	EBRT and/or BT at OLF (n = 25)	EBRT + BT at PI (n = 75)	p-value
Diagnosis to complete treatment (days), mean ± sd	117.4 ± 37.0	99.1 ± 62.1	0.177
Median	105	88	
Completed therapy in <60 days, n (%)	6 (24.0)	44 (58.7)	0.005
Completed therapy in days, mean ± sd	75.1 ± 21.3	58.7 ± 13.2	0.001
Median	70	58	
5-year survival, n (%)	7 (28.0)	28 (39.4)	0.344
Time from radiation end to last follow up/death (days), mean ± sd	1201 ± 1235	2068 ± 1548	0.015
Median follow-up time in days (from time of diagnosis to last follow-up)	1099	1573	0.106

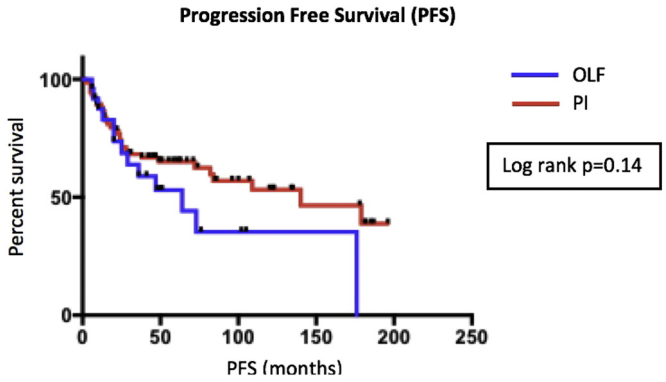

Fig. 2. Progression Free Survival; OLF: outlying facility; PI: primary institution.

cause of delayed therapy was secondary to patient non-compliance accounting for 7–11.5% of delays in treatment [10,11].

Our finding that many patients do not complete radiation within the suggested guidelines is not unexpected. Overall compliance rates for all types of cancer for RT are lower than other cancer treatment modalities such as surgery and chemotherapy [8]. Cervical cancer, in particular, was also a statistically significant predictor of noncompliance [12]. Other predictors of noncompliance included treatment during winter months, low socioeconomic status, and use of a long treatment course [12]. Previous studies have demonstrated several factors that have a statistically significant impact on adherence to clinical practice guidelines for cervical cancer including age, stage of cancer and distance to treatment facility [8]. The small, retrospective nature of this study makes it difficult to detect other factors; alternatively completing radiation outside of the PI may outweigh other factors. In addition, there are several other factors that could affect completion of therapy that were not specifically addressed in this study such as lower socioeconomic status, caregiver support, and several other comorbidities.

National guidelines to complete treatment within 8 weeks are based on improved pelvic control and disease specific survival noted in older studies prior to the combined chemo-radiation era [4,13–15]. There is limited data regarding the importance of time to completion of radiation after the introduction of sensitizing chemotherapy. Some studies suggest that prolonged treatment may impact both progression free survival (PFS) and overall survival (OS) [16], while others found it only impacts pelvic control [17]. Shaverdian et al. found that with the addition of chemotherapy, treatment duration did not impact treatment efficacy [18]. A large data base study found that there was no survival benefit to completing treatment in 8 weeks, but that women who had radiation treatment duration >10 weeks and >12 weeks had a 15% and 23% higher risk of death [19]. Our study did demonstrate significantly decreased recurrence rates in the group that received all of their RT at the PI. Five year survival

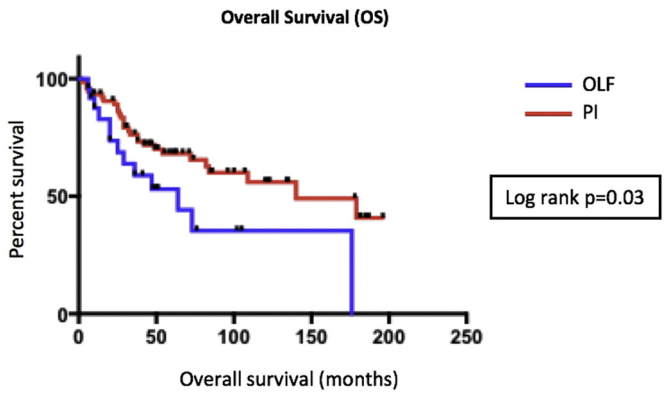

Fig. 3. Overall survival; OLF: outlying facility; PI: primary institution.

data also demonstrated a trend towards improved survival in this group, but this did not meet statistical significance. In this study observed differences in stage and nodal status may have contributed to improved overall survival without significant improvement in progression free survival, which was limited by sample size.

It has been established that the addition of brachytherapy significantly improves outcomes [3,20,21]. Brachytherapy treatment in combination with EBRT is associated with significantly higher cause specific survival (64.3% vs 51.5%) as well as overall survival rates (58.2% vs 46.2%) when compared to EBRT alone [2]. Interestingly, while there has been a clear and proven benefit of brachytherapy in the treatment of locally advanced cervical cancer, compliance rates for this treatment modality have decreased over a similar time frame. In a recent study, Han et al. demonstrated that brachytherapy use decreased from 83% in 1980 to 58% in 2009 with a demonstrated sharp decline of 23% in 2003 [2]. We found that even patients treated at outlying facilities received standard brachytherapy dosing, just with a longer treatment duration. However, there was an increased utilization of IMRT at outlying facilities. These patients received IMRT instead of standard BT which some studies suggest could affect PFS and OS.

While coordination of care seems to be a component, there are other factors that likely affect this observed difference. As a large referral center many patients are travelling long distances to the PI to see a gynecologic oncologist. Some patients traveled as far as 106 miles to their BT facility and 80.8 miles to their EBRT facility. BT was only performed centrally, as the smaller outlying facilities were not equipped to treat patients with this modality of RT. EBRT, on the other hand, was often performed at several smaller towns/cities remote from the PI. These patients often opt to have their EBRT closer to home and therefore undergo at least one component of their RT at an OLF. It is difficult, therefore, to determine if decreased compliance rates in these situations are due to a lack of coordinated care or are due to constraints with travelling long distances for BT treatments such as coordinating travel with a caregiver that might have delayed treatment.

Our study has several limitations. Data was collected from a single institution which may limit generalizability of results. However, most gynecologic oncologists see patients from a large geographic area, and therefore need to coordinate care between multiple sites. Additionally, this is a small retrospective study. While data regarding overall survival did demonstrate a trend towards better five year survival, our study was underpowered to demonstrate a statistically significant difference among the two groups. Patients who received all or part of their RT at an OLF were significantly older and the data suggested a trend towards more advanced disease with lymph node involvement. It is possible that these patients may not have been as compliant with screening guidelines and therefore had more advanced disease, but that information was not available in this data analysis.

Despite the limitations of our study we found a strong correlation between treatment location and time to completion of therapy. Moving forward, it is critical that these patients are recognized at the beginning of their care and efforts are made to ensure timely and coordinated care in order to improve compliance rates with RT. Using cancer navigators to help coordinate care between multiple sites and providers, providing patients with a treatment plan outline, and encouraging patients to meet with the radiation oncologist who will perform their brachytherapy at the start of therapy may help close the treatment duration gap. Several studies have noted improvement in care coordination with the use of cancer navigators including improved adherence to cancer appointments [22]. Multi-institution studies are necessary to confirm this finding, and to further evaluate treatment duration on recurrence rates and disease specific survival.

Authors' contribution

Corinne Calo, DO: Primary author. Performed majority of the chart review and wrote the bulk of the abstract/manuscript.

John Elliott, MPH, PhD: Helped to organize data and performed majority of statistical analyses.

Gary Reid, MD: Provided charts for chart review, helped in writing and editing the abstract and final paper.

Aine Clements, MD: Provided charts for chart review, helped in writing and editing the abstract and final paper. Performed statistical analysis and created figures for progression free survival and overall survival.

Kellie Rath, MD: Primary investigator/mentor for project. Helped to design the project and data collection sheet. Helped in writing and editing the abstract and final paper.

There are no conflicts of interest to disclose.

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