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Long-Term Outcome of Patients Who Received Pembrolizumab During Treatment for Carcinoma of the Cervix

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Abstract

Objectives: To investigate the long-term outcome of cervical cancer and its relationship with histo-pathology and pembrolizumab use.

Methods: A multi-site retrospective cohort study on patients with cervical squamous cell cancer (SCC) and adenocarcinoma (AC).

Results: 387 patients identified from 2004-2025. 294 (76%) had SCC and 93 (24%) had AC. 138 (35.7%) stage I, 100 (25.8%) stage II, 117 (30.2%) stage III, and 32 (8.3%) stage IV. HPV status was negative in 93 (23.9%) and positive in 150 (38.7%). PD-L1 status was negative in 13 (3.3%) and positive in 60 (15.5%). Most HPV and PD-L1 results were unknown (144, 37.4% and 314, 81.2%, respectively). Pembrolizumab was used in 52 (13.4%), (36.5% upfront, 63.5% recurrent). There was a significant difference in progression-free survival between receiving pembrolizumab vs. not (HR=4.59; 95% CI 2.79-7.56, p=<0.0001). There was no difference in overall survival for all-comers (HR=1.19; 95% CI 0.41-3.46, p=0.7402), nor for recurrent patients only (p=0.4424). In a subgroup analysis of stage III/IV patients (149, 38.5%), those treated with pembrolizumab vs. not had a significantly shorter median progression-free survival (17.9 *vs* 140.6 months, p<0.0001).

Conclusions: In our patient population the use of pembrolizumab was associated with a worsened progression-free survival and no difference in overall survival. Our results differ from recently published randomized controlled trials, potentially due to the small number of patients who received pembrolizumab and an overall worse prognosis in stage III/IV patients regardless of treatment. Most patients receiving pembrolizumab had recurrent disease. These results prompt continued analysis of longitudinal outcomes at our institutions.

Keywords: Cervical cancer; Vaccine; Pembrolizumab

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Introduction

Cervical cancer remains one of the most common cancers affecting reproductive-age women worldwide, with an incidence rate of 14 per 100,000 [1]. In the United States, it is the second most common cancer death in women between 20-39 years old [2,3]. Despite the implementation of widespread cervical cancer screening and the availability of the human papilloma virus (HPV) vaccine, mortality from disease has been stagnant in recent years and incidence has increased by 1.7% per year from 2012-2019 [2].

Early-stage cervical cancer is associated with excellent clinical outcome, with a reported overall 5-year survival rate of 83.3% to 95.8% [2,4]. Conversely, the prognosis is poor in patients with advanced stage cervical cancer, with an estimated overall 5-year survival rate of 14.7% to 60.8% and a 5-year progression-free survival of 16.0% to 55.0%, despite standard clinical interventions [2,4,5]. Recurrence rates for advanced stage cervical cancer are reported to be as high as 50.0% to 70.0% [6,7]. For many years, the standard treatment of locally advanced cervical cancer has

been a chemoradiation, with external beam radiation therapy administered with platinum-based chemotherapy, followed by brachytherapy [3,8,9]. In recurrent or metastatic cervical cancer, systemic chemotherapy is the first-line treatment including cisplatin or carboplatin with paclitaxel and bevacizumab [3,9,10]. However, given high recurrence and minimal survival benefit with current treatment options, there has been increased interest in exploring novel immunotherapeutic agents to improve the prognoses.

Pembrolizumab, a programmed death-1 (PD-1) inhibitor, was approved by the FDA in 2024 for the treatment of advanced stage cervical cancer [3]. Expression of PD-1 has been found to be upregulated in cervical cancer cells, allowing for tumorigenesis by evading natural immune responses [11,12]. The programmed death-ligand 1 (PDL-1) combined positive score is a scoring algorithm that is used to predict tumor response to pembrolizumab that reflects the expression of PDL-1 in specific tumors [13]. In cervical cancer, a combined positive score >1 is deemed positive while a score >10 predicts improved survival benefit with pembrolizumab [14]. Recent studies demonstrate improved survival with the addition of pembrolizumab to current regimens. Specifically, the KEYNOTE-A18 and KEYNOTE-856 trials have reported significant benefits in both progression-free survival and overall survival and in locally advanced and persistent, recurrent or metastatic cervical cancer [14,15]. We sought to investigate the long-term outcomes of patients in our institution with squamous cell cancer (SCC) and adenocarcinoma (AC) of the cervix and its relationship with pembrolizumab use.

Material and Methods

Patients

This study was a multisite retrospective chart review of patient medical records from January 2004 to September 2025. Institutional Board Review (IRB) approval was obtained (IRB protocol number 18-0927, December 2018). This study was exempt from requiring written informed consent by the IRB. Patients were included if they had a documented histological diagnosis of squamous cell carcinoma or adenocarcinoma of the cervix of any stage. All other histological subtypes were excluded. Data extracted included race, ethnicity, age at diagnosis, FIGO 2018 stage, histological subtype, HPV status, PDL-1 combined positive score, treatment regimens, and survival data. All data were obtained from electronic medical records. Data was stored in a secure Redcap database, and all patient data were de-identified prior to analysis. The outcomes were progression-free survival and overall survival. Progression-free survival was defined as time from date of diagnosis to the date of documented disease progression or death from any cause, whichever occurred first. If no disease progression or death is documented prior to study termination these endpoints were censored at the date of last follow-up. Overall survival was defined as time from the date of diagnosis to the date of death. If no death was documented prior to study termination, overall survival was censored at the last date the patient was known to be alive. In accordance with the journal's guidelines, we will provide our data for independent analysis by a selected team by the Editorial Team for the purposes of additional data analysis or for the reproducibility of this study in other centers if such is requested.

Statistical Analysis

Descriptive statistics were used to summarize patient demographics, disease characteristics, treatment patterns, and clinical outcomes. Categorical variables (e.g., race, ethnicity, etc.) were presented as frequencies and percentages. Continuous variables (e.g., age at diagnosis) were summarized using mean and standard deviation (SD), median and interquartile range (IQR), and range.

Analysis of progression-free survival and overall survival was accomplished by applying standard methods of survival analysis, i.e., computing the Kaplan-Meier product limit curves, where the data were stratified by group. The groups were compared using the log-rank test. The median rates for each group were obtained from the Kaplan-Meier1/Product-Limit Estimates and their corresponding 95% Confidence Intervals (CIs) were computed, using Greenwood's formula to calculate the standard error. Those factors that appeared to be associated with each of the outcome measures in the univariate analysis ($p<0.25$), or were considered clinically relevant, were included in a separate multivariable Cox proportional hazards model. The proportional hazards assumption was checked for each covariate in the Cox models using cumulative residual plots. Results are presented as hazard ratios (HRs) with corresponding 95% CIs.

Unless otherwise specified, a result was considered statistically significant at the $p<0.05$ level of significance. All analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC), R version 4.2.1, and RStudio.

Results

From January 2004 to September 2025 there were 387 patients with squamous cell carcinoma or adenocarcinoma of the cervix identified at Northwell Health. The median age was 53 (SD 15.28, range, 22 to 98 years, IQR: 43-65), with most patients being under the age of 65 (282, 72.9%). Patient race was reported as follows: White (191, 49.4%), African American (89, 23.0%), Other (59, 15.2%), and Asian (48, 12.4%). Hispanic patients constituted 21.4% (n=83) of the cohort (Table 1a). Most patients had FIGO 2018 stage I/II disease, with 138 (35.7%) patients having stage I, 100 (25.8%) patients stage II, 117 (30.2%) patients stage III, and 32 (8.3%) patients having stage IV. The most common stage was IIB at 82 (21.2%) patients. Squamous cell carcinoma was found in 294 (76.0%) patients, and 93 (24.0%) patients had adenocarcinoma. HPV status was positive in 150

Table 1a: Patient Demographics.

Characteristic	Patients, n (%)
Age at Diagnosis	54.51±15.28
	median = 53
	[IQR: 43-65]
Age categories	
<45	115 (29.7%)
[45-55)	86 (22.2%)
[55-65)	81 (20.9%)
65+	105 (27.1%)
Race	
White	191 (49.4%)
Asian	48 (12.4%)
African American	89 (23.0%)
Other	59 (15.2%)
Ethnicity	
Hispanic	83 (21.4%)
Non-Hispanic	304 (78.6%)

Table 1b: Disease Characteristics.

Characteristic	Patients, n (%)
FIGO 2018 stage	
IA1	25 (6.5%)
IA2	9 (2.3%)
IB1	67 (17.3%)
IB2	29 (7.5%)
IB3	8 (2.1%)
IIA1	16 (4.1%)
IIA2	2 (0.5%)
IIB	82 (21.2%)
IIIA	5 (1.3%)
IIIB	52 (13.4%)
IIIC1	50 (12.9%)
IIIC2	10 (2.6%)
IVA	10 (2.6%)
IVB	22 (5.7%)
Stage	
I	138 (35.7%)
II	100 (25.8%)
III	117 (30.2%)
IV	32 (8.3%)
Cell Type / Histology	
Squamous cell carcinoma	294 (76.0%)
Adenocarcinoma	93 (24.0%)
HPV Status	
Negative	93 (24.0%)
Positive	150 (38.8%)
Unknown	144 (37.2%)
p16 Status	
Negative	17 (4.4%)
Positive	166 (42.9%)
Unknown	204 (52.7%)
p63 Status	
Negative	16 (4.1%)
Positive	39 (10.1%)
Unknown	332 (85.8%)
PDL-1 Combined Positive Score	
< 1	13 (3.4%)
> 1	60 (15.5%)
Unknown	314 (81.1%)

Table 1c: Treatment Characteristics.

Characteristic	Patients, n (%)
1st Line Treatment	
Surgery	117 (30.2%)
Chemoradiation	224 (57.9%)
Chemoradiation with immunotherapy	5 (1.3%)
Radiation only	13 (3.4%)
Chemotherapy only	9 (2.3%)
Chemotherapy with immunotherapy	11 (2.8%)
Induction chemotherapy with radiation	2 (0.5%)
Other	6 (1.6%)
External beam radiotherapy	306 (79.1%)
Vaginal brachytherapy	258 (66.7%)
Chemotherapy Regimen	
None	90 (23.3%)
Cisplatin (Chemoradiation)	215 (55.6%)
Cisplatin/pembrolizumab (Chemoradiation)	6 (1.6%)
Carboplatin/Paclitaxel	18 (4.7%)
Carboplatin/Paclitaxel with Bevacizumab	14 (3.6%)
Carboplatin/Paclitaxel with Bevacizumab and Pembrolizumab	35 (9.0%)
Other	9 (2.3%)
Immunotherapy	
None	330 (85.3%)
Pembrolizumab	52 (13.4%)
Other	5 (1.3%)
Immunotherapy Regimen	
None	329 (85.0%)
Upfront therapy	19 (4.9%)
Recurrence therapy	37 (9.6%)
Maintenance therapy	2 (0.5%)

(38.8%) patients, negative in 93 (24.0%) patients, and unknown in 144 (37.2%) patients. PDL-1 combined positive score of >1 was identified in 60 (15.5%) patients, <1 in 13 (3.4%) patients, and unknown in 314 (81.1%) patients (Table 1b).

First-line treatments consisted of: chemoradiation in 224 (57.9%) patients, surgery in 117 (30.2%) patients, radiation only in 13 (3.4%) patients, chemotherapy with immunotherapy in 11 (2.8%) patients, chemotherapy only in 9 (2.3%) patients, no treatment in 6 (1.6%) patients, chemoradiation with immunotherapy in 5 (1.3%) patients, and induction chemotherapy followed by radiation in 2 (0.5%) patients. For the patients who received radiation, 306 (79.1%) patients received external beam radiotherapy, and 258 (66.7%) patients received vaginal brachytherapy. Chemotherapy was administered in a variety of regimens, including radio-sensitizing cisplatin alone in 215 (55.6%) patients, carboplatin with paclitaxel in 67 (14.3%) patients, radio-sensitizing cisplatin with pembrolizumab in 6 (1.6%) patients, or other chemotherapy agents in 9 (2.3%) patients. For those who received doublet carboplatin and paclitaxel, 35 (9.0%) patients received additional bevacizumab with pembrolizumab, and 14 (3.6%) patients received additional bevacizumab alone. For the overall cohort, pembrolizumab was administered in 52 (13.4%) patients of the patients (36.5% in the upfront setting, and 63.5% in the recurrent setting) (Table 1c).

Disease recurrence occurred in 90 patients (23.3%). At the time of last follow-up, 257 patients (66.4%) were alive without disease, and 109 patients (28.2%) were alive with stable disease. A total of 22 patients (5.7%) had died from their cancer.

In the univariate analyses, there was a significant difference between those who received pembrolizumab compared to those who

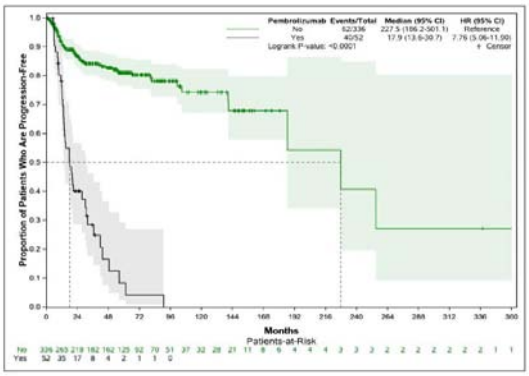

Figure 1: Kaplan-Meier estimated curves of progression-free survival.

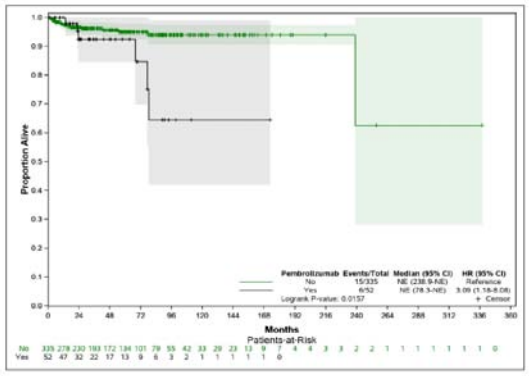

Figure 2: Kaplan-Meier estimated curves of overall survival.

did not at any point during their treatment course for progression-free survival (HR=7.76; 95% CI 5.06-11.90, p<0.0001, Figure 1) and overall survival (HR=3.09; 95% CI 1.18-8.08, p=0.0157, Figure 2).

After adjusting for age, histology, stage, and radiation use, there remained a statistically significant difference in progression-free survival between those who received pembrolizumab compared to those who did not at any point during their treatment course (HR=4.59; 95% CI 2.79-7.56, p=<0.0001), (Table 2). However, after adjusting for age, cell type, and stage, there was no significant difference in overall survival (HR=1.19; 95% CI 0.41-3.46, p=0.7542), (Table 3).

In a subgroup analysis of patients with recurrent disease, there was no significant difference in overall survival for those treated with or without pembrolizumab (p=0.4424), however median overall survival was not reached in the pembrolizumab group. Another subgroup analysis of stage III/IV patients (n=149, 38.5%) revealed that those treated with pembrolizumab had a significantly shorter median progression-free survival compared to those who did not receive pembrolizumab (17.9 *vs*. 140.6 months, p<0.0001). Due to the low number of available results for HPV and the PD-L1 combined positive score, these variables were not included in the survival analysis.

Discussion

To date, there are no randomized clinical trials demonstrating a worsened progression-free survival for patients with cervical cancer treated with pembrolizumab. There are subgroup analyses that suggest an uncertain benefit in those with a very low PD-L1 combined positive score, however these do not suggest inferior outcomes in patients who still received pembrolizumab [19]. The long-term, real-world results of our retrospective analysis of women with cervical cancer treated with pembrolizumab demonstrating a worsened progression-free survival and no difference in overall survival differ greatly from the recently published randomized controlled trials. This could potentially be explained by the small number of patients who received pembrolizumab (52, 13.4%) in our cohort, and an overall worse prognosis in the stage III/IV subgroup, regardless of treatment. Additionally, most patients who received pembrolizumab had recurrent disease indicating that our patient population had been heavily pretreated. As described in the KEYNOTE-158 trial, the patients who received pembrolizumab after multiple prior lines of chemotherapy had a shorter median progression-free survival (2.1 months) and a lower response rate compared to the overall cohort [17]. This can be attributed to a potential cumulative immunosuppressive effect of prior chemotherapy agents, immune exhaustion, and loss of tumor antigenicity.

Immune checkpoint inhibitors such as pembrolizumab target the PD-1 protein to act as a monoclonal antibody and thereby disrupt the effect of the receptor-ligand interaction and increase the immunogenicity of the tumor. The use of pembrolizumab has become well-established in both the first line and recurrent setting for the treatment of locally advanced and recurrent or metastatic cervical

Table 2: PFS Multivariable Cox Proportional Hazards Model.

Parameter		β Estimate	Standard Error	Hazard Ratio	95% Wald Confidence Limits		p-value
Pembrolizumab	Yes *vs*. No	1.525	0.254	4.59	2.79	7.56	<0.0001
Age	65+ *vs*. <45	0.396	0.288	1.49	0.85	2.61	0.1693
	[45-55) *vs*. <45	0.365	0.295	1.44	0.81	2.57	0.2167
	[55-65) *vs*. <45	0.653	0.302	1.92	1.06	3.47	0.0303
Cell Type	Adenocarcinoma vs. squamous cell carcinoma	0.516	0.275	1.68	0.98	2.88	0.0608
Stage	II *vs*. I	0.417	0.352	1.52	0.76	3.03	0.2368
	III *vs*. I	1.159	0.331	3.19	1.67	6.1	0.0005
	IV *vs*. I	1.652	0.39	5.22	2.43	11.2	<0.0001
EBRT	Yes *vs*. No	0.994	0.409	2.7	1.21	6.02	0.0151
VBT	Yes *vs*. No	-0.302	0.309	0.74	0.4	1.35	0.3278

Table 3: OS Multivariable Cox Proportional Hazards Model.

Parameter		β Estimate	Standard Error	Hazard Ratio	95% Wald Confidence Limits		p-value
Pembrolizumab	Yes *vs.* No	0.171	0.546	1.19	0.41	3.46	0.7542
Age	65+ *vs.* <45	0.476	0.648	1.61	0.45	5.73	0.463
	[45-55) *vs.* <45	-0.043	0.74	0.96	0.23	4.09	0.954
	[55-65) *vs.* <45	1.042	0.576	2.84	0.92	8.77	0.0704
Cell Type	Adenocarcinoma vs. squamous cell carcinoma	0.346	0.571	1.41	0.46	4.33	0.5452
Stage	II *vs.* I	-0.732	1.135	0.48	0.05	4.45	0.5189
	III *vs.* I	1.611	0.681	5.01	1.32	19.01	0.018
	IV *vs.* I	2.769	0.713	15.94	3.94	64.53	0.0001

cancer. The first use of pembrolizumab in the treatment of cervical cancer was investigated in 2017 by Frenel et al in a phase IB trial. This study demonstrated an overall response rate of 17% (95% CI, 5-37%) in the cervical cancer cohort with a safety profile consistent with that seen in pembrolizumab use amongst other tumor types [16]. This was followed by the phase II KEYNOTE-158 trial investigating pembrolizumab monotherapy in patients with previously treated, advanced solid tumors, again demonstrating a favorable objective response rate (34.3%, 95% CI 28.3-40.8%) and toxicities consistent with prior known pembrolizumab regimens [17]. This study led to the accelerated FDA approval of pembrolizumab in the treatment of advanced cervical cancer [18]. Following this, the results from the phase III KEYNOTE-826 study in 2021 allowed pembrolizumab to be approved by the FDA in combination with platinum-based chemotherapy, with or without bevacizumab, for first-line treatment of persistent, recurrent, or metastatic cervical cancer. From this study, a significantly longer progression-free survival (10.4 *vs* 8.4 months) and 24-month overall survival (53% *vs* 41.7%) was demonstrated in the patients who received pembrolizumab [14]. More recently, the KEYNOTE A18 study investigated the addition of pembrolizumab to chemoradiotherapy in the treatment of high-risk, locally advanced cervical cancer. This phase III randomized double blinded study demonstrated an improved progression-free survival (HR 0.7, 95% CI 0.55-0.89) with no statistically significant difference in overall survival [15].

Our study is limited by the small number of patients who received pembrolizumab, as well as the availability of PD-L1 combined positive score and HPV status results. This prevented a subgroup analysis of long-term outcomes stratified by PD-L1 combined positive score or HPV status, which was the original intent of our study. Additionally, a significant portion of our patients received pembrolizumab at time of recurrence versus at diagnosis, as currently used with concurrent chemotherapy and radiation.

This study highlights the importance of routine HPV testing in patients with cervical cancer, as well as PD-L1 combined positive score assessment to determine eligibility for pembrolizumab use in both the upfront and recurrent settings. This would allow for early recognition of patients who would most benefit from pembrolizumab therapy and avoid delaying the use of this effective immunotherapy until the patient has already received multiple lines of therapy. In summary, our retrospective study demonstrated a worsened progression-free survival and no difference in overall survival for patients with cervical cancer treated with pembrolizumab. These results prompt continued analysis of longitudinal outcomes at our institutions.

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