Journal of Gynecological Oncology

Case Report
Published: 12 Mar, 2026

The Use of Pembrolizumab Monotherapy in a Chemotherapy-Naïve Patient with Stage IVB Cervical Cancer: A Case Study

Panella L[1], Rothnie K[2], Shaw E[3], Bhana D[2], Danziger M[2], Lee T[4] and Kuo DYS[2]

[1]Department of Obstetrics and Gynecology, Long Island Jewish Hospital, United States

[2]Department of Gynecologic Oncology, Northwell Health Cancer Institute, United States

[3]Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, United States

[4]Department of Radiology, Long Island Jewish Hospital, United States

Abstract

Introduction: Chemotherapy remains the standard first-line treatment for advanced cervical cancer. The addition of the immune checkpoint inhibitor pembrolizumab to conventional chemotherapy has been shown to improve both progression-free and overall survival. While pembrolizumab monotherapy has demonstrated activity in previously treated cervical cancer, evidence supporting its use as an initial treatment option for patients who are poor candidates for systemic chemotherapy remains limited.

Clinical Case: Here we present a case of a patient with advanced cervical cancer who had a high ECOG performance status score and was not a good candidate for standard chemotherapy. She received palliative radiation treatment and was subsequently treated with pembrolizumab monotherapy for 12 cycles, with significant regression of disease and improvement in quality of life.

Discussion: Immune checkpoint inhibitors such as pembrolizumab that target PD-1 and PD-L1 have become important therapeutic options in advanced cervical cancer. Although pembrolizumab has demonstrated safety and efficacy in previously treated cervical cancer, existing studies have rarely included treatment naïve patients or those with poor performance status. This case highlights the potential utility of pembrolizumab monotherapy as a first-line option for patients unable to tolerate systemic chemotherapy, underscoring the need for further research to clarify which patient populations may derive the greatest benefit.

Keywords: Chemotherapy; Cervical cancer; Pembrolizumab monotherapy

OPEN ACCESS

Correspondence:
Panella L, Department of Obstetrics and Gynecology, Long Island Jewish Hospital, 270-5 76th Avenue, New Hyde Park, NY 11040, United States, Tel: +1978-578-8500; Fax: +1718-975-5200;
E-mail: lpanella@northwell.edu

Received Date: *26 Feb 2026*
Accepted Date: *09 Mar 2026*
Published Date: *12 Mar 2026*

Citation:
Panella L, Rothnie K, Shaw E, Bhana D, Danziger M, Lee T, et al. The Use of Pembrolizumab Monotherapy in a Chemotherapy-Naïve Patient with Stage IVB Cervical Cancer: A Case Study. J Gynecol Oncol. 2026; 7(1): 1087.

Introduction

Cervical cancer remains a significant public health concern despite routine screening with Papanicolaou (Pap) screening and Human Papillomavirus (HPV) vaccination. In 2025, 13,360 new cases of invasive cervical cancer and 4,320 deaths are expected in the United States [1]. The age adjusted-incidence rate is 7.7 per 100,000 women annually in the U.S., with a lifetime risk of 0.6%. The current overall 5-year survival rate for cervical cancer in the U.S. is about 68%, but varies dramatically with stage at diagnosis: 91.4% for localized disease, 62.3% for regional spread, and 19.5% for advanced stage with distant metastases. Prognosis is strongly influenced by stage, patient age, tumor size, and demographic factors such as race/ethnicity and socioeconomic status [2].

For patients with advanced, metastatic cervical cancer, the cornerstone of treatment is systemic chemotherapy. Early randomized trials by the Gynecologic Oncology Group established cisplatin in combination with paclitaxel as the standard of care for advanced disease [3]. The GOG-240 trial subsequently demonstrated that the addition of the anti-angiogenic agent bevacizumab significantly improved median overall survival, thereby shifting the first-line standard to platinum doublet chemotherapy plus bevacizumab for eligible patients [4].

The treatment regimen was again expanded by the incorporation of immune checkpoint inhibition. The Keynote-826 trial showed that the addition of the programmed cell death protein 1 (PD-1) inhibitor pembrolizumab to platinum-based chemotherapy (with or without bevacizumab)

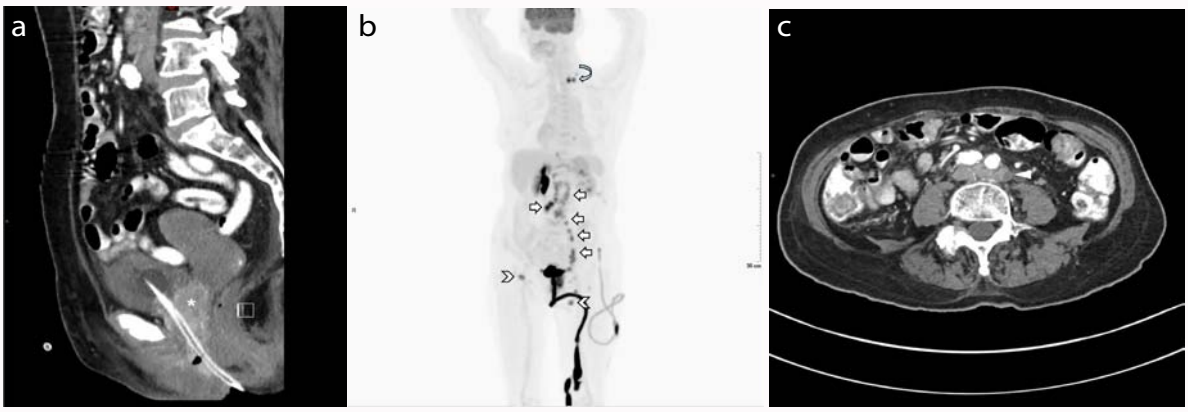

Figure 1: Pre-treatment images. (a) Contrast Enhanced CT scan with enhancing cervical mass extending to the vagina, base of the bladder and around a Foley catheter. (b) Maximum intensity projection (MIP) image from a PET/CT with left supraclavicular (curved arrow), retroperitoneal (white arrows), and inguinal (chevrons) adenopathy. (c) Axial CT image with bulky adenopathy (arrowhead) behind the left common iliac artery.

significantly improved progression-free survival and overall survival in patients with Programmed Death Ligand-1 (PD-L1) positive recurrent, persistent, or metastatic cervical cancer. This led to final FDA approval in 2021 and establishing chemoimmunotherapy as the current first-line standard in PD-L1-positive advanced disease [5]. In high-risk locally advanced disease, the Keynote-A18 trial showed improved progression-free and overall survival with pembrolizumab plus chemoradiotherapy, resulting in approval for FIGO stage III-IVA disease [6]. Pembrolizumab monotherapy has primarily been studied in previously treated metastatic disease. The KEYNOTE-158 trial demonstrated durable responses in patients with recurrent or metastatic PD-L1-positive cervical cancer who had progressed after chemotherapy, leading to approval in this setting [7].

Published data on the use of pembrolizumab as first-line monotherapy in de novo metastatic cervical cancer remain limited, and durable complete responses are considered rare. This underscores the novelty of the case we present in this report, in which our patient achieved disease resolution of newly diagnosed stage IVB cervical cancer following single agent pembrolizumab, without chemotherapy at any stage of treatment.

Case Presentation

An 83-year-old postmenopausal G2P2002 woman with a medical history of hypertension and atrial fibrillation with a pacemaker in place was referred to the gynecologic oncology office for a new pelvic mass. She was recently on a trip abroad where she presented to the local emergency department with urinary retention, weakness, and fatigue. A Computed Tomography (CT) of the abdomen and pelvis was performed, which demonstrated a pelvic mass. A urinary Foley catheter was placed to relieve the urinary retention. Her last general gynecology visit was many years prior.

On initial evaluation, she reported pelvic pain, vaginal spotting, and unintentional weight loss. Examination revealed a protruding cervical mass and biopsy confirmed moderately differentiated keratinizing squamous cell carcinoma. CT imaging of the abdomen and pelvis with IV and PO contrast revealed a 5.0 cm enhancing mass in the lower cervix and vaginal canal, with direct posterior bladder involvement. Additionally, moderate left-sided hydroureteronephrosis was noted, likely due to mass effect or direct involvement of the left ureter vesicular junction by the tumor. Extensive lymphadenopathy in the abdomen and pelvis suggested metastatic disease.

The patient was admitted to the hospital for percutaneous nephrostomy tube placement, as well as pelvic examination under anesthesia with vaginal and cervical biopsies, cystoscopy, and sigmoidoscopy to assess the extent of disease. Vaginal exam revealed a cervix and upper 1/3 of the vagina infiltrated with tumor. The distal vagina appeared free of disease, with no parametrial thickening, and cystoscopy and sigmoidoscopy were unremarkable. Pathology from the cervical biopsy resulted with superficially invasive squamous cell carcinoma in a background of high grade squamous intraepithelial lesion with a depth of invasion of approximately 1 mm. Vaginal biopsy resulted with superficial fragments of squamous cell carcinoma with focal stromal invasion. PD-L1 immunohistochemistry testing showed a Combined Positive Score (CPS) of >1. Postprocedural vaginal bleeding required vaginal packing and two blood transfusions, and the patient received 20Gy in 5 fractions of palliative external beam radiation to stop her bleeding.

After discharge home, the patient had a Positron Emission Tomography-Computed Tomography (PET/CT) scan which showed a positive supraclavicular node with a PET avid value of 15.2, as well as other significant lymph node activity in the descending aorta, in the retroperitoneum, and the common iliac and pelvic area (Figure 1a-1c). As a result, she was given a diagnosis of FIGO 2018 stage IVB squamous cell carcinoma of the cervix.

Given patient's ECOG Performance Status (PS) of 3 and concerns about her tolerance of a regimen that included systemic chemotherapy, the decision was made to start the patient on single agent pembrolizumab. Her pre-treatment labs were only notable for an elevated Thyroid Stimulating Hormone (TSH), and the patient was started on Levothyroxine. The treatment plan was in line with previous recommended regimens, with infusion of pembrolizumab 200 mg every 3 weeks.

At the time of this case report, the patient has received 12 cycles of pembrolizumab with excellent response. With each subsequent treatment, she became progressively more ambulatory and independent, and the Foley catheter was removed after two cycles. PET/CT after six cycles showed marked reduction in tumor burden with only mildly active left common iliac lymphadenopathy. The

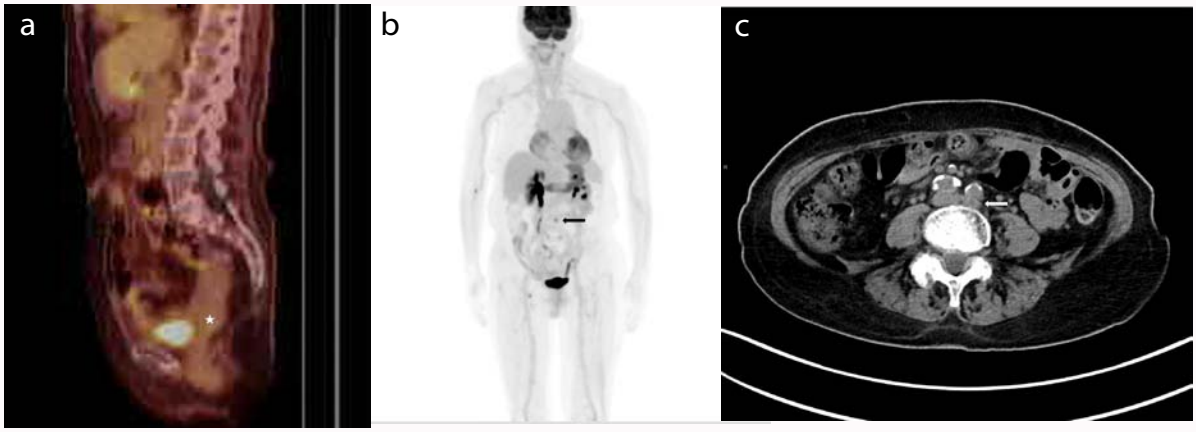

Figure 2: Post treatment images. (a) Sagittal fusion images from a PET/CT with resolution of bulky mass. Minimal radiotracer uptake in the region of the cervix (star). (b) MIP image from the PET/CT with resolution of supraclavicular and inguinal adenopathy. Small residual retroperitoneal radiotracer uptake (long black arrow). (c) Axial CT image from the PET/CT behind the left common iliac artery in the region of radiotracer uptake with decreased size of adenopathy since pre-treatment imaging (long white arrow).

percutaneous nephrostomy tube was removed after 7 cycles after imaging confirmed increased patency of the ureter from disease regression. Overall, the patient has responded extremely well on pembrolizumab monotherapy with no significant side effects, and significant improvement of disease. PET/CT after cycle 12 showed unchanged mildly active left iliac lymphadenopathy and minimal FDG uptake at the cervix that was unchanged from previous scan (Figure 2a-2c).

Discussion

Programmed Cell Death Protein 1 (PD-1) is a protein expressed on the surface of T cells, B cells, dendritic cells, and natural killer cells. PD-1 binds to its primary ligands, programmed cell death ligand 1 and 2 (PD-L1 and PD-L2). PD-L1 is widely expressed on normal tissues and has variable expression in different malignancies. It functions within the normal immune system by binding to the PD-1 receptor on immune cells to decrease T-cell activation and function, preventing autoimmune overactivation. PD-L1 upregulation in tumor cells decreases antitumoral immune responses, enabling immune evasion [8].

Immune checkpoint inhibitors are monoclonal antibodies targeting PD-1 (i.e., pembrolizumab, nivolumab, dostarlimab, and cemiplimab) and PD-L1 (i.e., atezolizumab, avelumab, and durvalumab) that have emerged as important new additions to the standard of care of several malignancies. These drugs block the receptor-ligand interaction by binding to PD-1 or PD-L1, increasing the immunogenicity of the tumor. One study examined PD-L1 expression in HPV associated cervical dysplasia and cancer and demonstrated co-expression of HPV DNA and PD-L1 in dysplastic cervical tissues. The adjacent normal epithelium lacked PD-L1 expression, suggesting a role for PD-L1 in HPV-associated carcinogenesis and potential therapeutic targeting in cervical cancer [9].

Pembrolizumab was first introduced as a potential therapy for cervical cancer in the KEYNOTE-028 trial, which established the safety and efficacy of pembrolizumab in different PD-L1 positive, advanced solid tumors, including cervical cancer [10]. The phase II KEYNOTE-158 trial confirmed a manageable safety profile and clinically meaningful antitumor activity for Pembrolizumab monotherapy in patients with previously treated, advanced cervical cancer, leading to accelerated FDA approval [7]. The phase III KEYNOTE-826 trial established pembrolizumab plus chemotherapy, with or without bevacizumab, as first-line therapy for persistent, recurrent, or metastatic cervical cancer after demonstrating improved progression-free and overall survival [5].

Previous studies evaluating the safety and efficacy of pembrolizumab monotherapy have rarely included patients who were treatment-naïve, having not received prior chemotherapy or immunotherapy. In KEYNOTE-028 and KEYNOTE-158, nearly all patients had received prior chemotherapy and radiation therapy, and those with ECOG performance status >1 was excluded [7-10]. A previous multi-center retrospective study in Korea evaluated pembrolizumab in patients with persistent or recurrent cervical cancer in which more than half of the patients had an ECOG ≥ 2. Although more reflective of the real population of patients receiving treatment, results revealed significantly greater antitumor activity in patients with better performance status [11].

There are no previous articles in the literature examining pembrolizumab as initial therapy without preceding chemotherapy. Only one case study was identified where a patient with FIGO 2018 stage IV PD-L1 positive squamous cell cervical cancer was transitioned to Pembrolizumab after intolerance to three cycles of chemotherapy and Bevacizumab, and remained disease-free for two years with no metabolically active cancer on her most recent PET/CT [12]. Pembrolizumab is generally well tolerated; common adverse effects include fatigue, rash, and gastrointestinal symptoms, while rarer, more severe complications include anaemia, fistula, haemorrhage, and infections. Several immune-mediated adverse events have also been reported, including rash, colitis, thyroid dysfunction, and Guillain-Barré syndrome [10].

Conclusion

This case report suggests that pembrolizumab may serve as first-line monotherapy for advanced cervical cancer patients with positive CPS scores who are unable to tolerate systemic chemotherapy due to toxicity or poor performance status. However, further research needs to be done to examine patient tolerance, side effects, and quality of life on pembrolizumab monotherapy compared to standard

chemotherapy regimens with pembrolizumab. It is still not widely understood why certain patients respond so significantly to immune checkpoint inhibitors, and what biomarkers, tumor biology, immune microenvironments, or personal characteristics may contribute to overall response to these medications. A case study such as this one may indicate a benefit specifically for a subset of patients with positive PD-L1 status and who are not otherwise candidates for first-line treatment with systemic chemotherapy for advanced cervical cancer.

References

1. National Cancer Institute. Cancer Stat Facts: Cervical Cancer. Surveillance, Epidemiology, and End Results Program. Updated. 2025.
2. Siegel RL, Kratzer TB, Giaquinto AN, Sung H, Jemal A. Cancer statistics. CA Cancer J Clin. 2025;75(1):10-45.
3. Moore DH, Blessing JA, McQuellon RP, Thaler HT, Cella D, Benda J, et al. Phase III study of cisplatin with or without paclitaxel in stage IVB, recurrent, or persistent squamous cell carcinoma of the cervix: a Gynecologic Oncology Group study. J Clin Oncol. 2004;22(15):3113-19.
4. Tewari KS, Sill MW, Long HJ, Penson RT, Huang H, Ramondetta LM, et al. Improved survival with bevacizumab in advanced cervical cancer. N Engl J Med. 2014;370(8):734-43.
5. Colombo N, Dubot C, Lorusso D, Caceres MV, Hasegawa K, Shapira-Frommer R, et al. Pembrolizumab for Persistent, Recurrent, or Metastatic Cervical Cancer. N Engl J Med. 2021;385(20):1856-67.
6. Lorusso D, Xiang Y, Hasegawa K, Scambia G, Leiva M, Ramos-Elias P, et al. Pembrolizumab or placebo with chemoradiotherapy followed by pembrolizumab or placebo for newly diagnosed, high-risk, locally advanced cervical cancer (ENGOT-CX11/gog-3047/keynote-A18): Overall survival results from a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2024;404(10460):1321-32.
7. Chung HC, Ros W, Delord JP, Perets R, Italiano A, Shapira-Frommer R, et al. Efficacy and safety of Pembrolizumab in previously treated advanced cervical cancer: Results from the phase II keynote-158 study. J Clin Oncol. 2019;37(17):1470-78.
8. Khan H, Gucalp R, Shapira I. Evolving concepts: Immunity in oncology from targets to treatments. J Oncol. 2015;2015:1-15.
9. Mezache L, Paniccia B, Nyinawabera A, Nuovo GJ. Enhanced expression of PD L1 in cervical intraepithelial neoplasia and cervical cancers. Mod Pathol. 2015;28(12):1594-1602.
10. Frenel, JS, Le Tourneau C, O'Neil B, Ott PA, Piha-Paul SA, Gomez-Roca C, et al. Safety and efficacy of Pembrolizumab in advanced, programmed death ligand 1-positive cervical cancer: Results from the phase IB keynote-028 trial. J Clin Oncol. 2017;35(36):4035-41.
11. Choi MC, Kim YM, Lee JW, Lee YJ, Suh DH, Lee SJ, et al. Real-world experience of pembrolizumab monotherapy in patients with recurrent or persistent cervical cancer: A Korean multi-center retrospective study (KGOG1041). Cancers. 2020;12(11):3188.
12. Anipindi M, Smith RJ, Gilani M. Case report: Immune checkpoint inhibitors as a single agent in the treatment of metastatic cervical cancer. Front Oncol. 2022;12:856944.