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Case Report

Pembrolizumab in Vaginal Carcinoma: A Case Report and Review of the Literature

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Keywords
Vaginal cancer · Vulval cancer · Pembrolizumab · Immunotherapy · Case report

Abstract
Introduction: Vaginal cancer is a rare gynecologic malignancy. While in a localized disease, concurrent chemoradiation grants local control and better overall survival, in a metastatic setting, the management options are very limited. Furthermore, recurrent cervical, vulvar, and vaginal carcinomas notoriously develop resistance to treatment, and consequently, their prognosis is still poor. ***Case Presentation:*** We herein present the case of a woman with a nodal relapse of vaginal carcinoma, effectively treated with third-line immunotherapy. We will also provide a review of the literature on the new therapeutic strategies for advanced vaginal carcinoma, with a focus on pembrolizumab immunotherapy. ***Conclusion:*** Pembrolizumab might represent a promising option for the management of vaginal and vulvar cancer, but data to support its use in this setting are still lacking. This case highlights the need for further investigation and trial designs for this rare disease.

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Background

Primary vaginal cancer is a rare condition, which represents only 1–2% of all gynecological malignancies [1]. The incidence of vaginal cancer increases with age, with a peak in the sixth and seventh decades [2]. The prevalent histotype is squamous cell carcinoma (SCC) (80%), followed by adenocarcinoma (15%), melanoma, lymphoma, and sarcoma [3, 4]. About 2/3 of cases are associated with human papillomavirus (HPV) 16 [2–4], which is considered as a positive prognostic factor, together with squamous histology [2, 4] and a low MIB-1 proliferation index [4]. On the other hand, International Federation of Gynecology and Obstetrics (FIGO) stage III–IV represents a negative prognostic factor [3]. Most patients are diagnosed with early-stage or locally advanced disease, while approximately 13% are metastatic from the beginning. Distant recurrence rates range from 7 to 33%, usually occurring late in the disease's natural history [1].

In the diagnostic process, magnetic resonance imaging (MRI) represents the gold standard for the detection of primary tumors and the definition of size, near-soft tissue, and organ involvement [4]. The (18F) fluoro-deoxy-glucose (FDG) positron emission tomography (PET) in combination with computed tomography (CT) (18F-FDG PET/CT) is more accurate than CT in detecting primary tumors, nodal metastases, and distant metastases [4].

Given its rarity and the similarities to cervical cancer, therapeutic strategies are often the same [5]. Nevertheless, vaginal cancer could be defined as a malignancy which arises in the vagina, without clinical or histologic evidence of cervical or vulval carcinoma [1]. The treatment strategy strictly depends on the disease stage at diagnosis. Radical surgery is the only curative option and should always be considered for stage I tumors. Unresectable disease benefits from concurrent chemoradiation in a locally advanced setting, while metastatic patients have poor clinical outcomes and limited therapeutic options, with platinum-based palliative chemotherapy being the treatment of choice. In the last decade, the advent of immunotherapy has revolutionized the oncology area and increased patients' therapeutic chances. In particular, the anti-programmed cell death 1 (PD-1) antibody immune-checkpoint inhibitor (ICI) pembrolizumab has proven to be effective in most malignancies, including gynecological cancers. Namely, based on the data from the phase 3 double-blind KEYNOTE-826 trial, pembrolizumab gained European Medicines Agency (EMA) approval for the treatment of persistent, recurrent, or metastatic cervical cancer with programmed cell death ligand 1 (PD-L1) combined positive score (CPS) ≥1, in combination with chemotherapy, with or without bevacizumab [6]. Data to support its use in vaginal and vulval cancer are still lacking.

We herein present the case of a woman affected by unresectable vaginal carcinoma, treated with two previous lines of chemotherapy, who showed an impressive response to third-line immunotherapy. This paper will also provide a review of the latest updates in vaginal and vulvar cancer management, with a particular focus on pembrolizumab immunotherapy.

Case Presentation

In June 2020, a 47-year-old woman with no comorbidities presented to her gynecologist with pelvic pain and vaginal bleeding. At the clinical examination, a vaginal mass was found, and a biopsy was performed, diagnosing HPV p40 positive and p16 negative vaginal SCC with lymphovascular invasion and without perineural invasion. The cancer grading was not specified (Fig. 1a–c). A pelvic MRI evidenced a locally advanced carcinoma with full-thickness posterior vaginal wall infiltration. No enlarged lymph nodes were detected, except for bi-lateral inguinal nodes with a suspected round shape but smaller than 7 mm and therefore difficult to determine. A rectal endoscopic ultrasound detected rectal wall infiltration, with a final staging of uT4 uN1, stage IVA according to the FIGO classification and the American Joint Committee on Cancer (AJCC) 2017. No distant metastases were identified at the CT scan.

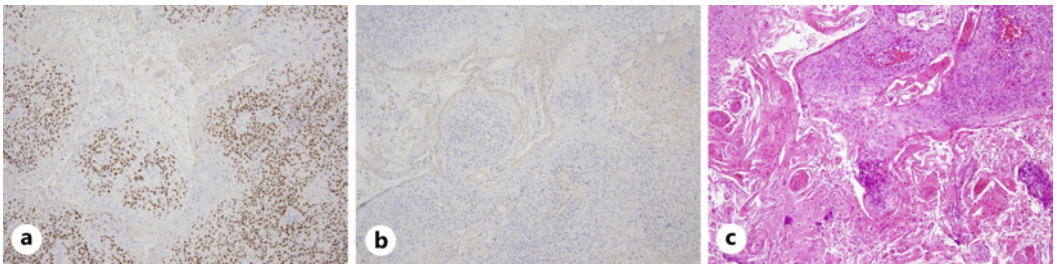

Fig. 1. Vaginal cancer photomicrographs. **a** Immunohistochemical detection of p40 which resulted in its expression. **b** Immunohistochemical detection of p16 which was not expressed at a ×20 magnification. **c** Hematoxylin-eosin immunohistochemistry of a section of SCC at a ×10 magnification.

After a multidisciplinary discussion and the placement of a protective colostomy, the patient started concurrent chemoradiotherapy, with cisplatin 40 mg/m^2 weekly for 5 weeks and concomitant radiotherapy (45 Gy in 25 daily fractions of 1.8 Gy). At the end of the treatment**,** a pelvic MRI showed a large reduction in the tumor size and no rectal wall infiltration. Considering the good treatment response, the program was completed with brachytherapy (28 Gy in 4 daily fractions). In February 2021, an abdomen MRI detected a further dimensional reduction of the mass. In April 2021, the same imaging showed the dimensional stability of the primary tumor, with the appearance of suspiciously enlarged right inguinal lymph nodes, with maximum standardized uptake value (SUVmax) of 9.6 at the 18F-FDG PET/CT. The biopsy of one of the right inguinal lymph nodes was positive for vaginal carcinoma recurrence. After a multidisciplinary meeting, nodal surgery and radiotherapy were excluded. The patient was thus a candidate for first-line chemotherapy with carboplatin (AUC 5) and paclitaxel (175 mg/m^2) administered every 3 weeks for 6 cycles. After 3 cycles of chemotherapy, the 18F-FDG PET/CT showed a dimensional and metabolic progression (SUVmax 20.5) of the right inguinal nodes. After multidisciplinary discussion, a fourth cycle of chemotherapy was administered. In September 2021, a clinical and radiological progression was detected, with the 18F-FDG PET/CT displaying a further dimensional increase associated with a slight decrease in uptake (SUVmax 18.2). The MRI confirmed the increased size of the right inguinal lymph nodes (37 mm vs. 14 mm of maximum diameter at the start of the combination chemotherapy). Next-generation sequencing (NGS) did not detect any genetically targetable alterations, and the mismatch repair (MMR) protein complex resulted intact at immunohistochemistry. PD-L1 expression assessed by CPS was 10%.

In October 2021, the patient started second-line chemotherapy with gemcitabine 1,000 mg/m^2 weekly for 2 weeks every 21 days. After 2 months, the patient complained of worsening inguinal pain that affected her walking capability, and the 18F-FDG PET/CT showed a dimensional increase of right inguinal lymph nodes (SUVmax 12.9) (Fig. 2a).

Considering the preliminary data of the phase II basket trial KEYNOTE-158, in January 2022, the patient started a third-line therapy with pembrolizumab 200 mg flat dose every 3 weeks. After only 2 months of treatment, her clinical conditions significantly improved: inguinal pain gradually disappeared, and she began to walk again without aids. In April 2022, the inguinal mass started to produce abundant blood serum fluid (Fig. 3a). Microbiological and cytological exudate analyses were negative. In April 2022, an 18F-FDG PET/CT highlighted an initial size reduction of the nodal recurrence, with a slight increase of the uptake (SUVmax 13.8), probably due to the inflammatory process (Fig. 2b). In July 2022, the 18F-FDG PET/CT showed further reduction both in size and in metabolic activity of the right inguinal mass (SUVmax 7.7) (Fig. 2c). The smaller diameter of the mass was clinically evident, with

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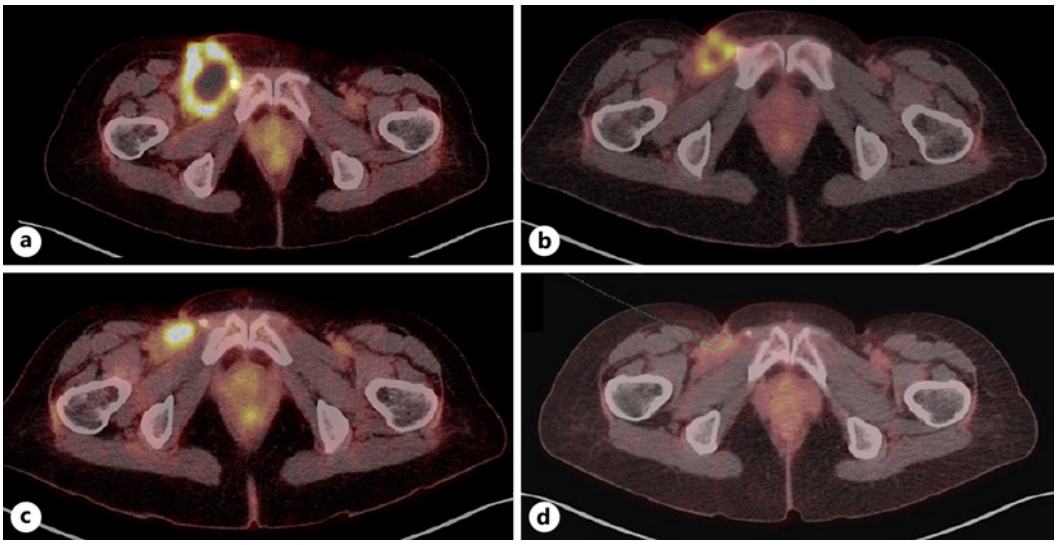

Fig. 2. PET/CT evaluations from the start of pembrolizumab. **a** Baseline PET/CT (December 2021), before the start of ICI therapy. **b** Metabolic partial response after 3 months of ICI therapy (April 2022). **c** Further metabolic response after 3 months of ICI therapy (July 2022).

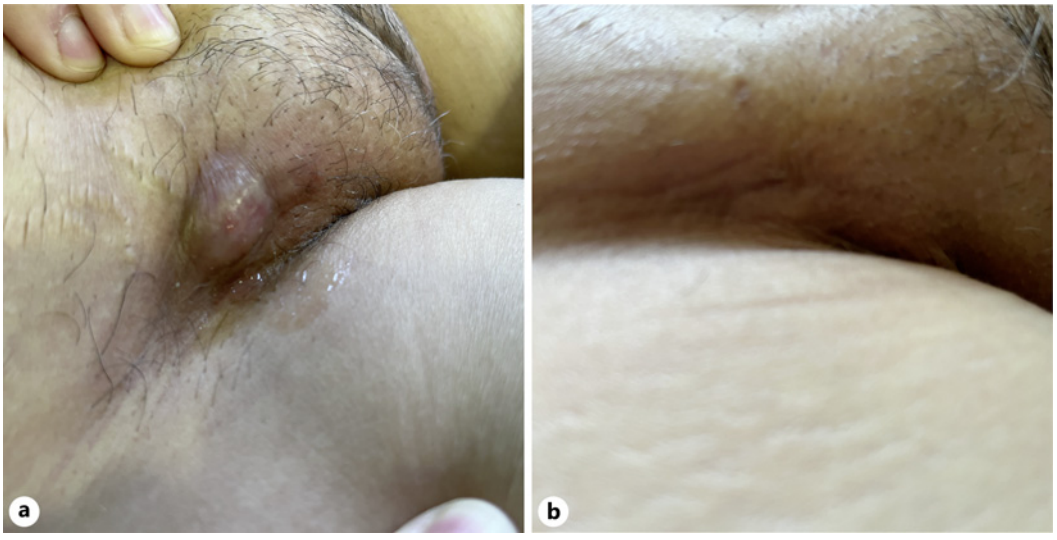

Fig. 3. Clinical presentation of the right inguinal mass in April 2022 (**a**) and in July 2022 (**b**).

softer and clearer overlying skin (Fig. 3b). The patient performed a total of 16 cycles of pembrolizumab until November 2022. The 18F-FDG PET/CT performed in November 2022 showed a bilateral and diffuse lung uptake, and, soon after, the patient was hospitalized for acute respiratory failure with radiologic evidence of an interstitial lung disease, treated with high-dose steroid therapy and rapid symptom resolution. In January 2023, the high-resolution CT scan showed a partial reventilation of the lung consolidations. Considering the severe immune-related toxicity, immunotherapy was discontinued, and clinical and radiological follow-up was started. The last radiological follow-up was performed in March 2023: the right inguinal mass appeared as avascular and dimensionally stable at the ultrasound and showed a further metabolic reduction (SUVmax 3.7) at the 18F-FDG PET/CT.

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Discussion

In this paper, we reported the clinical case of a young patient with unresectable vaginal cancer who was effectively treated in the third line with the immune-checkpoint inhibitor pembrolizumab for 1 year. So far, progression-free survival (PFS) has not been reached, even after the drug discontinuation for immune-related toxicity. Interestingly, our patient showed no strong predictive biomarkers of response to ICI therapy since she had negative HPV p16 and an intact MMR protein status.

Primary vaginal cancer is a rare gynecologic malignancy; thus, there are no randomized control trials to guide treatment decisions, and clinical care guidelines are based on limited retrospective and comparative studies. Due to the rarity of the disease, patients with vaginal cancer are often grouped together with vulval cancer in clinical trials. Considering the variable response rate to standard chemotherapies, there is need to explore other systemic treatment options. The role of immunotherapy is of interest, particularly for HPV-related cancers such as vaginal cancer.

As shown in Table 1, the data available on the use of pembrolizumab in vaginal or vulvar cancer involve basket studies, case series, and case reports. A phase II basket trial showed that pembrolizumab is a safe option and may provide significant clinical benefit in recurrent or metastatic vaginal or vulvar SCC. The trial included 2 patients with PD-L1 positive, metastatic, heavily pre-treated vaginal cancer. As best response, 1 patient demonstrated stable disease (SD) for 10 cycles, and the other progressed after 3 pembrolizumab infusions [7]. In the same trial, an 88-year-old woman with a PD-L1 positive (CPS 5) recurrent vulvar SCC who progressed after platinum-based chemotherapy experienced a 30% tumor reduction following 5 cycles of pembrolizumab. Due to a grade 3 treatment-related mucositis, ICI was discontinued after 5 cycles [7]. Our patient had progression disease as the best response during both the two lines of chemotherapy for metastatic disease: due to substantial refractory to chemotherapy, PD-L1 CPS score of 10%, and previous literature's data, we considered pembrolizumab as third line. As the last 88-year-old patient, our patient rapidly experienced a partial response with a substantial tumor shrinkage and decrease in metabolic activity at 18F-FDG PET/CT with pembrolizumab, even after its suspension for toxicity.

Pembrolizumab monotherapy was also evaluated in 101 patients with advanced vulvar SCC enrolled in the phase 2 multicohort, open-label KEYNOTE-158 study. This treatment regimen showed significant responses regardless of the PD-L1 status, with an acceptable safety profile (11.9% grade 3–5 TRAEs). The primary endpoint was objective response rate (ORR): ORR was 10.9% among all patients, 9.5% among the 84 PD-L1-positive, and 28.6% among the 7 PD-L1-negative tumors. Median PFS and overall survival were 2.1 and 6.2 months, respectively [8].

KEYNOTE-028, a non-randomized, phase Ib trial, investigated the use of single-agent pembrolizumab in PD-L1-positive advanced solid tumors, including 18 vulvar SCCs [9]. Among them, the median PFS was 3.8 months, and ORR was 7%. At 6 and 12 months, overall survival rates were 42% and 28%, and the PFS rates were 20% and 7%, respectively. 1 patient had a partial response (PR), 7 SD, and 6 experienced progressive disease (PD). There was a significant correlation between the PD-L1 CPS, which was available for 8 patients with vulvar SCC, and both ORR (p = 0.018) and PFS (p = 0.005) [9].

In a case series, 3 patients with pre-treated vulvar SCC received pembrolizumab monotherapy as second/third line. Two out of 3 patients had HPV-negative and PD-L1-positive (CPS 1 and CPS 60, respectively) tumors. Median time to progression was 3.3 months, and 1 patient had SD as the best response rate, while the remaining two experienced PD. About toxicity, only 1 patient suffered from moderate immune-related hypothyroidism [10].

In 2019, Shields published the first case report of a patient with recurrent vulvar cancer with PD-L1 100% who showed a complete clinical remission after 2 cycles of pembrolizumab

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Table 1. Pembrolizumab in vulval or vaginal cancer

Type of study	*N* of vulvar/vaginal cancer patients	Tumor features	Clinical efficacy	TRAEs	Reference studies
Phase II multicohort trial	101	Advanced vulvar SCC 7 PD-L1 < 1 84 PD-L1 ≥ 1	ORR 10.9% ORR 28.6% ORR 9.5%	50.5% (G3-5, 11.9%)	Shapira-Frommer et al. [8] 2022
Non-randomized-phase Ib trial	18	Advanced PD-L1 positive vulvar SCC	mPFS 3.8 mo ORR 7% OS at 12 mo 28% PFS at 12 mo 7%	66% (G3-5 14%)	Ott et al. [9] 2019
Phase II basket trial	3	Pt 1: G2 stage IVB vaginal SCC, PD-L1 5, moderate TIL infiltration (2/3) Pt 2: G2 stage IVB vaginal SCC, PD-L1 2%, moderate TIL infiltration (2/3) Pt 3: G1 vulvar SCC, PD-L1 5, moderate TIL infiltration (2/3)	Best response: PR Best response: PD Best response: PR	G2 fatigue G2 fatigue G1 maculopapular rash, G2 pruritus, G3 mucositis	How et al. [7] 2021
Case series	3	Advanced vulvar SCC Pt 1: HPV-negative, PD-L1 1–5 Pt 2: HPV unknown, PD-L1 60 Pt 3: HPV-negative, PD-L1 unknown	 TTP: 4 mo TTP: 3 mo TTP: 3 mo	 G2 fatigue, lymphedema None G2 lymphedema, hypothyroidism	Woelber et al. [10] 2021
Case report	1	Advanced G2 vulvar SCC, HPV-positive PD-L1 > 1	Best response: PR	G1 diarrhea, mucositis, rash	Praiss et al. [12] 2022
Case report	1	Advanced vaginal SCC, HPV-negative, PD-L1 50	Best response: CR	WEBINO, hypothyroidism	Ansari et al. [13] 2021
Case report	1	Advanced clear cell vaginal adenocarcinoma, PD-L1 2	Best response: SD	None	Egger et al. [15] 2021
Case report	1	Advanced vulvar verrucous carcinoma PD-L1 positive	Best response: CR	Arthritis	Wang et al. [14] 2021

Table 1 (continued)

Type of study	*N* of vulvar/vaginal cancer patients	Tumor features	Clinical efficacy	TRAEs	Reference studies
Case report	1	Recurrent vulvar clear cell carcinoma PD-L1 45	Best response: PR	G1 fatigue and diarrhea	Sachdeva et al. [16] 2021
Case report	1	Advanced vulvar SCC, PD-L1 100	Best response: CR	G1 diarrhea, nausea, arthralgias	Shields and Gordinier [11] 2019

N, number; TRAEs, treatment-related adverse events; SCC, squamous cell carcinoma; PD-L1, programmed death ligand; ORR, objective response rate; G, grade; mPFS, median progression free survival; OS, overall survival; TIL, tumor infiltrating lymphocytes; PR, partial response; PD, progressive disease; HPV, human papilloma virus; TTP, time-to-treatment progression; CR, complete response; SD, stable disease.

[11]. Last year, Praiss and colleagues [12] reported the case of a 64-year-old patient with a PD-L1 and HPV-positive metastatic vulval SCC, who achieved an unconfirmed PR on pembrolizumab therapy. Furthermore, Ansari reported the first case of chemotherapy-refractory vaginal SCC with complete response to pembrolizumab and concurrent pelvic radiotherapy. The patient presented wall-eyed bilateral internuclear ophthalmoplegia (WEBINO) as immune-related adverse event [13]. Pembrolizumab also showed efficacy in a patient with vulva verrucous carcinoma in neoadjuvant setting in association with chemotherapy [14]. Pembrolizumab also demonstrated good disease control in rare histologies, such as metastatic vaginal adenocarcinoma, clear cell carcinoma of the vulva, and vulvo-vaginal mucosal melanoma [15–18].

The CARE Checklist has been completed by the authors for this case report, attached as online supplementary material (for all online suppl. material, see https://doi.org/10.1159/000535041).

Conclusions

We herein reported the case of a patient with advanced vaginal cancer, with no predictive biomarkers of response to ICI therapy, who showed a substantial and durable response to third-line pembrolizumab immunotherapy. Metastatic or recurrent vaginal and vulvar cancer have limited treatment options and many of the existing recommendations are extrapolated from the broader squamous cell and cervical cancer guidelines. This case hints that immunotherapy might represent a promising option for patients with advanced vaginal and vulval cancer, also when heavily pre-treated and with no predictive factors of response to ICI therapy. Given the rarity of these malignancies, multicenter trials are needed to investigate treatment effects, and national registries should be used to study the clinical outcomes.

Statement of Ethics

Ethical approval is not required for this study in accordance with national guidelines. Written informed consent was obtained from the patient for publication of the details of their medical case and any accompanying images.

Conflict of Interest Statement

The authors declare that they have no competing interests.

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Author Contributions

M.G.V. and C.N. equally contribute to conceptualization, writing, and original draft preparation. M.D., R.S., L.B., A.B., C.C., C.B., S.P., F.B., and B.R contributed to supervision.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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