Case Reports in Oncology

Case Rep Oncol 2026;19:276–283
DOI: 10.1159/000550564
Received: September 10, 2025
Accepted: January 6, 2026
Published online: January 19, 2026

Case Report

Vulvar Metastasis from Breast Cancer Treated with Abemaciclib plus Fulvestrant: A Case Report

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Keywords
Vulvar metastasis · Abemaciclib · Breast cancer · Case report

Abstract
Introduction: Breast cancer is the most common malignant tumor in women, affecting approximately 1 in 9 women worldwide. In contrast, vulvar cancer remains rare, accounting for <1% of all cancers among women. Metastatic vulvar tumors are even rarer, constituting only 5–8% of all vulvar cancers. In some cases, breast cancer may metastasize to the vulva or vulvar tumors can arise from ectopic breast tissue. ***Case Report:*** We report the case of a 78-year-old woman with vulvar metastasis of breast origin occurring 17 years after the diagnosis of primary breast cancer. The recurrence was identified by a PET scan concurrent with the patient reporting episodes of vaginal bleeding. Diagnosis was confirmed by clinical examination and biopsy. The proposed treatment was combined cyclin-dependent kinases 4 and 6 (CDK4/6) inhibitor abemaciclib and anti-estrogen agent fulvestrant. The patient demonstrated a good response, with a favorable clinical outcome as she is still in complete remission. ***Conclusion:*** This case underscores the importance of long-term follow-up of hormone-sensitive breast cancer, including thorough clinical examinations. To the best of our knowledge, this is the first reported case of vulvar metastasis from breast cancer that was successfully treated with the combination of abemaciclib and fulvestrant, leading to a complete response. The use of CDK4/6 inhibitors for the treatment of vulvar metastases of breast origin represents a significant advance, offering a less invasive and potentially more effective alternative to current treatment protocols.

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Introduction

Breast cancer is the most common malignant tumor among women, impacting approximately 1 in 9 women worldwide. In contrast, vulvar cancer represents <1% of all female cancers. Metastatic vulvar cancers are even rarer, representing only 5–8% of all cases of vulvar cancer [1, 2]. Two mechanisms have been observed when the vulvar tumor is of mammary origin: metastasis coming from breast cancer or the development of a primary cancer arising from ectopic breast tissue [3, 4].

During the fifth week of gestation, mammary ridges form on the embryo's ventral surface through ectodermal thickening. These ridges extend along the primitive "milk line" from the armpit to the groin. Most of these ridges regress, leaving only the thoracic tissue to form the breasts. However, ectopic breast tissue can persist along this line and may be subject to the same pathophysiological processes as normal breast tissue, both benign and malignant [3–5].

Though breast cancer primarily spreads to lymph nodes, bones, lungs, liver, and brain, there have been a few reports in which it metastasized to the genital organs. In these cases, metastases are typically localized to the uterus or ovaries, but in exceptional cases they may reach the vulva [2–4, 6–8]. Other rare metastatic sites have also been described, particularly within the gastrointestinal tract, including the stomach, small intestine, and colon, and very rarely the duodenum. These uncommon localizations highlight the wide but unusual spectrum of breast cancer dissemination [9].

We report the case of a 78-year-old patient with vulvar metastasis of breast origin occurring 17 years after the primary diagnosis of breast cancer. This case emphasizes the importance of long-term follow-up, including comprehensive clinical examinations.

The proposed treatment was the combination of cyclin-dependent kinase (CDK) 4/6 inhibitor with an anti-estrogen agent. Abemaciclib is a selective inhibitor of CDK4/6. This drug is indicated for the treatment of hormone receptor-positive, locally advanced, or metastatic breast cancer without human epidermal growth factor receptor 2 (HER2) expression. It is used in combination with an aromatase inhibitor as a first-line endocrine therapy and combined with fulvestrant upon disease progression after hormone therapy [10]. In some situations, abemaciclib can also be used as an adjuvant treatment.

Case Report

Presentation and Initial Treatment

The patient was a 78-year-old woman with a medical history notable for type 1 diabetes, hypertension, and hypothyroidism. She had two natural deliveries and, in 1997, underwent a laparoscopic radical hysterectomy for a polyfibromatous uterus.

In June 2007, she was diagnosed with Scarff-Bloom-Richardson grade II (SBR II according to the Elston-Ellis modification; hormone receptor-positive, HER2-negative, Ki67 30%) infiltrating ductal carcinoma of the right breast measuring 2 cm × 1.2 cm (stage pT1cN0M0). Treatment consisted of quadrantectomy with axillary dissection. The sentinel lymph nodes showed no signs of cancer. The patient refused adjuvant radiotherapy and tamoxifen therapy.

In December 2007, a local recurrence in the right breast was suspected, so treatment with tamoxifen was initiated. Although the biopsy revealed only fibrosis, a 2 cm mass located in the lower outer quadrant of the right breast appeared suspicious on both ultrasound and MRI. Consequently, the patient underwent mastectomy. Pathological examination revealed a grade III infiltrating ductal carcinoma (hormone receptor-positive, HER2-negative, Ki67

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30%) measuring 7 mm. During the work-up, a 9-mm lesion was detected in segment IV of the liver. The patient was considered metastatic, and she started letrozole (stage pT1bN0M1).

In September 2008, MRI revealed progression of the liver lesion from 9 mm to 15 mm, prompting initiation of FEC100 chemotherapy (5-fluorouracil, epirubicin 100 mg/m^2, and cyclophosphamide; 6 cycles from February to June 2009). The lesion initially showed a favorable response, with complete radiological remission. However, in May 2010, the lesion increased in size to 3 cm. Management included a segment IV liver lobectomy. Histopathological analysis confirmed hepatic metastasis from breast cancer. Hormonal therapy was maintained thereafter.

In January 2012, routine mammography revealed suspicious microcalcifications in the superolateral quadrant of the left breast. The patient declined a biopsy and preferred to pursue a simple left mastectomy. Pathological analysis revealed a grade II infiltrating ductal carcinoma with a grade III intracanalicular carcinoma and micro- and macro-calcifications (hormone receptor-positive, HER2-negative, Ki67 33%), measuring 1.5 cm × 1.5 cm. Tamoxifen therapy was reintroduced for another 10 years.

In May 2015, the patient attended a consultation after self-palpating a mass on the vulva. Clinical examination revealed a firm, mobile, non-suspicious mass measuring 0.5 cm on the left labia minora. Surgical excision was recommended, but the patient declined, opting instead for watchful waiting. She was re-evaluated in July 2016. The indurated vulvar lesion measured approximately 6–7 mm and was not associated with skin ulceration. Clinically, the lesion did not appear suspicious. The patient again refused an excisional biopsy.

Recent Evolution

In December 2023, during a breast cancer follow-up, a PET scan (Fig. 1) revealed no suspicious lesions in the breasts but showed an abnormal lesion in the cervix/vagina. The patient, who was receiving tamoxifen, reported occasional vaginal bleeding for several months.

In January 2024, a clinical examination revealed a 4 cm × 2 cm lesion extending from the left labia minora to the clitoris. Pathological analysis of a biopsy of this lesion confirmed a poorly differentiated carcinoma consistent with breast cancer metastasis. Immunohistochemical analysis showed estrogen receptor positivity (Allred score 8), progesterone receptor positivity (Allred score 6), and expression of AE1/AE3 and GATA3, while the tumor was negative for PAX8, p40, synaptophysin, and CD45. HER2 immunohistochemistry was negative. Mammaglobin and GCDFP-15 were not performed as the immunophenotypic profile was considered sufficient to support a breast origin.

A pelvic MRI performed in January 2024 (Fig. 1) confirmed a suspicious left vulvar lesion measuring 36 mm × 26 mm × 20 mm, extending from the vaginal orifice to the clitoris. Imaging also revealed a 9 mm left inguinal lymphadenomegaly.

On January 31, 2024, treatment was initiated with 500 mg fulvestrant monthly and 150 mg abemaciclib twice daily. The patient was clinically monitored monthly; she demonstrated significant clinical regression of the lesion and of the left iliac node (Fig. 2).

Due to gastrointestinal side effects, specifically diarrhea and nausea, the dose of abemaciclib was reduced to 100 mg twice daily. Although initially dissatisfied with the treatment, the patient agreed to continue at the reduced dose.

In the context of recurrent bilateral breast tumor, the patient underwent an oncogenetic consultation, which found a pathogenic variant of the ATM gene (c.7874_7876delinsGC p.) that increases the risk of breast neoplasia but also of other neoplasias, such as pancreas and colorectal.

In this case, the main diagnostic challenge was to determine whether the lesion represented breast cancer metastasis or a primary extramammary malignancy. Given the long

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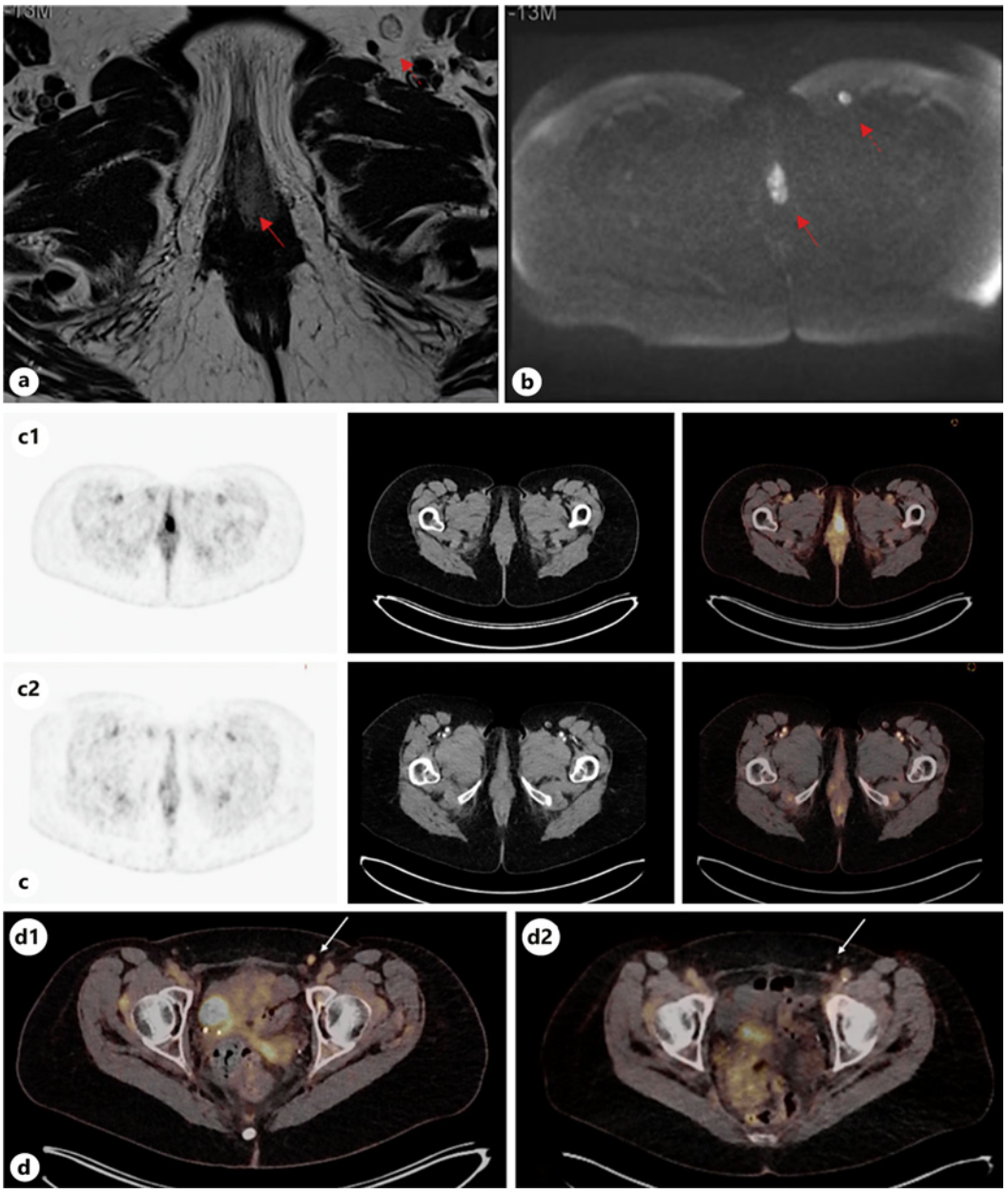

Fig. 1. Imaging of the vulvar metastasis. **a** MRI T2 sequence. The solid arrow indicates the vulvar lesion. The dotted arrow indicates the node in the left iliac region. **b** MRI diffusion sequence. The solid arrow indicates the vulvar lesion. The dotted arrow indicates the node in the left iliac region. **c** PET scan showing the vulvar metastasis (**c1**) and its regression (**c2**). **d** PET scan. The arrow indicates the node in the leD iliac region (**d1**) and its regression (**d2**).

disease-free interval of 17 years, the possibility of a second primary breast cancer or phenotypic evolution of the original tumor was carefully considered. However, a direct histopathological and immunohistochemical comparison between the vulvar lesion and the initial breast carcinoma showed identical features, strongly supporting a metastatic origin (Fig. 3). Furthermore, extensive clinical and radiological evaluation did not reveal any evidence of another primary tumor. Taken together, these findings suggest that the vulvar lesion is a late metastatic recurrence of breast cancer rather than a new primary malignancy.

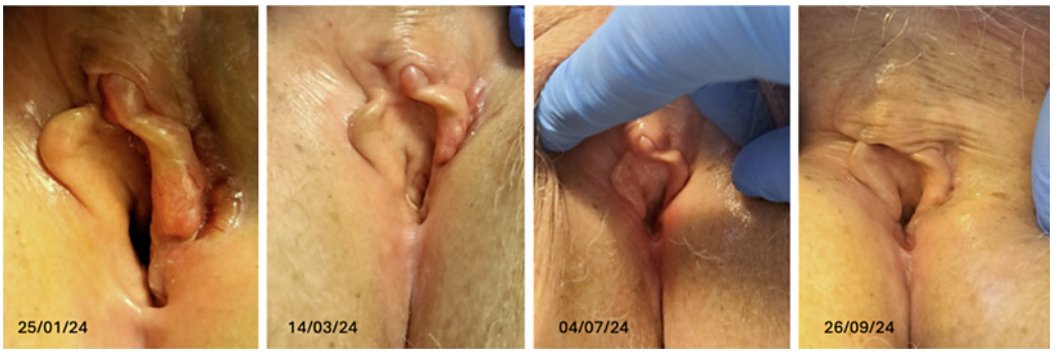

Fig. 2. Clinical evaluation of the vulvar metastasis showing complete disappearance within 8 months.

Discussion

Vulvar cancer is a rare pathology, accounting for a small proportion of gynecological cancers. Although primary vulvar cancers typically arise from the epithelial cells of the vulva, they can, in rare cases, be secondary to metastasis [1, 2]. Vulvar cancer originating from breast cancer may result from metastasis of a distant neoplasia or from a primary tumor arising from ectopic breast tissue. Differentiating between these two possibilities is critical for therapeutic management [3, 5, 11].

Perrone's team has established several criteria to differentiate these two possibilities. Metastatic vulvar tumors typically present histological, immunohistochemical, and hormonal profiles identical to the primary breast tumor. In contrast, primary tumors from ectopic breast tissue may have elements of normal breast tissue or in situ components [3, 5]. Porzio's study highlights that immunohistochemistry can differ between primary cancer and metastasis when there is a long interval between metastasis and primary disease, but the histology should remain consistent [12].

A primary vulvar carcinoma that originates from ectopic mammary tissue is an exceedingly rare condition. The lesion is treated as a primary malignancy. Most of the literature consists of case reports, and many authors recommend applying treatment strategies appropriate for orthotopic breast cancer of a similar stage. Therefore, management should be tailored to the patient's specific needs and can include surgery, chemotherapy, trastuzumab therapy for HER2-positive tumors, radiotherapy, and/or hormonal therapy depending on the tumor's receptor status and clinical extent [13]. In contrast, vulvar metastases from breast cancer reflect disseminated disease and require a systemic therapeutic approach tailored to the primary tumor. As illustrated in our case, targeted therapies, such as CDK4/6 inhibitors, seem to be a promising option.

Our case of vulvar metastasis originating from breast neoplasia is, to the best of our knowledge, the first description in the literature with the patient responding favorably to treatment with CDK4/6 inhibitor and showing significant regression of the vulvar lesion. This is in contrast to other studies in which patients with vulvar metastases of breast origin were treated primarily by excision of the vulvar lesion, hormonal therapy, radiotherapy, and/or chemotherapy [1, 5, 6]. Most of these patients presented at more advanced stages, and vulvar metastases were often an indicator of terminal disease [1, 4].

The importance of long-term follow-up for breast cancer patients cannot be overstated as it facilitates the early detection of both typical and atypical metastases. Only rigorous gynecological surveillance can ensure the early identification of unusual metastatic sites [2, 14, 15]. Vulvar metastases may occur many years after the initial breast cancer diagnosis.

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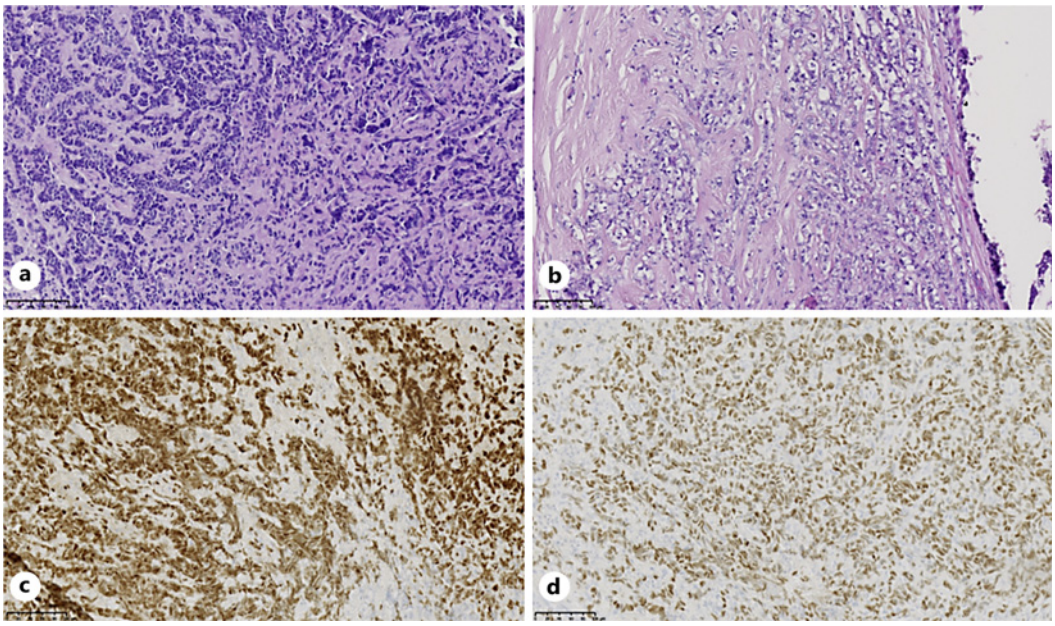

Fig. 3. Anatomopathology. **a** MetastaHc vulvar lesion showing neoplasHc proliferaHon of very poorly differenHated cells. **b** Primary breast neoplasia showing high-grade infiltraHng ductal carcinoma (NoNngham grade 3). **c**, **d** The vulvar lesion expressed ER receptors (**c**) and GATA 3 (**d**), confirming the mammary phenotype.

The Alligood-Percoco study described a patient with a vulvar metastasis appearing more than 20 years after the initial diagnosis. Though lobular carcinomas tend to metastasize later than ductal carcinomas, both have been documented in vulvar metastases [4, 14]. Lamovec and Bracko [16] examined the metastatic profile of breast cancer and noted that infiltrating lobular carcinoma was associated with a greater propensity to involve the internal genitalia than invasive ductal lesions. This contrasts with our observation because our patient had a ductal carcinoma vulvar metastasis detected 17 years after the initial diagnosis. The introduction of CDK4/6 inhibitor abemaciclib into the treatment of metastatic breast cancer offers promising therapeutic possibilities. This treatment appears to be a more effective and less invasive alternative than surgery, radiotherapy, or chemotherapy. Abemaciclib may provide significant benefit for patients with vulvar metastases originating from hormone-receptor-positive, HER2-negative breast cancer. Long-term follow-up of our patient is still necessary to assess the sustained efficacy of this treatment approach.

The choice of abemaciclib was guided by current standards of care in Belgium for hormone receptor–positive, HER2-negative metastatic breast cancer with progression under prior endocrine therapy. CDK4/6 inhibitors are recommended as first-line therapy in this setting. Other targeted therapies were not indicated: PARP inhibitors lack evidence outside of BRCA1/2-mutated cases, PI3K-targeted therapy was not considered due to the absence of a PIK3CA mutation, and everolimus is typically reserved for later treatment lines [17]. Overall, the treatment decision was based on disease biology and available molecular data rather than the presence of the ATM mutation.

This report has inherent limitations due to its single-case nature. Observations from this case cannot be generalized. Metastatic involvement of the vulva from breast cancer is extremely rare, and management must be individualized based on disease biology, prior treatments, and patient factors. This case contributes to the limited literature rather than defining a standard therapeutic approach.

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Conclusion

This case underscores the importance of long-term surveillance and rigorous follow-up in hormone-sensitive breast cancer patients to detect metastases, even in infrequent locations such as the vulva. Distinguishing between vulvar metastases and primary tumors of ectopic breast origin remains crucial in guiding therapeutic decisions. Although vulvar metastases are rare, they can occur years after the initial diagnosis of the primary cancer and require appropriate management. The use of CDK4/6 inhibitor in association with fulvestrant proved to be very beneficial, offering a less invasive and potentially more effective alternative for treating such lesions. This treatment may offer new options for patients with vulvar metastases from hormone-dependent, HER2-negative breast cancer.

Acknowledgments

The authors would like to thank Guilhem Vanden Berghe and Quentin Lorge for reviewing the case report. We are grateful to the patient who agreed to share her case for educational purposes.

Statement of Ethics

This study does not require ethical approval under local or national guidelines. The patient provided written informed consent for the publication of this case report and accompanying images. This case report was prepared in accordance with the CARE guidelines, and the CARE checklist was completed by the authors and is provided as an online supplementary file (for all online suppl. material, see https://doi.org/10.1159/000550564).

Conflict of Interest Statement

The authors declare no conflict of interest.

Funding Sources

This study was not supported by any sponsor or funder.

Author Contributions

Dr. Vanden Berghe Clémence carried out the literature review and drafted the manuscript. Dr. de Codt Matthieu identified and managed the clinical case and contributed to data collection and patient follow-up. He also reviewed and corrected the case report. Pr. D'hondt is the patient's oncologist. He is responsible for her oncological follow-up. He actively participated in writing the manuscript. Dr. Nicaise Nicole provided expertise in radiology (IRM). Pr. Vander Borght Thierry provided expertise in radiology (nuclearist). Dr. Laka Antxustegi Andoni provided expertise in anatomopathology. Dr. Moerman is the general practitioner.

Data Availability Statement

All data generated or analyzed are included in this article and its online supplementary material files. Requests for further information should be addressed to the corresponding author.

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