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CASE REPORT

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First successful desensitization with Abemaciclib in an adult patient with breast cancer: A case report

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Abstract
Abemaciclib, a cyclin-dependent kinase 4/6 (CDK4/6) inhibitor, is an effective targeted therapy for hormone receptor-positive (HR+), HER2-negative, advanced or metastatic breast cancer. While nonimmediate hypersensitivity reactions (NIHRs) have been reported, no immediate hypersensitivity reactions (IHRs) to abemaciclib have been documented to date. Here, we report the first successful desensitization protocol for a patient who developed IHR to abemaciclib. A 75-year-old female with stage II breast cancer underwent a partial mastectomy followed by chemotherapy. Abemaciclib was initiated as part of adjuvant treatment. One hour after the third dose, she presented to the emergency department with lip swelling and urticaria. Symptoms resolved following the administration of intravenous methylprednisolone (0.5 mg/kg) and maleate pheniramine (45.5 mg/mL). Skin prick testing with abemaciclib was negative; however, a drug provocation test led to recurrence of urticaria at a cumulative dose of 150 mg. Given the clinical necessity of abemaciclib and the lack of alternatives, a 12-step desensitization protocol was implemented using 300 mg of abemaciclib dissolved in 100 mL of distilled water. The protocol was completed over 4 h, with no complications observed during the procedure or in the subsequent 3-month follow-up. The patient continued abemaciclib at 300 mg/day without recurrence of symptoms. This case highlights the importance of drug desensitization in oncology, particularly in patients for whom no alternative therapies are available.

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Introduction

Breast cancer is the most common malignancy in women, and hormone receptor-positive, HER2-negative breast cancer is its most prevalent subtype, accounting for 68% of cases in this large patient population. CDK4/6 inhibitors combined with aromatase inhibitors or fulvestrant are now considered the preferred first-line treatment.[1] CDK4/6 inhibitors have been shown to improve progression-free and overall survival compared to endocrine therapy alone, while their toxicity profiles are more tolerable than chemotherapy.[2,3] As of 2023, abemaciclib is the only oral CDK4/6 inhibitor approved in the adjuvant setting for HR+/HER2− high-risk early-stage breast cancer, and it is also the only agent approved for previously treated metastatic breast cancer patients.[4,5]

Abemaciclib is generally well tolerated, with cutaneous toxicities being among the most common adverse effects. Mild skin-related side effects occur in approximately 15% of patients, including alopecia, rash, and pruritus.[6] While nonimmediate hypersensitivity reactions (NIHRs) have been reported, no immediate hypersensitivity reactions (IHRs) have been documented.

Desensitization is a process that enables the safe administration of essential medications while protecting patients from severe reactions triggered by anaphylactic or anaphylactoid mechanisms.[7] Given the life-saving nature of abemaciclib and its critical role in improving survival, desensitization may be considered a viable option for patients who develop urticaria and angioedema during treatment.

To date, no desensitization protocol for abemaciclib has been reported. In this article, we describe a patient who experienced an IHR to abemaciclib and present the first desensitization protocol for its safe administration.

Case Report

A 75-year-old female patient was diagnosed with stage II breast cancer and underwent a left partial mastectomy. After receiving chemotherapy, abemaciclib treatment to hormonal therapy was added to her regimen. Within 1 h following the third dose of abemaciclib, the patient presented to the emergency department with complaints of lip swelling and urticaria on her body. This was her first episode of urticaria, and no suspicion of drug or food exposure was identified, nor were any signs or symptoms of concomitant infection observed. The lesions were evaluated as consistent with urticaria and angioedema, and the patient was treated with intravenous 0.5 mg/kg methylprednisolone and 45.5 mg/mL maleate pheniramine. Her symptoms subsided 2 h after treatment.

To confirm hypersensitivity to abemaciclib, we performed a 1/1 prick test with the tablet form, which yielded a negative result. Since a parenteral form was not available, an intradermal test could not be performed. Subsequently, we conducted a drug provocation test with abemaciclib, and at a cumulative dose of 300 mg, the patient developed urticaria plaques on her arms, legs, and abdomen in 10 min.

Given the critical importance of abemaciclib and the lack of alternative treatment options, desensitization was necessary. Since no desensitization protocol for abemaciclib was previously published, we developed a novel protocol. For the preparation of the desensitization protocol, a 300 mg abemaciclib oral tablet was dissolved in 100 mL of distilled water to obtain a 3 mg/mL solution, which was administered orally.

The 12-step desensitization protocol, with 30-min intervals as shown in Table 1, was successfully performed to reach the patient's daily oral dose of 300 mg abemaciclib. During the desensitization procedure, which lasted 4 h, the patient's vital signs were closely monitored, and the procedure was completed without any complications.

No hypersensitivity reaction was observed in the 3-month follow-up after desensitization, and the patient continued abemaciclib treatment at a dose of 300 mg/day without any complaints.

Discussion

This case report is the first successful desensitization protocol for an IHR to abemaciclib and highlights the importance of desensitization in patients with no alternative treatment options.

Various dermatologic adverse events (AEs) have been reported among CDK4/6 inhibitors. Abemaciclib is generally associated with fewer dermatologic AEs compared to palbociclib and ribociclib; however, erythema multiforme stands out as an exception.[8] Common skin reactions, such as alopecia, rash, and pruritus, have been reported across all inhibitors, while specific skin conditions (e.g., cutaneous lupus erythematosus, vitiligo, and TEN) were observed more frequently with certain inhibitors.[8] Nonetheless, these skin reactions do not affect the overall risk-benefit profile; CDK4/6 inhibitors have been shown to extend progression-free survival significantly and are generally well tolerated, highlighting the importance of desensitization.[9]

Desensitization involves the gradual administration of small doses of drug antigens at specific intervals, allowing patients to receive full therapeutic doses without the risk

Table 1 Abemaciclib desensitization protocol (oral tablet).

Step	Time (minute)	The amount of solution applied in each step (mL)	The dose administered at each step (mg)	Cumulative dose (mg)
1	0	0.1	0.3	0.3
2	20	0.3	0.9	1.3
3	40	0.5	1.5	2.7
4	60	1	3	5.7
5	80	2	6	11.7
6	100	4	12	23.7
7	120	6	18	41.7
8	140	8	24	65.7
9	160	12	36	101.7
10	180	16	48	149.7
11	200	20	60	209.7
12	220	30	90.3	300

of anaphylaxis. For patients with drug allergies who have no alternative treatment options, the only viable therapeutic approach is the application of a drug desensitization protocol. Temporary tolerance can be achieved and sustained within hours through the administration of drug antigens at regular intervals, depending on the pharmacokinetic parameters of the drug.[7] During desensitization, if drug intervals exceed more than twice the drug's half-life, reapplication of the desensitization protocol may be necessary. Given that the half-life of abemaciclib is between 18 and 28 h, administering the drug every 24 h enhances the effectiveness of desensitization, eliminating the need for repeated protocols.[4] Based on this principle, the desensitization protocol for our patient was completed through a 12-step process lasting approximately 4 h, aiming to reach the patient's daily therapeutic dose. Throughout the protocol, the patient tolerated the total oral dose of the medication without any complaints or complications, and the daily administration of abemaciclib allowed for the successful management of the IHR. In the 3-month follow-up after desensitization, the patient continued her abemaciclib treatment at 300 mg/day in the oral tablet form without experiencing any allergic reactions.

We emphasize the importance of a multidisciplinary approach in oncology patients, highlighting the need for early recognition and appropriate management of HRs. Although angioedema is rarely reported, involvement of the pharynx and larynx can pose a life-threatening risk during an IHR.

Conclusion

This case report demonstrates a successful desensitization protocol for abemaciclib in patients with IHRs, emphasizing the importance of desensitization in cases where no alternative treatment options are available.

Author's Contribution

All authors contributed equally to this article.

Conflicts of Interest

The authors have no relevant financial interests to disclose.

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