Case Report

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Mepolizumab and pregnancy: A case of severe eosinophilic asthma in a patient who conceived during mepolizumab treatment

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Abstract:

A 30-year-old female patient with steroid-dependent severe eosinophilic asthma and chronic eosinophilic pneumonia had been successfully treated with mepolizumab for 15 months. At the 16th month of mepolizumab treatment, she reported an unplanned pregnancy at four weeks gestation. Biological treatment was discontinued, and the patient was managed with a combination of inhaled corticosteroids (ICS), long-acting beta-agonists (LABA), and oral steroids. Despite experiencing frequent exacerbations during follow-up, appropriate treatments were administered. The patient delivered a healthy baby via normal spontaneous vaginal delivery at 39 weeks. In the management of pregnant women with asthma, the risk-benefit ratio of the medications used should be carefully evaluated, considering the potential risk of exacerbation or uncontrolled disease if the treatment is discontinued. In the presented case, after discontinuing mepolizumab treatment, the patient experienced three exacerbations despite regular use of systemic steroids.

Keywords:

Asthma, biological treatment, chronic eosinophilic pneumonia, mepolizumab, pregnancy

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Introduction

Asthma is one of the most common chronic respiratory diseases, affecting approximately 330 million people worldwide.[1] It is also the most common respiratory disease during pregnancy, occurring in 3–6% of pregnant women.[2,3] Uncontrolled asthma during pregnancy can result in both maternal and fetal complications.[4] A significant factor contributing to uncontrolled asthma in pregnant women is inadequate treatment, often due to fears of medication side effects.[2,3] Asthma treat-

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ments should be continued to maintain asthma control during pregnancy and to ensure that pregnant women with asthma deliver a healthy baby.[5] However, there is no data on the use of biological drugs, other than omalizumab, for asthma control in pregnant women.[6]

Here, we present a case of a patient diagnosed with severe eosinophilic asthma and chronic eosinophilic pneumonia who conceived while receiving mepolizumab treatment, to contribute to the literature.

Case Report

A 30-year-old female patient with severe asthma and chronic eosinophilic lung disease had been followed up regularly. She was diagnosed with asthma and was on regular high-dose treatment; however, her asthma remained uncontrolled, with frequent exacerbations requiring systemic steroid use. Peripheral eosinophilia was noted on complete blood counts, particularly during exacerbations. High-resolution thoracic computed tomography during exacerbation episodes revealed findings consistent with chronic eosinophilic pneumonia. The patient was a non-smoker, and her medical history showed no evidence of atopy. A skin prick test for sensitization to seasonal and persistent aeroallergens, including house dust mites, animal dander, cockroaches, mold spores, and pollens, was negative. Her body mass index was 26.9 kg/m2. She demonstrated peripheral eosinophilia, with counts as high as 2430 cells/μL. The total Immunoglobulin E (IgE) level was 795 IU/ml, and specific IgE tests for Aspergillus and other allergens were negative. Additionally, her c-ANCA (cytoplasmic anti-neutrophil cytoplasmic antibody) and p-ANCA (perinuclear anti-neutrophil cytoplasmic antibody) tests were negative. The patient was being treated with oral deltacortril (10 mg) in addition to a high-dose inhaled combination of budesonide and formoterol. Despite this treatment, the disease remained uncontrolled, with an asthma control test score of 14 and frequent exacerbations, approximately three times a year. Due to poor disease control, mepolizumab treatment was initiated at a dose of 100 mg every four weeks, administered subcutaneously, with a diagnosis of severe eosinophilic asthma and chronic eosinophilic pneumonia. Before initiating mepolizumab treatment, the patient was informed about the drug's effects, side effects, and the necessity of using birth control, and her consent was obtained. With mepolizumab treatment, disease control was achieved, and the patient's asthma control test score improved to 25. During follow-up, the dose of deltacortril was gradually reduced to 5 mg twice a week. She experienced only one asthma exacerbation during the tenth month of mepolizumab treatment. At the 16th month of treatment, the patient reported that she was four weeks pregnant. Mepolizumab treatment was discontinued following a mutual decision with the patient. In consultation with the gynecology and rheumatology clinics, deltacortril was continued at a dose of 5 mg every other day, alongside high-dose inhaled corticosteroids and long-acting beta-2 agonists. During this period, the patient experienced three asthma exacerbations, which required short-term increases in the deltacortril dose. In the 39th week of pregnancy, the patient delivered a healthy boy. The newborn had an APGAR (Appearance, Pulse, Grimace, Activity, and Respiration) score of 9, a birth weight of 3500 grams, and a height of 51 centimeters.

Discussion

Biological drugs are characterized by low risks of off-target toxicity due to their high target specificity. However, they still carry the potential for teratogenic effects, making it essential to evaluate their safety during pregnancy.[7] Obtaining safety data for biologics during pregnancy is particularly challenging. The primary reason is that biologic therapies are typically reserved for severe asthma phenotypes and are prescribed relatively infrequently. Therefore, birth control is recommended for women of childbearing age when initiating biological therapy. For the treatment of severe asthma during pregnancy, omalizumab is the best-studied drug, with available safety data being reassuring.[6] However there is insufficient safety data regarding the use of mepolizumab and other biologics approved by the U.S. Food and Drug Administration (FDA) during pregnancy. However, data regarding the pregnancy process and outcomes are valuable in women who become pregnant and continue their pregnancy while using biological agents, despite existing recommendations.[8]

Mepolizumab is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that inhibits interleukin-5 by blocking its binding to the interleukin-5 receptor expressed on eosinophils. It is transported linearly across the placenta during pregnancy, with its potential effects

on the fetus expected to be greater in the second and third trimesters.[9] Theoretically, this means the fetus is not significantly exposed to mepolizumab during the organogenesis period. A study conducted in cynomolgus monkeys showed no evidence of fetal harm when mepolizumab was administered to pregnant animals at doses higher than the maximum recommended human dose.[9] Case reports from the last few years provide hope regarding the safety of mepolizumab use during pregnancy. In 2022, a case was reported involving a young woman with severe eosinophilic non-allergic asthma who achieved excellent asthma control with mepolizumab. She became pregnant, continued mepolizumab treatment throughout her pregnancy, and delivered a healthy baby without complications for either the mother or the infant.[8] These data suggest that mepolizumab may be safe during pregnancy. The case presented herein adds further insight into this topic. However, a single case with brief exposure during early pregnancy is insufficient to establish the drug's safety definitively. More data are needed to support this hypothesis. Therefore, any pregnancy occurring during biological treatment should be reported to pharmacovigilance systems.

Lastly, in the management of pregnant women with asthma, the risk-benefit ratio of the medications used should be carefully evaluated, considering the potential risk of exacerbation or uncontrolled disease if the treatment is discontinued. In the presented case, after discontinuing mepolizumab treatment, the patient experienced three exacerbations despite regular use of systemic steroids.

Informed Consent

Written consent was obtained from the patient for the case presentation.

Authorship Contributions

Concept – K.A., M.Y., H.Ç.T., O.T., Ö.A., F.D.Ç.; Design – K.A., M.Y., H.Ç.T., O.T., Ö.A., F.D.Ç.; Supervision – K.A., M.Y., H.Ç.T., O.T., Ö.A., F.D.Ç.; Funding – K.A., M.Y., H.Ç.T., O.T., Ö.A., F.D.Ç.; Materials – K.A., M.Y., H.Ç.T., O.T., Ö.A., F.D.Ç.; Data collection &/or processing – K.A., M.Y., H.Ç.T., O.T., Ö.A., F.D.Ç.; Analysis and/or interpretation – K.A., M.Y., H.Ç.T., O.T., Ö.A., F.D.Ç.; Literature search – K.A., M.Y., H.Ç.T., O.T., Ö.A., F.D.Ç.; Writing – K.A., M.Y., H.Ç.T., O.T., Ö.A., F.D.Ç.; Critical review – K.A., M.Y., H.Ç.T., O.T., Ö.A., F.D.Ç.

Conflicts of Interest

There are no conflicts of interest.

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