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Safety of azathioprine and methylprednisolone during breastfeeding: A Case Report

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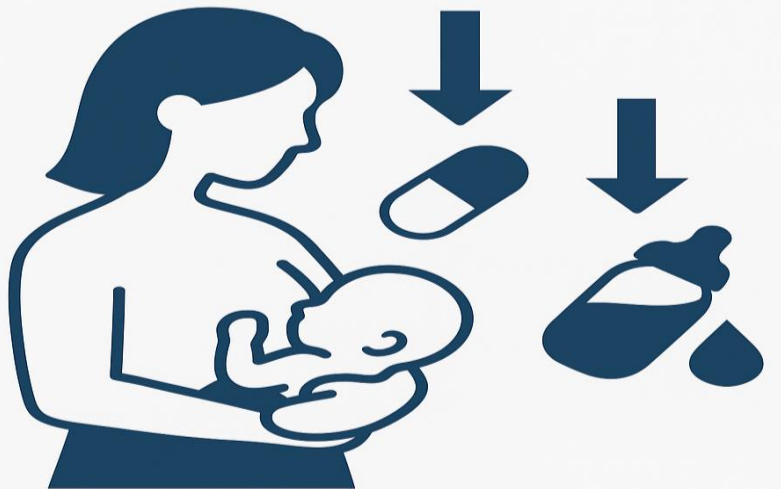
Introduction: Autoimmune hepatitis (AIH) is a chronic inflammatory liver disease characterized by the presence of autoantibodies in the circulation and high serum immunoglobulin levels, which can lead to necrosis and fibrosis in the liver. The clinical presentation of the disease can vary from asymptomatic to cirrhosis, liver failure, and even death. It can occur in all age groups, with a higher prevalence in women. In the treatment of AIH, oral glucocorticoids are often used alone or in combination with azathioprine to induce remission and prevent progression of liver damage. Maintenance therapy typically involves low-dose prednisone or azathioprine to keep the disease under control. According to current literature data, the use of glucocorticoids and thiopurines during lactation is considered safe when certain precautions are taken .

It has been shown that 6-mercaptopurine, the active metabolite of azathioprine, reaches its highest concentration in breast milk within the first 4 hours after administration of the drug. The American College of Rheumatology recommends expressing and discarding breast milk for the first 4 hours after azathioprine administration to reduce the risk of immunosuppression, and monitoring blood cell counts in infants with a history of frequent infections. Methylprednisolone also passes into breast milk. The concentration in breast milk reaches its peak approximately one hour after the maternal dose and falls below detectable levels after 12 hours. Considering potential adverse effects such as growth retardation in the breastfed infant, it is recommended to avoid breastfeeding for 4 hours after the maternal dose of methylprednisolone .

Methods: Our 37-year-old patient diagnosed with AIH was the mother of two children aged four years and four months. She was referred to our Trabzon Teratogenicity Information Service (Trabzon-TIS) by a gastroenterologist regarding the use of azathioprine and methylprednisolone during lactation. The patient's demographic information, clinical history, and laboratory parameters were recorded. The patient had been using methylprednisolone and azathioprine until she learned of her pregnancy and had discontinued the medications under the supervision of a gastroenterologist during her pregnancy. At 39 weeks of pregnancy, she gave birth to a healthy baby girl weighing 3080 grams and measuring 48 cm. Four months after delivery, the mother consulted us regarding the use of methylprednisolone (40 mg/day) and azathioprine (50 mg/day) during breastfeeding due to impaired liver function, as advised by her gastroenterologist. Based on current pharmacology literature, it was recommended to avoid breastfeeding for the first 4 hours after taking the medication, and the baby's development was monitored.

Results: Our patient started using azathioprine and methylprednisolone when her baby was 4 months old and continued breastfeeding until the 7th month, as recommended. During this period, the baby, who was fed only breast milk, weighed 6,500 grams at 7 months of age, had an increased frequency of infections, and remained in the 5–15th percentile. The infant was hospitalized four times due to infections before reaching one year of age. Currently 14 months old, the infant weighs 8,400 grams, measures 74 cm, and has no diagnosed medical conditions.

Conclusions: In this case, the use of azathioprine and methylprednisolone during breastfeeding was managed in accordance with current pharmacological recommendations, such as avoiding breastfeeding for the first four hours after taking the medication. Despite adherence to the recommendations, the infant developed low percentile and recurrent infections. A single case may not be sufficient to question the safety of azathioprine and methylprednisolone during breastfeeding. However, this situation highlights the importance of individually assessing the benefit-risk ratio in cases receiving immunosuppressive treatment during breastfeeding, conducting close pediatric follow-up, and monitoring growth and infection frequency.



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