Safety and Efficacy of Mepolizumab during Pregnancy and Postpartum

Segurança e Eficácia do Mepolizumab durante a Gravidez e Pós-Parto

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Palavras-chave: Anticorpos Monoclonais Humanizados; Asma/tratamento farmacológico; Antiasmáticos/tratamento farmacológico; Gravidez; Período Pós-Parto/efeitos dos fármacos

Asthma is the most common chronic respiratory disease complicating pregnancy, with symptoms worsening in approximately one third of women during early gestation. Poor asthma control increases adverse maternal and perinatal outcomes. Mepolizumab, an anti-interleukin-5 monoclonal antibody, is approved for the treatment of severe eosinophilic asthma. Despite established efficacy and safety in non-pregnant populations, limited pregnancy data have led to its precautionary avoidance.[1,2]

We describe a case in which mepolizumab was safely and effectively continued throughout pregnancy and the postpartum period in a patient with severe allergic eosinophilic asthma.

A 34-year-old non-smoking woman with childhood-onset allergic asthma and chronic rhinosinusitis without nasal polyps remained stable until adolescence, when respiratory symptoms worsened, with seven to eight annual exacerbations requiring oral corticosteroids (OCS). The assessment showed an allergic-eosinophilic phenotype with symptomatic sensitization to dog, cat and olive-tree pollen allergens, and irreversible bronchial obstruction. Omalizumab (300 mg/4w) was initiated; however, despite optimized therapy, she experienced worsening symptoms, recurrent exacerbations and OCS dependence. After five years, omalizumab was switched to mepolizumab (100 mg/4w), leading to improvement of exacerbations, pulmonary function, inflammatory biomarkers, and OCS withdrawal (Table 1).

After seven years of continuous mepolizumab therapy, the patient became pregnant. Following a multidisciplinary meeting at the Severe Asthma Unit, mepolizumab and budesonide/formoterol (400/12µg twice daily) were continued, with the hospital's Pharmacy and Therapeutics Committee approval and written informed consent. The pregnancy and delivery were uneventful. During the first and second trimesters, the patient reported intermittent dyspnea, wheeze and fatigue requiring short-acting bronchodilators, without exacerbations or OCS use. These symptoms were considered compatible with physiological changes of pregnancy, anxiety or transient disease variability. Fractional exhaled nitric oxide increased during the second trimester without clinical deterioration and oxygen saturation remained stable. A healthy infant was delivered vaginally at 39 weeks + three days (Apgar 9/10, weighting 3020 g). Asthma control remained excellent during seven months of postpartum follow-up. Breastfeeding was avoided due to uncertain risks, and the child developed normally.

To date, one case report supports the safety of mepolizumab during pregnancy and early lactation. Discontinuation before conception led to clinical decline; after

Table 1 – Pulmonary function tests and clinical parameters before, during and after pregnancy follow-up under mepolizumab treatment

	Pre-pregnancy		Pregnancy		Post-pregnancy		
	Pre-mepolizumab	Post-mepolizumab	1st trimester	2nd trimester	2 months	4 months	7 months
ACT	21/25	22/25	11/25	15/25	24/25	24/25	24/25
AQLQ	5.75/7	5.81/7	4.09/7		6.46/7	6.68/7	6.81/7
SNOT-22	20/110	22/110	17/110		10/110	19/110	7/110
VAS	25/100	20/100	40/100		30/100	25/100	20/100
TAI	45/50	46/50	50/50		45/50	44/50	47/50
Nijmegen questionnaire	11/64	9/64	11/64		9/64	4/64	2/64
AIRQ			5/10		0/10		0/10
FVC (L/%)	3.75/93	3.92/94			2.21/64	3.81/91	3.96/95
FEV1 (L/%)	2.01/53	2.35/68			1.78/52	2.21/64	2.52/73
FEV1/FVC (%)	53.0	60.1			57.6	58.0	76.0
FeNO (ppb)	232	114	116	146	122	99	123
Eosinophils (per mL)	640	60	50	80	120		
IgE (kU/L)	517	206					
ECP (µg/L)	134	55					
Prednisolone (mg/day)	10	0	0		0		
Exacerbations requiring OCS	7 - 8/year	0	0		0		

ACT: asthma control test; AQLQ: Asthma Quality of Life Questionnaire; SNOT-22: sinonasal outcome test; VAS: visual analogue scale for sino-nasal symptoms severity; TAI: test of adherence to inhalers; AIRQ: Asthma Impairment and Risk Questionnaire; FVC: forced vital capacity; FEV1: forced expiratory volume in 1 second; FeNO: fractional exhaled nitric oxide; ECP: eosinophilic cationic protein.

re-initiation, conception occurred four months later with two exacerbations, highlighting the risks of biologic interruption.[3] Pharmacovigilance data have yielded mixed pregnancy outcomes with asthma biologics. For mepolizumab, adverse outcomes were reported for 42% of cases (64/154; OR 0.23), with higher reporting of fetal death (OR 1.87) and spontaneous abortion (OR 2.75) but lower reporting of pregnancy and delivery complications (OR 0.17 and OR 0.21) compared to non-biologic asthma medications; however, spontaneous reporting limits causality assessment.[4] Ongoing prospective studies are expected to provide more definitive data.[5] Additionally, IgG monoclonal antibodies have limited first-trimester placental transfer and low breast milk concentration, with partial infant gastrointestinal degradation, supporting relative safety in pregnancy and lactation.[2,3,5]

Although limited to a single case, this report supports the potential safety and efficacy of continued mepolizumab therapy during pregnancy and postpartum, emphasizing the importance of multidisciplinary management. Further data is required to guide clinical decision-making in this population.

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AUTHOR CONTRIBUTIONS

JMS, DV: Literature review, writing of the manuscript.
DL, JDO, MLB: Critical review of the manuscript.
All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

PATIENT CONSENT

Obtained.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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Joana MARQUES SIMÕES [1], Daniela VIDAL[2], Daniel LAORDEN [3], Magdalena LLUCH-BERNAL [4], Javier DOMÍNGUEZ-ORTEGA [4]

1. Department of Pulmonology. Unidade Local de Saúde Santa Maria. Lisbon. Portugal.
2. Department of Pulmonology. Hospital Guillermo Grant Benavante. Concepción. Chile.
3. Department of Pulmonology. Hospital Universitario La Paz. Madrid. Spain.
4. Department of Allergy. Hospital Universitario La Paz. Institute for Health Research (IDIPAZ). Madrid. Spain.

✉ **Autor correspondente:** Joana Marques Simões. joanafmsimoes@gmail.com

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