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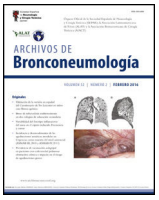

Clinical Letter

Experience With the Use of Biological Therapy for Asthma Control During Pregnancy: Preliminary Results

To the Director,

Studies on the safety of monoclonal antibodies for bronchial asthma during pregnancy are scarce. The Task Force Report[1] considers the classification of biologics for safety in pregnancy (although not based on randomized controlled trials) in the following grades; *compatible:* when there is sufficient anecdotal evidence from use during human pregnancies that the embryofetal risk is very low or non-existent; *probably safe*: when there is limited experience from trials during human pregnancy (or during lactation), but the characteristics of the drug and/or drugs in the same class suggest low risk; and *possibly safe* for second-line use if better proven treatment options fail.

In the latter grade are most of the biologics used in asthma, where the benefit is likely to outweigh the potential risk during pregnancy and/or lactation, although the exact risks are unknown.[2]

We present our experience on the use of biologic therapy in a sample of pregnant women with severe asthma follow-up clinic during pregnancy. We collected asthmatic pregnant women who had been administered biologic therapy at some time during gestation or during the entire pregnancy, as well as their relationship with fetal biometry (biparietal diameter, abdominal circumference and femur length), newborn weight and the presence of malformations during follow-up and/or delivery.

Out of a total of 140 severe asthmatic pregnant women under follow-up by the Difficult-to-Control Asthma Unit, a subgroup of 13 patients were found to be exposed to a monoclonal antibody at some time during pregnancy, with a mean age of 33 years (± 6.3). In no case was biological treatment initiated during pregnancy.

Of the 13 pregnant women, 10 were administered omalizumab with a mean exposure of 2.88 doses and a maximum of 8 doses, and 3 were administered mepolizumab with a mean exposure of 3 doses and a maximum of 7 doses.

The evolution of the pregnancy and the parameters of the newborn are shown in Table 1. All patients included in the study were closely monitored during pregnancy by the Asthma Unit and the Obstetrics High Risk Unit. No differences were observed in fetal biometry or birth weight. There was no evidence of an increased risk of major congenital anomalies among pregnant women exposed to monoclonals.

As in previous studies of biologic therapy administered to a limited number of pregnant women, we have not observed an apparent increase in the frequency of fetal malformation.[3,4]

In any case, the decision to use them should be approached on an individualized and consensual basis in each case, depending on the clinical situation and the potential benefits and risks for the mother, fetus and newborn.

Table 1
Characteristics of Severe Asthmatic Pregnant.

Asthmatic Pregnant	With Biological Therapy *n* = 13	Without Biological Therapy *n* = 127
Age (SD)	33 (± 6.3)	28 (± 7)
Biological therapy (mAbs)		–
Omalizumab (*n*)	77% (10)	–
Mepolizumab (*n*)	23% (3)	–
Exposure during pregnancy		
First trimestre-1T (*n*)	84.6% (11)	–
Complete pregnancy: 1T-2T-3T (*n*)	15.4% (2)	–
Delivery		
Eutocic delivery	61.5%	53%
Cesarean delivery	38.5%	45%
Abortion/stillbirth	0%	2%
Birth weight	3090 g (2442–4160)	3110 g (2550–4000)
Gestational age at delivery	39.3 weeks	39 weeks
Apgar test 1 min		
10 points	60%	70%
9 points	20%	20%
8 points	10%	10%
7 points	10%	–
<7 points	0%	–

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More data on the biosafety of these drugs are needed and additional studies on extended follow-up beyond birth, including markers of development and health.

References

1. Middleton PG, Gade EJ, Aguilera C, MacKillop L, Button BM, Coleman C, et al. ERS/TSANZ Task Force Statement on the management of reproduction and pregnancy in women with airways diseases. Eur Respir J. 2020;55(2):1901208, http://dx.doi.org/10.1183/13993003.01208-2019. PMID: 31699837.
2. L Ramos C, Namazy J. Monoclonal antibodies (biologics) for allergic rhinitis, asthma, and atopic dermatitis during pregnancy and lactation. Immunol Allergy Clin N Am. 2023;43(1):187–97, http://dx.doi.org/10.1016/j.iac.2022.07.001.
3. Shakuntulla F, Chiarella SE. Safety of biologics for atopic diseases during pregnancy. J Allergy Clin Immunol Pract. 2022;10(12):3149–55, http://dx.doi.org/10.1016/j.jaip.2022.08.013.
4. Naftel J, Jackson DJ, Coleman M, d'Ancona G, Heaney LG, Dennison P, et al. An international consensus on the use of asthma biologics in pregnancy. Lancet Respir Med. 2024, http://dx.doi.org/10.1016/S2213-2600(24)00174-7. Published online August 28.

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