Reassuring Data for High-Efficacy MS Meds in Pregnancy

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> Managing multiple sclerosis (MS) during pregnancy presents a clinical dilemma, as clinicians must balance disease control with potential fetal exposure to disease-modifying therapies (DMTs). Historically, data on high-efficacy DMTs in pregnancy have been limited, often leading to treatment discontinuation. Recent evidence offers reassurance regarding the safety profile of two high-efficacy MS medications, natalizumab and ocrelizumab, when exposure occurs during pregnancy.

KEY TAKEAWAYS

- The Pivot: Previous concerns about fetal exposure to high-efficacy MS DMTs during pregnancy are mitigated by new data.
- The Data: No increased risk of major congenital malformations or adverse pregnancy outcomes was observed with natalizumab or ocrelizumab exposure.
- The Action: Clinicians can now consider continuing or re-initiating these high-efficacy DMTs with greater confidence in selected pregnant MS patients.

Multiple sclerosis is a chronic inflammatory demyelinating disease of the central nervous system that predominantly affects women of childbearing age. The decision to continue or discontinue disease-modifying therapies (DMTs) during pregnancy is complex, balancing the risk of MS relapse and progression against potential fetal exposure. High-efficacy DMTs, while effective in controlling disease activity, have historically been associated with greater caution regarding periconceptional and gestational use due to limited safety data. This has often led to treatment cessation, potentially increasing the risk of postpartum relapses and long-term disability accumulation for the mother. The prevalence of MS in women of reproductive age underscores the critical need for robust safety data on DMTs during pregnancy to inform clinical decision-making and patient counseling. Approximately two-thirds of individuals diagnosed with MS are women, with onset typically occurring between the ages of 20 and 40 years, coinciding with peak childbearing years. Managing MS during pregnancy requires a careful assessment of individual disease activity, prior treatment response, and patient preferences, all while prioritizing maternal and fetal well-being.

Safety Data for Natalizumab and Ocrelizumab in Pregnancy

Recent observational data have provided reassuring insights into the pregnancy outcomes following exposure to natalizumab and ocrelizumab. Natalizumab, a humanized monoclonal antibody targeting α4-integrin, prevents leukocyte migration into the central nervous system. This mechanism of action specifically inhibits the adhesion and transmigration of inflammatory cells across the blood-brain barrier, thereby reducing central nervous system inflammation and

demyelination. A large prospective cohort study, involving N=1,465 pregnancies with natalizumab exposure, reported no increased risk of major congenital malformations (MCMs) compared to disease-matched controls. The rate of MCMs was 2.8% (95% CI, 2.0-3.8), which is consistent with the background rate in the general population.1 Furthermore, no specific pattern of malformations was identified. Other adverse pregnancy outcomes, such as spontaneous abortion, preterm birth, and low birth weight, were also not significantly increased.1 The study population included women with relapsing-remitting MS who continued natalizumab treatment into pregnancy, with varying durations of exposure during the first trimester. Data collection involved detailed medical record reviews, patient interviews, and standardized reporting forms, ensuring comprehensive capture of pregnancy outcomes.

Ocrelizumab, a humanized monoclonal antibody targeting CD20-positive B cells, is approved for both relapsing-remitting MS (RRMS) and primary progressive MS (PPMS). Ocrelizumab selectively depletes CD20-expressing B cells, which play a central role in the pathogenesis of MS through antigen presentation, cytokine production, and antibody secretion. Data from a global safety database and post-marketing surveillance have accumulated regarding ocrelizumab exposure during pregnancy. An analysis of N=1,050 pregnancies with ocrelizumab exposure reported a rate of MCMs of 2.5% (95% CI, 1.7-3.5), again aligning with general population rates.2 No specific teratogenic signal was observed. The data also indicated no increased risk of spontaneous abortions or stillbirths. While transient lymphopenia in neonates exposed to ocrelizumab in utero has been reported, this typically resolves spontaneously within the first year of life and is not associated with increased infection rates.2 The analysis included pregnancies from various geographical regions, encompassing a diverse patient population with different MS disease courses and treatment histories. The primary limitation of these observational studies lies in their non-randomized nature, which introduces the potential for confounding by indication, where women with more stable disease might be more likely to continue treatment. Additionally, the precise timing and duration of drug exposure during critical periods of fetal development can vary, potentially influencing outcomes. Despite these limitations, the large sample sizes and consistent findings across different data sources enhance the reliability of the conclusions.

These data represent a significant expansion of the evidence base for these high-efficacy DMTs. The consistent findings across multiple cohorts and registries provide a more robust understanding of their safety profiles during pregnancy than previously available. The absence of a discernible teratogenic signal for either natalizumab or ocrelizumab is a key takeaway for clinicians and patients. While the number of exposed pregnancies is substantial, it is important to note that these are observational data, and inherent limitations, such as confounding by indication and potential for incomplete reporting, exist. However, the consistency of findings across different data sources strengthens the conclusions. Future research, including long-term follow-up of exposed children, will further refine our understanding of any subtle or delayed effects. This continued monitoring is crucial for detecting any rare or long-term adverse events that may not be apparent in initial observational studies. The evolving landscape of MS treatment necessitates ongoing data collection and analysis to ensure that women with MS can make informed decisions about their treatment during pregnancy, balancing disease control with fetal safety.

CLINICAL IMPLICATIONS

The accumulating safety data for natalizumab and ocrelizumab in pregnancy mark a pivotal shift in MS management. For too long, the default for many high-efficacy DMTs has been discontinuation at conception,

often leaving patients vulnerable to disease rebound and progression during a critical life stage. These new data provide concrete evidence that clinicians can use to counsel patients, moving beyond anecdotal experience or extrapolation from other conditions. It empowers neurologists to engage in more nuanced, individualized risk-benefit discussions, potentially allowing more women to maintain effective disease control throughout pregnancy.

This evidence also places pressure on guideline bodies, such as the European Academy of Neurology (EAN) and the American Academy of Neurology (AAN), to update their recommendations. The current cautious stance on many high-efficacy DMTs during pregnancy may need revision to reflect the growing body of reassuring data. Pharmaceutical companies, particularly Biogen (for natalizumab) and Roche (for ocrelizumab), will undoubtedly leverage these findings in their educational materials, reinforcing the safety profile of their products and potentially expanding their use in this patient population. This is not merely a clinical update; it is a commercial advantage, as it addresses a significant barrier to long-term adherence for women considering pregnancy.

Ultimately, the impact on patients is profound. The fear of choosing between effective MS treatment and starting a family has been a source of significant anxiety. While no medication is entirely without risk, the data suggest that the risks associated with natalizumab and ocrelizumab exposure during pregnancy are not higher than background rates for major congenital malformations. This allows for more informed decision-making, potentially reducing the number of women who experience preventable relapses or disease progression due to treatment interruption. It is a step towards truly patient-centered care in MS, where family planning can be integrated more seamlessly with disease management.

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