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MULTIPLE SCLEROSIS AND PREGNANCY: A SYSTEMATIC LITERATURE REVIEW (2018–2026)

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ABSTRACT

Introduction and purpose: Multiple sclerosis (MS) predominantly affects women of reproductive age, necessitating a delicate balance between maternal disease control and fetal safety. This review aims to synthesize contemporary evidence regarding therapeutic management during pregnancy, labor, and the puerperium to optimize clinical outcomes.
Description of the state of knowledge: Pregnancy induces systemic immunomodulation (Th2-shift), reducing annualized relapse rates (ARR) by 70–80% in the third trimester. Current evidence indicates that MS does not adversely impact fertility or obstetric outcomes. Landmark data on ocrelizumab (N=3244) confirm that peri-conceptional exposure does not correlate with increased congenital malformations. Conversely, the "rebound effect" remains a significant risk following the cessation of high-efficacy therapies (HET) such as natalizumab. Pharmacokinetic analyses support the safety of breastfeeding under monoclonal antibody coverage, as the Relative Infant Dose (RID) for most agents remains below 1%, well within the 10% safety threshold.
Conclusions: MS management must transition from mandatory drug discontinuation to personalized risk stratification. A shared decision-making model involving neurologists, obstetricians, and patients is essential. Future research should prioritize long-term neurodevelopmental data for infants exposed to novel biological therapies.

KEYWORDS

Multiple Sclerosis, Pregnancy, Disease-Modifying Therapies, Monoclonal Antibodies, Postpartum Relapse, Lactation

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Introduction

Multiple sclerosis (MS) is a chronic, inflammatory-demyelinating autoimmune disorder of the central nervous system. It represents a primary cause of non-traumatic neurological disability among young adults [1]. While the precise etiology of the disease remains elusive, current hypotheses emphasize the multifactorial influence of serum vitamin D deficiency, tobacco use, human herpesvirus 6 (HHV-6) infection, exposure to the Epstein-Barr virus (EBV), and human endogenous retroviruses [2]. It is estimated that approximately 2.8 million individuals worldwide live with MS, with roughly 85% of cases initially manifesting as the relapsing-remitting phenotype [1]. Contemporary epidemiological data indicate that women are diagnosed three times more frequently than men, a disparity that has shown an upward trend in recent decades [3]. The typical age of onset ranges between 20 and 45 years [5], which bears significant clinical implications as it directly coincides with the reproductive years.

Pregnancy constitutes a period of unique immunological adaptation designed to protect the fetus while preserving maternal immunocompetence. Hormonal fluctuations–specifically elevated levels of estrogens and progesterone–induce a systemic cytokine shift from a pro-inflammatory Th1 profile toward an anti-inflammatory Th2 response [2, 7, 25]. Due to these physiological processes, disease activity typically declines, particularly during the third trimester. However, it is imperative to note that the rapid resolution of these immunological adaptations postpartum is associated with a heightened risk of significant exacerbations during the puerperium [2].

Establishing a diagnosis during the family planning stage poses substantial challenges from both obstetric-gynecological and neurological perspectives, influencing reproductive decisions in over half of affected patients [2]. Patients with multiple sclerosis exhibit higher rates of childlessness compared to the general population, primarily due to concerns regarding the impact of pregnancy on disability progression, the risk of postpartum relapses, and the potential teratogenicity of disease-modifying therapies (DMTs) [2, 3].

A rigorous debate persists in current literature and clinical practice regarding therapeutic paradigms in the context of procreation. The traditional approach prioritized fetal safety through the mandatory discontinuation of treatment prior to conception. This paradigm is currently being revised in favor of personalized strategies centered on a favorable benefit-risk ratio regarding maternal health over potential fetal risk [1, 5]. The most significant controversies involve the risk stratification of newer monoclonal antibodies, such as ocrelizumab or natalizumab, which necessitate balancing the benefits of maternal inflammatory control against potential neonatal immunological risks [1, 6]. Personalized management aims to circumvent both a standard recurrence of disease activity and the hazardous "rebound effect"–a phenomenon characterized by a far more aggressive and dangerous reactivation of the disease compared to its baseline state following drug withdrawal [5]. Consequently, contemporary guidelines emphasize that the unjustified cessation of high-efficacy therapy (HET) poses a substantial threat to maternal well-being [5].

The objective of this study is to analyze the current state of knowledge concerning preconception care, the course of pregnancy, labor, and the postpartum period in patients with multiple sclerosis.

Methodology

This study constitutes a systematic review of the relevant literature concerning the clinical management of patients with multiple sclerosis (MS) during the reproductive period. The search and selection process was conducted in strict accordance with the principles of scientific transparency and rigorous academic inquiry.

The primary data source utilized for this review was the international PubMed database. The search strategy was structured using the core keywords: "multiple sclerosis" and "pregnancy." The review encompassed publications from the last eight years (2018–2026), a timeframe selected to ensure the incorporation of the most recent and dynamically evolving therapeutic recommendations.

The article selection process followed a two-stage approach. In the initial stage, a comprehensive search utilizing the phrases "pregnancy" and "multiple sclerosis" yielded 913 original research and review articles. In the final stage, to enhance the precision of the analysis, the search scope was refined by incorporating the additional term "postpartum." The application of these specific criteria allowed for the identification of a refined subset of articles, which were subsequently subjected to an in-depth evaluation based on their substantive and clinical merit.

A total of 30 publications were qualified for the final analysis, all of which met the stringent quality standards of Evidence-Based Medicine (EBM). These included international consensus guidelines (e.g., MENACTRIMS [4]) and clinical pregnancy registries, which serve as paramount data sources regarding the safety profiles of monoclonal antibodies and other DMTs during the gestational and postpartum periods.

Results

The Impact of Pregnancy on the Clinical Course of Multiple Sclerosis

When examining current literature, it is essential to consider the reciprocal relationship between gestation and multiple sclerosis (MS), specifically how pregnancy modulates the course of this neurological condition and how the disease itself may influence gestational outcomes.

Evidence demonstrates that pregnancy exerts a profound immunomodulatory influence on MS. The maternal immune system undergoes physiological adaptation to ensure fetal alloantigen tolerance, a process mediated by a marked escalation in steroid hormone concentrations, including estradiol, estriol, and progesterone. These hormones provide a systemic protective environment against inflammatory activity by promoting a cytokine shift from pro-inflammatory Th1/Th17 phenotypes toward an anti-inflammatory Th2 profile. Furthermore, they stimulate the expansion of regulatory T cells (Tregs), which effectively suppress the activity of autoreactive lymphocytes [6, 7].

During gestation, a significant attenuation of the Annualized Relapse Rate (ARR) is observed, even in patients who have not been subjected to disease-modifying therapies (DMTs). Meta-analyses indicate a progressive decline in ARR across trimesters, reaching its nadir during the third trimester. This reduction in relapse activity during the final gestational phase may reach 70–80% compared to the pre-gestational period [1, 2].

This natural immunoprotection peaks just prior to parturition, correlating with maximal physiological hormone concentrations [2]. It must be noted, however, that while this protection is typically effective in patients with a mild disease course, it may prove insufficient for those with highly active inflammatory processes. Furthermore, emerging data indicate divergent disease trajectories in women with progressive MS phenotypes; pregnancy may impact these forms differently, necessitating vigilant postpartum monitoring of neurodegenerative activity [30].

Recent molecular inquiries suggest that epigenetic mechanisms, specifically DNA methylation changes occurring during pregnancy, may provide long-term disease stabilization. This is reflected in observations of decelerated disability accumulation on the Expanded Disability Status Scale (EDSS) among multiparous women [8].

The Impact of Multiple Sclerosis on Pregnancy Outcomes

Contemporary cohort data and international registry analyses confirm that multiple sclerosis does not adversely impact female fertility [2]. Moreover, the disease does not increase the risk of obstetric complications; the clinical course of pregnancy in women with MS is comparable to that of the general population [3]. Notably, no correlation has been observed between this neurodegenerative condition and an increased incidence of preeclampsia [2].

MS does not appear to elevate the probability of stillbirth or congenital malformations. A meta-analysis of ten studies confirmed that the risk of spontaneous abortion is consistent with general population background rates [2]. However, clinicians must maintain high diagnostic vigilance regarding demyelinating symptoms during gestation. Differential diagnosis must prioritize Neuromyelitis Optica Spectrum Disorder (NMOSD), as its management during pregnancy and the puerperium may require distinct immunomodulatory strategies compared to standard MS protocols [29].

The management of demyelinating disease is inextricably linked to the therapeutic dilemma of balancing disease control with gestational safety [9]. Ocrelizumab currently represents the subject of the most extensive pharmacological analysis regarding its impact on pregnancy. In a safety study involving 3,244 pregnancies, the live birth rate was reported at 81.3%, with the incidence of major congenital malformations at 2.1% [10]. These figures align with general population norms, leading to the primary conclusion that ocrelizumab exposure does not significantly increase the risk of adverse pregnancy outcomes.

Nevertheless, certain studies indicate a potentially higher incidence of small-for-gestational-age (SGA) neonates. This phenomenon may be correlated with exposure to specific DMTs during the third trimester or, alternatively, with high maternal inflammatory activity [9, 11].

Labor and Delivery in Multiple Sclerosis Patients

The determination of the mode of delivery in patients with multiple sclerosis should be dictated exclusively by obstetric indications, as the diagnosis itself does not constitute an explicit indication for surgical intervention via Cesarean section. Consequently, spontaneous vaginal delivery remains the preferred route for the majority of patients [4, 9].

Statistically higher rates of labor induction or assisted delivery (instrumental vaginal delivery) are observed; however, these outcomes are typically not a result of maternal neurological deficits. Instead, they often stem from exacerbated maternal exhaustion during labor or the clinical attitudes of medical personnel, including concerns regarding the patient's potential for physical depletion [9, 11].

Within the general population, an increasing number of patients opt for obstetric analgesia [11]. Retrospective studies indicate that the administration of neuraxial anesthesia—including both epidural and spinal techniques—is considered safe. No significant correlation has been established between regional anesthesia and the risk of postpartum relapses or an accelerated progression of disability [9, 11, 22].

Regarding neurological indications for Cesarean section, such instances are exceedingly rare. Neurological grounds for surgical intervention are generally limited to cases of advanced motor disability that may impede effective maternal cooperation during the second stage of labor [4].

The Puerperium and Relapse Risk

The postpartum period, specifically the first three to six months, represents a critical window for patients with MS. This timeframe is associated with a heightened susceptibility to the "rebound effect," characterized by a rapid and aggressive reactivation of inflammatory activity. This risk is particularly pronounced in patients who experienced relapses during gestation or those who utilized high-efficacy disease-modifying therapies (DMTs) prior to conception and discontinued treatment before planned gestation.

Postpartum fatigue (PPF) also warrants careful clinical assessment. According to recent data, PPF may serve as a prodromal marker of an impending relapse, particularly when it is characterized by a sudden increase in intensity and a lack of resolution through rest [12]. To prevent the accumulation of permanent disability during the puerperium, it is essential to identify these early warning signals and promptly initiate therapeutic intervention [4].

Breastfeeding and Disease-Modifying Therapies

Lactation remains a pivotal component of postpartum counseling. Research indicates that exclusive breastfeeding for a minimum of two to six months exerts a moderate protective effect, reducing the risk of postpartum relapses by approximately 37% to 43% [5, 13].

However, this protective effect should not justify the postponement of treatment reinitiation in high-risk patients. From a pharmacological perspective, monoclonal antibodies (mAbs) are characterized by high molecular weight, which results in minimal penetration into human breast milk [23]. The negligible oral bioavailability in the infant ensures that the Relative Infant Dose (RID) for most agents in this class–including ocrelizumab (0.16%) and rituximab (0.04%)–remains substantially below the established 10% safety threshold [6, 14]. Given these pharmacological properties, continued lactation is permissible alongside the resumption of high-efficacy therapy in high-risk patients [13, 15]. Furthermore, interferon-beta preparations and glatiramer acetate are currently recognized as safe for use throughout both pregnancy and lactation [3,16].

The salient points delineated above are synthesized and presented in Table 1

Table 1. Summary of the impact of pregnancy, labor, and the puerperium on multiple sclerosis course and obstetric outcomes

Clinical aspect	Key observations and parameters	Practical conclusions and recommendations
Impact of pregnancy on MS	Progressive reduction in the Annualized Relapse Rate (ARR) by 70–80% during the third trimester. Immunological shift from pro-inflammatory Th1/Th17 profiles toward an anti-inflammatory Th2 phenotype; expansion of regulatory T cells (Tregs).	Pregnancy exerts a potent immunomodulatory effect mediated by steroid hormones. Multiparous women may exhibit decelerated disability progression (EDSS), potentially linked to gestational DNA methylation changes.
Impact of MS on pregnancy	No deleterious impact on female fertility or increased risk of preeclampsia, spontaneous abortion, or congenital malformations.	The clinical course of a typical pregnancy in women with MS is comparable to that of the general population.
Fetal and neonatal Development	Potential slightly higher incidence of small-for-gestational-age (SGA) neonates.	The incidence of SGA neonates may be correlated with high maternal inflammatory activity or specific third-trimester DMT exposure.
Labor and anesthesia	Spontaneous vaginal delivery is preferred. Neuraxial anesthesia (epidural and spinal) is considered safe.	MS does not constitute an indication for Cesarean section, except in cases of extreme motor disability. Anesthesia does not elevate the risk of postpartum relapses.
Postpartum period (puerperium)	High risk of disease reactivation (rebound effect) within 3–6 months postpartum.	Peak risk is observed in patients who experienced gestational relapses or those who discontinued high-efficacy DMTs prior to conception.
Postpartum Fatigue (PPF)	Exacerbated fatigue with sudden onset and resistance to rest.	PPF may serve as a prodromal marker of an impending relapse; necessitates prompt diagnostic evaluation and rapid treatment reintroduction.
Breastfeeding	Exclusive breastfeeding (2–6 months) reduces the risk of postpartum relapses by 37–43%.	Lactation is permissible alongside the use of interferon-beta, glatiramer acetate, or monoclonal antibodies (mAbs).
Drug Safety (RID)	Extremely low Relative Infant Dose (RID) for mAbs: ocrelizumab (0.16%), rituximab (0.04%)—substantially below the 10% safety threshold.	Negligible infant oral bioavailability of mAbs allows for the safe integration of lactation with the resumption of high-efficacy therapy.

Discussion

Analysis of Key Findings

The synthesis of the collected evidence underscores a significant evolution in the therapeutic management of patients with multiple sclerosis throughout the reproductive cycle. Optimal care necessitates a continuous and proactive approach encompassing the preconception period, gestation, and the immediate postpartum phase [2].

The most pivotal conclusion derived from contemporary research is the established safety of continuing selected disease-modifying therapies (DMTs) to circumvent rebound relapses, which historically represented the primary clinical threat during the peripartum period [3, 6, 24]. Current data indicate that the physiological reduction in the annualized relapse rate during the third trimester–reaching 70% to 80%–is an insufficient protective factor for patients with high pre-conception disease activity [1, 17]. Furthermore, landmark data regarding ocrelizumab (based on an analysis of 3,244 pregnancies) demonstrate that peri-conceptional exposure to anti-CD20 antibodies does not correlate with an increased risk of major congenital malformations, thereby facilitating safer family planning for women requiring high-efficacy therapies [10].

Comparison with Previous Literature

Contemporary evidence redefines the classical observations originating from the 1998 PRIMS study, which advocated for the mandatory discontinuation of all pharmacological interventions prior to conception. Current literature emphasizes risk individualization, highlighting that the cessation of treatment in patients previously stabilized on natalizumab or fingolimod [5, 6, 24, 26] is associated with an unacceptably high risk of severe postpartum relapses and even breakthrough relapses during pregnancy.

Conversely to historical concerns, recent meta-analyses do not confirm any deleterious impact of regional anesthesia on the clinical course of MS, effectively resolving the debate regarding the safety of neuraxial procedures in this population [4, 9]. Moreover, the 2019 regulatory status update by the European Medicines Agency (EMA) regarding interferon-beta preparations serves as formal confirmation of their safety, contrasting sharply with earlier, more restrictive guidelines [11].

Clinical Significance and Implications for Medical Personnel

The implications derived from this literature review are multidimensional and necessitate the engagement of a multidisciplinary therapeutic team. For neurologists, precise scheduling of biological agent infusions and the implementation of extended interval dosing (EID) strategies are paramount for patients treated with natalizumab [1, 4]. Obstetricians and gynecologists should prioritize fetal growth monitoring to mitigate the risk of small-for-gestational-age outcomes, which have been reported at statistically higher frequencies in certain MS cohorts [7, 8, 10, 11].

The role of midwives is critical during the puerperium, particularly regarding lactation education. Pharmacokinetic data indicate that the Relative Infant Dose for most monoclonal antibodies remains below 1%, permitting safe breastfeeding alongside the resumption of high-efficacy treatment, thus protecting the patient from disability accumulation [6, 13].

Controversies and Ambiguities

Despite significant scientific progress, several contentious areas persist in international literature. A primary controversy involves the optimal timing for the reintroduction of immunizations in neonates exposed to anti-CD20 therapies during the second and third trimesters. While most international experts recommend deferring live-attenuated vaccines until 6 or even 12 months of age, there is still a lack of uniform global guidelines regarding the precise B-cell (CD19+) threshold that would guarantee both safety and optimal vaccine efficacy [10, 14].

This issue is particularly relevant in specific healthcare systems, such as in Poland, where the tuberculosis (BCG) vaccine is routinely administered within the first 24 hours of life. This necessitates strict adherence to national recommendations–including those from the Polish Neurological Society–which require the attending physician to issue a formal certification to defer live vaccines until laboratory confirmation of B-cell repopulation in the neonate [4, 27].

Further ambiguity remains regarding the reported incidence of SGA infants. While some registries indicate a significant correlation, others suggest that low birth weight may stem from confounding factors, such as lifestyle modifications or diagnostic stress, rather than the underlying pathophysiology of MS [5, 8].

Study Limitations

The majority of available data is derived from observational studies and case series. Ethical constraints preclude the performance of randomized controlled trials (RCTs) in pregnant women, which inherently limits the level of evidence for current conclusions [2, 10]. Furthermore, study cohorts for the newest agents, such as ofatumumab or cladribine, remain relatively small, complicating definitive conclusions regarding rare congenital malformations. Additionally, a risk of selection bias exists in breastfeeding studies, as patients with a milder disease course are more likely to pursue exclusive lactation [13, 18].

The Paradigm of Interdisciplinary Care

Optimal management of MS patients requires seamless coordination between the neurologist and obstetrician, initiated at the preconception planning stage. International consensus statements based on the Delphi method emphasize that therapeutic success is predicated on early family planning within a shared decision-making model [23].

Comprehensive supervision must encompass both the stabilization of maternal neurological status and the monitoring of fetal well-being. A cornerstone of this interdisciplinary model is psychological and psychiatric support, justified by high levels of anxiety regarding disability progression and concerns over genetic transmission [2]. Survey data indicate that subjective patient experiences and fears regarding family planning often diverge from clinical perspectives, necessitating rigorous personalization of counseling [28]. Statistically, MS patients are at an elevated risk for peripartum depression, making mental health care an integral component of standard protocols [2, 19, 20].

Evidence suggests that patients managed under a broad-profile care model exhibit superior treatment adherence, resulting in fewer unauthorized treatment cessations and higher rates of successful lactation [4, 21]. Modern multidisciplinary teams should extend beyond physicians to include clinical pharmacists–to assist in drug safety assessments–and lactation consultants, to facilitate the integration of breastfeeding with complex pharmacotherapy [9, 19]. The approach to lactation in MS has undergone a significant paradigm shift; historical concerns regarding maternal health have been superseded by evidence supporting the safety of modern DMTs. Robust education regarding the feasibility of combining pharmacotherapy with breastfeeding enhances maternal psychological well-being and fosters infant bonding without exposing the patient to the risk of inflammatory reactivation [13, 20].

Conclusions

Synthesis of the current literature suggests that pregnancy, characterized by profound systemic physiological adaptations, represents a safe period for the majority of patients with multiple sclerosis. Evidence indicates that gestation does not exert a detrimental effect on long-term disability progression or adverse obstetric outcomes [2, 3, 6].

The clinical course of multiple sclerosis remains dynamic, necessitating the recognition that the peripartum period–specifically the puerperium–is associated with a precipitate escalation in inflammatory activity. This phenomenon requires heightened clinical vigilance and meticulous coordination regarding the timing of reintroducing disease-modifying therapies. While gestation is typically defined by physiological stability and a significant reduction in annualized relapse rates, the risk of postpartum reactivation remains a primary clinical concern [10, 17].

In the era of modern neuroimmunology, the individualization of medical care based on disease activity risk stratification is fundamental. Therapeutic strategies must account for the specific pharmacokinetic and pharmacodynamic profiles of the prescribed agents. Notably, current evidence supports the feasible continuation of selected monoclonal antibodies into the third trimester and the safety of breastfeeding under the coverage of high-efficacy therapies (HETs) [6, 13]. Clinical decision-making in this domain should be anchored in a shared decision-making model that integrates the interdisciplinary expertise of the neurologist and obstetrician-gynecologist with the patient's informed preferences [5, 13, 23, 28].

Despite the ongoing optimization of clinical protocols, a robust need for further prospective research persists. Ambiguities remain regarding the long-term neurodevelopmental outcomes of children exposed *in utero* to novel biological agents, such as ofatumumab or cladribine [4, 9]. While long-term data from the CLARITY trials demonstrate a stable safety profile for cladribine in relapsing MS [25], its specific mechanism of action necessitates rigorous adherence to established wash-out periods prior to planned conception [4, 27]. Continuous and systematic data collection within international pharmacovigilance registries remains indispensable for the development of unified global guidelines to minimize clinical controversies surrounding drug wash-out durations and neonatal immunization schedules [1, 10, 27].

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