

## Original Research Article

# Pregnancy in multiple sclerosis in Baghdad 2024: a case control study

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## ABSTRACT

**Background:** Multiple sclerosis (MS) is an inflammatory demyelination illness affecting the central nervous system, with a higher prevalence in women, especially in childbearing age. Objectives of the study to measure pregnancy-related complications for both MS women and their newborns, to determine pregnancy's impact on MS relapses, and to evaluate the impact of disease-modifying therapies.

**Methods:** A case-control study that included 265 women with MS and their 265 matched controls. The study was conducted at Baghdad teaching hospital, medical city health directorate, and the AL-Saidyia primary health care center. All information was collected through the direct interviews by using a pre-prepared questionnaire from 15<sup>th</sup> March to December 2024; odds ratio (OR) was calculated, and a class interval that does not contain 1 is considered statistically significant.

**Results:** Pregnancy-related complications were reported in 27.5% of cases and 19.6% of controls. Miscarriages were significantly more common in the MS group (12.3% vs. 1.9%, OR 7.2, CI 2.78-18.89). Infants reported a total complication of 13.3% vs. 7.8%, with low birth weight (17%) as the most common complication in fetuses who were born to women with MS. Breastfeeding was less common in MS mothers (9.8% vs. 20.7%,  $p=0.001$ ). Only 10.2% of MS patients continued disease modifying therapies (DMTs) (interferon beta) during pregnancy, with no significant link to adverse outcomes.

**Conclusions:** Pregnant women with MS and their fetuses experienced more complications like a higher rate of miscarriages and low birth weight. Interferons are not associated with adverse pregnancy outcomes. Multidisciplinary prenatal, natal, and postnatal care is essential for women with MS.

## INTRODUCTION

Multiple sclerosis (MS) is a persistent, inflammatory demyelinating disorder that impacts the central nervous system (CNS). Most experts agreed that MS's pathophysiology is complex, necessitating a multilayer therapeutic strategy.<sup>1</sup>

### Pathophysiology of the disease

The role of vitamin D in MS pathogenesis was studied, and it was found that low vitamin D levels in the body may play a role in MS pathology.<sup>2</sup> Vitamin D may regulate

signaling pathways in the brain, reduce neurodegeneration by maintaining constant  $\text{Ca}^{+2}$  levels, reducing oxidative stress, inhibiting inflammation, and preventing the synthesis and aggregation of pathogenic proteins. Also, vitamin D may affect the development and regulation of T cells, so deficiency in this vitamin may lead to the developing of MS.<sup>3</sup>

On the other hand, genetic and environmental factors may influence the development of MS. For genetic factors, regulating T cells are functionally impaired in MS patients.<sup>4</sup> Infections, especially Epstein-Barr virus (EBV) infections, are the most common associated environmental

factor. This is because the EBV antigen mimics the self-antigen (myelin sheath antigen), making the sheath a target for the same reaction against the EBV antigen.<sup>5</sup> Following infection, CD4 T helper cells will migrate to the central nervous system at the time of blood-brain barrier disruption. These T cells with the antigen-presenting cells (dendritic cells and macrophages) will target the oligodendrocytes (myelin sheath makers of the central nervous system) and activate the plasma cell to secrete antibodies against it.<sup>6</sup>

### ***Epidemiology of the disease***

This disabling disease is increasing in incidence; the world health organization (WHO) predicted that over 1.8 million individuals worldwide had MS in 2023, and the mechanisms behind its increasing incidence remain unclear.<sup>7</sup>

Women are more likely to suffer from this illness than men, and its onset typically happens between the ages of 20 and 40 years. This means that the majority of individuals diagnosed with MS are women of childbearing age.<sup>8</sup>

In Iraq, the incidence and prevalence are also increasing, as the rest of the world. In 2018, the prevalence of MS in Iraq was determined to be 11.73/100,000, with a female-to-male ratio of 2.18:1.<sup>9</sup>

### ***MS and pregnancy***

Many neurologists directed patients with MS to avoid pregnancy, believing it to worsen the MS course. Later on, further studies were done and discovered that pregnancy may not pose a risk to MS; thus, from 2006 to 2014, the percentage of pregnant women with MS increased from 7.91% to 9.47%.<sup>10</sup>

### ***Using of DMTs in pregnancy***

The most common DMTs used are: The oldest DMTs are injectable, like interferon beta-1a, interferon beta-1b and glatiramer acetate. They probably not increase the risk of miscarriage or congenital malformation in humans.<sup>11,12</sup> Oral immunomodulatory agents like fingolimod and teriflunomide and others. It is advisable to discontinue some of these oral DMTs due to potential fetal risk.<sup>13</sup> Another category of disease-modifying therapy is monoclonal antibodies (mAbs). They can traverse the placenta and induce neonatal hematological abnormalities if administered during the second trimester or thereafter.<sup>13</sup>

Many previous studies discussed the relation between MS and pregnancy. Some researchers but not all found an increase in the risk of preterm birth, cesarean section, and low birth weight.<sup>14-17</sup> However, rare outcomes such as chorioamnionitis, infections, and postpartum hemorrhage have received less attention. In the evaluation of newborn abnormalities, a review study examined data from eight

clinical trials and generally found no risk for congenital abnormalities in fetuses born to women with MS, but the sample size was small.<sup>18</sup> Additional research indicates that immunomodulatory medications may affect neonates, and the likelihood of MS relapses diminishes during pregnancy and escalates postpartum.<sup>15,19</sup>

### ***Research hypotheses***

*Hypothesis 1:* Those with MS may have a higher chance of adverse pregnancy outcomes in comparison to those without MS.

*Hypothesis 2:* Those who take MS medication during pregnancy may experience a higher rate of adverse pregnancy outcomes.

### ***Research rationale***

The existing knowledge about pregnant women with MS in Iraq is limited with the increase of the disease incidence over time, especially in women of childbearing age.

### ***Research objectives***

Objectives were to measure the proportions of pregnancy-related complications (like preeclampsia, ectopic pregnancy, and others) in women with MS compared to those without MS, to measure the health outcomes of newborns, including birth weight, preterm birth rates, etc., and to identify the effect of disease-modifying therapies on pregnancy outcomes and list relapse rates during and after pregnancy.

## **METHODS**

### ***Study design***

A case-control study was conducted.

### ***Study settings and duration***

The study was done at the MS outpatient clinic at Baghdad teaching hospital, medical city health directorate, and at the AL-Saidyia primary health care center from the 15<sup>th</sup> of March to the end of December 2024. The data was collected during the working hours of the study settings, on the basis of three days per week, 2 hours per day.

### ***Study population and sampling method***

For the cases, a cluster sampling technique was adopted: there are three outpatient clinics specialized in diagnosing and treating MS in Baghdad (at Al-Yarmouk teaching hospital, Baghdad teaching hospital-medical city health directorate, and neurosurgery teaching hospital). By simple random sampling, the MS outpatient clinic at Baghdad teaching hospital, medical city health directorate, was chosen, and all patients with MS who had at least one

pregnancy post-diagnosis and agreed to participate during the time of data collection were included in the study.

For the controls, any women attending the AL-Saidyia primary health care center who had at least one pregnancy was included in the study (whatever the reason for the visit, except having the disease under study). Cases and controls were matched based on age, gravida, parity, and financial status to eliminate the confounders, using group matching for the process.

### ***Inclusion criteria***

Any woman who were diagnosed by a neurologist using McDonald's criteria and had at least one pregnancy after diagnosis were included.

### ***Exclusion criteria***

Women with serious medical conditions other than MS, such as uncontrolled diabetes mellitus, other autoimmune diseases, epilepsy, and hypothyroidism, etc., or women who have multiple pregnancies, such as twins or triplets, were excluded from the study. The study also excluded women who were unmarried or nulliparous.

### ***Ethical considerations***

The ethical and scientific committee of the department of family and community medicine, college of medicine, university of Baghdad, and the council of family and community medicine, Iraqi board of medical specialization, provided the agreements. Likewise, officials' agreements were obtained from the study settings, and all participants gave their consent after being informed of study's purpose and assured of confidentiality.

### ***Method of data collection and data collection tool***

Data was collected via direct interviews for both cases and controls with equal interview time. Based on WHO ICD-10-CM diagnosis codes for pregnancy and delivery. It contained five sections:

Section 1 this section contained five questions related to the patient's sociodemographic information. This included the patient's age, which was grouped into two categories based on pregnancy risk: 20-40 years as low-risk pregnancy and 41 years and above as high-risk. An individual's occupation was grouped into employed or unemployed/retired. The patient's education was classified according to the Iraqi national education system and placed as illiterate/read and write, primary, intermediate/secondary, or institute/college/higher. The economic situation was classified into three strata: poor, with a monthly income of less than 500,000 Iraqi dinars; fair, with 500,000 to 1,000,000 Iraqi dinars; and good, with more than 1,000,000 Iraqi dinars. The patient's residency was categorized as either living in Baghdad or outside of Baghdad in other governorates.

Section 2 consisted of 8 questions about past obstetric history, past medical, drug, and social histories.

Section 3 consisted of 13 questions that pertain to the pregnancy period.

Section 4 consisted of 9 questions about delivery time.

Section 5 consisted of 6 questions about the postpartum period.

The respondents answered each question in sections 3, 4, and 5 with a yes or no.

### ***Data management and analysis***

The result was analyzed using the statistical package for social sciences (SPSS) version 27; quantitative variables were presented as mean $\pm$ SD and categorical variables were presented as frequencies and proportions. A chi-square test was performed, and a confidence level of 95% was used to assess the association. The odds ratio (OR) was calculated, and a  $p < 0.05$  for a class interval that does not contain one is considered statistically significant.

### ***Pilot study***

A pilot study was done on 30 cases in Al-Yarmouk teaching hospital at the MS outpatient clinic to pretest the study's tool, investigate any challenges during data collection and to identify any questions that are unclear.

Following the pilot trial, no major adjustments were made, and the participants in the pilot study were excluded.

### ***Definition of variables***

Pregnancy-related complications are divided into pregnancy period complications, delivery time complications and postpartum period complications. Pregnancy period complications include either outcomes associated with fetal death, like miscarriage, which refers to the death of a fetus before the 28<sup>th</sup> week of pregnancy, or IUFD/stillbirth, which refers to death of a fetus after 28<sup>th</sup> week of pregnancy.<sup>21</sup> Additionally, there are other complications in this period, like GDM (hyperglycemia with blood glucose values above normal after 24<sup>th</sup> week of pregnancy, antepartum hemorrhage (bleeding from the genital tract during second half of pregnancy, specifically after 20<sup>th</sup> week of pregnancy, and others.<sup>22,23</sup> For delivery time complications, it includes preterm birth, which refers to a fetus who is born alive before 37 weeks of pregnancy; post-term, which refers to a pregnancy that extends to 42 weeks of gestation; low birth weight, which refers to a birth weight of below 2500 gm (5.5 pounds); and others.<sup>24,25</sup> Postpartum period outcomes focused on relapses, which were assessed based on: inpatient admission 90 days before conception, during pregnancy, and at postpartum period (42 days after delivery) or outpatient visit during these periods with MS as primary

or secondary diagnosis, plus corticosteroid prescription/plasmapheresis.<sup>26</sup>

## RESULTS

The response rate was 96% for cases and 100% for controls. Table 1 comprised 265 women with MS and 265 without the disease. The age ranged from 20 to 50 years, and the predominant age group of women was 20 to 40 years in both groups. The mean was  $35 \pm 7.45$  years SD for cases and  $35.57 \pm 7.57$  years SD for control. Women with MS possess higher educational attainment, and they are more likely to be employed. Most of the women in both study groups lived in Baghdad, and their financial status produced comparable results due to the matching.

Regarding the obstetrical history, the results were quite similar because both groups were matched. For smoking history, only 6 (2.3%) of cases were smokers, compared to 15 (5%) of the control group; none of these women were smoking during pregnancy, and none of them had any family history of congenital anomaly.

Table 2 presents the calculated OR and p for pregnancy outcomes. The total percentage of complications occurring during the pregnancy period for the cases was 27.16% vs. 19.6% for the control. Cases showed a higher percentage of miscarriages compared to control (12.3% vs. 1.9%), and the difference between the two groups for miscarriage (OR 7.2, CI 2.78-18.89) was statistically significant.

Both study groups had no women who had undergone in vitro fertilization, molar pregnancy, deep venous thrombosis. All women in both groups had the minimum visits for antenatal care.

For the outcomes at delivery time (table 3), the sample size was 224 for cases and 256 for controls (women with abortion or ectopic pregnancy did not reach the time of delivery). The total percentage of complications occurring to the fetuses at the time of delivery for the cases was 12.9% vs. 7.8% for the control. Women who underwent CS were marginally greater than cases (69.6% vs. 45.1%); however, this result was statistically not significant. Women with MS have higher rates of regional anesthesia and fetal weight under 2.5 kg compared to those without the condition (44.4% vs. 17.9% and 7.5% vs. 2%, respectively), and both results statistically significant. The control group showed a higher rate for congenital anomaly and preterm, but the results lacked statistical significance.

No women in either study group had experienced a vaginal laceration or fetal damage at birth.

Table 4 showed that women with MS failed to breastfeed their newborns compared to the control group (OR=0.4, CI=0.2-0.7,  $p=0.001$ ), and this result was statistically significant. There were no postpartum hemorrhages, surgical wound infections.

Figure 1 illustrated the number of women with relapses occurring 90 days prior to conception, throughout gestation, and postpartum.

A crucial element of this study was the impact of disease-modifying therapies on pregnancy outcomes. Twenty-seven out of 265 women (10.2%) were undergoing therapy during pregnancy, all of them were taking interferon beta. The results indicated no association between the administration of MS treatment during pregnancy and negative pregnancy outcomes.

**Table 1: Sociodemographic characteristic of studied groups in Baghdad 2024.**

Sociodemographic characteristic	Cases, (n=265)		Control, (n=265)	
	N	%	N	%
<b>Age group (in years)</b>				
20-40	203	76.6	201	75.8
41 and older	62	23.4	64	24.2
<b>Level of education</b>				
Illiterate/read and write	25	9.4	40	15.1
Primary	37	14	50	18.9
Intermediate/secondary	76	28.7	88	33.2
Institute college and higher	127	47.9	87	32.8
<b>Occupation</b>				
Unemployed	179	67.5	232	87.5
Employee	86	32.5	33	12.5
<b>Residency</b>				
Baghdad	258	97.4	261	98.5
Another governorate	7	2.6	4	1.5
<b>financial status</b>				
Poor	35	13.2	35	13.2
Fair	141	53.2	136	51.3
Good	89	33.5	94	35.4

**Table 2: Distribution of the studied groups in Baghdad 2024 according to their results during the pregnancy period.**

Variables	Cases, (n=265)		Controls, (n=265)		OR	95% CI	P value
	N	%	N	%			
Ectopic pregnancies	6	2.3	2	0.8	3.05	(0.6-15.32)	0.285
Miscarriage	32	12.3	5	1.9	7.24	(2.78-18.89)	<0.001
Still birth	3	1.3	2	0.8	1.69	(0.28-10.21)	0.67
Antepartum hemorrhage	8	3	9	3.4	0.9	(0.33-2.3)	0.78
Gestational diabetes mellitus	5	1.9	11	4.2	0.44	(0.15-1.28)	0.124
Gestational hypertension	12	4.5	21	8	0.54	(0.26-1.13)	0.1
Placenta previa	6	2.3	2	0.8	3	(0.6-15.1)	0.285
Total	72	27.16	52	19.6			

**Table 3: Results at the delivery time for the studied groups in Baghdad 2024.**

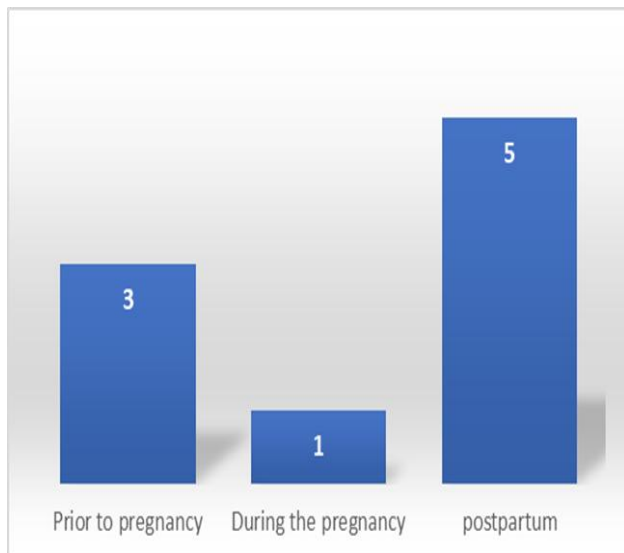
Variables	Cases, (n=224)		Controls, (n=256)		OR	95% CI	P value
	N	%	N	%			
Maternal							
Normal vaginal delivery	64	28.6	77	29	0.93	(0.62-1.37)	0.76
Caesarian section	160	45.1	179	69.9	1.07	(0.72-1.59)	0.72
Type of anesthesia used during CS							
Regional	71	44.4	31	17.9	3.66	(2.23-6)	<0.001
General anesthesia	89	55.6	148	82.6			
Fetal							
Preterm	6	2.7	3	1.1	2.31	(0.57-9.34)	0.31
Post date	3	1.3	3	1.3	1.14	(0.22-5.37)	1
Weight <2.5 kg	17	7.5	5	2	4	(1.48-11.25)	0.003
Congenital anomaly	3	1.3	9	3.5	0.99	(1.6-0.15)	0.238
Total	29	12.9	20	7.8			

**Table 4: Distribution of the studied groups in the Baghdad 2024 according to their results of the postpartum period.**

Variables	Cases, (n=224)		Controls, (n=256)		OR	95% CI	P value
	N	%	N	%			
Postpartum blues	37	16.4	44	17.2	0.94	(0.58-1.52)	0.9
Type of feeding: Breast feeding	22	9.8	53	20.7	0.41	(0.24-0.71)	0.001

**Table 5: Association between taking MS medication during pregnancy and adverse pregnancy outcomes among MS cases.**

Variables	Took medication, (n=27)		Not, (n=238)		OR	95%CI	P value
	N	%	N	%			
Miscarriage	6	2.2	26	9.8	2.53	(0.93-6.93)	0.1
Placenta previa	1	0.3	5	1.8	1.78	(0.2-15.8)	0.48
Cesarean section	14	5.2	146	55	1.1	(0.39-3.28)	1
Preterm	0	0	6	100	1.03	(1-1.05)	1
Weight ≤2.5 kg	2	0.7	15	5.6	1.41	(0.3-6.6)	0.65
Congenital anomaly	1	0.37	2	1.5	3.56	(0.35-35.9)	0.31
Total	24	88	200	84			



**Figure 1: Number of MS women who had relapses, (n=265).**

## DISCUSSION

### *Pregnancy outcomes*

This study finds an elevated risk of certain conditions during pregnancy, including miscarriage. Several prior studies conducted in Italy, Canada, and the USA agreed on the elevated incidence of miscarriage in women with MS; however, not all investigations reached this conclusion.<sup>27-30</sup> Autoantibodies in autoimmune diseases can cause miscarriage by increasing coagulation in veins and arteries, leading to placental insufficiency and preventing fetal implantation in the uterus.<sup>31,32</sup> Also, the use of certain MS drugs, such as dimethyl fumarate and teriflunomide, during early pregnancy contributed to increasing the risk of miscarriages.<sup>33</sup>

Furthermore, gestational DM, hypertension, and congenital anomaly proportions were higher among the control group; a healthy lifestyle adopted by women with MS after getting the diagnosis may be the cause for these results; it includes regular physical activity and a balanced diet. By focusing on their health, women can manage MS more effectively, improve their quality of life, reduce the risk for chronic diseases, and maintain their independence.

### *Delivery time and postpartum outcomes*

There is a pelvic floor dysfunction, especially with the severe form of MS, which leads to a prolonged second stage of delivery and increases risks of CS in cases.<sup>34</sup> But the results of this study show comparable cesarean section rates between cases and control groups; the most reasonable cause for this finding is the elevated rate of elective CS in Iraq for the control group, two times higher than the WHO recommendation due to maternal requests and physician preferences, which contributed significantly

to the trend, with the private healthcare sector seeing the highest.<sup>35</sup>

In this study a higher rate of regional anesthesia was used, and this type of anesthesia frequently used for women with MS during specific surgical interventions to accelerate recovery and preserve airway function. On the other hand, some research showed that general anesthesia is preferred over regional anesthesia to reduce the risk of relapses that can be caused by regional anesthesia due to stress.<sup>36</sup>

The present study revealed that fetuses delivered by women with MS weighed under 2.5 kg. Many studies have documented this finding, potentially attributing it to familial history or nutritional influences.<sup>8,37</sup>

The breast-feeding rate is lower in cases than in controls. Fatigue or diminished energy levels may prevent cases from properly positioning their infants during feeding, and she may take specific DMTs that influence milk production and may be expelled in the milk, thus harming the nursing child.<sup>38</sup>

### *Relapses*

In this study only one woman experienced a relapsing attack during the first trimester of her pregnancy (she had not taken her medication for over six months prior to the incident), and five cases had a postpartum relapse. Postpartum relapses are attributed to several variables, including hormonal fluctuations, encountering significant stress, or modifications in the DMTs to suit her current condition after childbirth.

### *DMTs and pregnancy*

Although most patients discontinued DMTs in this study, interferon beta appeared safe, consistent with European registry data.

### *Limitations*

Cases and control may differ in how they recall past exposures and MS is a highly heterogeneous disease, with varying types and variant symptoms; this variability can complicate the interpretation of outcomes. Future research can make an association between MS type or severity with the adverse pregnancy outcomes.

## CONCLUSION

For the pregnancy period, miscarriages are the most common complication that occurs to MS women. At the time of delivery, both the MS group and the control group exhibit a high proportion of CS, and low birth weight was more in cases than controls. For the postpartum period, breastfeeding was lower among cases. Only 27 out of 265 cases took their DMTs during pregnancy, and no association was found between taking MS medication



(betaferon) during pregnancy and adverse pregnancy outcomes.

### Recommendations

Implement preconception counseling programs for women with MS to discuss medication adjustment and lifestyle modifications. During pregnancy, create a multidisciplinary team, including neurologists and obstetricians, to monitor the disease activity and to educate her about possible modes of delivery. Enhance postpartum care, including relapse monitoring and breastfeeding support.

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