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Adverse Pregnancy Outcomes and Rheumatoid Arthritis: a Retrospective Matched Cohort Study

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ABSTRACT

Background & Objective: Rheumatoid Arthritis (RA) is an autoimmune-driven chronic systemic inflammatory disease. It could result in miscarriage, pre-eclampsia, and preterm labor, among other unfavorable pregnancy outcomes. Thus, this study was conducted to investigate the adverse pregnancy outcomes in pregnant women with RA.

Materials & Methods: Two cohorts of pregnant women with and without RA referred to the Ayatollah Mousavi Hospital's Gynecology and Obstetrics Clinic in Zanjan, Iran, during 2019-2020 were enrolled in a retrospective matched cohort study. Using their medical records, each participant completed a checklist of study variables. We used binary Logistic regression, chi-square test, Analysis of Variance, and independent samples t-test to analyze data using SPSS v.23.

Results: The study included 280 pregnant women. The mean age of the RA and control group (pregnant women without RA) was 32.4 ± 6.6 and 29.5 ± 6.7 years, respectively. The most prevalent adverse outcome was spontaneous abortion (54, 19.28%), which was significantly higher in the RA group (25% vs. 13.6%, P= 0.015). Cesarean section (24.3% vs. 10.7%, P= 0.003) and low birth weight (LBW) were both significantly higher in the RA group (15% vs. 5%, P= 0.005). RA increased the probability of spontaneous abortion, cesarean section, and LBW by more than 1.3 (odds ratio, 1.38; 95% CI, 0.45-5.46; P= 0.017), 2.2 (odds ratio, 2.24; 95% CI, 1.29-6.54; P =0.004), and 2.6 (odds ratio, 2.67; 95% CI, 1.86-7.05; P= 0.008) times, respectively.

Conclusion: Pregnant women with RA are more likely to experience spontaneous abortion, cesarean section, and having LBW infants comparing to pregnant women without RA.

Keywords: Rheumatoid Arthritis, Pregnancy, Cesarean Section, Spontaneous Abortion, Low Birth Weight

Introduction

Rheumatoid Arthritis (RA) is a chronic systemic inflammatory disease of autoimmune origin that is one of the most common chronic arthritis, affecting 2-3 times more women than men on average (1). Age of onset and gender are influential factors that significantly impact the disease course, outcome, and treatment (2).

According to the statistics, the prevalence of RA is estimated to be 0.4 to 1.3% worldwide, with the majority of cases occurring in women of reproductive age (3, 4).

It has long been debated how to effectively manage RA in pregnant women to prevent adverse pregnancy outcomes. Because most RA drugs are not safe during pregnancy, it is difficult for clinicians to choose the most suitable drug for pregnant women with RA (5, 6).

On the one hand, pregnancy may influence the clinical course and severity of RA, and some evidence suggests that it may be an etiological factor for RA (3). RA has been found to peak in the first 12 months after delivery, with several possible contributing factors, such as the effect of pregnancy-related hormonal and immunological changes or the re-adjustment of the body's immune response to a non-pregnant state during the postpartum period in susceptible women (7). A pregnancy complicated by RA, on the other hand, may result in adverse outcomes such as low birth weight (LBW), preterm birth, small for gestational age (SGA), pre-eclampsia, and more Cesarean section compared to normal vaginal delivery (NVD). However, the majority of studies have not found a significant difference in terms of maternal death and postpartum hemorrhage (5, 6). It is worth noting that women with RA are more likely to be hospitalized for longer periods, most likely due to pregnancy complications and cesarean section, which imposes higher costs on the health care system and patients (8).

Existing evidence suggests that pregnancy has a beneficial effect on RA; for instance, anti-rheumatic drug consumption may decrease during pregnancy due to low disease activity in a significant number of patients (4). A meta-analysis revealed that disease activity improves in 60% of pregnant women and increases in approximately half of patients after delivery (9).

The severity of the disease during pregnancy considerably impacts pregnancy outcomes. It is important to note that higher levels of disease activity during the third trimester can result in adverse pregnancy outcomes, regardless of factors such as prednisone use, parity, fetal sex, smoking, maternal age, gestational age, and maternal education level. However, pregnancy outcomes in women with optimal disease control during pregnancy were not significantly different from those in pregnant women without RA (3). Emerging evidence suggests that obstetricians should be aware that women with RA are more likely to give birth before 37 weeks of gestation and that these deliveries usually end up in cesarean section (3).

Few studies on pregnancy outcomes in women with RA have been conducted thus far. Pregnancy outcomes studies in RA patients can provide useful evidence for rheumatologists and obstetricians to better control the disease during pregnancy until the birth of a normal fetus. Therefore, this study was aimed at comparing the consequences of pregnancy in women with rheumatoid arthritis to those in healthy pregnant women.

Materials and Methods

Study design and subjects

This study was a retrospective matched cohort study conducted in Zanjan, Iran, during 2019-2020 on a population of pregnant women referred to the Ayatollah Mousavi Hospital's Gynecology and Obstetrics Clinic. Pregnant women with RA (aged 16-45 years) were matched 1:1 in terms of age, parity, and year of delivery to pregnant women without RA as the control group. The Zanjan University of Medical Sciences Ethics Committee [IR.ZUMS.REC.1398.333] approved the research protocol. The obligation to safeguard the confidentiality of patient's information was fulfilled.

Inclusion and exclusion criteria

Pregnant women with RA diagnosed by a rheumatologist using the American College of Rheumatology (ACR) 2010 criteria (9), with a 1 to 5-year interval between RA diagnosis and pregnancy, no systemic involvement, and disease activity (DAS28-CRP) before conception of ≤3.2 were included in the study. The control group consisted of pregnant women without RA and no history of taking any particular medications before pregnancy.

Exclusion criteria were a history of diseases other than rheumatoid arthritis affecting pregnancy outcomes (e.g., systemic lupus erythematous, cardiovascular disease, kidney disease, hypertension, diabetes, and hypothyroidism), a lack of access to sufficient information through patient records or interviews, the need for diagnostic or therapeutic procedures in mother and fetus, and consuming drugs during pregnancy other those related to RA.

Study variables

The data on participants' basic and clinical characteristics and pregnancy outcomes, including spontaneous abortion (a pregnancy loss before 20 weeks of gestational age), preterm birth (birth before the 37th week of pregnancy), type of delivery (cesarean or vaginal), LBW (infants weighing <2500 g at birth), small for gestational age (SGA), stillbirth, overt anomaly, eclampsia, pre-eclampsia, and preterm delivery were extracted from the medical records, where necessary, through in-person or phone interviews with the participants and their physicians. SGA was defined as birth weight less than the 10th percentile for gestational age (4), and gestational hypertension was defined as blood pressure greater than 140.90 mm Hg after 20 weeks of gestation. Eclampsia was defined as blood pressure greater than 140.90 mmHg after the 20th week of pregnancy and protein excretion in the urine greater than 500 mg per 24 hours. Seizures and pre-eclampsia were defined as blood pressure greater than 140.90 mmHg after 20 weeks gestation and protein excretion in the urine greater than 500 mg per 24 hours (4). In addition, confounding variables, maternal age during pregnancy, parity, maternal body mass index (BMI), maternal education, place of birth (Secondary or tertiary level), place of residence (town/village), and history of adverse pregnancy outcomes were also included in the study.

Statistical analysis

The data were entered into the SPSS software v.23. For numerical data, descriptive statistics were reported as the mean ± standard deviation (SD) if the data followed a normal distribution and the median (25^{th}, 75^{th} quartiles) if the data were not distributed normally. Categorical data

were reported in frequency (%). The chi-square test was performed in analytical statistics to compare categorical data in separate groups. The mean of numerical data from three or more groups was compared using variance analysis. Independent samples t-test was used to compare the mean of numerical data between two groups. The predicting variables of pregnancy outcomes were determined using logistic regression analysis. A two-tailed P-value less than 0.05 was considered statistically significant.

Results

This study included 280 pregnant women (31.0 ± 6.8 yrs), including 140 with RA and 140 matched controls. None of the RA patients were taking biologic DMARDs (disease-modifying anti-rheumatic drugs). All patients received conventional DMARDs (hydroxychloroquine and sulfasalazine) and prednisolone.

Table 1 shows the frequencies (%) of the participants' basic characteristics. The variables were compared using the $\chi 2$ test between RA and control groups. None of the variables showed a statistically significant difference between the two groups (all with P-values greater than 0.05). (Table 1).

Table 1. Comparisons of women with and without RA according to socio-demographic characteristics

Variables	Exposed group	Non-exposed group	P-value*
	N (%) / Mean ± SD		
Spontaneous abortion	32.4 ± 6.6	29.5 ± 6.7	0.202[a]
Maternal education			
HSD	81 (57.8)	86 (61.4)	
B.S.	32 (22.8)	34 (24.2)	0.571[b]
>B.S.	4 (2.8)	5 (3.5)	
Parity	1.7 ± 0.75	1.9 ± 0.9	0.116[a]
Maternity Hospital	127 (90.71)	132 (94.28)	
Secondary level	2 (1)	0 (0)	0.835[b]
Tertiary level	138 (99)	140 (100)	
Dwelling			
Rural	40 (27.58)	50 (35.71)	0.435b
Urban	100 (71.42)	90 (64.28)	
History of adverse pregnancy outcomes			
Yes	18 (12.8)	16 (11.4)	0.520b
No	122 (87.1)	124 (88.5)	
BMI, kg/m2	24.8 ± 1.53	24.6 ± 1.94	0.128a

HSD: High School Diploma, B.S.: Bachelor's Degree, BMI, Body Mass Index.
*P < 0.05
a P-values obtained from independent samples t-test
b P-values obtained from χ^2 test

The mean age at pregnancy for women with RA and the control group was 32.4 ± 6.6 and 29.5 ± 6.7, respectively. Spontaneous abortion, as the most common outcome, was observed among 54 participants (19.2%), with 35 (25%) in the RA group and 19 (13.6%) in the control group. Cesarean section was observed in 49 cases (17.5%), with 34 (24.2%) in the RA group and 15 (10.7%) in the control group. We found no participants with eclampsia, pre-eclampsia, and SGA (Table 2).

Table 2. Comparisons of women with and without RA according to pregnancy outcomes

Outcome	RA patients	Control group	P-value
	N (%)		
Spontaneous abortion			
Yes	35 (25)	19 (13.6)	0.015*
No	105 (75)	121 (86.4)	
Preterm labor			
Yes	13 (9.28)	8 (5.71)	0.25
No	127 (90.71)	132 (94.28)	
Still birth			
Yes	1 (0.71)	0 (0)	0.31
No	139 (99.3)	140 (100)	
Congenital anomaly			
Yes	4 (2.9)	0 (0)	0.44
No	136 (97.1)	140 (100)	
Delivery mode			
CS	34 (24.3)	15 (10.7)	0.003*
NVD	106 (75.7)	125 (89.3)	
LBW			
Yes	21 (15)	7 (5)	0.005*
No	119 (85)	133 (95)	
Gestational hypertension			
Yes	6 (4.3)	2 (1.4)	0.15
No	134 (95.7)	138 (98.6)	

CS: Caesarean Section, NVD: Normal Vaginal Delivery, LBW: Low Birth Weight
*P < 0.05, obtained from χ^2 test

When comparing the two groups, there was a statistically significant difference in spontaneous abortion, LBW, and type of delivery. Women with RA had more spontaneous abortions than the control group (25% vs. 13.6%, P-value= 0.015). Having a cesarean section was more frequent in the RA group (24.3% vs. 10.7%, P-value = 0.003). Furthermore, the majority of 28 LBW newborns were born to mothers with RA (15% vs. 5%, P-value = 0.005). Other pregnancy outcomes revealed no significant difference between the two groups (All with P-values more than 0.05) (Table 2).

A binary logistic regression was used for further analysis. Spontaneous abortion, preterm birth, stillbirth, overt anomalies, type of delivery, LBW, and gestational hypertension were outcome variables. The presence or absence of RA was a predictor variable, and confounding variables included maternal BMI, maternal age, parity, place of residence, place of delivery, education level, and history of adverse pregnancy outcomes (Table 3).

According to logistic regression analysis, spontaneous abortion, cesarean section, and low birth weight were significantly associated with RA (P= 0.015, P=0.003, and P=0.005, respectively). Additionally, the odds ratios imply that having RA increases the odds of spontaneous abortion, cesarean section, and low birth weight by more than 1.3, 2.8, and 2.6 times, respectively.

Table 3. Multivariable and univariable logistic regression results

	Multivariable logistic regression		Univariable logistic regression	
Outcome variables	Odds ratio (95% CI)	P-value	Odds ratio (95% CI)	P-value*
Spontaneous abortion	1.385 (0.45, 5.46)	0.015	1.311 (1.01, 3.93)	0.017
Preterm labor	1.216 (0.38, 5.16)	0.257	1.689 (0.26, 4.21)	0.261
Still birth	1.156 (0.95, 3.87)	0.999	1.142 (0.77, 3.81)	0.996
Congenital anomaly	1.182 (0.76, 4.46)	0.999	1.162 (0.67, 4.25)	0.997
Delivery mode	2.248 (1.29, 6.54)	0.003	2.273 (1.38, 5.17)	0.004
LBW	2.676 (1.86, 7.05)	0.005	2.653 (1.37, 8.16)	0.008
Gestational hypertension	1.173 (0.71, 4.24)	0.151	1.165 (0.53, 4.03)	0.172

LBW: Low Birth Weight, CI: Confidence Interval
*P < 0.05

Discussion

Our findings revealed that pregnant women with RA had significantly more spontaneous abortions, LBW newborns, and cesarean sections; the odds of having such outcomes were also significantly higher in this group. Thus, the findings of the present study support the existing evidence for the adverse impacts of RA on pregnancy outcomes.

According to a recent meta-analysis, there is a significant association between RA and adverse maternal and fetal outcomes. As a result, the study has demonstrated that the odds of developing the following adverse pregnancy outcomes are significantly higher in pregnant women with RA than in those without RA: preterm birth, small for gestational age, low birth weight, congenital anomalies, stillborn, cesarean section, pre-eclampsia, gestational hypertension, and spontaneous abortion **(11)**.

Aside from the findings of several studies that support the findings of our study **(5, 6, 8, 10, 12-14)**, some studies show no significant association between RA and adverse pregnancy outcomes or even a beneficial effect of RA on pregnancy outcomes **(15, 16)**.

Lin et al. discovered that among mothers with RA, the odds of experiencing LBW, SGA, pre-eclampsia, and cesarean section were 1.47, 1.2, 2.22, and 1.19 times higher than those without RA **(5)**.

A recent population-based study has reported that the prevalence of pre-eclampsia in pregnant women with RA is 2.82% **(17)**. In our study, no pregnant women with RA developed pre-eclampsia or eclampsia. However, previous literature on such outcomes has suggested conflicting evidence **(17)**.

Lin's study **(5)** confirms our findings regarding an increased risk of LBW and CS. Despite our results, Lin's study found no significant difference in the outcomes of spontaneous abortion between the two groups of pregnant women. Furthermore, in our study, the presence of RA increased the odds of cesarean delivery by 2.2 and LBW by 2.6 times, whereas these ratios were lower in Lin's study (LBW, 1.47, and CS, 1.19).

A probable contributing factor to the increased risk of LBW in pregnant women with RA is disease activity during pregnancy. A significant negative relationship has been reported between high levels of disease activity and birth weight, implying the possibility of an immune-mediated mechanism. Nonetheless, we only included patients in the current study whose RA has a low level of activity (DAS28-CRP $\leq$ 3.2) during pregnancy, and we found a significant association with LBW **(18)**.

According to Krause et al., women with RA have a higher risk of cesarean section, preterm birth, and pre-eclampsia than the general population. Nonetheless, the outcome of congenital anomaly has not been reported to be significantly different than the normal population. Furthermore, newborns' birth weight is

inversely associated with the disease's clinical activity during the third trimester. Our findings are consistent with Krause's study, which found no significant relationship between RA and an increased risk of cesarean section and LBW outcomes, as well as RA and a newborn developing overt anomaly **(19)**. Indeed, unlike the outcome of a cesarean section, the risk of having a newborn with congenital anomalies is not significantly higher among pregnant women with RA **(13, 20)**.

In a study of 1199 women with RA in Denmark and Sweden, the prevalence of preterm labor was 7.8% between the 32nd and 36th gestational weeks and 1.4% before the 32nd week. Giving birth between the 32nd and 36th gestational weeks was found to be the most prevalent adverse pregnancy outcome among women with RA **(21)**. The results of our study uncovered that spontaneous abortion, in 25% of cases, was the most common adverse pregnancy outcome, and preterm labor was observed in 9.2% of pregnant women with RA, which is higher than the mentioned study.

However, based on the existing evidence, it appears that the relationship between RA and pregnancy is not limited to what has been mentioned. Women with a history of adverse pregnancy outcomes appear to be exposed to a higher risk of developing rheumatoid arthritis **(22, 23)**. Besides, having a history of two or more adverse pregnancy outcomes has been linked to a significantly poorer functional outcome in women with inflammatory polyarthritis **(24)**.

It appears that early diagnosis and effective RA control may reduce the incidence of such consequences. For instance, a 2015 study in California by Bharti et al. found that SGA and preterm birth were associated with RA severity during early pregnancy and that providing effective and early treatment of the disease, as well as optimal pregnancy management, could significantly reduce such adverse outcomes **(12)**. In other words, if women with RA plan to become pregnant under the strict supervision of their physicians, they may have no more adverse outcomes than the general population, and the disease may disappear during pregnancy in some cases **(25)**.

Limitation

Since we obtained our raw data from participants' medical records, which are not designed for research purposes, poor-quality data could be a potential limitation of the present study. However, we did our best to address the limitation by conducting face-to-face or telephone interviews with participants or their physicians as needed.

Conclusion

To conclude, we found that having rheumatoid arthritis is associated with a higher risk of some adverse pregnancy outcomes, such as increasing the odds of spontaneous abortion, cesarean section, and LBW. Our findings, which are consistent with the existing evidence, confirm that pregnancy in women with rheumatoid arthritis requires much more attention and careful clinical management. As a result, we can ensure a safe pregnancy for both the fetus and the mother, as well as prevent adverse pregnancy outcomes.

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Not applicable.

Authors' Contributions

A. S., R. H., A. Z., N. N., A. KM., and Z. KM., designed the study. M. R., N. N., A. S., R. H. and A. Z. provided the data and performed data analyses and quality control. A. Z. supervised the study. M. R. conducted the statistical analysis. M. R. wrote the main manuscript text. M. R. prepared all figures. A. Z. takes responsibility for the paper as a whole. All authors reviewed the manuscript.

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Conflict of Interest

The authors declare that they have no competing interests.

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