

ORIGINAL ARTICLE

Risk of adverse pregnancy outcomes in patients with pregnancy-harmful rheumatic diseases: A retrospective study

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ABSTRACT

Objective: To explore the risks of adverse pregnancy outcomes (APOs) in pregnant women with different pregnancy-harmful rheumatic diseases (PH-RDs), including systemic lupus erythematosus (SLE), primary Sjögren's syndrome (pSS), obstetric antiphospholipid syndrome (OAPS), and undifferentiated connective tissue disease (UCTD). **Methods:** Medical records for women confirmed of ongoing pregnancy at 20 weeks of gestation at West China Second University Hospital, Sichuan University from January 2018 to December 2023 were retrospectively scanned. Patients diagnosed of SLE, pSS, OAPS, and/or UCTD with singleton pregnancies were included. The primary outcomes were live birth rate, preterm birth rate, preeclampsia, and fetal growth restriction (FGR). **Results:** A total of 102, 427 medical records were scanned for the study, resulting in the inclusion of 2518 patients with SLE ($n = 281$), pSS ($n = 144$), OAPS ($n = 1870$), UCTD ($n = 175$), or the combination of two of these PH-RDs ($n = 48$). For the difference between single and two combined PH-RDs, the live birth rate was comparable, and the incidence of preterm birth, preeclampsia, and FGR were significantly higher in the combined PH-RDs groups ($P < 0.001$, $P = 0.009$, $P = 0.003$). For the difference between different PH-RDs, the live birth rate in the OAPS group was significantly lower than in the UCTD group ($P = 0.019$). The incidence of preeclampsia was higher in the SLE group than in the pSS and UCTD groups ($P = 0.004$). **Conclusion:** The effects of PH-RD on pregnancy are mainly seen in placenta-related APOs and complications such as preterm birth, preeclampsia, and FGR, especially SLE and OAPS. The combination of two PH-RDs may further affect the pregnancy outcomes.

Keywords: rheumatic diseases, placenta-related pregnancy complications, preeclampsia, fetal growth restriction

INTRODUCTION

Rheumatic diseases are a range of chronic disorders characterized by abnormally activated immune

responses, mainly including systemic lupus erythematosus (SLE), primary Sjögren's syndrome (pSS), rheumatoid arthritis, antiphospholipid syndrome (APS).^[1,2] And those with clinical and serological signs but haven't

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progress to a defined rheumatic disease are classified as undifferentiated connective tissue disease (UCTD).^[3] Rheumatic diseases often occur in females of child-bearing age and therefore affect reproductive health by increasing the risks of various pregnancy complications.^[4] Meanwhile, pregnancy may also influence the progress of some rheumatic diseases due to changes in steroid hormones.^[2] As reproductive medicine, obstetrics and rheumatology continue to develop and interact with each other, more and more females with rheumatic diseases are able to have successful pregnancies. However, this is accompanied by an increasing proportion of pregnant females with rheumatic diseases, which brings more challenges for physicians to prevent and manage pregnancy complications and to enable successful live births.

It is generally recognized that the risk of pregnant complications or adverse pregnancy outcomes (APOs) tend to be higher in pregnancy with rheumatic diseases.^[5] In addition, due to different pathological mechanism in different rheumatic diseases, they might have different risks of causing various complications during pregnancy. Among others, SLE, pSS, UCTD, and APS are usually considered harmful to pregnancy and are of concern. The study aims to explore the risks of APOs and pregnancy complications among pregnant women with these pregnancy-harmful rheumatic diseases (PH-RDs).

MATERIALS AND METHODS

Study population

We conducted a single-center retrospective cohort study at West China Second University Hospital, Sichuan University. Medical records for women who were confirmed of ongoing pregnancy by obstetric ultrasound at 20 weeks of gestation from January 2018 to December 2023 were scanned. The study was approved by the Ethics Committee of West China Second University Hospital (No. 2023-116) and written informed consent was waived.

We included all women with confirmed obstetric APS (OAPS), SLE, pSS, and/or UCTD to calculate the crude prevalence of PH-RDs in pregnant women from 2018 to 2023. To explore the risk of different PH-RDs, we included these PH-RD patients with singleton pregnancies and collected information on baseline characteristics and pregnancy outcomes. Exclusion criteria included: (1) diagnosed with cancer, hypertension or endocrine disorders (such as diabetes mellitus and thyroid disorder) before pregnancy; (2) combined with uterine structural abnormalities or organic lesions; (3) combined with polycystic ovarian syndrome; (4) combined with chromosomal abnormalities. To better present the impact of PH-RD compared with the real-

world population, we also collect the epidemiological data on pregnancy outcomes for the general population with singleton pregnancy.

Definition and diagnostic criteria

OAPS was diagnosed based on the 2006 revised Sydney criteria.^[6] Patients fulfilling at least one clinical criterion for pathologic pregnancy and one laboratory criterion were classified as OAPS. SLE was diagnosed based on the 2019 European League Against Rheumatism (EULAR) /American College of Rheumatology (ACR) classification criteria^[7] or the 1997 ACR revised criteria for SLE.^[8] The pSS was diagnosed based on the 2002 American-European Consensus Group classification criteria^[9] or the 2016 ACR/(EULAR classification criteria for pSS.^[10] UCTD referred to disorders characterized by clinical and serological signs of systemic rheumatic diseases but not fulfilling the criteria for defined connective tissue diseases.^[11]

The primary outcomes were live birth rate, preterm birth rate, preeclampsia and fetal growth restriction (FGR). Secondary outcomes included gestational hypertension (GH), gestational diabetes mellitus (GDM), perinatal thrombosis events, oligohydramnios, polyhydramnios, and placental abruption. Baseline characteristics included age, gained weight during pregnancy, body mass index (BMI) before pregnancy, number of adverse pregnancy history (APH, including pregnancy loss and ectopic pregnancy), and duration of hospital stay for delivery.

Preterm birth was defined as live birth after 28 weeks and before 37 weeks of pregnancy. GH was defined as a systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg on two occasions at least 4 h apart after 20 weeks of gestation, without proteinuria or end organ dysfunction in a female with a previously normal blood pressure. Preeclampsia was defined as GH with proteinuria and/or end organ dysfunction.^[12] FGR was defined as an estimated fetal weight or abdominal circumference less than the 10th percentile for gestational age. GDM was diagnosed based on the 2010 International association of diabetes and pregnancy study groups (IADPSG) criteria. Perinatal thrombotic events were defined as new thrombosis (arterial and/or venous) with corresponding clinical manifestations after 20 weeks of gestation, confirmed by ultrasonography, computed tomography, pulmonary angiography, or magnetic resonance imaging. Placental abruption was defined as the separation of the normally located placenta before delivery of the fetus. Oligohydramnios was defined as a single deepest pocket of < 2 cm and polyhydramnios was defined as a single deepest pocket of > 8 cm through ultrasound.^[13]

Statistical analysis and software

Comparisons were performed among different PH-RD groups, and between each PH-RD group and the general

population (excluding overlapping cases). A Kolmogorov-Smirnov test was used to estimate the normality of distribution for continuous variables. Normally distributed variables were presented as mean \pm standard deviation (SD) and analyzed by Student's *t*-test or by one-way ANOVA (Dunnnett *t*-test as appropriate). Non-normally distributed variables were presented as median (25th-75th percentiles) and analyzed by *Mann-Whitney U* test or by *Kruskal-Wallis* one-way ANOVA (Bonferroni method as appropriate). Categorical variables were presented as number of cases (percentage) and analyzed by *Chi-square* or Fisher's exact test as appropriate. *P*-value of less than 0.05 was regarded as statistically significant. All analyses were performed using the SPSS version 27.0 (SPSS Inc., Chicago, IL, UPL). Figures were drawn by Microsoft Excel and PowerPoint version 2021.

RESULTS

A total of 102,427 medical records were scanned for the study, resulting in the inclusion of 2518 patients with SLE ($n = 281$), pSS ($n = 144$), OAPS ($n = 1870$), UCTD ($n = 175$), or the combination of two of these PH-RDs ($n = 48$) (Figure 1).

Prevalence of APOs and PH-RDs during 2018-2023

During the 6 years in this center, the incidence of pregnancy with PH-RD was 2.48%, with the highest incidence of pregnancy with OAPS at 1.95%. During this period, the annual incidence of pregnancy with OAPS was the most variable, ranging from 0.64% to 2.69%, without clear trends ($R^2 = 0.270$, $P = 0.291$). Besides, there was a slight upward trend in the annual incidence of UCTD ($R^2 = 0.915$, $P = 0.003$, $b = 0.001$) (Figure 2, Supplementary Table 1, Supplementary Table 2).

The prevalence of APOs and complications in singleton pregnancies of general population during 2018-2023 was shown in Table 1. Out of 102,427 medical records, 94,355 women had singleton pregnancies. Among them, the live birth rate was 96.73% and the preterm birth rate was 7.93%. As for the pregnancy complications, the incidence of preeclampsia was 3.01%, and the incidence of FGR was 1.68% (Table 1). During the period, there were no clear trends in the annual incidence of live birth and preeclampsia, while there was a slight upward trend in the annual incidence of FGR and a slight downward trend in the annual incidence of preterm birth (Figure 3, Supplementary Table 1).

Risk of APOs and complications in single and combined PH-RDs

The baseline characteristics and risks of APOs and complications in single PH-RD group and combined PH-

RDs group were shown in Table 1. The age, gained weight during pregnancy, BMI, and the number of previous APHs were comparable between single PH-RD group and combined PH-RDs group. The duration of hospital stay for delivery was significantly longer in women with two combined PH-RDs ($P = 0.009$). As for APOs and complications, the live birth rate was comparable between the two groups, and the incidence of preterm birth, preeclampsia, and FGR were significantly higher in the combined PH-RDs groups ($P < 0.001$, $P = 0.009$, $P = 0.003$). The incidence of other pregnancy complications was comparable between the two groups.

Compared to the general population, patients with PH-RD (single or combined) showed significantly lower rate of live birth and polyhydramnios and higher rate of preterm birth, preeclampsia, FGR, oligohydramnios, and thrombosis.

Risk of APOs and complications between different PH-RDs

The baseline characteristics and risks of pregnancy complications in SLE, pSS, APS, and UCTD groups were shown in Table 2. There were significant differences in age ($P < 0.001$), gained weight during pregnancy ($P < 0.001$), duration of hospital stay for delivery ($P < 0.001$), and number of previous APH ($P < 0.001$) among the four groups, while the BMI was comparable. As for pregnancy outcomes and complications, the live birth rate in the OAPS group was significantly lower than in the UCTD group ($P = 0.019$). The incidence of preeclampsia was higher in the SLE group than in the pSS and UCTD groups ($P = 0.004$). The incidences of preterm birth and FGR were comparable among the four groups. As for other complications, the incidence of GDM was higher in the OAPS group than in the SLE and pSS groups, and in the UCTD group than in the SLE group. The incidence of gestational hypertension, placental abruption, oligohydramnios, polyhydramnios, and thrombosis were comparable among the four groups.

When compared with general population, the SLE and OAPS groups were significantly lower in the live birth rate and higher in the incidence of preterm birth and preeclampsia, and the SLE, OAPS, and UCTD groups were higher in the incidence of FGR. As for other pregnancy complications, the incidences of GDM in the SLE and pSS groups were lower than in the generation population. The incidence of oligohydramnios was significantly higher in the SLE and OAPS groups and the incidence of thrombosis was significantly higher in the OAPS group than in the general population.

DISCUSSION

This single-center retrospective study, based on a large

Table 1: Outcomes of singleton pregnancy with single and/or combined PH-RDs

	Total (n = 2476)	Single PH-RD (n = 2428)	Combined PH-RDs (n = 48)	P value
Age (years)	32.0 ± 4.0	32.0 ± 4.0	31.7 ± 3.5	0.598
Gained weight (kg)	11.97 ± 4.56	11.97 ± 4.58	12.06 ± 3.26	0.862
BMI (kg/m ²)	21.16 ± 2.86	21.17 ± 2.86	21.01 ± 2.86	0.724
No. of APH	1.8 ± 1.3	1.8 ± 1.3	1.9 ± 1.7	0.793
Hospital stay (day)	5.0 ± 3.3	5.0 ± 3.2	6.6 ± 4.3	0.009
Live birth	2309 (93.3) *	2267 (93.4)	42 (87.5)	0.108
Preterm birth	339 (13.7) *	324 (13.3)	15 (31.3)	< 0.001
Preeclampsia	176 (7.1) *	168 (6.9)	8 (16.7)	0.009
FGR	159 (6.4) *	151 (6.2)	8 (16.7)	0.003
GDM	476 (19.2)	469 (19.3)	7 (14.6)	0.410
GH	46 (1.9)	45 (1.9)	1 (2.1)	0.907
Placental abruption	35 (1.4)	34 (1.4)	1 (2.1)	0.691
Oligohydramnios	104 (4.2) *	103 (4.2)	1 (2.1)	0.460
Polyhydramnios	46 (1.9) *	44 (1.8)	2 (4.2)	0.232
Thrombosis	26 (1.1) *	26 (1.1)	0	0.471

Data are presented as mean ± SD or n (%). PH-RD: pregnancy-harmful rheumatic disease; BMI: body mass index; APH: adverse pregnancy history; FGR: fetal growth restriction; GDM: gestational diabetes mellitus; GH: Gestational hypertension. * significantly different compared to the general population excluding overlapping cases (n = 91, 877).

Table 2: Risk of APOs between different PH-RDs

	SLE (n = 279)	pSS (n = 140)	OAPS (n = 1838)	UCTD (n = 171)	P value
Age (years)	30.4 ± 3.8 ^a	31.6 ± 3.5 ^b	32.3 ± 4.0 ^b	32.1 ± 4.0 ^b	< 0.001
Gained weight (kg)	11.07 ± 4.66 ^a	11.01 ± 5.05 ^{ab}	12.13 ± 4.53 ^b	12.53 ± 4.41 ^b	< 0.001
BMI (kg/m ²)	21.16 ± 2.88	21.07 ± 2.65	21.21 ± 2.88	20.72 ± 2.68	0.325
Hospital stay (day)	5.7 ± 3.7 ^a	4.8 ± 2.9 ^b	4.9 ± 3.3 ^b	4.5 ± 2.9 ^b	< 0.001
No. of APH	0.9 ± 1.1 ^a	1.1 ± 1.2 ^{ac}	2.1 ± 1.3 ^b	1.3 ± 1.2 ^c	< 0.001
Live birth	259 (92.8) ^{ab*}	135 (96.4) ^{ab}	1705 (92.8) ^{b*}	168 (98.2) ^a	0.019
Preterm birth	49 (17.6) *	19 (13.6)	237 (12.9) *	19 (11.1)	0.147
Preeclampsia	28 (10.0) ^{a*}	3 (2.1) ^b	132 (7.2) ^{ab*}	5 (2.9) ^b	0.004
FGR	20 (7.2) *	4 (2.9)	119 (6.5) *	8 (4.7) *	0.257
GDM	19 (6.8) ^{a*}	13 (9.3) ^{ab*}	410 (22.3) ^c	27 (15.8) ^{bc}	< 0.001
GH	7 (2.5)	3 (2.1)	30 (1.6)	5 (2.9)	0.513
Placental abruption	4 (1.4)	4 (2.9)	23 (1.3)	3 (1.8)	0.457
Oligohydramnios	16 (5.7) *	6 (4.3)	72 (3.9) *	9 (5.3)	0.485
Polyhydramnios	3 (1.1)	0	40 (2.2)	1 (0.6)	0.100
Thrombosis	2 (0.7)	2 (1.4)	20 (1.1) *	2 (1.2)	0.914

Data are presented as mean ± SD or n (%). SLE: systemic lupus erythematosus; pSS: primary Sjogren's syndrome; UCTD: undifferentiated connective tissue diseases; OAPS: obstetric antiphospholipid syndrome; BMI: body mass index; APH: adverse pregnancy history; FGR: fetal growth restriction; GDM: gestational diabetes mellitus; GH: gestational hypertension. ^{abc}Data within a row denoted by the same superscript letter are not significantly different ($P \geq 0.05$). Different superscript letters indicate a statistically significant difference between groups ($P < 0.05$). *significantly different compared to general population excluding overlapping cases (n = 94, 074 for SLE, n = 94, 213 for pSS, n = 92, 515 for OAPS, n = 94,182 for UCTD).

sample size, provided an epidemiologic overview of obstetrical data from 2018 to 2023 at West China Second University Hospital and an analysis of APOs and pregnancy complications for patients with PH-RDs. The study compared the live birth rate and pregnancy complications between women suffering from one

single PH-RD and two combined PH-RDs, and between different PH-RDs. Comparisons were also made with the general population, intending to identify indicators of pregnancy that need to be aware of for each rheumatic disease, and to provide ideas to refine the hypothesis of the mechanism of rheumatic disease

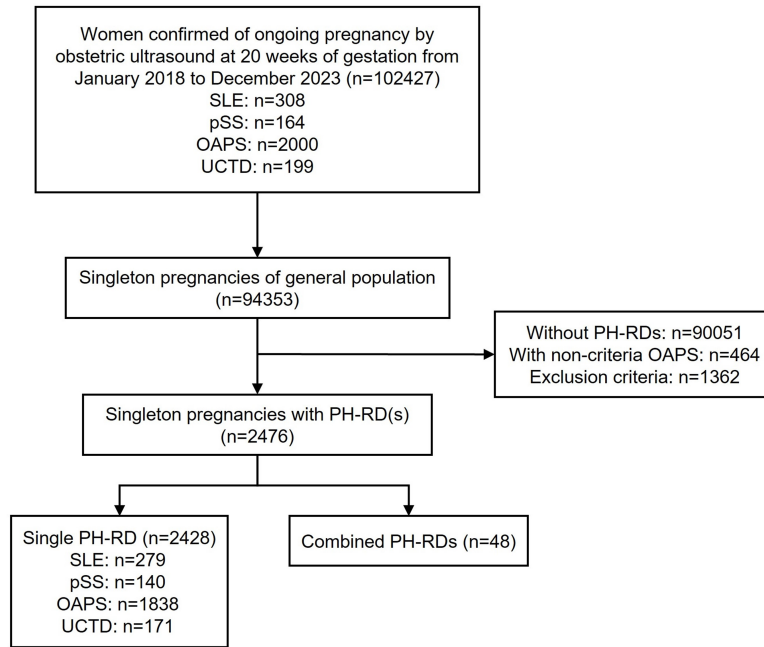


Figure 1. Flowchart. PH-RD: pregnancy-harmful rheumatic disease; SLE: systemic lupus erythematosis; pSS: primary Sjogren's syndrome; UCTD: undifferentiated connective tissue diseases; OAPS: obstetric antiphospholipid syndrome.

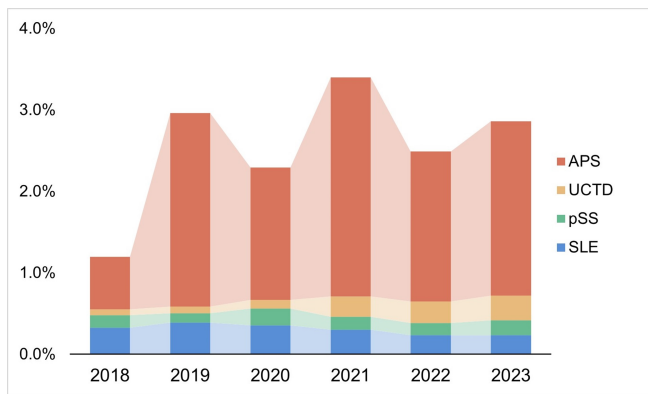


Figure 2. Annual incidence of pregnancy with PH-RD (s). SLE: systemic lupus erythematosis; pSS: primary Sjogren's syndrome; UCTD: undifferentiated connective tissue diseases; OAPS: obstetric antiphospholipid syndrome.

activity during pregnancy.

Overview of pregnancy outcomes in singleton pregnancy in 2018~2023

The annual live birth rate in this center has been stable over the 6 years, ranging from 96.5%–97.1%, with no significant trend, demonstrating that the quality of care at our center has been stable, and the subsequent comparisons are credible. On this basis, there has been a slight and statistically significant downward trend in the preterm birth rate at our center, which is related to increased awareness and medical care for full-term birth.

As for the pregnancy complications, statistically significant upward trends were seen in the incidence of FGR, GDM, and thrombosis, and a significant downward trend was observed in the incidence of placenta previa. These trends may be the result of many factors such as people's habits and living environment, and may be representative of the region.

Prevalence of PH-RDs in pregnant women

The annual incidence of SLE, pSS, or UCTD in pregnancy has been stable over the 6 years, while the annual incidence of OAPS has been variable. Between 2018 and 2019, there appeared to be a noticeable increase in the incidence of OAPS, and after 2019, it fluctuated between 1.63 and 2.69%. The variability in the annual incidence of OAPS may be related to the ongoing controversy over the principles of diagnosis and management for OAPS.^[14-17] Although in this study we included only patients with criteria OAPS who met Sydney criteria, since clinical criterion can only be obtained by physicians through patient descriptions and laboratory tests are not routine in pregnancy, diagnostic results may be influenced by physicians' recognition of OAPS, resulting in the variability in the incidence between years. In spite of the variability, OAPS remains the most common PH-RD. This may be because pregnancy itself is one of the most important inducing factors for OAPS.

SLE and OAPS may increase the risk of placenta-related complications

PH-RD significantly affects both live birth and preterm

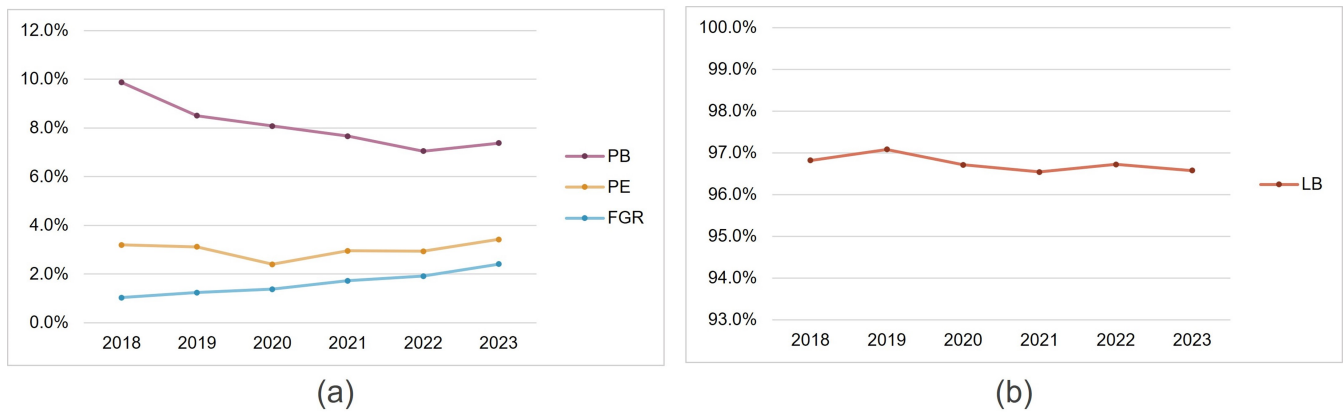


Figure 3. Annual incidence of live birth, preterm birth, preeclampsia, and FGR in singleton pregnancies of general population. (a) Annual incidence of live birth; **(b)** Annual incidence of preterm birth, preeclampsia, and FGR in singleton pregnancies. LB: live birth; PB: preterm birth; PE: preeclampsia; FGR: fetal growth restriction.

birth rates, and the risk is further increased when combining two PH-RDs. Specific analysis of each pregnancy complication revealed that PH-RD mainly increased the risk of placenta-related pregnancy complications, including preeclampsia, FGR, and oligohydramnios. In late pregnancy, placenta-associated pregnancy complications have been thought to be associated with placental microthrombosis and inflammatory responses, which are highly consistent with the pathomechanisms of systemic autoimmune diseases, especially APS.^[18–20] In this study, patients with OAPS comprised the majority of patients and the comparison between different PH-RDs also revealed that OAPS and SLE appeared to have the most significant impact on pregnancy outcomes. On the one hand, this may be due to the larger number of pregnancies with SLE and OAPS, which makes it easier to draw statistically significant results. On the other hand, this may be related to the pathophysiologic mechanisms of SLE and OAPS themselves.

Previous studies have already showed that OAPS may be related to a higher risk of APOs and placental disorders, such as preeclampsia and FGR.^[21] The complications and adverse outcomes in OAPS pregnancy, especially stillbirth, are considered to be caused by placental dysfunction and are strongly associated with antiphospholipid antibodies, which maybe take part in thrombosis, angiogenic imbalance, and/or localized inflammation.^[22–24] Our study also observed the effect of OAPS on thrombosis.

SLE and pSS have long been recognized as similar disorders, with extensive overlap in clinical and serological features and pathological mechanisms.^[25] There was concordance between pSS and SLE patients in the incidence of GDM in this study, which revealed that SLE and pSS might decrease the risk of GDM. It has been suggested that SLE activity may be associated with

cachexia, a trend that is consistent with the reduced incidence of GDM.^[26] Our results seem to be contrary to a recent Swedish cohort^[27] but consistent with a Chinese study.^[28] In addition, a meta-analysis also demonstrated that SLE may not increase the risk of GDM.^[29] These differences might be due to different diagnosis criteria and management among countries.^[30] While pSS and SLE have many similarities, they still have differences. According to previous studies, the increased incidence of placenta-related complications such as preeclampsia in pSS is not as remarkable as in SLE,^[31] which was consistent with our results. This may be related to the risk of renal lesions and angiogenic factor imbalance in SLE patients yet not proved in pSS patients.^[32]

As for UCTD, it can remain stable for years with minimal activity, and the association between UCTD and APOs remains unclear according to previous studies.^[33] The results of this study show that UCTD also potentially increases the risk of placenta-related pregnancy complication. When compared with differentiated connective tissue diseases, this risk seems to be weaker than that of SLE but may be stronger than that of pSS.

Limitations

This study still has many limitations. Firstly, we did not focus on the guideline-based classification of activity and progress of each rheumatic disease during pregnancy. Secondly, most characteristics in this study were collected and analyzed as binary variables for statistical analysis, which helps to identify problems in this multi-group comparative study, but at the same time ignores the impact of different subtypes or different degrees of characteristics or outcomes on the results. Thirdly, we did not analyze the effects of treatment (especially medications) of rheumatic diseases on pregnancy, including its efficacy in rheumatic diseases and adverse

effects in pregnancy. Finally, given that certain PH-RDs, particularly APS and SLE, are associated with an increased risk of early pregnancy loss, our inclusion criterion (ongoing pregnancy at 20 weeks of gestation) may have introduced selection bias and potentially underestimated the true impact of PH-RDs on overall pregnancy outcomes. Therefore, our findings are primarily applicable to pregnancies that have progressed beyond 20 weeks and may not be generalizable to early pregnancy outcomes.

CONCLUSION

The incidence of pregnancy with PH-RDs stabilized between 2018 and 2023, except for higher variability in the incidence of OAPS. The effects of PH-RD on pregnancy are mainly seen in placenta-related APOs and complications such as preterm birth, preeclampsia, FGR, and oligohydramnios, especially SLE and OAPS. The combination of two PH-RDs may further affect the pregnancy outcomes.

DECLARATION

Acknowledgement

None.

Author contributions

Hu ZY wrote the first draft of manuscript, analyzed the data, performed the statistical analysis, and prepared the materials. Zeng RJ and Han JB wrote the first draft of manuscript, collected and analyzed the data. Qin L and Qin S designed the study and provided clinical support. All authors reviewed and commented on previous versions of the manuscript.

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Ethical approval

The study was approved by the Ethics Committee of West China Second University Hospital (No. 2023-116).

Informed consent

Patient consent was waived since this was a retrospective study with all the personal information unidentified.

Conflict of interest

The authors declare that they have no competing interests.

Use of large language models, AI and machine learning tools

None declared.

Data availability statement

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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