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Original Article

Association Between Vaginitis and Adverse Pregnancy Outcomes in Women with Gestational Diabetes Mellitus: A Retrospective Cohort Study

Y ***Li***, Q ***Xu***, L ***Zhang***, J ***Yu***, X ***Chen***, X ***Xu***

Abstract ***Objective:*** To investigate the association between vaginitis and adverse pregnancy outcomes in women with gestational diabetes mellitus (GDM). ***Methods:*** We retrospectively analysed maternal and neonatal data from 1565 women diagnosed with GDM who delivered at the Affiliated Maternity and Child Health Care Hospital of Nantong University between January 2019 and August 2022. Propensity score matching (PSM) was applied based on the presence or absence of vaginitis as the grouping criterion. Chi-square tests and multivariate logistic regression were employed to compare group differences and estimate odds ratios (ORs) with 95% confidence intervals (CIs). ***Results:*** After 1:2 PSM, 400 women with GDM and vaginitis and 705 women with GDM alone were included. Multivariable logistic regression showed that vaginitis was associated with a higher risk of macrosomia (OR 1.712, 95% CI 1.219-2.405; P=0.002) and a lower risk of preterm birth (OR 0.422, 95% CI 0.231-0.772; P=0.005). The lower incidence of low birth weight (1.8% vs 8.9%) was likely attributable to the reduced preterm birth rate. ***Conclusion:*** This study identified distinct associations between vaginitis and adverse pregnancy outcomes among women with gestational diabetes mellitus. Vaginitis was associated with an increased risk of macrosomia and a lower risk of preterm birth. These findings suggest that the interactions between metabolic dysregulation, vaginal health, and pregnancy outcomes may be more intricate than previously recognised. Further prospective studies are needed to elucidate the underlying pathways and clinical implications of these associations.

Key words Gestational diabetes mellitus; Macrosomia; Pregnancy outcome; Preterm birth; Vaginitis

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Introduction

Gestational diabetes mellitus (GDM) is one of the most common metabolic complications of pregnancy and has become a major public health concern worldwide. The latest data from the International Diabetes Federation show that GDM affects 14% of pregnant women globally, with the prevalence increasing annually. In Southeast Asia, the prevalence can reach up to 20.8%.[1,2] Existing studies have shown that the infants of women with GDM are significantly more likely to suffer from preterm birth, low birth weight, neonatal asphyxia, small for gestational age, and macrosomia.[3,4] The adverse effects persist in the long term, significantly increasing the risk of their offspring developing cardiovascular, respiratory, and neurological diseases.[5-7] Given the intergenerational impact associated with GDM, effective management of GDM is essential for maternal and infant health.

Vaginitis is the most common gynaecological disorder among women of reproductive age. In the United States, bacterial vaginosis has been reported in 5.8-19.3% of pregnant women.[8] The incidence of pregnancy complicated with vaginitis can even reach 26-50% in certain developing countries.[9,10] Studies have shown that vaginitis can lead to adverse health consequences such as pelvic inflammatory disease and endometritis,[11] and confirmed that persistent vaginitis can reduce a woman's fertility by up to 43%.[12] The vaginal microbiota is a complex and dynamic micro-ecosystem that colonises from a woman's birth and persists throughout her lifetime until death. During pregnancy, hormonal fluctuations cause changes in vaginal pH. Under normal circumstances, the vaginal flora is in a relatively balanced state, protecting the vaginal epithelial cells from microbial attack. The vaginal micro-ecological environment can be altered by a weakened immune response or pregnancy complications, leading to imbalanced flora and subsequent vaginitis. However, some patients may not show clinical manifestations of vaginitis,[13] which attenuates its adverse effects on pregnancy outcomes. Associations have been reported between vaginitis and adverse pregnancy outcomes such as preterm birth, miscarriage, small for gestational age, premature rupture of membranes, low birth weight, and macrosomia.[14-18] However, Oittinen et al presented contradictory conclusions and indicated a critical association only between vaginitis and pregnancy outcomes.[19] Therefore, the association between vaginitis and adverse pregnancy outcomes needs further exploration.

Ameelia Sadaqat reported that 45% of women with GDM experienced vaginitis symptoms during pregnancy, compared to 27% of normal pregnant women.[20] This highlights the higher susceptibility of GDM women to vaginitis and emphasises the importance of giving them adequate attention and concern. However, previous evidence was limited by small sample sizes, inadequate control of confounding factors, or non-representative study populations.[21-23] Given that existing studies have primarily focused on comparing women suffering from vaginitis with healthy individuals, neglecting the specific subgroup of GDM women, the present study focuses on pregnant women with GDM as the control group to investigate the impacts of GDM with vaginitis on adverse pregnancy outcomes.

The objective is to investigate the association between GDM with vaginitis and pregnancy outcomes, thereby assisting healthcare professionals in improving maternal and infant outcomes during the perinatal period more effectively.

Materials and Methods

This retrospective cohort study collected maternal and infant information from the discharge medical record system of the Affiliated Maternity and Child Health Care Hospital of Nantong University. The study included 1565 GDM mothers who were hospitalised and delivered in the obstetrics ward of the hospital between January 2019 and August 2022. Inclusion criteria comprised age >18 years, gestational week ≥28 weeks, singleton pregnancy, live birth, medical diagnosis of GDM or vaginitis, and complete medical record data. Exclusion criteria encompassed age >45 years, gestational week >42 weeks, pregnancy comorbidities independently affecting obstetric outcomes, assisted reproductive technology usage, history of gynaecological oncology or infectious diseases, and history of mental illness. The study was reviewed and approved by the Ethics Committee of the Affiliated Hospital of Nantong University (approval number: 2021-K004-01). All methods were performed in accordance with the relevant guidelines and regulations (Declaration of Helsinki). All participants signed informed consent.

All participants underwent a routine 75 g oral glucose tolerance test (OGTT) at 24-28 weeks of gestation. The diagnostic criteria for GDM were defined as follows: (1) fasting blood glucose concentration ≥5.1 mmol/L, (2) blood glucose concentration at 1 hour after OGTT

≥10.0 mmol/L, (3) blood glucose concentration at 2 hours after OGTT ≥8.5 mmol/L. GDM was diagnosed when any of the above three criteria were met. The diagnosis of vaginitis involved collecting vaginal secretions from the posterior fornix for a six-point test (acetylaminoglucosidase activity, sialidase activity, glucuronidase activity, leukocyte esterase activity, hydrogen peroxide concentration, and pH value). Different types of vaginitis (bacterial vaginosis, trichomonal vaginitis, and vulvovaginal candidiasis) could be diagnosed based on the results of the vaginal secretion examination. All mothers had documented medical diagnoses of either GDM or vaginitis in their discharge records. Mothers were categorised into two groups: GDM with vaginitis group (n=484) and GDM alone group (n=1081), depending on the presence of vaginitis. To minimise differences between the two groups, propensity score matching (PSM) was employed to select 404 women with GDM and vaginitis and 808 women with GDM who met the screening criteria according to a 1:2 matching principle. Ultimately, a total of 400 women with GDM and vaginitis and 705 women with GDM were selected as research subjects (Figure 1).

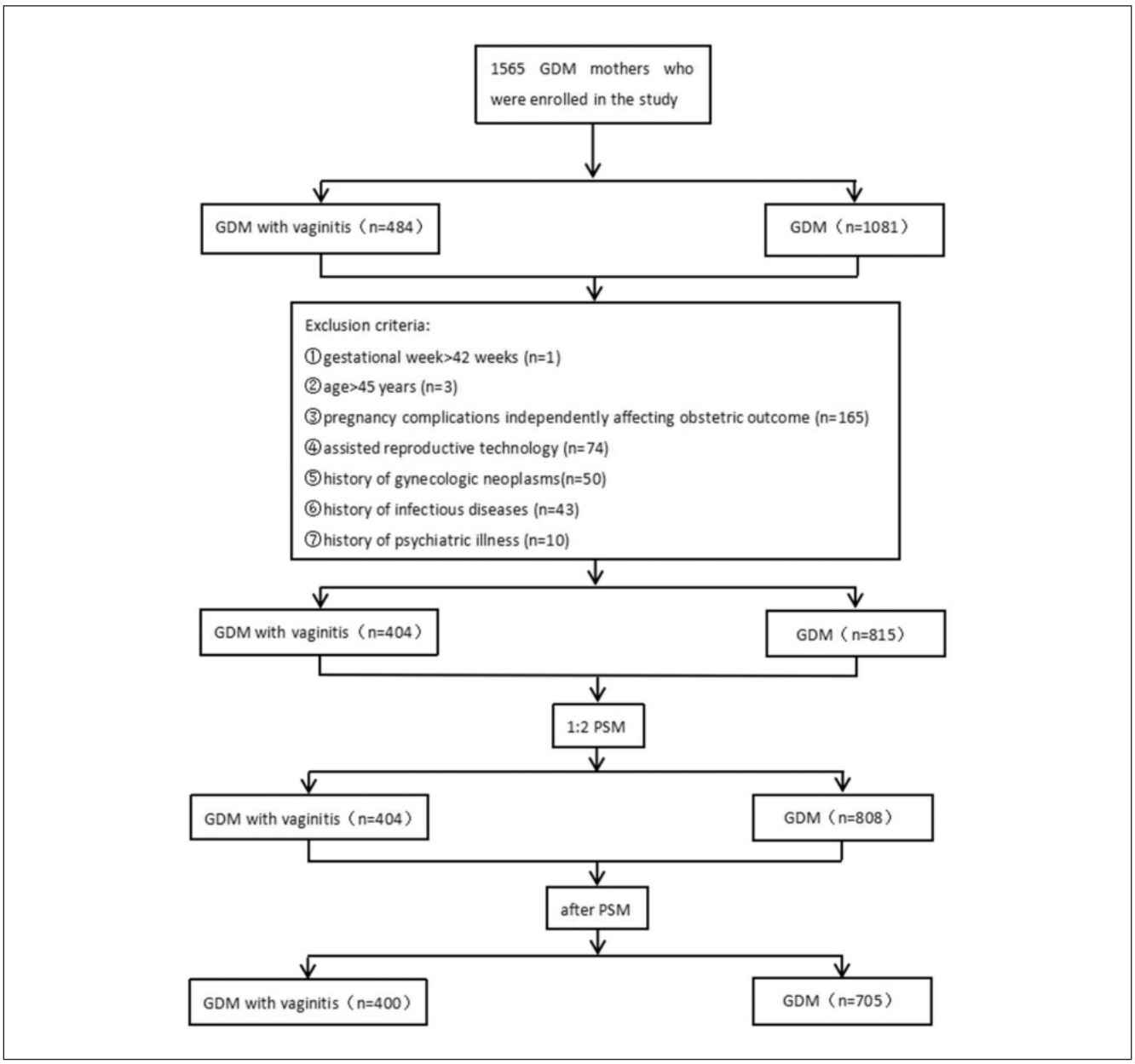

Figure 1 Sample selection.

The neonatal birth information retrieved from the discharge medical record system includes premature rupture of membranes, macrosomia, low birth weight, neonatal asphyxia, and neonatal malformations. Preterm birth is defined as gestational age ranging from 28 to less than 37 weeks; premature rupture of membranes refers to spontaneous foetal membrane rupture before delivery; macrosomia denotes newborns with a birth weight equal to or exceeding 4000 g; low birth weight is characterised by newborns weighing less than 2500 g but greater than or equal to 1500 g at birth; neonatal asphyxia is described as the inability of a newborn to establish normal respiration following delivery due to various factors, resulting in hypoxia, acidosis, and potentially severe pathophysiological conditions leading to multi-organ damage; neonatal malformation encompasses an array of structural anomalies, functional defects, metabolic disorders, and behavioural developmental abnormalities observed in newborns.

Several covariates that may affect pregnancy outcomes were included as matching variables in this study, namely age, gravidity, parity, mode of delivery, and obesity. The subjects were divided into two groups according to age, 19-34 years and ≥35 years; three groups were split on the basis of gravidity and parity, 1, 2, and ≥3; mode of delivery was classified into spontaneous delivery and caesarean delivery; and obesity was defined as a BMI of >28 kg/m² and was recorded as "yes" or "no" based on the presence of obesity. All data were obtained from medical records in the discharge medical record system.

Data were analysed through PSM with IBM SPSS Statistics for Windows, V27.0 plug-in. Frequency (n) and constitutive ratio (%) were used to describe the count data. A chi-square test was applied to compare the GDM with vaginitis group with the GDM alone group before and after PSM to compare the significant differences in general information between the two groups. The nearest neighbour matching method was adopted according to the 1:2 matching principle. Matching variables included age, gestational age, parity, obesity, and mode of delivery with a tolerance of 0.1. Multivariate logistic regression was used to estimate risk ratios and 95% confidence intervals for adverse pregnancy outcomes, with the GDM alone group as reference. The significance test level was $\alpha=0.05$, and the P value was two-sided probability. $P<0.05$ indicated a statistically significant difference. The data that support the findings of this study are available from the corresponding author upon reasonable request.

Results

Prior to PSM, 404 women with GDM and vaginitis and 808 women with GDM were included for analysis. The group of women with GDM and vaginitis had a significantly higher percentage of primigravida (44.3% vs 37.3%) and primipara (62.6% vs 54.0%) compared to the group of women with GDM alone before PSM (Table 1). In other words, the group of women with GDM alone experienced more pregnancies and deliveries than the group with GDM and vaginitis. After performing a 1:2 PSM, the baseline characteristics between the two groups were equalised. Finally, 400 women in the GDM with vaginitis group and 705 women in the GDM alone group were included (Table 1).

The incidence of macrosomia was higher in the GDM with vaginitis group compared to the GDM alone group after PSM (20.0% vs 11.6%, P<0.001). Additionally, the GDM with vaginitis group had lower rates of preterm birth (4.5% vs 14.9%, P<0.001) and low birth weight (1.8% vs 8.9%, P<0.001) compared to the GDM alone group (Table 2). The reduced low birth weight rate is likely attributable to the substantially lower preterm birth rate in the vaginitis group, as preterm infants are more prone to low birth weight.

The results of multivariate logistic regression analysis showed that compared with the GDM alone group, the risk of macrosomia was 71.2% higher in the GDM with vaginitis group (OR 1.712, 95% CI 1.219-2.405, P=0.002), while the risk of preterm birth was reduced by 57.8% (OR 0.422, 95% CI 0.231-0.772, P=0.005) (Table 3).

Discussion

A study conducted in Sweden found that 75% of women in their reproductive age experienced vaginitis, with 50% of them being first infected or experiencing a recurrence during pregnancy.[24] Pregnant women with GDM, who are at high risk for vaginitis, may be more susceptible due to the persistent hyperglycaemic state leading to vaginal glycogen accumulation and weakened immune defence mechanisms. This susceptibility can increase the likelihood of developing vaginitis during pregnancy. Despite GDM and vaginitis posing serious threats to maternal and foetal health, there is still a lack of research on their combined effects on pregnancy outcomes.

Table 1 Baseline characteristics of the study population stratified by the presence or absence of vaginitis before and after propensity score matching

	Before PSM				After PSM			
	GDM with vaginitis (n=404)	GDM (n=808)	χ2	P	GDM with vaginitis (n=400)	GDM (n=705)	χ2	P
Age [n(%)]			0.004	0.952			0	0.994
19-34	351 (86.9)	703 (87)			349 (87.25)	615 (87.2)		
≥35	53 (13.1)	105 (13)			51 (12.75)	90 (12.8)		
Gravidity [n(%)]			**6.797**	**0.033**			2.627	0.269
1	179 (44.3)	301 (37.3)			178 (44.2)	272 (39.6)		
2	113 (28)	232 (28.7)			113 (28)	197 (28.7)		
≥3	112 (27.7)	275 (34)			112 (27.8)	218 (31.7)		
Parity [n(%)]			**8.478**	**0.014**			3.805	0.149
1	253 (62.6)	436 (54)			252 (62.5)	391 (56.9)		
2	129 (31.9)	324 (40.1)			129 (32)	260 (37.8)		
≥3	22 (5.4)	48 (5.9)			22 (5.5)	36 (5.2)		
Mode of delivery [n(%)]			0.015	0.903			0.077	0.781
Spontaneous delivery	193 (47.8)	389 (48.1)			193 (47.9)	335 (48.8)		
Cesarean delivery	211 (52.2)	419 (51.9)			210 (52.1)	352 (51.2)		
Obesity [n(%)]			1.383	0.24			1.459	0.227
Yes	87 (21.5)	151 (18.7)			86 (21.3)	126 (18.3)		
No	317 (78.5)	657 (81.3)			317 (78.7)	561 (81.7)		

PSM: propensity score matching; GDM: gestational diabetes mellitus

Table 2 Adverse pregnancy outcomes among GDM with vaginitis and GDM groups

	GDM with vaginitis (n=400)	GDM (n=705)	χ2	P
Preterm birth	18 (4.5)	105 (14.9)	27.869	**<0.001***
Macrosomia	80 (20)	82 (11.6)	14.286	**<0.001***
PROM	53 (13.3)	122 (17.3)	3.148	0.076
LBM	7 (1.8)	63 (8.9)	22.211	**<0.001***
Neonatal asphyxia	5 (1.3)	21 (3)	3.319	0.068
Neonatal malformation	3 (0.8)	6 (0.9)	0.032	0.857

GDM: gestational diabetes mellitus; PROM, premature rupture of membrane; LBM, low birth weight

*P<0.05

Table 3 Multivariate logistic regression analysis of adverse pregnancy outcomes

	Preterm birth		Macrosomia		PROM		LBM		Neonatal asphyxia		Neonatal malformation	
	OR (95%CI)	P	OR (95%CI)	P	OR (95%CI)	P	OR (95%CI)	P	OR (95%CI)	P	OR (95%CI)	P
No	1.00 (Reference)		1.00 (Reference)		1.00 (Reference)		1.00 (Reference)		1.00 (Reference)		1.00 (Reference)	
Yes	**0.422 (0.231-0.772)**	**0.005***	**1.712 (1.219-2.405)**	**0.002***	0.934 (0.647-1.347)	0.714	0.411 (0.165-1.024)	0.056	0.608 (0.216-1.71)	0.608	1.066 (0.259-4.381)	0.93

PROM, premature rupture of membrane; LBM, low birth weight

*P<0.05

In a systematic review and meta-analysis designed to analyse the impact of bacterial vaginosis on maternal and infant outcomes, it was observed that bacterial vaginosis is associated with a significantly increased risk of preterm birth, premature rupture of membranes, low birth weight, and neonatal asphyxia.[25] A prospective cohort study conducted by Hassan et al involving 600 pregnant women in their third trimester revealed different findings regarding the influence of aerobic vaginitis on maternal and infant outcomes.[21] Adjusted analyses demonstrated that pregnant women with aerobic vaginitis had a significantly higher risk of preterm birth and premature rupture of membranes. However, no correlation was found between aerobic vaginitis and low birth weight or neonatal asphyxia. In addition, prospective cohort studies by Kindinger et al and Powell et al and revealed no significant negative effect of bacterial vaginosis on hypertensive disorders of pregnancy and preterm birth.[26,27] Thus, the findings of existing studies investigating the impact of vaginitis on preterm birth remain inconclusive.

The results of this study suggest that vaginitis is associated with a reduced risk of preterm birth among GDM women, which is contrary to most previous research findings. This finding is undoubtedly interesting. We posit that the disparity in findings may be attributed to the fact that previous studies primarily focused on comparing pregnant women with vaginitis to healthy pregnant women, while this study focuses on GDM women with vaginitis, which is a comorbidity. Additionally, the gestational weeks of GDM women were longer than those of healthy women, partially explaining why GDM women with vaginitis had a lower likelihood of premature birth.

A previous study by Zhang et al reported that among women with GDM, those with abnormal vaginal flora had higher frequencies of premature rupture of membranes, preterm delivery, chorioamnionitis, and puerperal infection compared to those with normal flora.[28] These findings differ from our results, where vaginitis was associated with a reduced risk of preterm birth. Possible explanations include differences in study populations (e.g., diagnostic criteria for abnormal flora/vaginitis), adjustment methods (our use of PSM to balance covariates), or the specific impact of vaginitis in the context of GDM hyperglycaemia, which may alter microbial dynamics or immune responses differently.

A study conducted by Son et al from South Korea involved 593 singleton pregnant women, whose vaginal secretions were routinely collected in obstetric clinics from 2011 to 2016.[29] The objective was to investigate the correlation between abnormal vaginal flora and preterm birth. The study found no significant association between abnormal vaginal flora in the third trimester and preterm birth. On the contrary, pregnant women with abnormal flora in the third trimester were more likely to deliver full-term babies compared to those with normal flora. On the basis of this research, a population-based retrospective cohort study was conducted in Chongqing, China, collecting results of vaginal secretion examinations from 57,708 pregnant women within one year before pregnancy.[15] The aim was to explore the association between pre-pregnancy reproductive tract infection and adverse pregnancy outcomes. After adjusting for potential confounding factors, the results still demonstrated that women with bacterial vaginitis before pregnancy had an increased risk of macrosomia (OR=1.58, 95% CI: 1.06-2.34), which is consistent with the findings of our research that vaginitis is associated with an increased risk of macrosomia. Scholars suggest that vaginitis may be caused by poor blood glucose control in pregnant women with GDM. Therefore, the significant differences in macrosomia between groups could be attributed to high blood glucose levels during pregnancy, which lead to excessive transport of glucose and nutrients through the placenta for foetal growth and development, ultimately resulting in macrosomia.

The findings of increased macrosomia risk associated with vaginitis in this study are consistent with other reports, prompting further exploration of the underlying biological mechanisms.

Regarding the increased risk of macrosomia, a plausible mechanistic pathway involves the synergistic interaction between maternal hyperglycaemia and vaginal inflammation. In GDM, elevated glucose levels promote glycogen accumulation in vaginal epithelial cells, fostering pathogenic microbial proliferation and sustaining vaginitis. The resulting chronic low-grade inflammation may further exacerbate insulin resistance, leading to poorer glycaemic control and enhanced transplacental glucose transport. This, in turn, stimulates foetal hyperinsulinaemia and excessive somatic growth, consistent with the classical Pedersen hypothesis.[30]

By contrast, the reduced risk of preterm birth observed in this study is more controversial and probably multifactorial. A key potential explanation is the greater intensity of medical surveillance and intervention received by women with both conditions. The diagnosis of vaginitis often triggers more frequent antenatal consultations, intensified glycaemic monitoring, timely therapeutic

adjustments (e.g., insulin optimisation), and antimicrobial treatment when indicated. Such enhanced care may contribute to better overall pregnancy management and a lower likelihood of preterm delivery. Given the retrospective nature of this study, we lacked detailed information on antenatal visit frequency, HbA1c trajectories, or specific interventions, rendering it challenging to fully adjust for this surveillance bias. In addition, differences in vaginal microbiota composition or the timing of vaginitis onset in the context of GDM-related metabolic changes cannot be excluded. Certain microbial profiles might not elicit the strong pro-inflammatory responses (e.g., prostaglandin release and cervical ripening) typically associated with preterm birth. Nevertheless, these remain speculative hypotheses. Prospective studies incorporating longitudinal microbiota profiling, comprehensive glycaemic data, and detailed records of prenatal care intensity are warranted to elucidate the underlying mechanisms and validate the observed associations.

The innovation of this study primarily lies in two aspects. Firstly, in terms of research perspective, the majority of previous studies have primarily focused on the pairwise correlation between GDM, vaginitis, and adverse pregnancy outcomes. However, as a high-risk factor for vaginitis, GDM has not been studied to explore the impact of GDM with vaginitis on pregnancy outcomes. To the best of our knowledge, few previous studies have specifically compared adverse pregnancy outcomes between women with GDM with and without vaginitis. The second innovation in this study is the use of PSM in statistical methodology. This method helps to equalise covariate differences between groups and reduce selection bias, maximising control over confounding factors and enhancing the credibility of the results.

This study has certain limitations. Firstly, the retrospective cohort design resulted in missing covariates due to follow-up limitations. Future studies could employ a higher-quality prospective cohort design to establish the causal relationship between vaginitis and adverse pregnancy outcomes more effectively. Secondly, due to the limited sample size, this study did not examine the impact of different bacterial strains on adverse pregnancy outcomes. Future investigations could include stratified analysis based on pathogen types for a more comprehensive understanding. Thirdly, this study adopted a single-centre sampling method, which to a certain extent lacks sample representativeness and limits the extrapolation of the results. Therefore, conducting a multi-centre study would ensure data comparability and consistency, as well as enhance overall applicability and reliability of conclusions. Fourth, birth weight was originally classified using absolute thresholds (macrosomia ≥4000 g, low birth weight <2500 g) without calculating gestational age- and sex-specific percentiles (large for gestational age and small for gestational age) using standardised Chinese reference standards. This prevented post hoc analysis of adjusted foetal growth measures, as recommended in the literature to disentangle effects from differing preterm rates. Future prospective studies should routinely incorporate these adjusted outcomes. Fifth, as a retrospective cohort study, we were unable to account for differences in the intensity of prenatal care between the two groups. Women diagnosed with vaginitis may have received more frequent antenatal visits, stricter glycaemic monitoring, and more aggressive interventions, which could have contributed to the observed lower preterm birth rate (surveillance bias). This unmeasured confounding factor limits causal inference. Future prospective studies should collect detailed data on antenatal visit frequency, HbA1c levels, and treatment details to better control for this bias.

The findings of this study suggest the impact of GDM with vaginitis on adverse pregnancy outcomes, helping clinicians identify risk factors early and develop comprehensive and individual-based treatments for pregnant women to avoid adverse pregnancy outcomes, so as to effectively safeguard maternal and infant health during childbirth. Based on the research results, we hypothesise that moderating variables such as blood glucose fluctuation, medication use, disease duration, and severity during pregnancy may introduce bias in the relationship between vaginitis and adverse pregnancy outcomes. In addition, samples collected at a single point in time are only representative of disease severity in the short term and do not explain the vaginal flora changes characterised by hormonal fluctuations throughout the gestational cycle. Therefore, we recommend that pregnant women with GDM receive enhanced attention during prenatal examinations, with a focus on comprehensive questioning and clinical assessment to promptly identify the onset of vaginitis. Additionally, if possible, it is advisable to collect vaginal secretion samples at multiple intervals throughout the first, second, and third trimesters of pregnancy in order to gain a more profound understanding of the associations among GDM, vaginitis, and adverse pregnancy outcomes. In summary, although these findings demonstrate the association between the

comorbidity of vaginitis and GDM and adverse pregnancy outcomes, further high-quality research is needed for validation.

Conclusion

This study identified a distinct pattern of associations between vaginitis and adverse pregnancy outcomes among women with gestational diabetes mellitus. Specifically, vaginitis was associated with an increased risk of macrosomia and a decreased risk of preterm birth. However, the latter finding contrasts with the prevailing body of evidence and suggests that unmeasured clinical or behavioural factors may have contributed to the observed associations.

These findings indicate that the interplay between metabolic dysfunction and vaginal dysbiosis in the context of gestational diabetes may be more complex than currently understood. Future prospective studies integrating metabolic, microbiological, and perinatal care factors are needed to clarify the underlying mechanisms and determine the clinical significance of these associations.

Contributions Statements

Yanran Li contributed to the analysis and interpretation of data, as well as wrote the manuscript. Qinwen Xu contributed to the study concept and design. Liqin Zhang contributed to acquisition of data. Jie Yu performed the validation. Xiaofang Chen performed the visualisation. Xujuan Xu performed the supervision and administration of the project. All the authors contributed to the final manuscript.

Ethics Approval

The study was reviewed and approved by the Ethics Committee of Affiliated Hospital of Nantong University (approval number: 2021-K004-01).

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Declaration of Interest Statements

The authors report there are no competing interests to declare.

Data Availability Statements

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

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