

ORIGINAL RESEARCH

Prevalence of Hypothyroidism in Pregnancy and Its Associations with Adverse Pregnancy Outcomes Among Pregnant Women in A General Hospital: A Cross Sectional Study

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Background: Hypothyroidism affects 3-5% of all pregnant mothers, making it the most common thyroid disorder associated with pregnancy. Furthermore, it is associated with adverse outcomes of pregnancy and newborn. Therefore, this research is aimed at determining the magnitude and pregnancy adverse outcomes associated with hypothyroidism among pregnant women having maternity services in a general hospital in Somalia.

Methods: A cross-sectional study was conducted on pregnant women who delivered in the hospital between December 2022 and May 2023. Subjects were selected through systematic sampling and data collected through an interviewer-based questionnaire. Adjusted odds ratios (AORs) of P values and 95% confidence intervals (CIs) were used to assess the correlation between variables. **Results:** The prevalence of hypothyroidism was 23.6% (95% CI: [19.4–27.8]). Overt DM (AOR=9.125, CI (3.106–26.812)). History of Recurrent pregnancy loss (AOR=12.938, CI (4.958-33.763), hypertension during pregnancy (AOR=6.718, CI (2.326-19.994)) and preterm delivery (AOR=7.015, CI (3.234-13.958)) were variables associated with hypothyroidism in pregnancy.

Conclusion: The study has shown a high prevalence of hypothyroidism during pregnancy at Daruxannan Hospital compared to previous studies around the world. This finding highlights the need for national and regional surveys to identify the prevalence and associated factors that contribute to hypothyroidism in pregnancy to set up interventions and determine policy directions.

Keywords: hypothyroidism, pregnancy outcome, Somalia

Introduction

Globally, next to diabetes, thyroid disorders are the most common endocrine disorder and are relevant to public health^{1,2} Hypothyroidism is a prevalent thyroid disorder during pregnancy, affecting approximately 3–5% of pregnant women. However, the prevalence can vary based on factors such as diagnostic criteria, maternal iodine status and pregnancy stage. Pregnancy-related hypothyroidism has been associated with various negative outcomes for both the mother and the newborn. These include an increased risk of spontaneous abortion, anemia, pre-eclampsia, gestational hypertension and placental abruption. 3-10

The prevalence of hypothyroidism in pregnancy in low- and middle-income countries has been reported to be 5–31.6%, which is higher than the prevalence in developed countries.^{7,11–16} Furthermore, factors such as old age, chronic medical disease, adverse maternal and newborn outcomes, and a personal and family history of thyroid dysfunction have been correlated with hypothyroidism during pregnancy. 7,13,15,17,18

Moderate-to-severe iodine deficiency has been a problem in sub-Saharan Africa. ¹⁹ Furthermore, Somalia has poor access to iodized salt and a high prevalence of cultural beliefs and barriers that prevent optimal consumption of micro-nutrients like

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iodine. 19 Studies have shown that iodine deficiency is strongly associated with hypothyroidism. However, data related to hypothyroidism in pregnancy has been limited in Somalia. Furthermore, the evidence on the risk factors and correlates of adverse maternal and neonatal outcomes of pregnant women with hypothyroidisms are limited. Understanding the associated factors of hypothyroidism in pregnancy will help reduce the magnitude and associated adverse outcomes. Therefore, the current study aims to determine the magnitude and adverse pregnancy outcomes related with hypothyroidism among pregnant women seeking maternity service at Daruxannan Hospital.

Methods

Study Design, Area, and Period

A prospective hospital-based cross-sectional study was conducted at Daruxannan Hospital in Burao, Somaliland, Somalia. The data collection period was from December 2022 to May 2023. All pregnant women who were admitted to the hospital after the gestational age (GA) of 24 completed weeks to give birth during the study were the study population. Pregnant women who delivered after GA of 24 completed weeks and gave written informed consent were included. We excluded those women who had known the result of thyroid stimulating hormone (TSH) during the current pregnancy and those on treatment for thyroid disorders. Additionally, pregnant women before the GA of 24 weeks and those who had communication difficulties were excluded.

Sample Size and Sampling Procedure

Single population proportion formula was used to calculate the sample size. Since there is no available study done with similar socio-demographic characteristics in the country, we took a P value of 0.50. Using the power of 80%, the estimated sample size was 386 adding a marginal error of 5% and a contingency rate. Systematic random sampling was utilized to collect the sample size.

Data Collection Procedures

Data was collected 24 hours after delivery using interviewee administered structured questionnaires. Consistency was checked by preparing the questionnaires in English and translating it to Somali and then translated back to English. Pretest and appropriate modification was carried out on the questionnaire. The principal investigator trained the data collectors in pre-tested checklists. Completeness, accuracy, and consistency of the collected data were checked daily by the principal investigator.

For the thyroid hormone parameter, venous blood was collected from the recruited mothers at the time of admission for delivery and the TSH values were analysed. For the abnormal range of TSH values, we checked the free levels of T3 and T4. The American Thyroid Association Guidelines 2011 was used to evaluate the results of thyroid hormone values taking a reference range of 0.3–3.0 m IU/L for third trimester.8 According to the same guideline, patients were classified as subclinical hypothyroidism if the TSH levels were elevated and a normal serum free T3 and T4 levels; high TSH levels and low levels of free T3 and T4 were classified as overt hypothyroidism. After diagnosis, the patient was referred to the treating physician for further investigation and treatment.

Hypothyroidism (TSH above 3.0 miu/l) was the dependent variable. Independent variables were sociodemographic characteristics (age, educational status, place of residency, and marital status), reproductive history (gravidity, parity, abortion, singleton versus multiple gestation and mode of conception), and risk factors (Personal/family history of thyroid dysfunction, thyroid surgery, prior adverse pregnancy outcome, chronic medical illness, history of infertility, use of iodised salt) and pregnancy outcomes (mode of delivery, GA at delivery, neonatal birth weight, maternal and newborn complications).

Data Management and Analysis

Each questionnaire was visually checked for completeness after data collection and code was given. Epi-info version 3.5.1 was used for data entry, and Statistical Package for Social Science (SPSS) version 25 software packages was used for analysis. Additionally, cross checking, data cleaning, and necessary corrections were performed by the principal Dovepress Abadi et al

investigator before data analysis. Descriptive statistics was used for sociodemographic characteristics, reproductive history, and risk factors for hypothyroidism in pregnancy. Independent factors associated with hypothyroidism in pregnancy were identified using bivariate and multivariate logistic regression. First, the crude association between independent and outcome variables was observed after bivariate analysis was carried out. Then, a multivariate model was used for variables with a P value <0.2 in bivariate analysis. Hosmer-Lemeshow goodness-of-fit was used to evaluate the goodness-of-fit of the logistic regression model. Finally, using the odds ratio with a 95% confidence interval and a P value of <0.05 statistically significant variables in the multivariate regression model was identified.

Ethical Consideration

The Declaration of Helsinki served as the guide for conducting the current investigation. The Burao University Institutional Review Board (IRB) granted ethical approval, and subjects under the age of 18 were required to provide informed written consent by their legal guardian or parents. The hospital administration gave the study's administrators permission to carry it out. After describing the study's goals to each participant, their informed consent was obtained. We did not gather or keep any identifying information about participants in order to protect their privacy. The manuscript includes all of the data sets that were used and/or examined throughout the current study.

Results

During the study period, a total of 386 patients participated, with 91 participants having hypothyroidism. This indicates the prevalence of hypothyroidism at 23.6% (95% CI: [19.4–27.8]). Out of the 91 participants with hypothyroidism, 31 individuals (8%) had overt hypothyroidism and the remaining ten (15.6%) had subclinical hypothyroidism. Ten (2.6%) participants had hyperthyroidism, among which two (0.5%) had subclinical hyperthyroidism and eight (2.1%) had overt hyperthyroidism.

Socio-Demographic Characteristics

Among different age groups, the rate of hypothyroidism was comparable. Furthermore, comparable rates of hypothyroidism were observed among housewives and employed participants. Participants who were unable to read and write had more hypothyroidism (P=0.000). Furthermore, those who lived outside of the city of Burao had a higher rate of hypothyroidism (P=0.002) (Table 1).

Table I Distribution of the Pregnant Women According to Their Socio-Demographic Characteristics with or Without Hypothyroidism

Variable (n=386)	Frequency n (%)	TSH>3MIU/L n (%)	TSH<= 3 MIU/L n (%)	Chi-Square (P- value)
Age group				0.301(0.583)
<19	20 (5.2%)	8 (40%)	12 (60%)	
20–34	320 (82.9%)	67 (20.9%)	253(79.1%)	
35 and above	46 11.9%)	16(34.8%)	30 (65.2%)	
Educational status				
Unable to write and read.	126 (32.6%)	48 (38.1%)	78(61.9%)	25.44(0.000)*
Primary school	140 (36.3%)	33 (23.6%)	107(76.4%)	
High school	91 (23.6%)	4 (4.4%)	87(95.6%)	
College or above	29 (7.5%)	6(20.7%)	23(79.3%)	

(Continued)

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Table I (Continued).

Variable (n=386)	Frequency n (%)	TSH>3MIU/L n (%)	TSH<= 3 MIU/L n (%)	Chi-Square (P- value)
Place of Residency				9.66 (0.002)*
Burao	378 (97.9%)	83(22%)	295(78%)	
Outside of Burao	8 (2.1%)	6(75%)	2(25%)	
Occupation				
Housewife	353 (91.5%)	80(22.7%)	273(77.3%)	0.112(0.738)
Self-employed	8 (2.1%)	2(25%)	6(75)	
Government Employee	6 (1.6%)	2(33.3%)	4(66.7%)	
Private employee	12 (3.1%)	4(33.3%)	8(66.7%)	
Student	7 (1.8%)	3(42.3%)	4(57.7%)	
Marital status				0.637(0.425)
Married	378 (97.9%)	90(23.8%)	288(76.2%)	
Divorced	8 (2.1%)	I (12.5%)	7(87.5%)	

Note: *Statically significant P values<0.05.

Reproductive Characteristics and Risk Factors

A comparable rate of hypothyroidism was observed between different gravidities. Similarly, the prevalence of hypothyroidism among women with multiple pregnancies was comparable to those with a singleton pregnancy. However, those with a personal or family history of thyroid dysfunction had a higher prevalence than those with no self- or family history (P=0.001 and P=0.026 respectively). Similarly, the participants with chronic hypertension (P=0.000), overt DM (P=0.000), and a history of RPL (P=0.000) had a higher percentage of hypothyroidism. However, the rate of hypothyroidism was similar among those who had used iodised salt in their diet and those who had not (Table 2 and Table 3).

Table 2 Analysis of the Reproductive Characteristics of the Pregnant Women with or Without Hypothyroidism

Variable Name (n=386)	Frequency n (%)	TSH>3MIU/L n (%)	TSH<=3MIU/L n (%)	Chi Square (P -value)
Gravidity				0.122(0.727)
ı	59 (15.3%)	22(37.3%)	37(62.7%)	
2–5	254 (65.8%)	42(16.5%)	212(83.5%)	
>5	73(18.9%)	27(37%)	46(63%)	
Parity				0.313(0.576)
0	81(21.0%)	30 (37%).	51(63%)	
1–4	255(66.1%)	41(16%)	214(84%)	
>4	50(13.0%)	20(40%)	30(60%)	
Abortion History				0.887(0.346)
Yes.	112(29.0%)	30(26.8%)	82(73.2%)	
No	274(71.0%)	61(22.3%)	213(77.7%)	

(Continued)

Table 2 (Continued).

Variable Name (n=386)	Frequency n (%)	TSH>3MIU/L n (%)	TSH<=3MIU/L n (%)	Chi Square (P -value)
Type of gestation				
Multiple	18(4.7%)	7(38.9%)	11(61.1%)	2.203(0.138)
Singleton	368(95.3%)	84(22.8%)	284(77.8%)	
Mode of Conception				
Induction	12(3.1%)	4(33.3%)	8(66.7%)	0.606(0.436)
Spontaneous	374(96.9%)	87(23.3%)	287(76.7%)	

Table 3 Distribution of Pregnant Women According to the Risk Factors with or Without Hypothyroidism

Variable Name (n=386)	Frequency n (%)	TSH>3MIU/L n (%)	TSH<=3MIU/L n (%)	Chi-Square (P- value)
Personal history of thyroid dysfunction				10.202(0.001)*
Yes.	46 (11.9%)	20(43.5%)	26(56.5%)	
No.	340(88.1%)	71(20.9%)	269(79.15)	
Family history of thyroid dysfunction				4.949(0.026)*
Yes	49(12.7%)	18(36.7%)	31(63.3%)	
No.	337(87.3%)	73(21.7%)	264(78.3%)	
Overt DM				8.259(0.004)*
Yes.	16(4.1%)	9(56.3%)	7(43.7%)	
No.	370(95.9%)	7(1.9%)	288(98.2%)	
History of recurrent pregnancy loss (RPL)				14.969(0.000)*
Yes	21(5.4%)	13(61.9%)	18(28.1%)	
No.	365(94.6%)	78(21.4%)	287(78.6%)	
History of preterm birth				0.673(0.412)
Yes.	5(1.3%)	2(40%)	3(60%)	
No.	381 (98.7%)	89(23.4%)	292(76.6%)	
Chronic hypertension				14.664(0.000)*
Yes.	10(2.59%)	8(80%)	2(20%)	
No.	376(97.4%)	83(22.1%)	293(77.9%)	
Subfertility History				0.011(0.916)
Yes.	35(9.1%)	8(22.9%)	27(77.1%)	
No.	351(90.9%)	83(23.6%)	268(76.4%)	
Use of Iodized Salt				0.009(0.922)
No.	304(78.7%)	72(23.7%)	232(76.3%)	
Yes.	82(21.2%)	19(23.2%)	63(76.8%)	

Note: *Statically significant P values<0.05.

Pregnancy Outcomes

Pregnant women who delivered before GA of 37 completed weeks had a higher prevalence of hypothyroidism (P=0.002). Likewise, those with maternal complications of hypertension during pregnancy, Ante-Partum Hemorrhage (APH), and Post-Partum Hemorrhage (PPH) had more hypothyroidism (P=0.000). Moreover, hypothyroidism was more noted among participants with newborn complications of APGAR score less than seven, still birth and Congenital anomaly (P=0.013) (Table 4).

Adverse Pregnancy Outcomes Associated with Hypothyroidism During Pregnancy

Overt DM, a history of RPL, chronic hypertension, and multiple gestation and adverse pregnancy outcomes of hypertension during pregnancy, preterm delivery, cesarean section, and low APGAR score were found to be associated with hypothyroidism during pregnancy in bivariate analysis. Then, a multivariable logistic regression model was used for these variables. Finally, using the odds ratio with a 95% confidence interval and a P value of <0.05 statistically significant variables in the multivariate regression model was identified. Overt DM (9.125 (3.106–26.812)), History of Recurrent pregnancy loss (12.938 (4.958–33.763)), hypertension during pregnancy (6.718 (2.326–19.994)) and preterm delivery (7.015 (3.234–13.958)) were variables associated with hypothyroidism in pregnancy (Table 5).

Table 4 Analysis of the Pregnancy Outcomes in Pregnant Women with or Without Hypothyroidism

Variable Name (n=386)	Frequency n (%)	TSH>3MIU/L n (%)	TSH<=3MIU/L n (%)	Chi Square (P-value)
Mode of delivery				5.379(0.200)
cs	201(52.1%)	57 (28.4%)	144(71.6%)	
SVD	185(47.9%)	34(18.4%)	151(21.6%)	
Birth Weight				
<2500	35(9.1%)	12(34.3%)	23(65.7%)	0.006(0.938)
2500–4000	302(78.2%)	64(21.2%)	238(78.8%)	
>4000	49(12.7%)	15(30.6%)	34(69.4%)	
Maternal complications				
РРН	12(3.1%)	4(33.3%)	8(66.7%)	36.917(0.000)*
АРН	13(3.4%)	2(15.4%)	11(84.6%)	
HDP	22(5.7%)	14(63.6%)	8(36.4%)	
Newborn complications				
APGAR<7	16(4.1%)	8(50%)	8(50%)	10.785(0.013)*
Still birth	11(2.8%)	4(36.4%)	7(63.6%)	
Congenital anomaly	7(1.8%)	4(57.1%)	3(42.9%)	
GA at delivery				9.512(0.002)*
<37 weeks	35(9.1%)	16(45.7%)	19(54. 3%)	
37–41 weeks	323(83.7%)	71(22%	252(78%)	
>41 weeks	28(7.3%)	4(14.3%)	24(85.7%)	

Note: *P values<0.05.

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Table 5 The Bivariable and Multivariable Logistic Regression results on Variables Associated with Hypothyroidism in Pregnancy

Variables	Bivariable and Multivariable Logistic Regression				
	Frequency of Hypothyroidism	COR with 95% CI	AOR with 95% CI		
Overt DM					
No	82	I	I		
Yes.	9	4.51(1.63–12.49)	9.125 (3.106–26.812)*		
History of RPL					
No	78	I	I		
Yes.	13	5.97(2.39–14.93)	12.938 (4.958–33.763)*		
Multiple Pregnancy					
No	84	I	I		
Yes.	7	2.152(0.809–5.723)	2.980 (0.994–8.932)		
Chronic hypertension					
No	83	I	I		
Yes.	8	14.120(2.942–67.773)	8.002 (0.958–66.878)		
Hypertension During Pregnancy					
No	77	I	I		
Yes.	14	6.52(2.64–16.11)	6.718 (2.326–19.994)*		
Preterm Birth					
No	69	I	I		
Yes.	22	4.16(2.16–7.99)	7.015 (3.234–13.958)*		
Cesarean Section					
No	57	ı	I		
Yes.	34	1.75(1.05–2.5)	1.327 (0.737–2.392)		
Low APGAR score					
No	83	ı	I		
Yes.	8	3.45(1.25–9.4)	1.038 (0.158–6.808)		

Note: *P < 0.05.

Abbreviations: COR, crude odds ratio; AOR, adjusted odds ratio.

Discussion

The current research is conducted at Daruxannan General Hospital to evaluate the magnitude of hypothyroidism during pregnancy and the adverse pregnancy outcomes associated with hypothyroidism. The prevalence of hypothyroidism during pregnancy in our study is 23.6% (95% CI: [19.4–27.8]). Overt DM, history of RPL were the risk factors significantly associated with hypothyroidism in pregnancy. Furthermore, hypertension during pregnancy and preterm delivery were the adverse pregnancy outcomes associated with hypothyroidism in pregnancy.

The magnitude of hypothyroidism in pregnancy in our study is greater than the 2% to 18% prevalence reported worldwide. It is also not in line with the study done in Africa Ivory Coast and Nigeria, which reported

a prevalence of 12.1% and 18%, respectively. 15,16 However, a prospective observational study carried out in a tertiary care institute in Punjab, North India has shown a prevalence of 31.6% prevalence of hypothyroidism in pregnancy, which is higher than our study. Moderate-to-severe iodine deficiency has been a problem in sub-Saharan Africa. Somalia is a coastal country, and the main source of dietary iodine is groundwater. According to our study only 20% of the participants reported use of iodized salt in their diet. It has also been noted that there is a lack of access to iodized salt and a significant prevalence of cultural attitudes and impediments to poor consumption of micro-nutrients, especially iodine. The large percentage of high-risk patients in hospitals and the country's inadequate access to health-care services may be the factor for the significant proportion of hypothyroidism among pregnant women in the current study.

In countries with different cultures and development, factors correlated to hypothyroidism in pregnancy appear similar and disproportionately associate with old age, poor socioeconomic status, chronic medical illness, and history of adverse pregnancy outcomes. $^{18-20}$ Likewise, our study noted higher prevalence of hypothyroidism among pregnant women who were not able to write and read, lived outside of the city (P=0.002), maternal complications (P=0.000) and newborn complications. Additionally, chronic diseases such as diabetes mellitus are associated with hypothyroidism in pregnancy. A hospital-based cross-sectional study conducted at Bouget General Hospital, Abidjan, Ivory Coast illustrated that patients with reported type 1 diabetes mellitus had an increased risk of hypothyroidism (aOR: 12.6, 95% CI 1.9–100.8; p \leq 0.01). In line with this, the current study showed a significant association of overt diabetes mellitus with hypothyroidism in pregnancy. Potential explanations include the fact that patients with diabetes mellitus could also manifest concomitant autoimmune insult to other endocrine glands, including the thyroid. Moreover, the high rate of both diabetes and hypothyroidism in this could line with this explanation.

Numerous unfavorable maternal and newborn outcomes have been linked to hypothyroidism during pregnancy. A retrospective cohort study conducted in the Boston medical center in the United States (US) demonstrated that maternal serum TSH concentration >4 mIU/L during pregnancy was doubling the risks of prematurity and RDS in offspring. Elevated TSH was also associated with statistically not significant increases in the risk of fetal loss, preeclampsia/eclampsia, and low birth weight. Similarly, a cohort study of 41647 participants conducted in a tertiary academic medical center reported that overt hypothyroidism was related to the risk of severe PE (OR, 2.59; 95% CI, 1.05–6.37). Moreover, a cross-sectional study of hypertensive pregnant women in different trimesters in Warri (Pessu and Eboh Health Centers) showed that serum TSH was elevated (p < 0.035) among hypertensive pregnant women compared to non-hypertensive pregnant women.⁶ Our study has shown that hypothyroidism during pregnancy has a significant association with hypertension during pregnancy, including gestational hypertension, preeclampsia, and eclampsia. Although this finding is in line with previous evidence, more study with a methodology that can establish a cause-and-effect relationship may be needed. Furthermore, there is inconsistent evidence showing that the risk of recurrent pregnancy loss is associated with hypothyroidism in pregnancy. Hypothyroidism has a statistically significant relationship with recurrent pregnancy loss in the first trimester, according to a retrospective cohort study conducted in India on 163 non-pregnant women with recurrent pregnancy loss in a gestational age range up to 12 weeks that was confirmed by a pregnancy test or ultrasonography.⁴ The current study also showed a history of recurrent pregnancy significantly associated with hypothyroidism in pregnancy. However, the diagnosis of recurrent pregnancy loss was made by history and not confirmed with ultrasound or histology. This might have impacted the magnitude of the RPL. On the contrary, a systematic review and meta-analysis done in a university setting concluded that there is no association between RPL and subclinical hypothyroidism, although association was noted with sporadic abortion.²²

Preterm birth is linked to hypothyroidism and autoimmune thyroid disorders in pregnant women.²³ The relative risks of clinical hypothyroidism, subclinical hypothyroidism, and hypothyroxinemia during pregnancy on preterm birth were calculated to be 1.30 (95% CI: 1.05–1.61, p=0.013), 1.36 (95% CI: 1.09–1.68, p=0.005), and 1.31 (95% CI: 1.04–1.66, p=0.020) respectively in a systematic review and meta-analysis of 23 studies.²⁴ The current study has shown elevated risk of preterm delivery among hypothyroid patients. However, the gestational age of the participants was estimated from ultrasound performed during admission for those without an early ultrasound scan and unknown last normal menstrual period (LNMP). This could under or overestimate the gestational age at delivery.

The study's strengths include the prospective main data collection in a single interaction with each patient and a lower dropout rate. Additionally, the relatively lengthy period of data collection—about six months—could aid in capturing the

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variation over time and improve the representativeness of samples that might be used to forecast the outcome variable. The study also has limitations. The sample size calculation may not have been sufficient because it might not take into account how many variables were present. As any cross-sectional study, it could not explain the cause-and-effect relationship. Furthermore, being a single hospital-based study; the current study could have suffered from the possibility of selection bias. Moreover, limitation on accurate estimations of gestational age may limit the strength of the correlates. These factors together may limit the generalizability of the current findings.

Conclusions and Recommendations

The current study reveals a higher prevalence of hypothyroidism during pregnancy at Daruxannan Hospital compared to previous global studies. Factors such as a history of recurrent pregnancy loss and diabetes mellitus were found to be significantly associated with hypothyroidism in pregnancy. Hypertension during pregnancy and premature birth were the adverse outcomes of pregnancy associated with hypothyroidism. However, since cross-sectional studies do not establish causality, it may be necessary to conduct a case-control or cohort study to further investigate the potential adverse outcomes of hypothyroidism on newborns during pregnancy. In addition, national and regional surveys are needed to determine the prevalence of hypothyroidism during pregnancy and factors that contribute at the country level to determine policy directions and set up interventions.

Abbreviations

AOR, Adjusted Odd Ratio; CI, Confidence Interval; IRB, Institutional Review Board; LNMP, Last Normal Menstrual Period; OR, Odds Ratio; SPSS, Statistical Package for Social Science; US, United States; DM, Diabetes Mellitus; RPL, Recurrent Pregnancy Loss; HDP, Hypertension During Pregnancy; GA, Gestational Age; APH, Ante-Partum Hemorrhage; PPH, Post-Partum Hemorrhage.

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Disclosure

The authors report no conflicts of interest in this work.

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