HJOG An Obstetrics and Gynecology International Journal

Research

HJOG 2025, 24 (2), 81-90. | DOI: 10.33574/HJOG.0588

Role of 2D Doppler in the Prediction of Preterm Labor in High-risk Patients in Banha University Hospital; A Prospective Cohort Study

Hatem Elgendy[1], Moahmed A Elgazzar[1], Moahmed Shahat [2]

[1] Obstetrics and Gynecology, Faculty of Medicine, Banha University, Banha, Egypt
[2] Obstetrics and Gynecology, Faculty of Medicine, Assiut University, Abbasyia, Cairo, Egypt

Correspondence
Hatem Elgendy, Assistant Professor of Obstetrics and Gynecology, Faculty of Medicine, Banha University, Banha, Egypt, Phone: 00201118496169, Email: elgendyhatem52@gmail.com

Abstract

Background/Objective: Preterm labor is a major obstetric problem. Several ultrasound parameters are used to predict Preterm labor. This study aimed to assess the role of Doppler ultrasound in predicting preterm labor in high-risk patients.

Patients and methods: This observational cohort study was conducted between January and August 2024 at Banha University Hospital on 80 high-risk pregnant women for Preterm labor. We performed a Doppler examination of uterine arteries (S/D ratio, pulsatility index, and the presence or absence of notch unilaterally or bilaterally). UTA evaluation was conducted during three pregnancy periods: the first examination was 18-22 weeks $^{+6}$ days; the second visit was 28-31 weeks; and the third visit was 32- 35^{+6}. The primary outcome was the occurrence of spontaneous PTB before 37 weeks of gestation. Various statistical tests were used, including ANOVA for comparing means, Tukey's test for multiple comparisons, and Chi-square test or Fisher's exact test for qualitative data. Sensitivity, specificity, and predictive values were calculated with 95% confidence intervals. A significance level of $p<0.05$ was used.

Results: Sixty-eight women were included in the final analysis. Preterm delivery occurred in 50 patients (15 between 28-34 weeks, and 35 delivered 34 w $^{+1}$ d- 36w^{+6}). There was no significant difference in the S/D ratio for the likelihood of preterm delivery between 18.0-22^{+6} weeks and 28-32 weeks. A significant correlation was observed at 32^{+1}-36^{+6} weeks, suggesting that it could predict preterm birth at this stage. No significant correlation was found between the UtA-PI and the likelihood of preterm birth at 18-22 weeks and 28-32 weeks. However, at 32^{+1}-36^{+6} weeks, a significant correlation was identified between the S/D ratio and the likelihood of preterm birth, indicating its potential as an indicator at this stage.

Conclusion: The S/D ratio and UtA-PI showed potential as indicators for preterm birth likelihood at

specific stages of pregnancy.

Keywords: Doppler ultrasound, prediction, S/D ratio, pulsatility index, notch

Introduction

Preterm birth, defined as infants born before 37 weeks, affects 14.84 million babies globally. The preterm birth rate is 10.6% worldwide, with varying rates among regions and an increasing trend in most industrialized countries, including the US. Despite the majority of preterm births occurring in Africa and South Asia, it is a global problem (1-2)

Over the years, research has aimed to identify a link between early birth and various risk factors, including socioeconomic, medical, obstetric, and fetal factors, identifying some similarities. However, about two-thirds of premature births continue to happen without any apparent risk factors (3).

The remodeling of spiral arteries is essential for a healthy pregnancy. Failure in this process can lead to conditions like preeclampsia and restricted fetal growth.(4)

During normal pregnancy, there is a notable increase in the compliance of the uterine arteries, usually occurring between 8 to 16 weeks of gestation. This increase continues until 26 weeks but to a lesser extent. Doppler studies indicate that the uterine artery Systolic/Diastolic ratio is generally ≤ 2.6 in a normal pregnancy. If this ratio exceeds the specified level or a notch is present in the waveform, it indicates complications such as intra-uterine growth retardation, premature birth, stillbirth, placental abruption, and maternal pre-eclampsia. Uterine arteries Doppler velocimetry is crucial to comprehensive pregnancy surveillance (5).

However, studies have conflicting results on the association between spontaneous preterm birth and uterine artery resistance (6-7).

This study aimed to assess the role of Doppler ultrasound in predicting preterm labor in high-risk patients.

Patients and Methods

This observational cohort study was conducted between January and June 2024 at Banha University Hospital on 80 high-risk pregnant women for Preterm labor. The Department of Obstetrics and Gynecology approved the study protocol in January 2024 and then gained the approval of the Faculty of Medicine Research Ethical Committee (REC) of Banha University RC1052024. All women gave informed consent after explaining the study's purpose and procedures.

Study Population

Inclusion Criteria

All women with a singleton pregnancy and having had one or more previous spontaneous preterm births or preterm rupture of membranes at less than 37 weeks of gestation, last spontaneous second-trimester miscarriage, prior cervical surgery (large loop excision of the transformation zone, loop electrosurgical excision procedure, laser or cone excision), previous cervical cerclage for preterm delivery or an incidental finding of a cervical length of 25 mm or less in the index pregnancy. We began recruiting since their anomaly scan between 18 and 22 weeks of gestation.

Exclusion Criteria

The study excluded women whose pregnancies were affected by congenital fetal anomalies or fetal death before birth. Additionally, women were excluded if the data of interest was unavailable for the left and right uterine artery Doppler or if the preg-

Table 1. Demographic characteristics of the study population.

Parameters	Term birth group (control)	Premature birth group (PB group)		p-value
	>37 weeks (n=18)	28.0-34.0 weeks (n=15)	34^{+1}-36^{+6} weeks (n=35)	
Age (years)	26.79±4.32	26.88±5.26	28.58±3.85	0.386
BMI (kg/m2)	23.41±2.82	22.75±1.60	23.78±2.91	0.3911
Nulliparous (n,%)	13 (72.2%)	7 (46.7%)	15 (42.9%)	0.118
History of PTL	9 cases (25.7%)A	8 cases (53.33%)C	15 cases (42.85%)B	<0.001**
GA at delivery (weeks)	38.02±0.79A	32.77±0.50C	35.15±0.69B	<0.001**

Using: One-way Analysis of Variance test was performed for Mean±SD & Multiple comparisons between groups through Post Hoc test: Tukey's test; x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate

Different capital letters indicate significant differences at ($p<0.05$) among means in the same row

p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant

nancy outcome was unknown.

Procedure

All relevant clinical data was gathered, and the date of the patient's last menstrual period (LMP) was verified. The gestational age (GA) was determined using the LMP or calculated based on the crown-rump length measured in the first trimester. The first-trimester ultrasound measurements were utilized in discrepancies between LMP and US cases. A comprehensive obstetric history, maternal smoking during pregnancy, maternal height and weight, and the method of conception (whether spontaneous, through in vitro fertilization, ovulation induction, or intracytoplasmic sperm injection) were documented.

All ultrasonography examinations were done by a single observer (to abolish the interobserver bias) blinded to clinical features of women under study, with a standard Voluson 730 pro V; GE, USA (2D abdominal transducer probe, using the frequency of 4-8 MHZ). The Uterine Arteries (UtAs) were identified at the crossover with the external iliac artery by an abdominal approach.

During the Doppler examination of the uterine arteries, we assessed the S/D ratio, pulsatility index, and the presence or absence of notch unilaterally or bilaterally. UTA evaluation was conducted during three pregnancy periods: the first, during the anomaly scan from 18-22^{+6} weeks; the second visit was scheduled for 28-31 weeks; and the third visit was scheduled for 32- 35^{+6} weeks.

The S/D ratio was used as the index for peripheral resistance. In a normally progressing pregnancy, this ratio is expected to remain constant at values between 1.08 and 1.09.

The mean UtA PI (the sum of left and right PI divided by 2) was used to measure UtA resistance.

Notching is characterized by a persistent decrease in blood flow velocity in early diastole, below the diastolic peak velocity. If bilateral notching was detected during the fetal anomaly scan, increased surveillance was initiated. Women with bilateral notching underwent a follow-up ultrasound at 24 weeks of gestation, including fetal biometry and UtA Doppler. If persistent bilateral notching was found in the uterine arteries, ultrasound monitoring of fetal growth continued until fetal biometry fell within the normal range at 30 weeks of gestation (Camen et al., 2022).

The presence of notches could be either unilateral or bilateral.

The primary outcome is spontaneous PTB before 37 weeks of gestation.

Secondary outcomes were overall PTB before 37 weeks, iatrogenic PTB before 37 weeks, spontaneous

Table 2. Comparison between the control group and premature birth groups according to UtA-S/D ratio on Doppler velocimetry.

	Rt UtA S/D	Lt UtA S/D	S/D Rt UtA/Lt UtA
Initial assessment 18-22 GA wks.			
Median (IQR) PB	2.43(1.97-2.89)	2.73(2.21-3.25)	0.99(0.80-1.18)
Median (IQR) Control	2.63(2.13-3.13)	2.68(2.17-3.19)	1.07(0.87-1.27)
p-value	0.163	0.742	0.253
Second assessment 28-32 GA wks.			
Median (IQR) PB	2.36(1.91-2.81)	2.23(1.81-2.65)	1.1(0.89-1.31)
Median (IQR) Control	2.35(1.90-2.80)	2.32(1.88-2.76)	1.06(0.86-1.26)
p-value	0.821	0.410	0.638
Third assessment32^{+1}-36^{+6} GA wks.			
Median (IQR) PB	2.39(1.94-2.84)	1.91(1.55-2.27)	1.06(0.86-1.26)
Median (IQR) Control	2.04(1.65-2.43)	2.24(1.81-2.67)	0.95(0.77-1.13)
p-value	0.347	<0.001**	<0.001**

Using: Mann-Whitney test; IQR: Interquartile range, PB: Premature Birth

p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant

and iatrogenic PTB between 34 and 37 weeks, between 32 and 34 weeks, and between 22 and 32 weeks of gestation, and Gestational Age at birth.

Sample size justification

We used the MedCalc® version 12.3.0.0 program "Ostend, Belgium" to compute the sample size. The statistical calculations were based on a 95% confidence interval and a study power of 80%, with a 5% α error. Camen et al. (2022) (7) revealed a statistically significant difference in the S/D-UtA ratio and PI-UtA only at the third examination, which occurred at 32.0-35.6 weeks of gestation. This difference was correlated with the risk of premature birth ($p<0.05$), and the evaluation of the UtA showed a sensitivity of 73% and a specificity of 27%, with a precision of ± 25%. Based on these findings, the sample size was calculated, indicating that a minimum of 62 women were required to detect such a difference. Assuming a high drop-out rate as we are a university hospital, we increased the sample size to 80 women.

Statistical Analysis

The recorded data were analyzed using the statistical software SPSS version 23.0. Parametric data were presented as mean± standard deviation and ranges, while non-parametric data were presented as median with interquartile range. Qualitative variables were presented as numbers and percentages. The normality of the data was assessed using the Kolmogorov-Smirnov and Shapiro-Wilk tests. Various statistical tests were used, including. A one-way analysis of variance (ANOVA) when comparing more than two means san Post Hoc test: Tukey's test was used for multiple comparisons between different variables. Independent-sample t-test of significance was used when comparing between two means & Mann Whitney U test for two-group comparisons in non-parametric data. Chi-square test or Fisher's exact test for qualitative data. Sensitivity, specificity, and predictive values were calculated with 95% confidence intervals. A significance level of $p<0.05$ was used.

Results

Eighty women with high risk for PTL were included in the study. However, four declined to participate after their first sonographic assessment, and

Table 3. Comparison between PB at term birth and premature birth groups according to UtA-PI Doppler.

	Rt UtA-PI	Lt UtA-PI	mean PI	Percentiles
18-22^{+6} GA wks.				
Median (IQR) PB	1.08(0.87-1.29)	1.16(0.94-1.38)	1.12(0.91-1.33)	43.32(35.09-51.55)
Median (IQR) Control	1.07(0.87-1.27)	1.08(0.87-1.29)	1.07(0.87-1.27)	40.11(32.49-47.73)
p-value	0.770	0.385	0.545	0.539
28-31^{+6} GA wks.				
Median (IQR) PB	0.97(0.79-1.15)	0.89(0.72-1.06)	0.93(0.75-1.11)	54.69(44.30-65.08)
Median (IQR) Control	0.89(0.72-1.06)	0.89(0.72-1.06)	0.89(0.72-1.06)	55.54(44.99-66.09)
p-value	0.246	0.788	0.451	0.770
32-35^{+6} GA wks.				
Median (IQR) PB	0.72(0.58-0.86)	0.69(0.56-0.82)	0.7(0.57-0.83)	35.91(29.09-42.73)
Median (IQR) Control	0.86(0.70-1.02)	0.89(0.72-1.06)	0.86(0.70-1.02)	72.32(58.58-86.06)
p-value	0.006*	<0.001**	<0.001**	<0.001**

Using: Mann-Whitney test; IQR: Interquartile range PB : Premature Birth

p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant

eight women were delivered outside the hospital, so 68 women were included in the final analysis.

Our results revealed that 18 patients delivered after 37 weeks (we consider this as the control group), 15 between 28-34 weeks, and 35 delivered 34^{+1} w - 36w^{+6}.No statistically significant difference was found between the three groups regarding age, BMI, or percentage of nulliparity among the three groups (Table 1).

There was a statistically significant difference between the three groups regarding the history of previous PTL and the GA at delivery, but these two parameters are indubitable (Table 1).

During the initial assessment at 18-22^{+6} weeks of pregnancy, we observed no statistically significant difference between the S/D ratio and the likelihood of preterm delivery (p>0.05), indicating that this ratio has limited predictive value for preterm birth. During

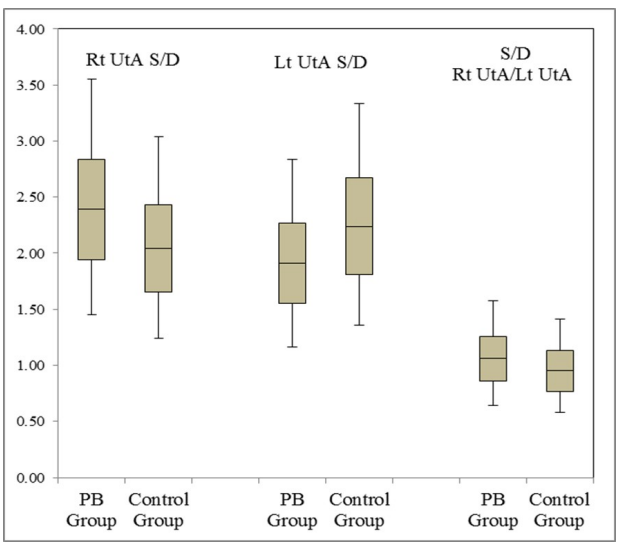

Figure 1. Box plot between the control group and premature birth groups according to UtA-S/D ratio on Doppler velocimetry third assessment 32^{+1}-36^{+6} GA wks.

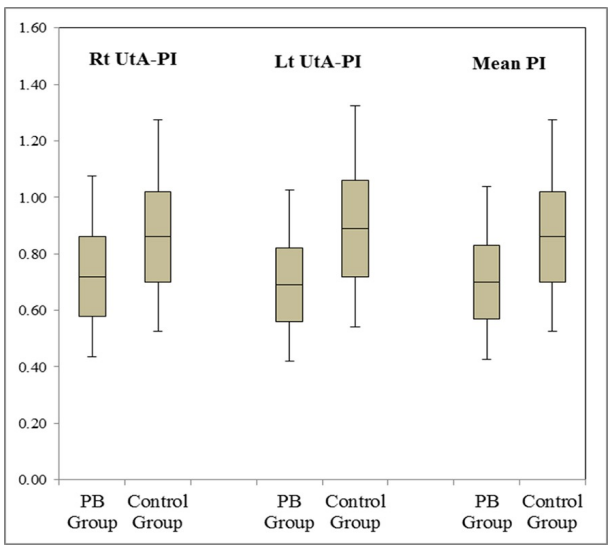

Figure 2. Box plot between PB at term birth and premature birth groups according to UtA-PI Doppler in 32-35^{+6} GA wks.

Table 4. Predictive accuracy of UtA Doppler.

	UtA (18-22 wk)	UtA (28-32 wk)	UtA (32^{+1}-36^{+6} wk)
Sens. (C.I. 95%)	92.7% (88.1%-97.3%)	77.3% (70.3%-85.8%)	75.2% (66.2%-86.5%)
Spec. (C.I. 95%)	30.0% (21.0%-39.0%)	28.9% (22.3%-35.3%)	28.9% (22.3%-34.7%)
PPV (C.I. 95%)	12.9% (9.7%-16.1%)	12.9% (8.9%-17.0%)	10.0% (6.9%-13.2%)
NPV (C.I. 95%)	96.1% (93.2%-99.0%)	92.7% (88.1%-97.3%)	92.7% (87.1%-98.3%)
LR+ (C.I. 95%)	1.298 (0.948-1.648)	1.061 (0.743-1.379)	1.02 (0.714-1.326)
LR- (C.I. 95%)	0.361 (0.271-0.451)	0.958 (0.699-1.217)	1.051 (0.809-1.272)

the second evaluation, which took place at 28-32 weeks of gestation, no statistically significant difference was observed in the S/D ratio regarding the likelihood of preterm birth ($p>0.05$). Thus, this ratio demonstrates limited predictive ability for preterm birth at this stage of pregnancy. The measurements taken during the third examination, at 32^{+1}-36^{+6} weeks of pregnancy, showed a significant correlation between the S/D ratio and the likelihood of preterm birth ($p<0.05$). This suggests that the S/D ratio could be a meaningful indicator of spontaneous preterm birth at this stage of pregnancy. (Table 2, Figure 1).

During the initial evaluation between 18-22 weeks of pregnancy, there was no notable variance in UtA-PI and the likelihood of preterm birth ($p>0.05$), indicating that this ratio was not a reliable predictor of preterm birth at this stage of pregnancy in our study. Between 28 and 32 weeks of gestation, no significant difference was found between UtA-PI and the risk of preterm birth, with $p>0.05$. Upon the subsequent assessment between 32^{+1}-36^{+6} weeks of gestation, a statistically significant difference was observed between UtA-PI and the risk of preterm birth ($p<0.05$), suggesting that this parameter could predict preterm birth at this gestational age. (Table 3 & Figure 2).

At 18-22 weeks of pregnancy, we observed nine notches on the left UtA and nine notches on the right UtA, with three being on both sides, which could be considered normal during this stage of pregnancy. Between 28-32 weeks of gestation, the number of instances with a notch decreased to 11, with 4 showing a notch on the left UtA and seven on the right UtA, without any bilateral cases. During 32^{+1}-36^{+6} weeks of gestation, there were only 4 cases, 2 with a notch on the left UtA and 2 with a notch on the right UtA. However, we could not perform a significant statistical analysis due to the limited number of cases.

Table 4 shows the correlation between abnormal UtA Doppler and premature birth at different gestational ages. Across all three analyzed gestational ages, the negative predictive values consistently remain high.

Given the low positive predictive value (10-12.9%), we can deduce that this percentage will represent pregnant women who give birth prematurely with an abnormal UtA Doppler result.

The negative predictive value of 92.7-96.1% indicates that in cases where the Doppler on the uterine arteries is expected, the high NPV suggests that if the UtA PI is normal, there is a low chance of preterm birth among high-risk women.

Discussion

Progress in preventing premature birth has been significant, but it still resulted in the deaths of around 1 million children under the age of 5 in 2015 (8).

Some studies suggest that assessing the Doppler in the second and third trimesters can effectively predict adverse outcomes. In contrast, others argue that the assessment should be performed in all trimesters of pregnancy (9-11).

Most researchers studied the role of uterine artery analysis in low-risk patients to predict preterm labor.

Our study stressed high-risk patients for the prediction of preterm labor.

The Doppler velocimetry of the uterine artery is more useful in high-risk patients compared to the low-risk population. A meta-analysis by Chien et al. involving 12 studies of high-risk patients showed that abnormal uterine artery Doppler studies can increase the prediction value for pre-eclampsia, intrauterine growth restriction, and perinatal death (12).

Our results and their interpretation

In the study, 80 high-risk women were initially included, but 12 were excluded, leaving 68 for the final analysis. The deliveries were 18 after 37 weeks, 15 between 28 and 34 weeks, and 35 between 34 weeks $^{+1}$ day and 36 weeks $^{+6}$ days. No significant differences among the three groups were observed in age, BMI, or nulliparity percentage. Still, we did find significant differences in the history of previous preterm labor and gestational age at delivery.

An increase in the Resistive Index (RI), Pulsatility Index (PI), or a diastolic notch in the uterine artery indicates high resistance in the uteroplacental vasculature. The criteria for abnormal RI values vary from a percentile to a single cut-off value. If the 95th percentile is used as the cut-off for the PI value measured in the first trimester, around 30.8% of antenatal patients later experience pregnancy complications (13).

Between 18-22^{+6} weeks and 28-32 weeks, there was no significant difference in the S/D ratio for the likelihood of preterm delivery. However, at 32^{+1}-36^{+6} weeks, a significant correlation was found between the S/D ratio and the likelihood of preterm birth, indicating its potential as an indicator at this stage. UtA-PI did not show any significant correlation with the likelihood of preterm birth at 18-22 weeks and 28-32 weeks. However, a significant correlation was observed at 32^{+1}-36^{+6} weeks, suggesting that it could predict preterm birth at this stage.

The diastolic notch appears due to elevated resistance to blood flow in the placental blood vessels. A reliable standard for diagnosing the diastolic notch is a decrease of at least 50 cm/s from the highest diastolic velocity after 20 weeks of gestation (14). In our study, the statistical analysis could not be performed due to the limited number of cases.

Numerous research studies have proven that the presence of a diastolic notch is a more effective indicator for predicting pregnancy complications such as pre-eclampsia than an elevated resistance index (15).

Comparison of our results to different studies

Kim et al. conducted a study to analyze the histopathologic discoveries in the placental bed and placenta of individuals experiencing preterm labor with intact membranes and healthy pregnant women at term. The average proportion of spiral arteries exhibiting a lack of physiologic transformation in the myometrium was notably higher in preterm labor patients than in term pregnant women (P=.0004). Similar results were found in the decidual portion of spiral arteries within the placental bed (P=.001) (16).

Afrakhteh et al. study involved 205 low-risk pregnant women. They underwent ultrasound evaluation in the second and third trimesters, which included a Doppler assessment of uterine arteries to determine the pulsatility index (PI), resistance index (RI), and presence of an early diastolic notch. The uterine artery PI and RI values for both second and third-trimester evaluations were significantly higher in patients with adverse pregnancy outcomes than in normal women. The results align with our results regarding the third-trimester measurements (17).

Van Zijl et al., 2020 found that the resistance of the uterine artery in the mid-trimester, measured at 18-22 weeks of gestation, is not a strong predictor of spontaneous preterm birth. Their study included 4521 women, and the rates of spontaneous and iatrogenic preterm births were 5.7% and 4.9%, respectively. In the group with spontaneous preterm birth,

the average uterine artery resistance was 1.12, compared to 1.04 in the term group (P = 0.004). The study showed that the risk of preterm birth increased with high uterine artery resistance (OR 2.9 per unit; 95% CI 2.4-3.9). We observed a notable statistical variance solely among instances of premature birth occurring after 32 weeks, during which we identified a substantial disparity in the average uterine artery S/D and UtA-PI (18).

Cobian-Sanchez and colleagues conducted a retrospective analysis of UtA Doppler findings at 18-23 weeks' gestation in 234 singleton pregnancies with spontaneous preterm labor and 5472 pregnancies delivered at term. The mean resistance index (RI) and the number of proto-diastolic notches in the uterine arteries were not found to be significantly different between the spontaneous preterm labor group and the normal group. Among the 62 preterm deliveries not preceded by spontaneous preterm premature rupture of membranes (PPROM), there was a notably higher RI and prevalence of bilateral notches compared to cases of preterm deliveries preceded by PPROM (n = 172). However, this discrepancy was not confirmed in a logistic regression model (19).

Camen et al. (7) included 116 pregnant women in a prospective study similar to our design. Of these, 85 gave birth prematurely, while 31 gave birth at term, forming the control group. The study involved UtA Doppler evaluation in three pregnancy periods: 18-22^{+6} weeks, 28-31^{+6} weeks, and 32-35^{+6} weeks. The results showed a statistically significant difference between the S/D-UtA ratio and PI-UtA only at the third examination, at 32-35^{+5} weeks of gestation, in correlation with the risk of premature birth ($p<0.05$). Although there was an association between UtA Doppler and late preterm birth, the predictive ability was low. Additionally, UtA Doppler was not statistically significant for preterm birth before 32 weeks of gestation. Based on the results obtained, we recommend a closer examination of women with abnormal UtA Doppler in the second trimester, as there was no statistical association between second-trimester UtA Doppler and preterm birth. According to the obtained results, UtA Doppler can predict especially iatrogenic premature birth, depending on the prediction of the most severe complications, severe preeclampsia, and SGA.

Strengths and limitations of our study: Our study's main strength is its inclusion of high-risk preterm delivery patients, unlike most studies involving low-risk patients. Its main limitations are the relatively small number of patients and its single-center design, which can contribute to a statistical bias.

Clinical implication of our study

In high-risk patients with heightened risk factors for preterm labor (PTL), the identification of those who have a previous history of preterm delivery or a related medical condition can help pinpoint individuals at an elevated risk of PTL. UtA Doppler assessments after 32 weeks gestation can be considered as part of the evaluation in high-risk pregnancies to identify those at lower risk of PTL. These high-risk patients may receive more frequent monitoring, and the utilization of dexamethasone for fetal lung maturity can lead to decreased fetal/neonatal morbidity and mortality.

Recommendation for further studies: Larger, multicenter studies are recommended to validate these findings and to explore the potential of combining UtA Doppler indices with other predictive markers for earlier prediction of PTL.

Conclusion

The S/D ratio and UtA-PI showed potential as indicators for preterm birth likelihood at specific stages of pregnancy. The negative predictive values remained consistently high at all stages of pregnancy,

suggesting a high likelihood of delivering at term when the Doppler on the uterine arteries is normal.

Authors contributions

All authors jointly contributed to the conception and design of the study.

Elgendy Hatem: Design of the study, helped in the review of literature, revision of results and data analysis, writing the manuscript, and submission to the journal

Mohamed Abdelmaabod Elgazzar; design of the study, revision of review of literature, and revision of manuscript

Moahmed Shahat: design of the study, revision of review of literature, and revision of manuscript

Funding

This research received no external funding.

Study registration

The study was registered in the Pan-African Clinical Trial

Disclosure of Interest

The authors declare no conflict of interest.

Ethics Approval and Informed Consent to Participate

Following local regulations, the protocol gainedEthical and research approval from the Faculty of Medicine Banha University Research Ethical Committee. RC952024. We Confirm that all methods were performed according to the relevant guidelines and regulations according to the Declaration of Helsinki.

Data Sharing

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

Acknowledgments

Not applicable .

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Received 8-1-2025
Revised 3-2-2025
Accepted 19-2-2025