

# Effectiveness of the First Trimester Samrakshan Protocol for the Identification of Pregnant Women at High Risk for Preterm Pre-eclampsia

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## Abstract

**Aim** To determine the effectiveness of the first trimester Samrakshan protocol for the identification of pregnant women at high risk for preterm pre-eclampsia (PE).

**Methods** Samrakshan uses a protocol that integrates routine first-trimester ultrasound assessment at 11 to 14 gestation weeks with the measurement of mean arterial blood pressure and mean uterine artery pulsatility index assessment to determine a customized risk for preterm PE and fetal growth restriction. Based on the risk assessment, pregnant women are classified as high or low risk.

**Results** The protocol had a high specificity (90.4%, 95% CI: 89.4%, 91.2%) and negative predictive value (98.1%, 95% CI: 97.6%, 99%) for preterm PE. The odds ratio and positive likelihood ratio for preterm PE were 16.7 (95% CI: 12.3, 22.6) and 6.64 (95% CI: 5.77, 7.63), respectively.

**Conclusions** The positive likelihood ratio and odds ratios indicate that pregnant women identified as high risk for preterm PE using the first-trimester protocol of Samrakshan are significantly more likely to develop preterm PE than low-risk women.

## Keywords

- ▶ preeclampsia
- ▶ screening
- ▶ first trimester
- ▶ pregnancy
- ▶ fetal doppler

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## Introduction

There is evidence that a competing risk Bayesian algorithm that utilizes clinical and demographic details, mean arterial blood pressure, and mean uterine artery pulsatility index measurement is effective in the early identification of pregnant women at high risk for preterm pre-eclampsia (PE).<sup>1-4</sup> This classification is useful as the ASPRE trial has provided evidence regarding the effectiveness of low-dose aspirin in the prevention of preterm PE.<sup>5,6</sup> Samrakshan is a prospective and ongoing national program of the Indian Radiological and Imaging Association (IRIA) that involves fetal radiologists at diagnostic centers, teaching hospitals, tertiary care centers, and individual practitioners and aims to reduce perinatal mortality in India with a focus on PE and fetal growth restriction (FGR).<sup>7,8</sup>

## Methods

Samrakshan uses a customized risk assessment at 11 to 14 gestation weeks that incorporates mean arterial blood pressure, mean uterine artery pulsatility index, and clinic-demographic details in a competing risk Bayesian model to classify consecutive pregnant women as high-or-low risk for preterm PE.<sup>7,8</sup> The mean arterial blood pressure was measured simultaneously in both arms using calibrated digital blood pressure instruments with the patient in a seated position and repeated after a 1-minute interval.<sup>4</sup> The mean uterine artery pulsatility index (PI) > 95th percentile was considered as abnormal.<sup>1-3</sup> The risk for each woman was estimated using an online calculator provided by the Fetal Medicine Foundation. Pregnant women identified as high risk (based on a cut-off of 1 in 150) were recommended low-dose aspirin 150 mg once daily at bedtime up to 36 weeks, childbirth, or development of preterm PE, whichever was earlier. The development of PE after 20 gestation weeks until 37 gestation weeks was assessed from the medical records of women during the third trimester fetal assessments from August 2019 to March 2022. Pregnant women with chronic hypertension were not included in this analysis.

## Results

The data of 4,372 pregnant women was analyzed. Most women (2,661, 60.86%) were nulliparous and 173 (3.96%) women had a history of PE in prior pregnancy. The data of 66 (1.51%) pregnant women with chronic hypertension were excluded from further analysis. **Table 1** presents the diagnostic effectiveness of the protocol for preterm PE. The odds ratio and positive likelihood ratio for preterm PE was 16.7 (95% CI: 12.3, 22.6) and 6.64 (95% CI: 5.77, 7.63) respectively. The area under the receiver operator characteristic (AUROC) curve was 0.76 (95% CI: 0.74, 0.82). Preterm PE developed in only 1.90% ( $n=72$ ) of women identified as low risk for preterm PE. Preterm PE did not develop in 75.6% ( $n=396$ ) of the women who were at high risk for preterm PE and were recommended low dose aspirin.

**Table 1** Effectiveness of the first trimester protocol of Samrakshan for pre-eclampsia

Parameter	Value (95% CI)
Sensitivity	64.0% (56.9%, 70.6%)
Specificity	90.4% (89.4%, 91.2%)
Positive predictive value	24.4% (20.8%, 28.3%)
Negative predictive value	98.1% (97.6%, 99%)
Positive likelihood ratio	6.64 (5.77, 7.63)
Negative likelihood ratio	0.39 (0.33, 0.48)
Diagnostic odds ratio	16.7 (12.3, 22.6)
AUROC	0.76 (0.74, 0.82)
True positives ( $n$ )	128
False negatives ( $n$ )	72
True negatives ( $n$ )	3710
False positives	396

Abbreviation: AUROC, area under receiver operator characteristic curve.

## Conclusions

The high specificity of the protocol indicates that a pregnant woman identified as high risk using the protocol is likely to develop preterm PE. The high negative predictive value of the protocol indicates that women who were screen negative were not truly at risk for preterm PE. The AUROC curve shows that the protocol has good discriminatory ability to discriminate between women at high-or-low risk for preterm PE in this population. The positive likelihood ratio shows that women identified as high risk using the protocol were 4.6 times more likely to develop preterm PE compared with women identified as low risk using the protocol. The lower sensitivity of the protocol can be attributed to the 1 in 150 cut-off used and a 1 in 50 or a 1 in 100 cut-off may have shown better sensitivity. However, reducing the number of false negatives is more important from the perspective of screening to identify pregnant women at high risk for pre-eclampsia. A 1 in 50 or 1 in 100 cut-off might improve the sensitivity and reduce false positives but will lead to an increase in the false negatives. The proportion of high-risk women (75.6%) that did not develop preterm PE after low-dose aspirin is consistent with the results of the ASPRE trial. This finding is important as a recent study reported that low-dose aspirin did not reduce the risk for pre-eclampsia in Hispanic or non-Hispanic black women; however, they had used a much lower dose (60 mg) of aspirin.<sup>9</sup> In conclusion, the use of the Samrakshan protocol is useful to stratify risk for preterm PE among pregnant women and to start preventative low-dose aspirin in this population of Asian Indian women.

### Conflict of Interest

None declared.

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