

## Risk-factor score for early preterm birth using cervical pessary in singletons

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### Objective

Identify the incidence and risk factors of early preterm birth (PB) <34 weeks in women with singleton pregnancies with asymptomatic short cervical length (<25mm) in the second trimester of pregnancy treated with a cervical pessary.

### Methods

Patient data were obtained from the PECEP Trial, a prospective, open-label, randomised clinical trial. We analysed 190 pregnant women with singleton pregnancies undergoing routine second-trimester ultrasonography at 18–22 weeks of gestation, with a cervical length of 25 mm and randomised to cervical pessary. Demographic and obstetric history was compared with identifying risk factors for early PB <34 weeks. Each demographic or obstetric variable has been reached between PB <34 weeks and ≥34 weeks. Multiple logistic regression analysis was used to identify predictors; the odds ratio for significant factors was used to generate a risk score. The risk score and risk of early PB were assessed with the receiver operating characteristic (ROC) curve. Perinatal outcomes compared by risk score. Finally, we applied our risk score to another high-risk preterm birth group.

### Results

Among 190 pregnant women included, 12 (6.3%) had spontaneous PB <34 weeks and 178 (93.7%) had a delivery ≥34 weeks. Comparing demographic, obstetric and ultrasound characteristics in bivariable analysis, only statistically significant differences were observed in mean cervical length (CL) at diagnosis and in the CL after pessary placement between those with and without early spontaneous PB. With multiple logistic regression analysis, maternal age (OR 0.818; 95% CI 0.690-0.968;  $p=0.020$ ), CL to diagnosis (OR 0.560; 95% CI 0.429-0.731;  $p<0.001$ ), and pregnant smokers (OR 7.276; 95% CI 1.022–51.800;  $p=0.048$ ) remained significantly associated with early SPB. In evaluating ROC curves, our multiple logistic regression analysis, including CL, maternal age and pregnant smokers, had an area under the curve (AUC) of 0.952 ( $p<0.001$ ). In evaluating the ROC curve, the risk score incorporating our three variables had an AUC of 0.864. A high-risk score was predictive of early spontaneous PB with a sensitivity of 75%, specificity of 84%, positive predictive value of 24%, and negative predictive value of 98%. Women with high-risk scores had a significantly reduced latency to delivery compared to the ones with a low risk (Mantel-Cox Log Rank  $p<0.001$ ) and worse neonatal outcomes (less gestational age at delivery, less birthweight and worse composite outcomes).

### Conclusion

Patients at high risk for early PB despite pessary therapy may be identified using cervical length at diagnosis of short cervix added to age and maternal tobacco use.