

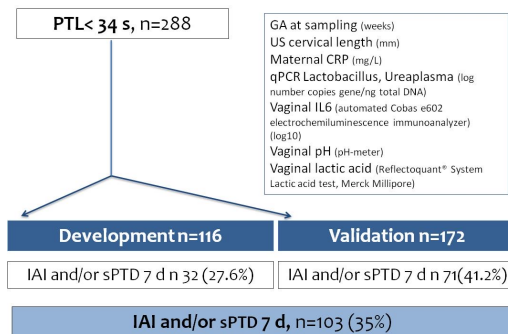
Objective

We modeled the best performing models integrating biochemical data with clinical and ultrasound information to predict a composite outcome of intra-amniotic infection (IAI) and/or spontaneous delivery within 7 days.

Methods and material

Prospective observational study (2015-2020) including women with diagnosis of preterm labor (PTL) below 34 weeks with an amniocentesis to rule in/out IAI.

We selected ultrasound, maternal blood and vaginal predictors that could be tested with rapid diagnostic techniques and developed prediction models employing Machine Learning that were applied in a validation cohort



Conclusions

These results provide proof-of-principle of how non-invasive methods suitable for point-of-care systems can select high-risk cases among women with PTL and might substantially aid in clinical management and outcomes, while improving use of resources and patient experience.

Results

288 women with PTL, of which 103 (35%) had IAI and/or spontaneous delivery within 7 days.

Four prediction models were proposed, including cervical length (using transvaginal US), maternal C-reactive protein, vaginal IL-6 (using autotated immunoanalyzer), vaginal pH (using pH meter), vaginal lactic acid (using reflectometer) and vaginal *Lactobacillus* genus (using quantitative-PCR)

IAI and/or spontaneous delivery ≤ 7 days										
	Number of variables	Predictors used	AUC (95% CI)	F1 (95% CI)	Sensitivity n (%)	Specificity n (%)	PPV n (%)	NPV n (%)	LR+	LR-
Model 1	4	IL-6, CRP, lactic acid, <i>Lactobacillus</i> genus	85.2(+3.1)	78.4(+3.5)	84.5	78.2	73.2	87.8	3.88	0.2
Model 2	3	IL-6, CRP, lactic acid	84.7(+3.0)	77.7(+3.2)	85.9	75.2	70.9	88.4	3.47	0.19
Model 3	4	IL-6, CRP, pH, cervical length	83.3(+3.1)	77.1(+3.8)	76.1	85.1	78.3	83.5	5.12	0.28
Model 4	3	IL-6, CRP, cervical length	82.2(+3.1)	76.9(+3.4)	84.5	75.2	70.6	87.4	3.41	0.21

Vaginal IL-6 (pg/mL), US Cervical length (mm), maternal C-reactive protein (CRP) concentrations (mg/L), vaginal pH as absolute value; vaginal lactic acid as mg/L; vaginal *Lactobacillus* genus as log number copies gene/ng total DNA. AUC: Area under curve; F1: F1-score; PPV: Positive predictive value; NPV: Negative predictive value; LR: Likelihood ratio; IAI: Intra-amniotic infection.