Primary prevention of preterm birth with vaginal chlorhexidine

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Objective
Preterm labor (PTB) is the leading cause of perinatal death and is currently considered a syndrome with many causes. One of the most important is ascending infection, which in turn closely relates with vaginal dysbiosis, especially in early pregnancy. Chlorhexidine has proven to be effective against vaginal dysbiosis and is effective against biofilms produced by bacteria without affecting gestation. We aimed to evaluate the effectiveness of a universal primary prevention strategy for PTB using intravaginal chlorhexidine applied before 16 weeks (preterm labor prevention using vaginal antiseptics, PLUVA study).

Methods
We performed a prospective observational study with two cohorts of pregnant women that were randomly assigned either to prevention of PTB by means of intravaginal chlorhexidine (Cum Laude CIX®, chlorhexidine digluconate 0.2%) before 16 weeks (N=401), or to absence of treatment following the usual hospital protocol (N=551). Primary outcomes were the incidence of spontaneous PTB <34 and <37 weeks, the incidence of PTB <34 and <37 weeks including inductions for premature rupture of membranes (PRM), and finally, the incidence of PTB <34 and <37 weeks, including inductions for PRM and other obstetrical indications for termination of labor. Incidences between cohorts and descriptive statistics were compared by mean of Mann-Whitney and Fisher tests. Significance was considered with a P-Value <0.05.

Results
The incidence of spontaneous PTB <34 and <37 weeks was 0% (0/401) and 1.5% (6/401) in the treated group and 1% (6/551) and 3% (17/551) in the untreated group (P<0.05, P=NS). The incidence of spontaneous PTB <34 and <37 weeks including induction for PRM was 0% (0/401) and 2.7% (11/401) in the treated group and 1.4% (8/551) and 4.5% (25/551) in the untreated group (P<0.05, P=NS). Finally, the incidence of spontaneous PTB <34 and <37 weeks including induction for PRM and other obstetrical indications for termination of labor was 0% (0/401) and 3% (12/401) in the treated group and 1.6% (9/551) and 6% (33/551) in the untreated group (P<0.05, P<0.05).

Conclusion
Universal treatment with vaginal chlorhexidine notably reduces the incidence of PTB especially before 34 weeks.