

RESULTS

177 patients were included: group 1 inflammatory (n = 125, 70.6%), group 2 vascular (n = 25, 14.1%), and group 3 with no abnormal findings (n = 27, 15.3%). Gestational age (GA) at delivery (25.2 ± 3.8 vs 27.2 ± 4.3 vs 27.2 ± 4.2 weeks, $p = 0.009$) and latency period between pPROM and delivery (26.9 ± 27.5 vs 50.6 ± 36.4 vs 35.7 ± 28.3 days, $p = 0.001$) were significantly lower in group 1. As expected, clinical chorioamnionitis occurred more frequently in cases with inflammatory lesions (14.4% in group 1 vs 0% in group 2 and 3.7% in group 3, $p = 0.04$). IUGR was associated with vascular lesions (36% in group 2 vs 11.9% in group 1 and 0% in group 3, $p = 0.001$). The overall survival was 51.4%, perinatal survival in cases delivered ≥ 24 weeks was 73.8%. Neonatal adverse outcome included neonatal sepsis (20%), moderate/severe bronchodysplasia (22.5%), intraventricular hemorrhage II-III-IV grade and periventricular leukomalacia (20%), necrotizing enterocolitis (13.3%), retinopathy of prematurity (25%), pulmonary hypoplasia (19.2%) and skeletal deformities (7.5%). Type of placental lesion did not influence perinatal outcomes. Long term follow up was available for 70/91 live born infants (76.9%); 14 of them had cerebral palsy (GA at pPROM 22.1 ± 3.6 vs 23.7 ± 2.9 weeks, $p = 0.08$ and GA at delivery 27.7 ± 2.9 vs 28.2 ± 2.3 weeks, $p = 0.49$ without CP), with no differences between groups.

CONCLUSIONS

Early pPROM may be classified according to placental histology into groups with different clinical characteristics. As expected the prevalent histological damage was inflammatory, however the determinism of pPROM was related to hypoxic-ischemic damage in 15% of cases. Type of placental damage did not influence perinatal or long-term outcomes.

ABS 50

EVALUATION OF THE QUANTITATIVE FETAL FIBRONECTIN TEST AND PARTOSURE™ (PLACENTAL ALPHA MICROGLOBULIN-1 [PAMG-1]) FOR THE PREDICTION OF SPONTANEOUS PRETERM BIRTH (SPTB) IN PATIENTS WITH SIGNS AND SYMPTOMS SUGGESTIVE OF PRE-TERM LABOR

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PURPOSE

To compare an established method with a novel method for assessing the risk of imminent spontaneous preterm birth (sPTB) in women with symptoms of preterm labor: (1) a test based on quantification of fetal fibronectin (qfFN) at four different cutoffs: 10 ng/ml, 50 ng/ml, 200 ng/ml, and 500 ng/ml; and (2) a qualitative test based on placental alpha microglobulin-1 detection (PartoSure™).

METHODS

Patients presenting with a singleton pregnancy, self-reported signs of preterm labor between 23.1 and 34.6 weeks of gestation, clinically intact membranes, no sexual intercourse within 24 hours, and cervical dilation ≤ 3 cm were recruited. qfFN was performed as a part of the standard of care at the hospital, while clinicians were blinded to the PAMG-1 test results. qfFN accuracy was evaluated at four thresholds of 10 ng/ml, 50 ng/ml, 200 ng/ml, and 500 ng/ml for its ability to predict imminent spontaneous preterm delivery within 7 and 14 days from the time of sample collection. The PAMG-1 test was evaluated based on its qualitative result for the same delivery endpoints.

RESULTS

72 patients met the inclusion/exclusion criteria. Median maternal and gestational age at presentation were 28 years and 31.5 days, respectively. 14% of patients (10/72) had a prior preterm birth; 58% (42/72) had active contractions at the time of presentation, with 4 contractions per hour on average. 57% of patients (41/72) had an fFN concentration of < 10 ng/ml fFN; 75% (52/72) < 50 ng/ml; 92% (66/72) < 200 ng/ml; 97% (70/72) < 500 ng/ml. The SN, SP, PPV, and NPV for fFN at each of the four cutoffs were calculated for both 7 and 14 days of delivery and are presented respectively: 10 ng/ml: 67%, 58%, 6%, 98% and 60%, 58%, 10%, 95%; 50 ng/ml: 67%, 77%, 11%, 98% and 60%, 78%, 17%, 96%; 200 ng/ml: 33%, 93%, 17%, 97% and 40%, 94%, 33%, 95%; 500 ng/ml: 0%, 97%, 0%, 96% and 0%, 97%, 0%, 93%. The PAMG-1 test was positive in 7% of patients (5/72). SN, SP, PPV and NPV for PAMG-1 were 67%, 96%, 40%, 99% and 40%, 96%, 40%, 96%, delivery ≤ 7 and ≤ 14 days respectively.

CONCLUSIONS

Compared to qfFN, the PAMG-1 test is a better predictor of spontaneous delivery within 7 and 14 days while maintaining a very high negative predictive value. The PAMG-1 test is an easy-to-use bedside test that provides rapid results, does

not require a speculum examination, and does not require specialized equipment to analyze results. As expected, compared to the conventional cutoff of fFN (50ng/ml), a higher fFN cutoff of 200 ng/ml does seem to increase the positive predictive value of the test. However this comes at a cost to the fFN test's sensitivity and negative predictive value, rendering it of little to no advantage in clinical practice.

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THE ROLE OF PARTOSURE™ TEST IN PREDICTING IMMINENT PRETERM BIRTH

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INTRODUCTION

An accurate risk assessment of preterm birth is clinically important in pregnancies with threatened preterm labor. This is particularly true with respect to both the administration of corticosteroids, as well as the transfer of patients to a tertiary care center capable of caring for the birth of premature infants. Clinical evaluation alone, with the measurement of cervical length and dilatation, are not sufficiently predictive of imminent delivery. Currently available biomarker tests, such as the detection of fetal fibronectin, have extremely poor predictive value for imminent delivery. The PartoSure™ test is a rapid, qualitative immunochromatographic test for the *in vivo* detection of placental alpha microglobulin-1 (PAMG-1) in vaginal secretions of pregnant women. PAMG-1 is a protein found in high concentrations in the amniotic fluid.

METHODS

We conducted a prospective observational study from March to June 2016. We enrolled 20 symptomatic patients between 24-34 week of gestation with singleton pregnancy, irregular uterine activity and/or lower abdominal pain and pelvic pressure, intact membranes, cervical length < 20 mm and funneling. Patients were initially managed according to the internal protocol: prophylactic corticosteroid betamethasone i.m. 12 mg/day for 2 days and primary tocolysis for 48 hours. 7 days after the therapy, we evaluated all the patients: 2 patients had delivered and 3 patients were excluded for premature rupture of membranes. In the final

analysis, we included 15 patients. The PartoSure™ test was performed for these patients. The result was interpreted once two lines were visible, or after 5 min elapsed since the insertion of the test strip into the sample vial. The patients were divided in two groups: the test was positive for two patients (Group A) and was negative for 13 patients (Group B). All patients had been reevaluated after 7 and 14 days from the execution of the test.

RESULTS

In group A, a patient delivered within 7 days, while the others delivered within 14 days from presentation. In group B, a patient delivered within 7 days, while 12 patients were still pregnant after 14 days.

CONCLUSIONS

In our study, the positive and negative predictive value of the PartoSure™ test seems to be high within 7 and 14 days (PPV 100%, NPV 92%). However, our conclusions are based on a small sample, so further studies are needed. If our results will be confirmed, the device could be considered an excellent test to rapidly assess the risk of preterm delivery within 7 or 14 days from time of collection of cervicovaginal sample in pregnant women with signs and symptoms of early preterm delivery, intact membranes and minimal expansion. A positive PartoSure™ test in these patients indicates with a high degree of accuracy that spontaneous preterm delivery will occur within 7 days. A negative result indicates that spontaneous preterm delivery within 14 days is highly unlikely.

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PRETERM BEHAVIORAL EPIGENETICS: SLC6A4 METHYLATION AND SOCIO-EMOTIONAL STRESS REGULATION IN VERY PRETERM INFANTS

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