EVALUATION OF THE PRACTICABILITY OF A RAPID INTRAPARTUM SCREENING BASED STRATEGY FOR PREVENTION OF GROUP B STREPTOCOCCUS PERINATAL INFECTIONS USING A REAL TIME PCR PERFORMED BY MIDWIVES AS A POINT OF CARE TEST.

Meex C., Sacheli R., Descy J., Hayette M.P., Huynen P., Kridelka F, Ieven M, Melin P.

Group B streptococcal (GBS) early onset disease leading neonatal sepsis and meningitis can be prevented through intrapartum antibioprophylaxis (IAP) given to all GBS positive women (vaginal/rectal colonization). The efficacy of antenatal screening based approach could be improved by using rapid test performed at the onset of labor. The Xpert GBS® assay (Cepheid) is a real-time PCR assay for accurate detection of GBS from vaginal swab; it can be use as a Point Of Care Test (POCT). This study aims to assess practicability and effectiveness of Xpert GBS® performed by midwives for all pregnant women admitted in labor.

In 2014, inclusion of 900 consecutive deliveries in 2 Belgian university hospitals following a 5 weeks pre-study (107 cases included). Collection of vaginal samples with double swabs from pregnant women admitted in labor: one swab used for Xpert GBS®; the second for culture performed by direct plating on GBS Differential Granada agar (Becton Dickinson, BD), inoculation in selective Lim broth (BD) subcultured after incubation on Granada and selective chromogenic agar, StrepBSelect (Biorad). Among others, recorded data in a case report form include delay from admission to delivery and results of antenatal GBS screening.

During the pre-study, 107/162 consecutive deliveries were included. Intrapartum vaginal colonization rate determined by culture among the 107 mothers was 14%, while the rate of antenatal GBS colonization among the non-included women was 37.5 %, therefore introducing a bias for further analysis. Xpert GBS testing by midwives seemed feasible; no major problem was reported and the turn around time (TAT) for obtaining results was < 1 hour. Out of the 107 included cases, 7 had no PCR result (PCR invalid or in error) and were excluded for the following calculations. Intrapartum culture being the gold standard, sensitivity (S) and specificity (Sp) of the intrapartum PCR were 76.9 and 98.9% respectively, leading to positive and negative predictive values (PPV, NPV) of 90.9 and 96.6%. Antenatal culture (35-37 weeks gestation) results were available for 90 women leading to S and Sp of 80 and 97.3% respectively and to PPV and NPV of 85.7 and 96.1%. A feed-back was given to the midwives, the study protocol was again explained insisting on the need to include all consecutive deliveries and technical precautions/instructions were also revised. Study is ongoing and complete results will be provided for the LISSSD.

The pre-study showed a low inclusion rate of 66% therefore introducing a bias for interpretation. Even if results of the pre-study lead to a sensitivity of the PCR lower than expected, PPV and NPV equal or surpass those calculated for antenatal culture. Further, the showed feasibility and TAT let glimpse an efficient diagnostic tool in order to offer IAP targeted to GBS carriers at time of risk. It highlighted the importance for appropriate analysis to include all women whatever was the antenatal screening result and was an opportunity to give a feed-back to the midwives before going further with the study.