

A method to identify patients at risk for subsequent stillbirth in the third trimester

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Technology description

Technology Summary:

This invention is a method of identifying patients at risk for subsequent stillbirth (only due to placental related disorder) in the third trimester using a maternal blood sample. A blood sample would be obtained at the beginning of the third trimester of pregnancy (30-34 weeks) and the concentrations of three analytes would be measured. The compounds are: placental growth factor (PIGF), soluble vascular endothelial growth factor receptor-1 (sVEGFR-1 or sflt-) and soluble endoglin (sEng). The inventors have established the thresholds that identify the patients who will have a fetal death with 80% sensitivity and 94% specificity, and a likelihood ratio of a positive test of 14.

The product that can be made is a multiplex assay for the quantification of the three analytes. This can be performed in a regular laboratory, or can be simplified so that it can be used at the point of care (prenatal clinic or labor and delivery floor).

The inventors believe the method this method will fill an unmet clinical need: the identification of the patient at risk for fetal death in the third trimester. Once patients are identified to be at risk, other tests of fetal well-being can be implemented (such as fetal movement count, non-stress test, amniotic fluid volume assessment, biophysical profile, umbilical artery Doppler, etc.).

The inventors also believe that they have found a drug to prevent fetal death in some case by giving pravastatin. It is believed that this treatment was effective in a single case of recurrent miscarriage (4 prior miscarriages) where the mother was able to carry the baby to term and was induced at 34 weeks. The successful use of Pravastatin to reverse an anti-angiogenic state, and prevent fetal death, in a 38-year-old pregnant woman with four prior early pregnancy losses is described, the last one of which was complicated by severe early-onset fetal growth restriction, anhydramnios, fetal demise at 20 weeks of gestation, and by placental findings suggestive of maternal floor infarction despite heparin and aspirin prophylaxis.

Benefit Analysis:

When fetal death occurs after 20 weeks of pregnancy, it is called stillbirth. Most stillbirths occur before labor begins. A small number of stillbirths occur during labor and delivery.

Stillbirth remains a major public health problem in high income countries where there has been little change in rates in recent decades. Almost 1% of births result in stillbirth, and stillbirths account for more than half of all perinatal deaths in wealthy countries. Unexplained stillbirth is the most common

classification of cause of death, accounting for 27–75% of all deaths, varying according to the classification system used (2011 data). As pregnancy progresses, the relative risk of stillbirth increases, as does the proportion of stillbirths that is classified as unexplained.

Internationally, a number of risk factors have been associated with stillbirth, including advanced maternal age, high pre-pregnancy body mass index (BMI) smoking, fewer than four antenatal visits, maternal ethnicity, fetal growth restriction and low socio-economic status but understanding of the epidemiology remains limited.

Currently, there is no standard test for evaluating a fetal demise, and various regulatory authorities vary in their recommendations. It is believed that proper execution of maternal and fetal risk factors and complications, which are detected during pregnancy and labor, could prevent a large proportion of the 4.5 million estimated annual global stillbirths.

Stillbirth is relatively rare, less than 1%, but these patients are closely monitored in subsequent pregnancies. SGA and preterm deliveries are much more common, 10 to 12%. These tragic deaths occur in about 1 in 160 pregnancies.

Recent global estimates suggest that at least 3.2 million babies are born dead each year. While the highest absolute numbers of stillbirths occur in South Asia, driven by the large population size of that region, the incidence rates are highest in sub-Saharan Africa. Wide variations exist: in high-income countries, stillbirth rates are below 5 per 1000 births, compared to approximately 32 per 1000 in South Asia and sub-Saharan Africa. These disparities also apply within countries, since economically deprived communities have higher stillbirth rates than wealthier populations due to disparities in risk factors and inequalities in access to and quality of health care.

Approximately 1.2 million stillbirths occur during birth (intrapartum) and 2.0 million before birth (ante-partum). Most intrapartum stillbirths are associated with obstetric emergencies (childbirth complications) and these deaths have been virtually eliminated in high-income countries. Ante-partum stillbirths are more commonly associated with maternal infections and fetal growth restriction. Placental abnormalities are seen in approximately 25% percent of cases according to many sources.

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