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Prospective study on feto-maternal outcome in anemic women : MINNIE study

Background

Blood transfusions in pregnancy are usually urgent, unpredictable, and occur in otherwise healthy women. There is evidence of increasing rates of maternal red blood cell (RBC) transfusion around childbirth both in Europe and in US. Indeed, they are recorded in approximately 0.4–1.6% of all deliveries. Although obstetric patients use a small proportion of the blood supply overall (3–4%), however over the last years there has been a significant increase (about 30%) in the use of blood and blood products throughout pregnancy. Most available data relate to the peri-partum period, defined as those occurring from 48 hours before delivery onwards.

Anemia in pregnancy is associated with increased maternal mortality and fetal intrauterine growth restriction (IUGR). The risk of these adverse effects is proportional to the severity of anemia; for instance, preterm birth and low birth weight rates are particularly high among women with a hemoglobin below 7 g/dL.

The presence of anemia in at-term pregnant women is a rather frequent and unrecognized risk factor for peri-partum hemorrhage (PPH) transfusion. In a retrospective investigation, we have calculated that almost 20% of at-term pregnant women show iron deficiency anemia. It has been suggested that reduction of RBC transfusion in the context of PPH may decrease maternal mortality and, at the same time, reduce costs.

Patient's Blood Management (PBM) is a well-known strategy based on 1) identification of anemia; 2) reduction of blood loss and 3) reduction of RBC transfusion. In several medical specialties, recommendations based on available evidence highlighted the concept that a restrictive RBC administration is safe and efficacious. Despite the fact that the WHO has recommended PBM early 2010, the majority of hospitals are in need of guidelines to apply PBM in daily practice.

Rationale

Anemia is a frequent and often unrecognized hallmark of at-term pregnancies. Systematic collection of data on transfusion practice during pregnancy and post-partum period are scarce.

The application of PBM in obstetrics is expected to improve pregnancy outcome and optimize resources.

Objectives

Objectives of the present study are

1. To estimate: frequency of anemia in pregnancy and feto-maternal complications, distribution of haemorrhage aetiologies and transfusion indications.
2. To evaluate associations of these outcomes with gestational age, and transfusion dose.

Design

Prospective observational study. All consecutive pregnant women referred from January 1st 2022 to January 30th 2023 to Ob/Gyn departments at University of Foggia, University of Bari and IRCCS “Casa Sollievo della Sofferenza “ , who will deliver at Ob/Gyn department in the same Institutions. We will collect baseline clinical characteristics, blood count and all available laboratory parameters. Afterwards, we will collect fetomaternal outcomes, included data on possible transfusions.

Estimated Sample size : We estimate to enroll 2000 pregnant patients.

Definitions

- Cases of anemia will include pregnant women with

1) a third-trimester hemoglobin level of less than 11 g/dL or 2) a diagnosis of anemia made during the delivery admission but before delivery (referred to as predelivery admission diagnosis of anemia (*Smith C, Ob Gynecol 2019*))

Analysis according to severity: Anemia severity will be categorized into four groups: mild (9–10.9 g/dL), moderate (7–8.9 g/dL), severe (less than 7 g/dL) and unspecified (predelivery admission diagnosis of anemia with third-trimester hemoglobin value missing or at 11 g/dL or greater).

- Preeclampsia will be defined according to the definition of the ACOG as the occurrence of gestational hypertension with significant proteinuria (urine protein excretion > 300 mg/24 h) occurred after the 20th gestational week in a previously normotensive woman.
- IUGR (Intra Uterine Growth Restriction) will be defined as those having a birth-weight below the 10th percentile for gestational age, according to Italian birth-weight distribution in the absence of congenital malformations or chromosomal abnormalities, recent cytomegalovirus infection, or drug or alcohol abuse (*Villani M, et al. J Thromb Haemost. 2012;10(2):223-228*).
- Placenta abruptio is the separation of the placenta from its attachment to the uterus wall before the baby is delivered.

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