ASSOCIATION OF PLACENTA REMOVAL METHOD AND POSTPARTUM LEUCOCYTOSIS

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STUDY PROTOCOL

OBJECTIVES

Cesarean section is one of the most common major abdominal operation in women worldwide and its rate is increasing every year. Although cesarean birth is considered as safe, it is a potentially morbid procedure with associated risks of hemorrhage, thromboembolic events, infection, and anesthesia risks. The incidence of postpartum infection has been estimated to be 1-4% after vaginal delivery and 10-20% after cesarean section. Manual removal of the placenta is widely accepted by surgeons worldwide. This method enables the surgeon quick intervention. Beside, it helps uterine cavity to be examined for damage and the presence of placental remnants. However, manual removal of the placenta is still a conflicting issue due to the risk of post-partum endometritis, post-partum hemorrhage and abnormal placentation in subsequent pregnancies. It is assumed that controlled cord traction reduces the risk of postpartum hemorrhage and infection.

The aim of this study is to examine whether there is an association between the method of removal of the placenta and increase in postpartum white blood cell counts

DESIGN

After informed consent, all patients are randomized according to the removal of placenta from the uterus after childbirth; manually (Group 1) or controlled cord traction without putting hands inside the uterus (Group 2). Patients are examined regarding to maternal infection. BMI measurement, obstetrics and medical history are recorded. The operative procedures are similar in all patients and followed the same technical steps. All the patients are asked to come to control on postpartum day 10.

METHODS

In both groups, oxytocin and a first-generation cephalosporin antibiotic are administered intravenously after the delivery of the infant. All uterine incisions were low transverse and all were closed without exteriorisation of the uterus. Complete blood count before delivery, on pastpartum day 1 and 2, fever during hospitalisation, average blood loss during operation and the endometritis cases are recorded. All the patients are asked to come to control on postpartum day 10. Also, patients are asked to come to control if they have fever, abnormal vaginal bleeding, abnormal vaginal discharge, general feeling of sickness and pain in the pelvis. Fever is defined as a temperature above 38.5°C on two consecutive days, excluding the first 24 hours.

No Intervention: control group

In group 1, plasenta is removed manually. Manual removal of the placenta will be performed by placing surgeon's dominant hand in the uterine cavity and removing the placenta by detaching it from the uterine wall as soon as possible after the delivery of the infant. The emptiness of the uterine cavity is verified manually.

Experimental: Study Group

In group 2, plasenta is removed by controlled cord traction. Spontaneous removal will be performed by external uterine massage and traction on the umbilical cord are performed to assist spontaneous delivery of the placenta.

Primary Outcome Measure:

1.Change from baseline leukocyte level at postpartum day 1

Complete blood count is measured before delivery and postpartum day 1.

2.Detection of leukocyte count

Complete blood count is measured on postpartum day 2.

3.Detection of number of patients with fever

Body temperature is measured 4 times in a day. Highest temparature will be record on postpartum day 1 and 2.

5.Number of patients with postpartum endometritis

All the patients are asked to come to control on postpartum day 7. Also, patients are asked to come to control if they have fever, abnormal vaginal bleeding, abnormal vaginal discharge, general feeling of sickness and pain in the pelvis.

Secondary Outcome Measures:

Average blood loss during cesarean section is calculated by change from baseline hematocrit level at postpartum day 1.

Inclusion Criteria:

18-45 years old females

Nonanemic pregnancies

Singleton pregnancies

Elective cesarean sections

Exclusion Criteria:

Gestational age less than 34 weeks

Patients having umbilical cord prolapse,

Patients having placenta previa

Intrapartum fever and suspected chorioamnionitis

Patients having maternal infection

Patients having multiple gestation

Patients having antepartum hemorrhage

Patients having severe pre-eclampsia

Patients having placenta previa

Patients having placental abruption

Patients having uncontrolled gestational diabetes

Heart disease

Liver disorders

Renal disorders

Coagulopathy

Sample size determination formula*;

$$\mathbf{n=\frac{Nt^2pq}{d^2(N-1)+t^2pq}}$$

$$n=\frac{(720)(1.96)^2(0.5)(0.5)}{(0.05)^2(720-1)+(1.96)^2(0.5)(0.5)}$$

The minimum number of patients to collect is 251.

* Yamane Taro (2010), Elementary Sampling Theory, Literatür publish, 3rd Edition

Statistical Analysis Plan

The study was approved by the Ethics and Clinical Investigation Committee. Statistical Package for the Social Sciences (SPSS; Version 20.0, Chicago, IL, USA) will be used for statistical analyses. Descriptive statistics will be presented as mean ± standard deviation (SD) for normally distributed data, and as counts and percentages for categorical data. The relationship between the categorical variables will be examined using the Chi-square test and Fisher Exact Test. Results will be evaluated with a confidence interval of 95%, and $p<0.05$/ $p<0,01$ will be considered statistically significant. Kolmogorov-Smirnov test will be used for the assessment of the normality of data. Mann- Whitney U test will be used for the data not normally distributed.