The Effect of Misoprostol Given Preoperative Versus Postoperative on Blood Loss with Elective Cesarean Section: Randomized Controlled Trial (RCT)

Thesis

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Presented By

Hany Hamdy Hassanen
M.B., B.Ch. 2010
Resident of Obstetrics and Gynecology
Abo-Elmatamir Hospital, Elbehira

Under Supervision of

Prof. Mohamed Ashraf Mohamed Farouk kortam
Professor of Obstetrics and Gynecology
Faculty of Medicine – Ain Shams University

Dr. Ahmed Mahmoud Hussein
Lecturer of Obstetrics and Gynecology
Faculty of Medicine – Ain Shams University

Faculty of Medicine
Ain Shams University
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Abstract

Background: Caesarean section is the delivery of foetus through abdominal incision in the abdominal wall (laparotomy) and uterine wall (hystorotomy) this definition does not include the removal of foetus from abdomen in ectopic abdominal pregnancy or ruptured uterus. Caesarean section is one of the most commonly performed major operations in women throughout the world. Postpartum haemorrhage (PPH) is defined as a blood loss of more than 1000 ml in the first 24 hours, following caesarean section.

Aims: The aim of the current study is to compare the efficacy of rectally administered misoprostol on blood loss in pre- and postoperative period in elective cesarean deliveries.

Methodology: The study was conducted in the labour ward in Ain Shams University Maternity Hospital between february 2016 to august 2016. Randomized, comparative observational clinical trial. A total number of 150 women all were consented and 6 women in group 1 missed to be followed before delivery and 4 women in group 2 missed to be followed . 140women delivered after completed 37 weeks of pregnancy by elective cesarean section.

Results:

The women under study were distributed in two groups

Group 1: Included 70 women who received 600 mg misoprostol rectally preoperatively after anaesthesia and urinary catheterization (as per WHO dose recommendation).

Group 2: Included 70 women who received 600 mg misoprostol postoperatively at operating theatre (as per WHO dose recommendation).

Conclusion: This study reported that preoperative use of misoprostol rectally appears to be safe and effective uterotonic to decrease blood loss during and after CS and decrease maternal deaths due to postpartum hemorrhage.

Recommendations: A future study with lower doses of misoprostol should be studied. A future study on pregnant women with high risk factors should be studied. A future multicenter double blinded RCT need to be studied to verify the results of current study.

Keywords: Caesarean section, Misoprostol given preoperative, PPH, Versus postoperative, Randomized controlled trial

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Contents

List of Abbreviations

aPTT : Activated partial thromboplastin time
CBC : Complete blood count
CS : Cesarean section
CT : Computed tomography
DIC : Disseminated intravascular coagulation
INR : International normalized ratio
ITP : Idiopathic thrombocytopenic purpura
LFTs : Liver function tests
LRS : Lactated Ringer's solution
MRI : Magnetic resonance imaging
NS : Normal saline
PGE : prostaglandin E
PGE1 : prostaglandin E1
PPH : Postpartum haemorrhage
PRBCs : Packed red blood cells
PT : Prothrombin time
VBAC : Vaginal birth after cesarean

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Introduction

Caesarean section is the delivery of foetus through abdominal incision in the abdominal wall (laparotomy) and uterine wall (hystorotomy) this definition does not include the removal of foetus from abdomen in ectopic abdominal pregnancy or ruptured uterus **(Cunningham et al., 2001).**

Caesarean section is one of the most commonly performed major operations in women throughout the world. Postpartum haemorrhage (PPH) is defined as a blood loss of more than 1000 ml in the first 24 hours, following caesarean section **(Weeks, 2015).** Postpartum haemorrhage (PPH) is the leading cause of maternal mortality worldwide, and the number of maternal deaths due to postpartum haemorrhage is estimated to exceed 100,000 maternal deaths each year **(Mousa and Alfirevic, 2009).**

Misoprostol is a synthetic PGE1 analogue, owing to its uterotonic properties; it is now one of the most popular drugs in obstetrics **(Chong et al., 2004).** The low cost of drug, safety, stability, and the ease of administration through multiple routes make it a good option in poor setting and in women who are vomiting under anaesthesia **(Derman et al., 2006).** The drug was proved to be effective in reducing blood loss when administered orally, buccally and rectally in many

previous studies **(Tang et al., 2002).** We were comparing the blood loss in pre- and post-operatively rectally administered 600 mg of misoprostol in elective caesarean delivery, in order to determine the optimal time for drug administration.

The use of Prophylactic administration of misoprostol rectally after caesarean delivery is increasing nowadays. We were comparing the effect of preoperative and post-operative rectally administrated misoprostol on operative blood loss at cesarean section. Misoprostol has an important effect in terms of decreased postoperative morbidity and a decrease in risks associated with blood transfusions **(Lapaire et al., 2006).**

Misoprostol has been investigated both for prevention and management of PPH due to its uterotonic effect. Rectal administration has a slower absorption rate, lower concentration level and consequently lower adverse effects compared to Sublingual misoprostol, which has the greatest bioavailability among all routes of administration and a higher incidence of complications **(Lapaire et al., 2006 & Tang and Ho, 2006).**

On the other hand, oral route has the highest side effects **(Khan and El-Refaey, 2003).** For these reasons, the rectal route was the preferred route of administration in the present study.

Aim of the Work

The aim of the current study is to compare the efficacy of rectally administered misoprostol on blood loss in pre- and postoperative period in elective cesarean deliveries.

Research hypothesis:

Null hypothesis, in women undergoing elective cesarean section (CS), preoperative administration of misoprostol may be effective as postoperative one in decreasing blood loss.

Research question:

In women undergoing elective CS, does preoperative administration of misoprostol effective as postoperative one in decreasing blood loss.

Cesarean section

Cesarean delivery is defined as birth of a fetus through incisions in the abdominal wall (laparotomy) and the uterine wall (hysterotomy) does not include removal of fetus from abdominal cavity ***(Cunningham et al., 2010).***

Incidence of cesarean Section

For many years, the incidence of the procedure was stable (3-5%) yet since 1960s, the rate of cesarean section was rising steadily reaching (20-25%) in the late 1980s ***(EL-Mahallawy et al., 2006).***

The reasons for the continued increase in the cesarean rates are not completely understood, but some explanations include the following:

1. Women are having fewer children, thus, a greater percentage of births are among nulliparas, who are at increased risk for cesarean delivery.
2. The average maternal age is rising, and older women, especially nulliparas, are at increased risk of cesarean delivery.
3. The use of electronic fetal monitoring is widespread. This technique is associated with an increased cesarean delivery rate compared with intermittent fetal heart rate auscultation.

4. Most fetuses presenting as breech are now delivered by cesarean
5. The incidence of forceps and vacuum deliveries has decreased.
6. Rates of labor induction continue to rise, and induced labor, especially among nulliparas increases the risk of cesarean delivery.
7. The prevalence of obesity has risen dramatically, and obesity increases the risk of cesarean delivery.
8. Rates of cesarean delivery for women with preeclampsia have increased, whereas rates of labor induction in these patients have declined.
9. Vaginal birth after cesarean—VBAC—has decreased from a high of 26 percent in 1996 to a rate of 8.5 percent in 2007.
10. Elective cesarean deliveries are increasingly being performed for a variety of indications including concern for pelvic floor injury associated with vaginal birth, medically indicated preterm birth, to reduce the risk of fetal injury, and for patient request.
11. Malpractice litigation continues to contribute significantly to the present cesarean rate

(Cunnigham et al., 2010)

A previously unexplored hypothesis for the increasing section rate is the evolution of birth weight and maternal pelvis size. It is proposed that since the advent of successful Cesarean birth over the last 150 years, mothers with a small pelvis and babies with a large birth weight have survived and contributed to these traits increasing in the population. Such a hypothesis is based upon the idea that even without fears of malpractice, without maternal obesity and diabetes, and without other widely quoted factors, the cesarean section rate would continue to rise simply due to slow changes in population genetics ***(Walsh, 2008).***

It was also found that; Teaching hospitals have a lower cesarean delivery rates rather than non-teaching hospitals, which may implement that private practice may have a role in increasing the rate of cesarean section for financial reasons ***(Sanchez et al., 1994).***

Cesarean section rates in Egypt:

Cesarean section rates have been increasing worldwide,. In Egypt, data on rates and indications of CS are variable based on the level of experience and on the whether the delivery was carried out at a private or a public setting ***(Helal et al., 2013).***.It was found caesarean section rates during the time period 1987-1992 was 4.6%, increased to