

INTRODUCTION

Normal Labor is defined as a physiologic process which includes spontaneous expulsion of a single mature fetus (37 completed weeks-42. weeks), presented by vertex through the birth canal, within a reasonable time (not less than 3 hours or more than 18 hours), without complications to the mother or to the fetus. This physiologic process is achieved by the gradual effacement and dilation of the uterine cervix as a result of the rhythmic contractions of the uterus with sufficient frequency, intensity and duration (*WHO, 2015*).

Normal labor includes 4 stages: The 1st stage begins with the onset of labor and ends with full cervical dilation followed by the 2nd stage of labor including the interval between full cervical dilation and the delivery of the infant, then the 3rd stage of labor which is the duration from the birth of the infant to the delivery of the placenta, umbilical cord and fetal membranes, the 4th stage or puerperium follows delivery and concludes with the resolution of the physiologic changes of pregnancy usually by 6 weeks postpartum in which the reproductive tract returns to the nonpregnant state and ovulation may resume (*Cunningham et al., 2014*).

The normal duration 3rd stage of labor is 5-15 minutes, with placental separation occurring along Nitabuch's layer and is a result of continued uterine contractions, these contractions control blood loss by compressing spiral arteries and also result

in migration of the placenta into the lower uterine segment and then through the cervix (*Carroli et al., 2008*).

During the third stage of labor complications are common and can threaten the mother's life. The most common complication is postpartum hemorrhage (PPH), which remains a leading cause of maternal mortality, especially in developing countries (25.0%), with placental retention and uterine atony are underlying causes of prolonged 3rd stage leading to postpartum hemorrhage, Women who survive PPH are likely to suffer from anaemia and other complications. Bleeding that cannot be controlled using drugs often requires surgery, including devascularization procedures, B-Lynch surgical technique, arterial embolization and hysterectomy (*Chamberlain, 2010*).

There are two quite different approaches to the clinical management of the third stage: Active management and expectant management. Active pharmacologic management of the third stage of labor is common today and has resulted in a significant decrease in early and late postpartum hemorrhage and in total maternal peripartum mortality and morbidity (*Gallos et al., 2015*). It involves the use of oxytocin or methylergometrine intravenously or intramuscularly after shoulder delivery, controlled cord traction once the uterus is contracted and uterine massage to prevent postpartum hemorrhage (*NCCWCH, 2007*). In contrast, expectant management involves waiting for signs of separation and

allowing the placenta to deliver spontaneously or aided by gravity or nipple stimulation. Expectant management is also known as conservative or physiological management (*Prendiville et al., 2002*).

The WHO recommends that all women giving birth should be offered uterotonics during the third stage of labour for the prevention of PPH; oxytocin (intramuscular/intravenous, 10 international units (IU) is the uterotonic drug of choice within 2 minutes after delivery of the fetus, delayed clamping of umbilical cord for 2 minutes and controlled traction of umbilical cord to prevent PPH (*WHO, 2012*).

However, the issue of maternal death due to PPH remains unresolved in low-resource settings. Attempts to address the problem need to go beyond the use of uterotonic drugs (*Novikova et al., 2015*).

One of the methods of Active Management of 3rd stage of labor is the administration of oxytocin via the umbilical vein for the delivery of placenta. Umbilical vein oxytocin injection directs treatment to the placental bed and uterine wall, resulting in earlier uterine contraction, the resulting tension causes the decidua spongiosa to give way with the formation of a hematoma, which then accelerates the process of placental separation (*Weeks et al., 2010*). Several studies and systematic reviews have been published on the use of intraumbilical oxytocics, but these studies assessed the use of intraumbilical

oxytocin for the treatment of retained placenta (*Sivalingam et al., 2001; Habek et al., 2010; Ghulmiyyah et al., 2007; Güngördük et al., 2011*). However, limited published literature is available evaluating the effect of umbilical vein oxytocin injection in routine practices for active management of the third stage of labor (*Makvandi et al., 2013*).

One of the Physiological management is Cord Drainage. Cord drainage in third stage of labor involves unclamping the umbilical cord and allowing the blood from the placenta to drain freely into appropriate receptacles for a duration of three minutes (*Du et al., 2014; Tehseen et al., 2008*).

The present study is aimed at studying and comparing the effectiveness of intraumbilical oxytocin and placental cord drainage in the management of third stage of labor.

PROTOCOL OF THE STUDY

What is already known on this subject?

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What does this study add?

The present study is aimed at studying and comparing the effectiveness of intraumbilical oxytocin and placental cord drainage in the management of third stage of labor.

Aim of the work:

The aim of this study is to compare the effectiveness of intraumbilical oxytocin and placental cord drainage in the management of third stage of labor.

Research question:

Can the use of intraumbilical vein oxytocin injection or the use of placental cord drainage shorten the duration of the third stage of labor, reduce the incidence of manual removal of placenta, reduce the incidence of retained placenta during the third stage of labor and reduce hemoglobin level drop in pregnant women after delivery of the infant?

Research Hypothesis:

Null Hypothesis: Both Intraumbilical Oxytocin and Placental Cord Drainage have no effect in the management of 3rd stage of labor and prevention of PPH.

Outcomes:

Retained placenta is defined as a placenta that remained in the uterus for 30 minutes or more after delivery (*Begley et al., 2014*).

- **1ry outcome:** Duration of the third stage of labor.
- **2ry outcome:** Retained placenta, the need for manual removal of placenta and the drop in Hb will be recorded.

Patients and Methods:

Study:

Study Design: A randomized controlled trial.

Study setting: The study will be conducted in Ain Shams University Maternity Hospital.

All pregnant women in the active phase of labour attending to delivery ward will be submitted to:

- 1) **Detailed complete history taking** with special emphasis to maternal age, Parity, Maternal weight, as well as presence of any disease.
- 2) **Clinical Examination:**
 - a. General examination.
 - b. Abdominal examination (Symphysis-fundal height) and pelvic examination.
- 3) **Investigation**
 - a. Ultrasound assessment to evaluate GA, fetal weight, AFI and Placental site.
 - b. Basal complete blood picture, urine analysis and random blood sugar.

The selected patients will fulfill the following criteria:

- A singleton fetus at a gestational age of 37 - 42 weeks in a cephalic vertex presentation.
- Neonatal birth weight of 2500 to 4500 grams.

Exclusion criteria:

- Indications for cesarean section.
- Previous CS or Previous Myomectomy.
- Hypertensive disorders of pregnancy.
- Intrauterine fetal death.
- Known or suspected fetal anomalies.
- Instrumental delivery.
- Multiple pregnancies.
- Antepartum hemorrhage
- Known coagulation disorder or any risk factor for PPH.
- Intrapartum hemorrhage before delivery of placenta.

Study population:

The present study will be conducted on 150 women recruited from the delivery ward of our hospital after they had received information on the purpose and course of the study from the medical investigator and had provided the written consent during routine prenatal visits, The 150 study participants will be divided into three groups using simple random distribution technique. After monitoring the duration of active phase and second stage of labor by following the partograph.

Randomization and Allocation concealment:

Randomization based on the sequence generation created by computer and the randomization tables will be kept with the

study supervisor. Consenting patients fulfilling inclusion criteria will be randomized into one of the 3 groups immediately after delivery of the baby. Randomized allocation will be kept in opaque sealed envelopes, with enrollment numbers written on the envelopes. The envelopes contain a card on which the designated study group is written. After enrollment of the patients in the study, the envelopes marked with study number will be unsealed and the patients allocated to either groups:

- **Group (A) “Study Group 1”:**

In the labor room women in Group A (n = 50) will receive intraumbilical vein injection oxytocin 20 units diluted in 20 ml of 0.9% saline solution immediately after delivery of the baby, clamping and cutting the cord.

- **Group (B) “Study Group 2”:**

The women in Group B (n = 50) will have placental drainage immediately after delivery. This scenario includes placental cord clamping and cutting after delivery of the baby followed by immediately unclamping of the maternal side, allowing the blood to drain freely for a duration of three minutes.

- **Group (C) “Control Group”:**

The women in Group C (n = 50) will be a control group, this scenario includes placental cord clamping and cutting after 2 minutes of delivery of the baby.

Intramuscular oxytocin 10 IU will be given to all women of the 3 groups immediately after delivery of the baby (***RCOG, 2016***).

Then the placenta in the women of the 3 groups will be delivered using controlled cord traction after appearance of clinical signs of placental separation, which include strong uterine contraction, vaginal bleeding, and descending of umbilical cord through the vulva.

The women will be kept under observation for 2 hours following delivery of the baby for any complications, and the vital signs and uterine tone were monitored every 15 minutes. (***Knight et al., 2009***).

Sample size calculation:

Sample size was calculated using PASS® version 11 program, sample size calculation was based on study carried out by (***Güngördük et al., 2011***). A preliminary power analysis was carried out to calculate the sample size using a formula: $d = \Delta/SD$, where d is standardized difference, Δ is the smallest clinically significant difference and SD is standard deviation of the test group. Duration of 1.6 minutes was observed based on the results of the study performed by (***Güngördük et al., 2011***) as the smallest clinically significant difference, so the SD (1.6 minutes) was selected based on the observation of the results of the study performed by (***Güngördük et al., 2011***). The power analysis suggested that a sample of 50 women in each group would provide a power of 95%, at 5% significance.

AIM OF THE WORK

The aim of this study is to compare the effectiveness of intraumbilical oxytocin and placental cord drainage in the management of third stage of labor.

Research hypothesis

Null Hypothesis: Both Intraumbilical Oxytocin and Placental Cord Drainage have no effect in the management of 3rd stage of labor and prevention of PPH.

Research Question

Can the use of intraumbilical vein oxytocin injection or the use of placental cord drainage shorten the duration of the third stage of labor, reduce the incidence of manual removal of placenta, reduce the incidence of retained placenta during the third stage of labor and reduce hemoglobin level drop in pregnant women after delivery of the infant?

THIRD STAGE OF LABOR

➤ Normal Labor and delivery:

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➤ **Definition of the third stage of labor:**

It's the interval from birth of the baby to the expulsion of the placenta. There is no universally accepted criterion for the normal length of the 3rd stage, two large series of consecutive deliveries observed that the average length was five to six minutes, and 90 percent of placentas was delivered within 15 minutes and 97 percent was delivered within 30 minutes of birth (*Begley et al., 2011*).

Placental separation occurs along Nitabuch's layer as a result of continued uterine contractions after expulsion of the fetus, these contractions controls blood loss by compressing spiral arteries and also result in the migration of the placenta into the lower uterine segment and then through the cervix (*Jakobovits et al., 2006*).

The duration of the 3rd stage is important as the prevalence of PPH increases as the duration lengthens (*Soltani et al., 2010*).

Gestational age is the major risk factor influencing the length of the 3rd stage of labor; where preterm deliveries are associated with longer 3rd stage of labor than term deliveries (*Dombrowski et al., 1995*).

The most common complication accompanying this stage is the postpartum hemorrhage (PPH), and prolonged 3rd stage of labor owing to Placental retention and uterine atony are

among the underlying cause of most cases of PPH, the average length of this stage is 5-15 minutes; however, in 25% of cases, retention of placenta occurs if no immediate treatment is undertaken, those women are at high risk of hemorrhage (*Shields et al., 2011*).

➤ **Physiology of the third stage of labor:**

After delivery of the fetus uterine contractions continue resulting in substantial reduction in the uterine surface area, this reduction is due to myometrial thickening and retraction following each successive contraction, resulting in shearing forces at the placental attachment site and placenta separata, this process generally begins at the lower pole of the placental margin and progress along adjacent sites of placental attachment, ‘ A wave of separation’ spreads upward so that the uppermost part of placenta detaches last (*Herman, 2002*).

Another mechanism of placental separation is retroplacental hematoma due to venous occlusion and vascular rupture in the placental bed due to uterine contraction (*Geller et al., 2006*).

As the placenta detaches, massive hemorrhage would occur from the exposed spiral arteries in the surface area of the placental bed; if not for the structure of the uterus. As the spiral vessels crosses a latticework of crisscrossing myometrial muscle fibers, which when contract and retract kink-off and occlude the spiral arteries after expulsion of placenta, that

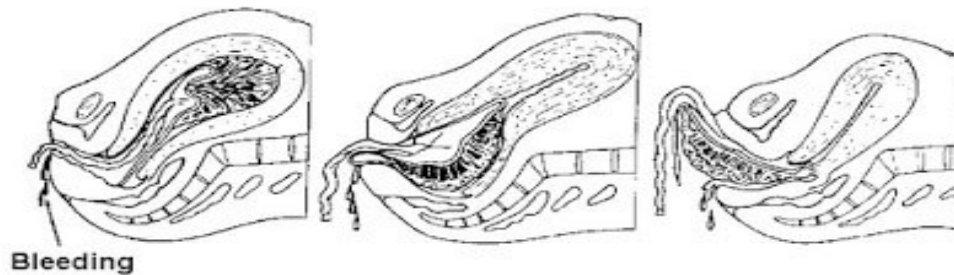
arrangement of uterine muscle fibers is referred to it as the ‘living ligatures’ or the ‘physiologic sutures’ of the uterus (*Baskett, 1999*).

250-350 ml blood is the average amount which is lost in most women following vaginal birth, while 12% of women will lose up to 500 ml blood, with the active management of the 3rd stage reduce that amount to 5% (*Magann et al., 2006*).

➤ **Signs of Placental separation:**

There are 4 signs of placental separation which includes: 1st is the lengthening of the umbilical cord which is the most reliable sign as the placenta migrates to the lower segment and the cord lengthens, 2nd is that the uterus becomes more globular in shape and firmer in consistency due to the myometrial thickening and retraction, 3rd is the rising of the uterus to the abdomen as the placenta lodges into the cervix then into the vagina displaces the uterus upwards and finally the 4th sign is the gush of the blood from the vagina (*Silverman et al., 2006*). With the delivery of the leading edge of the placenta and maternal surface first “Mathews Duncan method”, rather than the cord insertion and the fetal surface, which is the more common “Schultz method” (*Cunningham et al., 2014*).

Duncan mechanism



Schultze mechanism

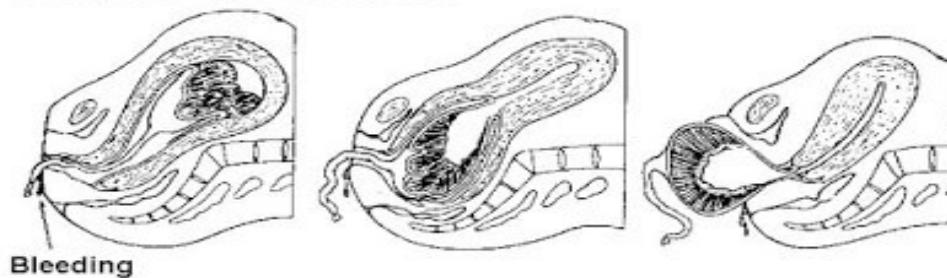


Figure (1): Mechanism of placental separation and delivery
(*Obstetrics and new born care, 2011*).

➤ **Complications of the 3rd stage of labor:**

The major complications of the 3rd stage of labor are: Hemorrhage, retained Placenta and Uterine inversion (*Aziz et al., 2016*).

1- Postpartum Hemorrhage (PPH):

It's best defined and diagnosed clinically as excessive bleeding from the genital tract that makes the patient symptomatic (e.g.: pallor, lightheadedness, weakness, palpitation, diaphoresis, restlessness, confusion, air hunger and syncope) and/or results in signs of hypovolemia (hypotension,