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Influence of placental cord drainage in management of the third stage of labor: A Randomized controlled trial

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Abstract: The third stage of labor refers to the interval immediately after the birth of the fetus to the separation and expulsion of the placenta and fetal membranes. Prolongation of the third stage of labor leads to an increased complication rate, particularly the incidence of postpartum hemorrhage. In addition, Postpartum hemorrhage (PPH) accounts for between one quarter to one third of all maternal deaths worldwide and is the major cause of maternal mortality.

Aim of work: To compare the effectiveness of placental cord drainage method as a part of management of third stage of labor in reducing the duration and amount of blood loss of the third stage, against cord clamping method.

Patients and Methods: This is a Prospective Randomized controlled trial. The study was conducted at Helwan University Maternity hospital at labor ward during the period between July 2019 and December 2019. The study included 70 patients attended the labor ward at Helwan University Hospital for uncomplicated vaginal delivery and were divided equally into two groups: a study group and a control group. In the study group, the placental cord was clamped. The duration and amount of blood loss of third stage of labor were recorded.

Results: The mean duration of third stage of labor in placental cord drainage group was 3.1 ± 0.3 minutes and in control group it was 4.3 ± 0.7 minutes (p<0.001). The mean blood-loss in placental cord drainage group was 181 ± 16 ml compared to 272 ± 33 ml in the control group (p<0.001). The mean post-delivery drop in hemoglobin was 1.46 ± 0.33 gm/dl in the control group, while it was 0.85 ± 0.22 gm/dl in the study group. The mean drop in hematocrit value was 3.40 ± 1.67 % in the control group and 1.96 ± 0.60 % in the study group (p<0.001).

Conclusion: Placental cord drainage is a simple, safe, and non-invasive method which reduces the duration and amount of blood loss of the third stage of labor when compared with Cord clamping method

Keywords: Third stage of labor- Placental cord drainage- Blood loss.

1. INTRODUCTION

Labor is a physiological process, but it is often associated with morbidity and mortality, with the most common cause being blood loss ⁽¹⁾. The majorities of these mortalities are caused by complications during the third stage of labor, and most commonly are from uterine atony and postpartum hemorrhage ⁽²⁾. This popularity of use has been gained primarily due to high long-term success rates and reversibility. Currently, there is an established evidence about their safety and efficacy. Additionally, they exhibit superior contraceptive potential 20 times over traditionally used oral contraceptive pills that translates to lower rates of unintended pregnancies ⁽²⁾.

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During third stage of labor that lasts for 10 to 45 minutes after birth of the baby, the uterus continues to contract to a smaller and smaller size, which causes a shearing effect between the walls of the uterus and the placenta, thus separating the placenta from its implantation site. Separation of the placenta opens the placental sinuses and causes bleeding. The amount of bleeding is limited to an average of 350 milliliters by the following mechanism: The smooth muscle fibers of the uterine musculature are arranged in figures of eight around the blood vessels as the vessels pass through the uterine wall. Therefore, contraction of the uterus after delivery of the baby constricts the vessels that had previously supplied blood to the placenta. In addition, it is believed that vasoconstrictor prostaglandins formed at the placental separation site cause additional blood vessel spass m⁽³⁾.

Prolongation of the third stage of labor leads to an increased complication rate, particularly the incidence of postpartum hemorrhage ⁽⁴⁾. In addition, Postpartum hemorrhage (PPH) accounts for between one quarter to one third of all maternal deaths worldwide and is the major cause of maternal mortality ⁽⁵⁾. So, the active management during the third stage of labor is recommended as a preventive strategy ⁽⁶⁾.

The timely expulsion of the placenta and an efficient uterine contraction to cease bleeding are important parts in preventing complications of the third stage of labor. Placental delivery is essential in allowing the uterus to contract and decrease blood loss during the third stage of labor. Placental expulsion depends on the separation of the placenta from the uterine wall, capillary hemorrhage, uterine muscle contractile ability after placental separation, maternal effort, and gravity of the placenta⁽⁷⁾.

Active management and physiological or expectant management are regarded as two different approaches to the clinical management of the third stage of labor. Expectant management of third stage of labor involves the process of waiting for the spontaneous separation and expulsion of the placenta without artificial intervention but can be aided by gravity or nipple stimulation⁽⁸⁾.

Interventions to prevent third stage of labor complications are called active management of the third stage of labor (AMTSL). These interventions include early umbilical cord clamping, administration of an oxytocin agent, and controlled cord traction until delivery of the placenta. Placental cord drainage is also considered as an AMTSL method ⁽⁹⁾.

Cord drainage in third stage of labor involves unclamping the previously clamped and separated umbilical cord and allowing the blood from the placenta to drain freely into appropriate receptacles ⁽¹⁰⁾.

It is physiologically plausible that draining blood from the placenta would reduce its bulkiness allowing the uterus to contract and retract effectively leading to delivery of placenta and may reduce the duration of 3rd stage of labor ⁽¹¹⁾.

Thus, we designed the current study to compare the effectiveness of placental cord drainage with no drainage in reducing the duration and blood loss in 3rd stage of labor.

AIM OF WORK

To compare the effectiveness of placental cord drainage method as a part of management of third stage of labor in reducing the duration and amount of blood loss of the third stage, against no cord drainage method.

2. PATIENTS AND METHODS

Study design: Prospective Randomized controlled trial.

Settings:

The study was conducted at Helwan University Maternity hospital at labor ward during the period between July 2019 and December 2019. The study was approved by the Ethics Committee of Helwan University and an informed written consent was taken from each participant in the study.

Study Population:

- The study included 70 pregnant women attending the labor ward at Helwan University Hospital for uncomplicated vaginal delivery.
- > Patients were randomly assigned to one of the two groups, as follows:



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- Group A: 35 female patients were not subjected to cord drainage after delivery of baby (Cord clamping), were used as control group.
- Group B: 35 female patients were subjected to cord drainage after delivery of baby, were used as study group.

Method of randomization:

Computer generated randomization sheet using MedCalc© version 18.2.1 was used for randomization.

Inclusion criteria:

- ☐ Maternal age 18 years or more
- \Box Singleton pregnancy.
- \Box Vertex presentation.
- □ Gestational age of 37 weeks or more (confirmed by certain LMP or early ultrasound).
- □ No maternal medical or obstetric complications.
- □ Patient expected to have spontaneous vaginal delivery.
- \Box No fetal compromise or anomaly.

Exclusion criteria:

- 1. Hb < 9 gm/dl
- 2. Previous history of postpartum hemorrhage
- 3. Antepartum hemorrhage
- 4. Previous cesarean section or Instrumental delivery
- 5. Multiple pregnancy
- 6. Malpresentations
- 7. Over distended uterus (Polyhydramnios or large fetus>3.5kg)
- 8. Patient with extensive extended vaginal or cervical tear.
- 9. Rupture uterus
- 10. Known coagulation disorders.
- 11. Previous surgeries on the uterus

Methods:

- A written informed consent was taken from each participant before recruitment in the study after explanation of the purpose and procedures of the study.
- Full personal, obstetric, menstrual, and detailed medical history was obtained.
- All participants had complete clinical examination (General- Abdominal pelvic). (These next procedures were done by staff members at labor ward under supervision of the author).
- ✓ General examination: -

Full general examination was done with special concern to vital signs: - Pulse, Blood pressure, temperature, respiratory rate, and general condition of patient.

✓ <u>Abdominal examination</u>: -

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For assessment of gestational age, fetal weight, amount of liquor, fetal lie and presentation, fetal heart sounds, uterine contraction, and scar of previous surgeries.

✓ <u>Pelvic examination including vaginal examination:</u>

For assessment of progress of labor as regard cervical dilation, effacement, vertex presentation, station, position, and pelvic adequacy.

- In each patient, the pre-delivery pulse rate, blood pressure, and Hb % and hematocrit value were recorded.
- In the study group, immediately after spontaneous vaginal delivery, after clamping and cutting the cord—the cord was unclamped and the blood was drained until the flow ceased, which was not the one used to measure blood loss while in the control group the placental end of the cut umbilical cord was kept clamped.
- In both groups, placenta was delivered by controlled cord traction (applying traction to the cord with counter-pressure on the womb to deliver the placenta) once signs of placental separation were seen. Intramuscular oxytocin 10 IU was given after delivery of fetus in both groups after exclusion of contraindication of its use as a part of routine care provided.
- The amount of blood lost was measured from the blood drained into a plastic bag, placed under the woman's buttocks immediately following delivery and drained into an appropriate recipient until delivery of the placenta to be measured in a calibrated bag. No gauze pads or compresses were used at this time. In cases who need episiotomy or if perineal tears occur, blood from episiotomy wounds or perineal tears was mopped and the mops was discarded.
- The duration of the third stage was calculated using a stopwatch.
- The patient's post-delivery pulse rate, blood pressure and state of uterus were noted by manual palpation of uterus to ensure proper contraction after placental delivery.
- The patients were kept under observation for the next 2 h to watch for complications if any as postpartum hemorrhage as an example.
- Blood Hemoglobin and hematocrit value were measured prior to and after 6 hours of delivery in both the groups and difference from that of the antenatal value was observed. After collecting all the data, the data was tabulated in a master chart and analyzed.

Study outcomes: -

Primary outcome: -

The current study was designed to assess the effectiveness of placental cord drainage method as a part of management of third stage of labor in reduction of the duration and amount of blood loss of the third stage, against Cord clamping method.

Secondary outcomes:

To clarify safety of this method regarding the incidence of postpartum hemorrhage(>500 ml blood loss in 24 hours postpartum), the incidence of a retained placenta, the requirement for the manual removal of the placenta, uterine curettage, the need for blood transfusion, changes in maternal hemoglobin and hematocrit value after delivery, additional uterotonic drugs required more than 10 IU oxytocin given to all patients in both groups, symptoms of anemia in the 24 hours postpartum, significant maternal pain during the third stage and adverse events at the time of drainage.

Statistical analysis:

Data was analyzed using SPSS Statistics version 23. Analysis was done on an intention to treat (ITT) basis. Normally distributed numerical data was presented as mean and SD, and skewed data as median and interquartile range. Qualitative data was presented as number and percentage. Comparison of normally distributed numerical data was done using the unpaired t test. Skewed data was compared using the Mann-Whitney test. Categorical data was compared using the chi-squared test or Fisher's exact test, if appropriate. P-value <0.05 is considered statistically significant.



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3. RESULTS

The current study was conducted at Helwan University Maternity hospital at labor ward during the period between July 2019 and December 2019.

There were no significant differences difference between the study and control group as regard demographic data including maternal age, Gestational age (GA) and parity.

The two groups then were compared regarding Blood loss and duration of the third stage of labor.

 Table (1): Comparison between study and control groups regarding duration and blood loss of the third stage of labor.

	Control (n=35)	group	Study (n=35)	group		95% CI		
Variable	Mean	SD	Mean	SD	Mean Difference	Lower	Upper	P-value*
Duration of 3 rd stage (min)	4.3	0.7	3.1	0.3	1.2	0.9	1.4	<0.001
Blood loss (ml)	272	33	181	16	90.9	78.4	103.3	<0.001

Data are mean and standard deviation (SD).

95% CI = 95% confidence interval.

*Unpaired t-test.

As shown in table 1, regarding duration and blood loss of the third stage of labor, P value was less than 0.0001 which is statistically significant.

The table shows that duration and blood loss in the third stage of labor were significantly lower in the study group than in the control group.

	Control (n=35)	group	Study (n=35)	group		95% CI		
Variable	Mean	SD	Mean	SD	Mean Difference	Lower	Upper	P-value*
-Pre-delivery pulse rate (bpm)	84	2	84	2	0.1	-0.8	1.0	0.855
-Pre-delivery SBP (mmHg)	111	7	109	7	2.7	-0.7	6.2	0.120
-Pre-delivery DBP (mmHg)	74	6	73	6	1.0	-1.7	3.7	0.459
-Post-delivery pulse rate (bpm)	91	2	89	2	2.4	1.6	3.2	<0.001
-Post-delivery SBP (mmHg)	98	6	102	6	-4.6	-7.3	-1.8	0.002
-Post-delivery DBP (mmHg)	63	5	68	5	-4.6	-7.0	-2.2	<0.001

Table (2): Comparison between both groups regarding post-delivery changes in hemodynamic variables

Data are mean and standard deviation (SD).

95% CI = 95% confidence interval.

*Unpaired t-test.

As shown in table 2, There is no significant difference between study and control groups regarding pre-delivery pulse rate, SBP (systolic blood pressure) and DBP (diastolic blood pressure).

Post-delivery SBP and DBP are significantly higher in study group than control group. SBP and DBP significantly decreased post-delivery in both groups.

Post-delivery Pulse rate significantly higher in control group than study group. Pulse rate significantly increased post-delivery in both groups.

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Table (3): Comparison between both groups regarding post-delivery changes in he	ematological	variables
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	Control (n=35)	group	Study (n=35)	group		95% CI		
Variable	Mean	SD	Mean	SD	Mean	Lower	Upper	P-value*
					Difference			
-Pre-delivery Hb (g/dl)	11.4	1.0	11.2	1.0	0.1	-0.3	0.6	0.557
-Pre-delivery Hematocrit (%)	33.0	2.4	32.6	2.4	0.4	-0.8	1.6	0.515
-Post-delivery Hb (g/dl)	9.9	0.9	10.4	0.9	-0.5	-0.9	0.0	0.032
-Post-delivery hematocrit (%)	29.6	2.7	30.6	2.3	-1.1	-2.2	0.1	0.080
-Drop in hemoglobin (g/dl)	1.46	0.33	0.85	0.22	0.62	0.48	0.75	<0.001
-Drop in hematocrit (%)	3.40	1.67	1.96	0.60	1.44	0.84	2.04	<0.001

Data are mean and standard deviation (SD).

95% CI = 95% confidence interval.

*Unpaired t-test.

As shown in table 3, There was no significant difference between the study group and control groups regarding predelivery hemoglobin and hematocrit value.

Post-delivery hemoglobin was significantly higher in study group than control group.

Post-delivery hematocrit was non-significantly higher in study group than control group. Post-delivery drop in hemoglobin and hematocrit value was significantly less in study group than in control group.

Table (4): Incidence of adverse effect in the study and control groups.

	<i>Control group (n=35)</i>		Study group(n=35)		
Adverse outcome	n	%	n	%	P-value*
Retained placenta	0	0.0%	0	0.0%	NA
Need for manual removal of placenta	0	0.0%	0	0.0%	NA
Need for uterine curettage	0	0.0%	0	0.0%	NA
Need for uterotonics	0	0.0%	0	0.0%	NA
Significant pain	0	0.0%	0	0.0%	NA
Symptoms / signs of anemia	13	37.1%	3	8.6%	0.009
Need for blood transfusion	3	8.6%	0	0.0%	0.239
Post-partum hemorrhage	0	0%	0	0.0%	NA

Data are number (n) and percentage (%).

NA = test not applicable.

*Fisher's exact test.

As shown in table 4, on comparing both groups as regard symptoms and signs of anemia 24 hours postpartum, P value was less than 0.001 which is statistically significant.

Symptoms and signs of anemia in the 24 hours postpartum were significantly less frequent among Study group than among control group.

No cases of retained placenta, postpartum hemorrhage, need for manual removal of the placenta, need for uterine curettage, need for uterotonics or significant pain during the third stage of labor were observed in either study or control group; whereas n=3 (8.6%) participants were in need of blood transfusion in the control group.

4. DISCUSSION

The current study is a randomized controlled study which was conducted at Helwan University Maternity hospital at labor ward during the period between July 2019 and December 2019.

The study included 70 pregnant women attending the labor ward at Helwan University Hospital for uncomplicated vaginal delivery. Patients were randomly assigned to one of the two groups, as follows:

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• **Group A**: 35 female patients were not subjected to cord drainage after delivery of baby (Cord clamping), were used as control group.

• Group B: 35 female patients were subjected to cord drainage after delivery of baby, were used as study group.

Results of this study showed that there was no significant difference between the two groups regarding demographic data including maternal age, Gestational age, and parity.

On the other hand, the mean duration of the third stage of labor for women included in the study group was 3.1 ± 0.3 min and in the control group was 4.3 ± 0.7 min and the mean amount of blood loss in women included in the study group was 181 ± 16 ml and in the control group was 272 ± 33 ml.

This showed that duration and blood loss of the third stage of labor were significantly lower in study group than in control group.

There are different results in the literature regarding the efficacy of placental cord drainage as apart of management of the third stage of labor in reduction of duration and amount of blood loss of the third stage of labor.

Results of our study agreed with that of **Kaba et al.**⁽¹⁴⁾, who included 112 low risk pregnant women admitted for vaginal delivery. There were 53 women in the placental cord drainage group, and 59 women in the cord clamping group without drainage. The median third stage duration in the study group was 3.40 (range: 0.35-16.20) minutes, and 5.10 (range: 2.30-11.00) minutes in the control group. This difference between the groups was statistically significant (p<0.01). Their study showed Placental cord drainage reduces the third stage duration following vaginal deliveries, which certified with our study.

Results of our study also agreed with that of **Afzal et al.**⁽¹⁵⁾, who included 200 females with 100 (50%) were in Placental cord drainage group and 100 females (50%) in the cord clamping group. The mean duration of third stage of labor in placental cord drainage group was 5.67 ± 1.81 minutes and in control group it was 8.44 ± 2.50 minutes (p<0.001). The mean blood-loss in placental cord drainage group was 174.69 ± 13.69 ml compared to 196.25 ± 15.06 ml in the control group (p<0.001). This showed that there was significant reduction in blood-loss and the duration of the third stage in normal vaginal birth patients. Results of this study are consistent with our study.

Mithala et al. ⁽¹⁶⁾ concluded that Placental cord drainage could reduce blood loss and the duration of the third stage of labor. A total of 180 pregnant women admitted for vaginal delivery were included in the study and divided equally into 2 groups: Placental cord drainage group and cord clamping group. The median duration of the third stage in the study group (3 (2,4) minute) was shorter than the control group (4 (3,6) minute, p < 0.05). The median blood loss in study group (300 (250, 330) mL) was also lower than the control group (320 (300, 350) mL, p < 0.05). Results of this study are consistent with our study.

Roy et al. ⁽¹⁾ conducted a study to evaluate the effectiveness of placental blood drainage after spontaneous vaginal delivery as part of active management of third stage of labor in decreasing the duration and blood loss of the third stage, against no drainage of placental blood. Two hundred pregnant patient who underwent a spontaneous vaginal delivery, were included in the study. The patients were prospectively randomized equally into two groups (100 each in the study (Cord drainage) and control groups (Cord Clamping).

The duration of third stage of labor was 210.5 s in the study group and 302.5 s in the control group. The 'p' value was statistically significant ($p \le 0.0001$). The mean blood loss in study group was 227.5 ml and was 313.3 ml in the control group ($p \le 0.0001$). Results of this study are consistent with our study.

Asicioglu et al. ⁽¹⁷⁾ study concluded that Active management of the third stage of labor with the cord drainage method significantly reduced blood loss and the duration of the third stage. This study included 485 patients who underwent vaginal delivery in two tertiary hospital. Subjects were randomly allocated to the cord drainage group, in which the cord was unclamped after cutting (n = 242), or the control group, in which the cord was left clamped (n = 243). The mean estimated blood loss was significantly lower in the cord drainage group than in the control group (207.04 ± 123.3 vs. 277.63 ± 246.9 mL, respectively: p < 0.001). The third stage of labor was significantly shorter in the cord drainage group than in the control group (3.5 ± 1.9 vs. 7.7 ± 3.4 minutes, respectively; p < 0.001). Results of this study are consistent with our study.

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Shravage and Silpa ⁽¹⁸⁾ concluded that placental cord drainage reduced the amount of blood loss and duration of the third stage of labor. Their study was conducted on 200 pregnant women having vaginal delivery and randomized to cord drainage and cord clamping groups. The average duration of third stage was 5 minutes in the study group and 7.4 minutes in the control group. The average third stage blood loss was 175 ml in the study group and 252 ml in the control group. These differences were statistically significant (P< 0.001). Results of this study are consistent with our study.

In another study by **Gulati et al.**⁽¹⁹⁾, Two hundred pregnant women undergoing vaginal delivery were studied to evaluate placental blood drainage as a method of shortening the duration of third stage and reducing amount of blood loss of third stage. The duration of the third stage was 5.72 minutes in the control group and 2.94 minutes in the study group. The amount of the blood loss in 3^{rd} stage was 247.59 ml in the control group and 193.63 ml in the study group. Results of this study are consistent with our study.

In contrast to our study, **Vasconcelos et al.** ⁽²⁰⁾ study showed that Placental cord drainage had no effect in reducing duration or blood loss during the third stage of labor. This study included 226 low-risk pregnant women undergoing vaginal delivery, 113 randomized to placental cord drainage and 113 to a control group not submitted to this procedure. Duration of the third stage of labor did not differ between the two groups (14.2 \pm 12.9 versus 13.7 \pm 12.1 minutes, p = 0.66). Likewise, there was no significant difference in mean blood loss (248 \pm 254 versus 208 \pm 187ml, p = 0.39). Results of this study are inconsistent with our study.

In our study, there was no significant difference between the study and control groups regarding predelivery Hemoglobin and Hematocrit value. The mean post-delivery drop in hemoglobin was 1.46 ± 0.3 gm/dl in the control group, while it was 0.85 ± 0.22 gm/dl in the study group. The mean drop in hematocrit value was 3.40 ± 1.67 % in the control group and 1.96 ± 0.60 % in the study group.

These results show that Drop in hemoglobin and hematocrit value was significantly less in study group than in control group.

These results agreed with **Roy et al.**⁽¹⁾ study that showed that the mean drop in Hb % level was 0.6 gm/dl in study group and 1.1 gm/dl in control group. These above differences were both statistically significant.

In our study, all procedures were successfully completed without severe complications or serious adverse reactions. No cases of retained placenta, postpartum haemorrhage, need for manual removal of the placenta, need for uterine curettage, need for uterotonics or significant pain during the third stage of labor were observed in either the study group or control group, whereas n=3 (8.6%) participants needed blood transfusion in the control group. Symptoms and signs of anaemia in the 24 hours postpartum was 37.1% in the control group and 8.6% in the study group. This shows that Symptoms and signs of anemia in the 24 hours postpartum were significantly less frequent among study group than among control group.

Like our study, **Asicioglu et al.**⁽¹⁷⁾ reported no adverse events occurring during the cord drainage period.

Our study also agreed with **Shravage and Silpa**⁽¹⁸⁾ who found that there were no cases of retained placenta, but they found that incidence of postpartum haemorrhage was 3% in the study group and 10% in the control group.

Unlike our study, **Gulati et al.**⁽¹⁹⁾ reported that retained placenta was observed in 4% in control group and 0% in the study group and the incidence of post-partum haemorrhage was 12% in control group and 6% in the study group.

 \succ We should state that the relative rarity of adverse events in our study may indicate the need for a larger study population to enable a meaningful comparison.

One of the major strength points in our study is: -

-It is a Prospective randomized Controlled trial study.

- Comparison of the outcomes of the study in the presence of control group.

-Randomization and allocation were done immediately after the delivery of the baby, there were no dropouts from this study (n started= n completed).

-This trial was non-invasive, with least chance of adverse effects.



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Limitations in this study: -

 \triangleright No adverse events were reported among the 70 patients during the drainage period. The relative rarity of adverse events may indicate the need for a larger study population to enable a meaningful comparison.

Despite of the sample size calculation that stated that 35 women in each group would achieve a power of 95%; however, the absence of abnormal outcomes limited the significance of the results of that outcome.

> Effects of placental cord drainage in different circumstances are needed.

5. CONCLUSION

Our study demonstrated that Placental cord drainage reduces the duration and amount of blood loss of the third stage of labor when compared with Cord clamping method because it is easy, simple, and non-invasive procedure. These advantages lend support to the use of Placental Cord Drainage as a form of active management during the third stage of labor.

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