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Active management of the third stage of labor (AMTSL) without controlled cord traction at Nongkai Hospital

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Objective : *To compare simplified active management of the third stage of labor (AMTSL) package with the full AMTSL package in the active management of the third stage of labor with respect to the amount of bleeding.*

Design : *Randomized controlled trial.*

Setting : *Nongkai Hospital.*

Materials and Methods : *Two hundred women with imminent vaginal delivery were randomized into two groups, namely: the study and control groups in the study group, simplified package of the third-stage-labor management [oxytocin injection, cord clamping, uterine message, without controlled cord traction (CCT)] were performed. In the control group, full package of the third-stage-management (oxytocin injection, cord clamping, controlled cord traction and uterine message) were performed. The primary outcome measure was blood loss during the third stage of labor. The duration of the third stage of labor, blood transfusion, the use of additional oxytocin to treat PPH, blood loss of 500 ml or more, incidence of retained placenta, manual removal of the placenta, additional surgical procedures (e.g. hysterectomy, ligation of blood vessels), incidence of uterine inversion were compared.*

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Results : *In 200 cases with vaginal delivery, 100 cases were assigned to the study group, and the rest 100 cases were assigned to the control group. The mean blood loss in the study group [without controlled cord traction (CCT)] and the control group (full AMTSL package) were 354.12 ml and 335.25 ml, respectively. The mean blood loss was 18.87 ml lower in the control group (full AMTSL package) than in the study group (without CCT): however, this difference was not statistically significant (P = 0.12). The duration of the third stage of labor in the control group (full AMTSL package) was statistically significantly less than the study group (without CCT) (6.85 ± 5.91 vs. 9.21 ± 3.64: P = 0.001). The incidence of postpartum hemorrhage, blood transfusion, the use of additional oxytocin to treat postpartum hemorrhage (PPH), retained placenta, manual removal of the placenta were lower in the control group (full AMTSL package) but there was not statistical difference. There was no additional surgical procedures (e.g. hysterectomy, ligation of vessels), incidence of uterine inversion in both groups.*

Conclusions : *Blood loss in third stage of labor in the simplified AMTSL package was higher than in the full AMTSL package, but without statistically significance. The present findings support a larger clinical trial to determine whether the simplified AMTSL package may not increase the risk of PPH and it may, therefore, be recommended for the peripheral levels of the health care system.*

Keywords : *Active management of third stage of labor (AMTSL), postpartum hemorrhage (PPH).*

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สุวิทย์ เด่นศิริอักษร. การดูแลเชิงรุกในระยะที่สามของการคลอดแบบไม่ดึงสายสะดือใน โรงพยาบาลหนองคาย. จุฬาลงกรณ์เวชสาร 2553 พ.ย. – ธ.ค.; 54(6): 581 – 91

วัตถุประสงค์ : *เพื่อศึกษาเปรียบเทียบการดูแลเชิงรุกในระยะที่สามของการคลอดแบบไม่ดึงสายสะดือกับการดูแลเชิงรุกในระยะที่สามของการคลอดแบบเต็มที่ โดยเปรียบเทียบปริมาณเลือดที่สูญเสียในระยะที่สามของการคลอด ในสตรีตั้งครรภ์*

วัสดุและวิธีการ : *เป็นการศึกษาแบบการทดลอง ณ.กลุ่มงานสูตินรีเวชกรรมโรงพยาบาลหนองคาย ระหว่างเดือน เมษายน ถึง มิถุนายน พ.ศ. 2553 ประกอบด้วย สตรีตั้งครรภ์เจ็บครรภ์คลอดที่คลอดทางช่องคลอดในโรงพยาบาลหนองคาย จำนวน 200 คน แบ่งออกเป็น 2 กลุ่ม กลุ่มละ 100 คน โดยการสุ่มกลุ่มศึกษาประกอบด้วยสตรีตั้งครรภ์จำนวน 100 ราย ทำการคลอดรกโดยการดูแลเชิงรุกในระยะที่สามของการคลอดแบบง่าย ประกอบด้วย ฉีดอ็อกซิโตซิน หนีบสายสะดือ ไม่ดึงสายสะดือและคลึงมดลูก กลุ่มควบคุมประกอบด้วยสตรีตั้งครรภ์จำนวน 100 ราย คลอดรกโดยการดูแลเชิงรุกในระยะที่สามของการคลอดแบบเต็มที่ ประกอบด้วย ฉีดอ็อกซิโตซิน หนีบสายสะดือ ดึงสายสะดือแบบควบคุม โดยเปรียบเทียบปริมาณเลือดที่สูญเสียในระยะที่สามของการคลอด ระยะเวลาของระยะที่สามของการคลอด การให้เลือด การให้อ็อกซิโตซินเพิ่มเติมเพื่อรักษาการตกเลือดหลังคลอด การเสียเลือดมากกว่า 500 มิลลิลิตร ภาวะรกค้าง การล้วงรก การผ่าตัดหลังคลอด ภาวะการปลิ้นของมดลูก*

ผลการศึกษา : *สตรีตั้งครรภ์คลอดทางช่องคลอดจำนวน 200 คน แบ่งเป็นกลุ่มศึกษาและกลุ่มควบคุมกลุ่มละ 100 คน ปริมาณเลือดที่เสียในระยะที่สามของการคลอดในกลุ่มศึกษา (ดูแลเชิงรุกในระยะที่สามของการคลอดแบบไม่ดึงสายสะดือ) และกลุ่มควบคุม (ดูแลเชิงรุกในระยะที่สามของการคลอดแบบเต็มที่) เท่ากับ 354.12 มิลลิลิตร และ 335.25 มิลลิลิตรตามลำดับ ปริมาณเลือดที่เสียในกลุ่มควบคุมมีค่าน้อยกว่ากลุ่มศึกษาแต่ไม่มีนัยสำคัญทางสถิติ (P=0.12) ระยะเวลาของระยะที่สามของการคลอดในกลุ่มควบคุมมีค่าน้อยกว่ากลุ่มศึกษาอย่างมีนัยสำคัญทางสถิติ (6.85 ± 5.91 vs 9.21 ± 3.64 P=0.001) ภาวะตกเลือดหลังคลอด การให้เลือด การให้อ็อกซิโตซินเพิ่มเติมเพื่อรักษาการตกเลือดหลังคลอด ภาวะรกค้าง การล้วงรก ในกลุ่มควบคุมพบอุบัติการณ์น้อยกว่ากลุ่มศึกษา แต่ไม่มีนัยสำคัญทางสถิติ ไม่พบอุบัติการณ์การผ่าตัดหลังคลอด ภาวะการปลิ้นของมดลูก ในการศึกษาครั้งนี้*

สรุป : *ปริมาณเลือดที่เสียในระยะที่สามของการคลอดในกลุ่มศึกษา (ดูแลเชิงรุกในระยะที่สามของการคลอดแบบไม่ดึงสายสะดือ) มีค่ามากกว่ากลุ่มควบคุม (ดูแลเชิงรุกในระยะที่สามของการคลอดแบบเต็มที่) แต่ไม่มีนัยสำคัญทางสถิติ การศึกษาครั้งนี้มีประโยชน์เพื่อนำไปทำการศึกษาเปรียบเทียบ การดูแลเชิงรุกในระยะที่สามของการคลอดแบบไม่ดึงสายสะดือ ไม่เพิ่มอุบัติการณ์ตกเลือดหลังคลอด และอาจนำไปใช้กับเจ้าหน้าที่สาธารณสุขที่อยู่ห่างไกลได้*

คำสำคัญ : *การดูแลเชิงรุกในระยะที่สามของการคลอด, การตกเลือดหลังคลอด.*

The third stage of labor refers to the period following the completed delivery of the newborn until the completed delivery of the placenta. Herein, certain degree of blood loss occurs in this stage due to the separation of the placenta from the uterine wall. This period is, therefore, risky because the uterus may not contract well after birth and heavy blood loss can endanger the life of the mother. Although serious complications may occur in this period, the third stages of labor is usually uneventful. The most common serious complication in this period is postpartum hemorrhage (PPH). While maternal mortality rates have declined dramatically in the developed world, PPH remains a leading cause of maternal mortality. The World Health Organization (WHO) statistics suggest that 25% of maternal deaths are due to PPH, accounting for more than 100,000 maternal deaths per year. [1,2] At Nongkai Hospital the incidence of PPH was 3.46%.

The third stage of labor is managed differently around the world. One intervention that has been promoted as effective in the prevention of PPH is the active management of the third stage of labor (AMTSL). AMTSL has been defined in various ways and the current international definition comprises three components, namely: administration of uterotonic drug immediately after the delivery of the baby; controlled cord traction; and uterine massage after the delivery of the placenta. [1,3] The primary aim of the active management is to reduce postpartum blood loss as a preventive intervention. In contrast to the active management, expectant management involves waiting for the signs of separation and allowing the placenta to be delivered spontaneously, or aided by the gravity or nipple stimulation. The expectant management is also known as conservative or physiological management. [4] Accordingly, AMTSL reduces the occurrence of severe postpartum hemorrhage by approximately 60 – 70%. [4] A Cochrane review of comparing active versus expectant management of the third stage of labor found that AMTSL was associated with reduced risks of the following: maternal blood loss during the postpartum period of more than 500 ml, severe PPH, and need for blood transfusion during the puerperium. [5] Despite the overall beneficial effects of AMTSL, it is important to assess the effects of its individual components in order to use the simplest, most effective, and safest intervention.

Cord traction was introduced into the obstetric practice by Brandt (1933) and Andrews (1940) known as the so-called Brandt-Andrews maneuver. The aim is to facilitate the delivery of a placenta that is already separated. In 1962 the term “controlled cord traction” (CCT) was introduced which was aimsed to facilitate the separation of the placenta once the uterus contracts. [6] In performing CCT placental separation is not waited and once the uterus contracts the CCT is initiated. The third stage is usually completed in less than 10 minutes when CCT is used. [6] Cord traction is applied during the active management only when counter traction is applied. Counter traction is performed by trapping the body of the uterus above the symphysis pubis and directing it cephalad and then backward. Traction is applied in a continuous, downward manner only when the uterus is well contracted. There is concern raised by clinicians that traction on the cord prior to placental separation may lead to maternal complications such as separation of the cord from the placenta and uterine inversion. [7]

There is little direct evidence for or against the effects of CCT in isolation. [8] CCT requires training to acquire this manual skill. Evaluation of CCT component is important because if it does not add any beneficial effects it can be dropped out from the AMTSL package with important programmatic implications.

The presence of a skilled birth attendant is essential for childbirth. Birth attendants are required, not only for basic care during the first and second stage of labor but also in the third stage when hemorrhage risk is the greatest and also for the immediate care of the newborn. In the out-of-hospital setting, the availability of healthcare personnel with skills to implement the full AMTSL package may be more difficult to ensure. Therefore, evaluation whether a simplified package without CCT is non-inferior to the full AMTSL package has both the clinical and public health importance.

This study is aimed to identify the relative effect of CCT which required manual skill training in the third stage of labor. Evaluation of CCT component is important because if it does not add any beneficial effect, and therefore it may be dropped out from the AMTSL package. It would greatly reduce programmed costs associated with training, and enable the intervention to be used by lower levels of healthcare providers, especially in the peripheral levels of the health care system.

Material and Method

The women aged 18 years or older with single term pregnancy, and no indication of cesarean delivery and no contraindication to prophylactic oxytocin who were admitted to the labor room, Nongkai Hospital, from April to June 2510 and met the study criteria were recruited. The women will be approached early labor for consent for participation except those who are under the following circumstances: advanced first stage of labor (> 6 cm cervical dilatation), severe acute complications (e.g. pre-eclampsia and hemorrhage) that were present during labor which requires emergency actions.

The women who received AMTSL regardless of whether they are of high or lowrisk for hemorrhage. The subjects were randomized, either into the study group or the control group according to the code kept in a sealed envelope. The envelope was opened during second stage when vaginal delivery is imminent. For all subjects, the time of birth was recorded and then the cord was clamped and cut immediately after birth.

Sample size calculations:

The sample size was calculated by the formula

$$Nt = (Z_\alpha + Z_\beta)^2 \sigma^2 (r+1) / (\mu t - \mu c)^2 r$$

The sample size was calculated on the basis of a previous study that the median blood loss in the full AMTSL package group and the simplified AMTSL package group (without CCT) was 282.0 ml and 310.2 ml, respectively(standard deviation 60ml). [9] We estimated that the sample size of which at least 71 patients would be required in each group.

Interventions

Experimental armed: simplified package (without CCT)

The simplified package will include:

• Uterotonic

Oxytocin 10 IU IM. Oxytocin will be administered as soon as possible after birth preferably within one minute. If the woman has an IV line oxytocin can be administered through the IV line by slow injection.

• Cord clamping

The cord will be clamped following observation of a uterine contraction either manually or visually. For practical purposes, it is estimated to be around 1–3 minutes. It is recommended to clamp the cord close to the perineum.

• Placental delivery

Cord traction is omitted. Placenta should be delivered passively by aid of gravity and maternal effort. The caregiver should observe the placental separation and as the placenta delivers it should be held in two hands and gently turned so that the membranes do not tear off.

• Uterine massage

No uterine massage is recommended before placental delivery. After placental delivery the uterus will be rubbed and any clots expressed. For a period of two hours the uterus will be massaged gently until it contracts. This procedure will be repeated every 15 minutes.

Standard intervention arm: Full AMTSL package (with CCT)

The full package includes:

• Uterotonic

Oxytocin 10 IU is administered IM. Oxytocin will be administered as soon as possible after birth preferably within one minute. If a woman has an IV line oxytocin can be administered through the IV line by slow injection.

• Cord clamping

Cord will be clamped following observation of a uterine contraction either manually or visually. For practical purposes this is estimated to be around 1–3 minutes. It is recommended to clamp the cord close to the perineum.

• Placental delivery

Placenta will be delivered by controlled cord traction immediately after cord clamping and cutting. The cord will be gently pulled while applying counter traction to the uterus with the other hand. As the placenta delivers it should be held in two hands and gently turned so that the membranes do not tear off.

• Uterine massage

No uterine massage is recommended before placental delivery. After placental delivery the uterus will be rubbed and any clots expressed. For a period of two hours the uterus will be massaged gently until it contracts and this procedure will be repeated every 15 minutes.

The two intervention packages will differ only in placental delivery technique. If the umbilical cord has been clamped early because of newborn indication cord traction should be applied only after the uterus has contracted as above. The primary outcome was blood loss during the third stage of labor. Secondary outcomes were the rates of PPH e" 500mL and e" 1000mL, the duration of the third stage of labor, and the use of additional oxytocin. Need of blood transfusion, manual removal of the placenta, uterine curettage, and/ or other therapeutic maneuvers were also assessed.

Blood loss was collected in bowl by firmly pressing the bowl against the perineum after the delivery of the baby. Soaked gauges, pads and blood were weighed. The weight in grams was converted to

milliliters by dividing the weight in grams by 1.06 (blood density in grams per milliliter). [10]

Side effects will be recorded. Any side effect requiring treatment will be regarded as an adverse event and a separate form will be filled.

A retained placenta was diagnosed if the time of third stage was more than 30 minutes, and the placenta was delivered by manual removal.

Postpartum hemorrhage was defined as the clinically estimated blood loss over 500 ml in the labor room or in the obstetric ward.

Statistical analysis was performed with SPSS version 16 for Windows XP (SPSS, Chicago, USA). Unpaired t-test was analyzed for continuous variables, Chi-square or Fisher exact test for categorical variables. Results were expressed as number, percentage and relative risk (RR) including the corresponding 95% confidence interval. The descriptive data were shown in mean ± SD. A p-value of <0.05 was considered statistically significant.

This study was approved by the Ethical Committee of the Nongkai Hospital.

Results

During the 3-month period, from the 236 eligible women in early labor who were invited to participate, 36 were excluded. Two hundred women were recruited and randomized, 100 women were in the study group, and 100 women were in the control group. There were no statistical significant differences between the study and the control group regarding maternal age, weight, height, gestational age, parity, and pre delivery hematocrit, as shown in Table 1.

There were no significant differences in birth weight, and placental weight. Mean duration of third stage labor was significantly shorter in the control group (full AMTS package) compared to the study group (simplified AMTSL package) (6.85 ± 5.91 vs. 9.21 ± 3.64: p value = 0.001) (Table 2).

Table 1. Maternal demographic data.

	Study groups	Control groups	p-value
Age (year)	25.94 ± 5.9	26.16 ± 5.85	0.792
Age >35 (n)	9	10	0.81
Body weight (kg)	63.83 ± 8.32	64.27 ± 8.97	0.791
Height (cm)	156.62 ± 6.47	157.46 ± 5.76	0.334
Gestational age (week)	38.9 ± 1.2	38.76 ± 2.06	0.558
Primigravida (%)	40	45	0.474
Mulliparous : more than 4(%)	6	9	0.421
Hct :pre delivery (vol%)	36.24 ± 2.98	35.22 ± 2.91	0.15

Data were represented as mean ± SD.

Statistical significance ($p < 0.05$)

Table 2. Labor and delivery characteristics.

Labor and delivery characteristics	Study group	Control group	p-value
Duration of 3rd stage labor (min)	9.21 ± 3.64	6.85 ± 5.91	0.001
Birth weight (gram)	3061.5 ± 400.32	3057.5 ± 393.37	0.943
Placental weight (gram)	505.9 ± 66.17	502.42 ± 67.07	0.713

Data were represented as mean ± SD

Statistical significance ($p < 0.05$)

Mean blood loss in the study group (simplified AMTSL package) and the control group (full AMTS package) was 354 ml. and 335 ml., respectively. Mean blood loss was 18.87 ml. lower in control group (full AMTS package) than in the study group (simplified AMTSL), although this difference was not statistically significant (P = 0.12).The overall incidences of PPH in the study group (simplified AMTSL package) and in the control group (full AMTS package) was 7 % and 5% respectively, but there was no statistical significance. The incidence of PPH ≥ 500 mL and PPH ≥ 1000 ml was 20% and 50% lower, respectively, in control group (full AMTS package), although this reduction was not statistically significant. (Table 3)

The incidence of retained placenta was lower in the control group (full AMTS package) than in the study group (simplified AMTSL package) 1% vs. 2% but no statically significantly. More patients in the study group required blood transfusion (simplified AMTSL package. n = 3: and full AMTS package. n = 2), and more patients in the study group (simplified AMTSL package) required additional uterotonic drug to control blood loss (5 vs. 3). However, the results of need for blood transfusion and required additional uterotonic drug did not reach statistical significance.

Table 3. Blood loss, PPH and complications in the third stage of labor.

Blood loss / Perinatal complications	Study group	Control group	P-value	RR (95%CI)
Primary outcomes				
Blood loss at one hour mean ฑ SD, ml	354.12 ± 90.85	335.25 ± 77.78	0.120	
Secondary outcomes				
PPH	7	5	0.55	1.192 (0.39 - 3.67)
- Blood loss e" 500 mL	5	4	1.0	
- Blood loss e"1000 mL	2	1	1.0	
Blood transfusion	3	2	0.65	1.52 (0.25 - 9.27)
The use of additional uterotonics (%)	5	3	0.47	1.70 (0.39 - 7.32)
Third stage longer than 30 min	2	1	0.56	2.02 (0.18 - 22.65)
Manual removal of placenta	2	1	0.56	2.02 (0.18 - 22.65)
Additional surgical procedures	0	0		
Uterine inversion: n (%)	0	0		

In the control group, one case required manual removal of the placenta because the third stage was prolonged. Two cases in study group required manual removal of the placenta. No additional surgical procedures and uterine inversions were observed. Blood lossed, PPH and complications of the third stage of labor are presented in Table 3.

Discussion

The primary objective is to determine whether the simplified AMTSL package (without CCT), is no less effective than the full AMTSL package (with CCT) with regard to blood loss in the third stage of labor. This study found that the mean blood loss in the study group (simplified AMTSL package) was higher than the control group(full AMTSL package) 354 ml and 335 ml, respectively. but this is not statistically significant. The duration of the 3rd stage of labor was significantly shorter in the control group. However, the duration in both groups was not longer than 30 minutes; it is not clinically significant.

Regarding the safety of the simplified AMTSL package (without CCT) in the active management of the third stage of labor, the data from the present study revealed that no statistically difference in the complications of the third stage of labor (PPH, retained placenta, additional surgical procedures, uterine inversion) in both groups.

Visual estimates of blood loss ranged from 30 to 50% of actual losses. [11–13] Of great importance, this inaccuracy increases with increasing blood loss. [12] Underestimation may delay or deter diagnosis of postpartum hemorrhage. In this study blood loss was measured in an objective and accurate measurement. This procedure may be the explanation for the higher incidence of PPH in this study than a previous report from our hospital (6 - 7% vs. 3.4%)

Overall, the presented data show that the simplified AMTSL package (without CCT) does not increase postpartum complication. No implications for practice can be concluded from the present study, but several recommendations for research can be made. The findings support conducting a larger trial to determine adequately whether simplified AMTSL package (without CCT) can be recommended with the advantage of not requiring training to acquire the manual skill to perform this task.By avoiding the need for a manual procedure that requires training, the practice is also feasible and useful in preventing PPH at the most peripheral levels of the health care system.

Conclusions

Blood loss in the third stage of labor in the simplified AMTSL package was higher than in the full AMTSL package, but this is no statistical significance. The present findings support conducting a large trial to determine whether the simplified AMTSL package may not increase risk of PPH and may be recommended for the peripheral levels of the healthcare system.

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