**Impact of "Natural" cesarean delivery on peripartum blood loss. A randomized controlled trial**

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**Abstract**

**Objective:** Early skin to skin contact (ESTSC) after vaginal delivery increases milk production, lactation, and may increase oxytocin release, leading to reduction in postpartum hemorrhage (PPH) rate. The present trial aims to examine the impact of "natural" cesarean deliveries (NCD) on peripartum maternal blood loss.

**Study Design:** Randomized controlled trial conducted at a single hospital between August 2016 and February 2018. The laboratory component was completed in February 2019. Term singletons gestations, scheduled for a planned CD under spinal anesthesia were included. Women were randomized at a ratio of 1:1 to NCD (study group) or traditional CD (control group). Women in the NCD group were able to watch fetal extraction through the abdominal incision, ESTSC immediately after cord clamping, and breastfeed until the end of surgery. Neonates in the control group were presented to the mother for few minutes. Breastfeeding was not offered. Blood sample was drawn from all women during fascia closure and was subsequently analyzed for determining oxytocin levels using an Elisa kit (IBL international GmbH:RE52331. Flughafenstrasse 52a, D-22335 Hamburg, Germany). The primary outcome was postpartum hemoglobin (Hb) levels. In order to detect a difference of 0.5 g/dl between the groups with α=0.05 and β=80%, 214 women in both groups were needed.

**Results:** Of all 214 women who gave consent and randomized, 23 were excluded from the final analysis. There were no significant differences in demographic and obstetric variables between the groups. Postpartum Hb levels were 10.1±1.1 and 10.3±1.3 in the study and control groups respectively (p=0.19). There were no significant differences in estimated blood loss, blood transfusion or need for additional uterotonics. Pain scores and analgesia use was comparable. The maternal satisfaction score was similar as well (p=0.68). Exclusive breastfeeding rate at discharge did not differ between the two groups (p=0.39). Maternal oxytocin blood levels were 389.5 ±183.7 and 408.5±233.6 pg/mL in the NCD and SCD groups respectively (p=0.96). Every single neonatal outcome examined was similar between the groups.

**Conclusion:**  NCD does not affect maternal blood loss. Maternal oxytocin blood levels in NCD and traditional CD are similar.

Clinical Trial Registration: clinicaltrials.gov Identifier: NCT02768142

**Background**

Early skin to skin contact (ESTSC) after vaginal delivery increases milk production, lactation, and may improve outcomes.1-3 Studies published as early as the 1970s showed a change in maternal and neonatal behavior after ESTSC.1 Mothers practicing ESTSC and suckling, breastfeed their infants longer than did routine care mothers.2 A Cochrane meta-analysis concluded that ESTSC promotes breastfeeding, though other conclusions were challenging due to methodological quality and small sample size of the trials.3

Breastfeeding, nipple stimulation, and ESTSC increases oxytocin levels post-partum.4-8 Therefore, ESTSC is expected to reduce the incidence of postpartum hemorrhage (PPH).9 A retrospective study found that women who did not have ESTSC were almost twice as likely to have PPH compared to women who had both ESTSC and breastfeeding within 30 minutes of birth.10

Although the delivery goal for many women is to experience a vaginal birth, a cesarean delivery (CD) is sometimes mandatory due to medical maternal or fetal indications. Recent attention has focused on the description and putting into practice techniques in the operating ward to incorporate ESTSC and breastfeeding. The first approach of modifying the CD was described in 2008 by Smith et al. and was termed the ''natural CD" (NCD).11 One of the main aspects was to mimic the situation of vaginal birth and to give parents a better birthing experience (Family-Centered CD).

Nevertheless, there is a lack of adequate methodological studies on the impact of CD incorporating ESTSC and breastfeeding, i.e., NCD, and maternal outcomes.11

The present trial aims to examine the effect of NCD on peripartum blood loss compared to traditional CD. Additionally, to examine the impact on women's satisfaction, exclusive breastfeeding, and other maternal and neonatal outcomes.

**Methods**

This randomized controlled trial was conducted in the labor and delivery ward of a single university teaching hospital in Afula, Israel. The clinical trial was conducted between August 2016 and February 2018, while the laboratory component was completed in February 2019. The local institutional review board approved the study protocol (registration number 0137-15-EMC). Clinical Trial Registration: clinicaltrials.gov Identifier: NCT02768142.

Pregnant women scheduled to planned CD at our institution were given the option to participate in the trial. Eligible women were randomly assigned in a 1:1 ratio to NCD (study group) or traditional CD (control group). The inclusion criteria of both groups included maternal or fetal indication for CD, planned CD under spinal anesthesia at term, maternal age between 18-45 years, viable fetus, and confirmed dating by last menstrual period and first or early second-trimester ultrasound. Women with unplanned CD had multifetal gestation, major fetal malformations, fetal conditions requiring immediate neonatologist evaluation estimated fetal weight below the 5th percentile, non-controlled diabetes mellitus, severe pre-eclampsia, human immune deficiency virus carriers and women unable to give inform consent were excluded. Women were excluded from the analysis after recruitment if they had failed spinal anesthesia requiring general anesthesia, or their newborns needed immediate medical care after delivery.

In the study group only, the intravenous line was inserted in the non-dominant hand. In the operating room, the blood pressure cuff was placed on the non-dominant side as well or on the leg. The pulse oximeter was placed on the toe. Woman’s arms were not tied down, and at least one arm was free from clothing. The ECG stickers were placed on the mother's back, leaving the chest free. The drape, separating the surgical field, was placed closer to the abdomen, in a way that allows smooth lowering down and creating a relatively large free chest area. At head delivery, the surgical drape was lowered in women electing to watch the slowly ‘‘walk’’ of the baby out. The scrubbed midwife received the neonate from the surgeon and directly put on the naked skin of the mother's breast to initiate ESTSC and encourage suckling. The neonate was covered with a warm blanket. At this stage, the surgical drapes were lifted up again before removing the placenta. Usual neonatal care, such as assigning Apgar score and placing a name tag, was done during ESTSC. Weighing the neonate was postponed until ESTSC was terminated. The midwife remained alongside the mother, constantly, as long as the neonate was on the mother's chest.

ESTSC was terminated on maternal request, or any compromise in maternal or neonatal wellbeing, mandating medical care, or at the end of the surgical procedure.

Women in the control group, i.e., traditional CD, were not offered to watch extraction and did not breastfeed during surgery. After the midwife received the neonate and assessed the need for medical care, she dried, weighed, name tagged, and covered the neonate. Following that, the neonate was held adjacent to its mother, allowing her to see it, or was given to be held by the escort for a few minutes and then was transferred to the nursery unit.

In both groups, complete blood count (CBC) was taken on admission as part of surgical preparation. Antibiotic prophylaxis before skin incision was given to all participants prior to surgical incision. Both groups were allowed an escort of her choice in the surgery suite, after confirmation of adequate spinal analgesia. Delayed cord clamping for nearly 60 seconds was made similar. Uterotonic medications to prevent PPH were given according to the department protocol. Following the delivery of the neonate, five units oxytocin was given in a slow intravenous push followed by 20 units in a 1000mL Lactated Ringer’s solution as the standard regimen. Higher doses of oxytocin or the use of other uterotonic medications were considered if needed to treat uterine atony. Other surgical techniques were identical between the two groups. Perioperative analgesics or sedatives were given according to the anesthesiologist's discretion.

Maternal oxytocin levels were examined in both groups to attain much more reliable evidence of the impact of ESTSC and lactation on oxytocin release. For that purpose, blood samples were obtained from all women during fascia closure and were subsequently analyzed in a designative laboratory for determining oxytocin levels among the groups using an Elisa kit (IBL International GmbH: RE52331. Flughafenstrasse 52a, D-22335 Hamburg, Germany). Blood samples were drawn into chilled serum or EDTA (1mg/mL blood) tubes containing Aprotinin (500 KIU/mL of blood) and were centrifuged within 10 minutes at 1,600 x g for 15 minutes at 4°C. The serum of all participants was stored in a plastic tube at -70°C, until kit application after completion of the clinical trial. Oxytocin extraction from an equal volume (500µl) of serum spiked with 100pg of oxytocin across all samples and was carried out with a standard protocol using the C18 Sep-Pak column, according to the manufacturer's instructions. An oxytocin standard curve was provided in the ELISA kit with a limit of detection of 15 pg/mL.

Post-operative pain relief medication during hospitalization was given according to a department protocol. Post-operative pain score was measured according to visual analog scale (VAS) from 0 to 10 cm where “no pain” scores 0 and the “worst pain” scores 10.

Post-operative routine CBC was drawn within 24 hours after surgery. Additional CBC was taken 2 to 3 days after delivery. Other blood tests were drawn according to clinical judgment. Prior to discharge women were asked to complete a self-reporting satisfaction questionnaire related to their childbirth experience. A satisfaction questionnaire that was previously validated for use in clinical trial, was used.12 The questionnaire contains 38 questions and each answer scores on a scale of 1 to 6 (1 least satisfied and 6 most satisfied). An average score was made rather than the total score since a number of women did not answers all questions as they assume that they were not relevant.

Neonates in both groups were assessed at the nursery on admission, including measurement of temperature and glucose level as indicated.

**The primary outcome**

ESTSC after vaginal delivery increases milk production, lactation, and may improve outcomes. Additionally, oxytocin release, responsible for early PPH reduction, has been reported to increase following ESSC.4-8 Accordingly, the primary outcome examined was the level of postpartum hemoglobin (Hb) at 2 to 3 days after delivery.

Secondary outcomes included the need for additional perioperative uterotonics use, need for blood transfusion, maternal pain scores, need for additional analgesia or sedatives during and in the immediate post-operative period, maternal infections until discharge, exclusive breastfeeding at discharge, maternal satisfaction, and maternal oxytocin levels. Neonatal outcomes included Apgar scores and a composite outcome that comprised neonatal hypothermia, hypoglycemia, jaundice and NICU admission

**Sample size**

Power analysis was based on Hb level after CD. We examined Hb levels of 150 women who underwent planned CD during the year before study initiation. We found that the average Hb level was 10.4 ± 1.3 gr/dL. In order to detect 0.5 gr/dL difference in favor of women undergoing NCD, 214 women (107 women in each group) were needed with a level of signiﬁcance of 95% (a = 0.05) and a power of 80% (b = 0.2). The analysis was performed according to the intention-to-treat principle.

**Randomization**

Computer randomization sequence generation was used to produce the randomization. Eligible women who signed informed consent were randomly assigned in a 1:1 ratio for one of the two groups. The randomization sequence was kept in a sealed envelope, and the sequence was concealed until intervention was assigned. Women were allocated to randomization code numbers in chronological order. Due to the nature of the intervention, women and the dedicated staff were not blinded to group allocation. The data analysis individuals were unaware of the group assignments.

**Statistical analysis**

A series of  tests or Fisher's exact tests (when the assumptions of the parametric test hadn’t met), and Student's t test or nonparametric Mann–Whitney U tests (in the case where the underlying distribution is not normal) were conducted to analyze the differences between women characteristics in both groups. We computed the 2-tailed P values, where *P* < 0.05 was considered a statistically significant result. Statistical analyses were performed using the SAS software package version 9.4 (SAS Institute, Cary NC).

Oxytocin levels were calculated using a four-parameter logistic curve-fitting model (Excel, Microsoft), and results were compared using a two-tailed student t-test.

**Results**

During the study period, 7240 deliveries took place; of those 1286 were cesarean deliveries (17.7%). Of all CDs, 625 were planned (48.6%). Of all planned CDs, 214 eligible women gave consent and randomized. Of all randomized women, 23 (10.7%) women were excluded from the final analysis: 6 (3 in the study and 3 in the control group) had general anesthesia due to failed spinal, 6 (3 in the study and 3 in the control group) underwent emergent CD within 24 hours before the scheduled CD, 11 withdrew consent (10 and 1 in the study and control groups respectively), (Figure 1). Among the study group, all had ESTSC. Forty-two (41.2%) women succeeded to breastfeed during the entire period of ESTSC. Twenty-six (25.5%) elected to watch extraction. None of the controls had ESTSC or breastfeed.

Demographic and obstetric data of the study and control groups were comparable and are presented in Table 1. Postpartum Hb levels were 10.1 ± 1.1 and 10.3 ± 1.3 in the study and control groups, respectively (p=0.19). Estimated blood loss >1000mL, differences in Hb and hematocrits levels before and after the cesarean, and use of uterotonic agents, did not differ between the groups (Table 2). The length of maternal stay and rate of scar infection were also comparable between the groups. Exclusive breastfeeding rate at discharge did not differ as well between the two groups (p=0.39) (Table 2).

Pain scores were comparable between groups as well as analgesia use during operation and in the immediate post-operative period. The maternal satisfaction score was similar between the two groups (5.4 ± 0.74 and 5.4 ± 0.5 in the study and control groups, respectively (p=0.68), (Table 3).

Subgroup analysis was performed among the NCD group comparing only women who had ESTSC and, at the same time, succeeded to breastfeed during the entire surgery compared to the controls. The primary outcome, i.e., post-surgical Hb levels, was comparable between the two groups (10.26 ± 7.9 and 10.1 ± 7.6 in the study and control groups, respectively, p=0.88). There was a higher rate of exclusive breastfeeding rate at discharge (52.4% and 33.7%, in the study and control groups respectively, p=0.04). Other outcomes examined did not differ significantly between the groups.

Neonatal outcomes are presented in Table 4. None differed between the groups; nevertheless, the incidence of composite outcome that included neonatal hypothermia, hypoglycemia, jaundice, and NICU admission was higher among the NCD compared to the control (p=0.04).

Oxytocin levels were successfully determined in 182 women out of 191 (95.3%) women who were included for analysis of the primary outcome (97 and 85 in the study and control groups respectively). There were no significant differences in demographic and obstetric variables or Hb levels before or after surgery between the groups. Maternal oxytocin blood levels were 389.5 ±183.7 and 408.5±233.6 pg/mL in the study and control groups, respectively (p=0.96).

**Discussion**

The results of this randomized trial involving women designated to have a planned CD at term demonstrate that NCD leads to a similar perioperative blood loss compared to traditional CD. Perioperative Hb levels` decline, blood transfusion rate, and total perioperative uterotonics use were identical. Moreover, ESTSC and breastfeeding resulted in comparable maternal oxytocin levels, as measured via the Elisa kit, compared to traditional CD. Furthermore, maternal pain scores, need for additional analgesia or sedatives during and in the immediate post-operative period, and maternal satisfaction were all comparable. There were no adverse maternal or perioperative effects related to NCD. In terms of neonatal outcome, there was no difference in any particular outcome examined; nevertheless, the incidence of composite outcome that included hypothermia, hypoglycemia, jaundice, and NICU admission was higher among the study compared to the control groups.

Administration of artificial oxytocin in the third stage of labor has been approved in reducing the rate of PPH.13 Given that; it is reasonable to suggest that the reduction of the occurrence of PPH in cases of NCD as previously reported is related to both ESTSC and breastfeeding that stimulate endogenous oxytocin release.5,9 Accordingly, the effect is supposed to be absent or diminished with the separation of the newborn immediately after birth from the mother. Besides, the separation has been reported to create a state of distress that, in combination, may block the release of oxytocin, and atony may result.9.10 A previous study found that women who did not practice ESTSC or did not breastfeed within 30 minutes of birth were almost twice as likely to have PPH.10 Nevertheless, it is worth mentioning that the study had several limitations, including the retrospective nature that could lead to several errors. Additionally, the association found may be related to reverse causation, i.e., absent ESTSC due to PPH, as the authors stated. Moreover, the collected data was not controlled, and the ESTSC technique was not standardized.

Lack of effect of ESTSC on blood loss, shown in the present study, was also described in a randomized trial among women delivered vaginally.14 The comparable oxytocin levels found in the current study support this observation.

There is little information on pain scores and the need for analgesia or sedatives during CD combined with ESTSC. The findings of the current study showed that pain scores and the use of additional analgesia or sedatives during surgery and the immediate postpartum hours were comparable. The results are in consistent with the finding of Nolan et al.15 Others reported a decrease in the need for sedatives in women who elected to breastfeed during CD; however, this study was not controlled, and the results were compared to historical control.16

Maternal satisfaction was comparable between the study and the control group. In contrast, Armbrust et al. showed in a randomized trial that ESTSC improved maternal satisfaction and improved rate of breastfeeding.17 Nevertheless, the groups were not entirely similar since women from the ESTSC group had a significantly higher level of education, a factor that may affect satisfaction. Additionally, Baethge et al18 reported that influential conclusions could not be drawn from this study17 due to an additional number of critical errors in design and interpretation.

The impact of NCD on exclusive breastfeeding at discharge is conflicting.19 Prior study found an increase in exclusive breastfeeding rates for women undergoing a CD from 8% to 19% following initiation of ESTSC in the operating ward.20 Though in the current study, exclusive breastfeeding was comparable between the groups, both groups had higher rates at discharge (nearly 34% to 43%) compared to the cited article.

There is a paucity of literature regarding the impact of ESTSC on neonatal outcomes. ESTSC was described as a helpful tool in maintaining neonatal thermoregulation and blood glucose level after vaginal delivery21, yet hypothermia after a cesarean can occur.22 Consistent with another report,23, the results of the current study did not show a difference in any particular neonatal outcome examined, nevertheless composite of neonatal outcome that included hypothermia, hypoglycemia, jaundice, and NICU admissions was higher in cases of NCD compared to the traditional CD. Similarly, one study reported a higher rate of unplanned NICU admission after the introduction of family-centered CD from 7 to 21%.19

Following the promising publication of NCD in 2008 by smith et al.,11 the Editor commented that, no outcomes or safety data are presented to justify widespread utilization of this technique and that the technique should be adequately studied with appropriate clinical trials.24 Additionally, Newman et al., reported that the term “natural” implies a process associated with fewer adverse outcomes than the traditional technique though the practice changes suggested by Smith et al. do not reduce any of the significant adverse effects related to CD.25 To date only small sample size studies regarding safety were published,26,27 with a lack of consistency and missing data, not enabling to draw conclusions. The strengths of this study are in its randomized nature and the objective measures that were examined. Measuring oxytocin levels is a significant contribution that further strengthens the results.

Limitations of this study are worth mentioning. Other than the primary outcome, the trial was not designed to detect significant differences in secondary outcomes. Additionally, compared to multicenter studies, interventions examined in a distinct institution may be less generalizable. However, several advantages linked to a single-center trial are present. During the entire study period, the same surgical, perinatal, neonatal, and laboratory teams managed all the cases and applied the same peripartum management and oxytocin measurements technique.

In conclusion, NCD, according to the present study, does not improve maternal wellbeing or surgical results. The procedure is accompanied by higher costs, mainly due to the time-consuming of the nursing staff. Additionally, disappointment may be expressed by women and families when NCD is not available because of the shortage of nurse staffing and equipment to fulfill all maternal expectations.27 Nevertheless, efforts to change practice that might improve women's experiences for having a CD should continuously be considered in birthing wards.

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