Immediate Skin-to-Skin Contact and Breastfeeding During Caesarean Section: A Randomized Controlled Trial on Early Neonatal Hypoglycemia in Late Preterm and Term Infants

1. Introduction

Neonatal hypoglycemia is a common and serious metabolic issue in late preterm and term infants, potentially leading to severe neurodevelopmental sequelae if not promptly managed[1]. The World Health Organization strongly endorses skin-to-skin contact (SSC), recommending that the practice should begin immediately after birth by placing the naked infant on the mother's bare chest. This approach is vital for stabilizing glucose levels and supporting neonatal adaptation to extrauterine life[2].

Despite the well-documented advantages of SSC in vaginal births, such as thermal regulation, breastfeeding initiation, and bonding, implementing this practice during cesarean sections (CS) presents significant challenges[3]. These challenges primarily stem from the need to maintain a sterile surgical environment and the logistical complexities of performing SSC immediately post-surgery[4]. However, research indicates that immediate, continuous SSC within 5–10 minutes of neonatal delivery during and after CS can foster earlier breastfeeding initiation, increase breastfeeding self-efficacy and exclusive breastfeeding rates during hospitalization, and enhance maternal satisfaction[5]. Additionally, it can reduce the incidence of neonatal hypothermia and cumulative blood loss within 24 hours postpartum.

Despite the advantages noted in the literature, there is limited systematic research on the implementation of SSC during CS and its specific impact on neonatal hypoglycemia and breastfeeding outcomes[4]. This study aimed to address this gap by evaluating the effects of immediate SSC and breastfeeding during CS on early neonatal hypoglycemia in late preterm and term infants. Through a randomized controlled trial, we sought to provide robust evidence on the feasibility and benefits of integrating these practices into standard CS protocols. Our findings could inform clinical guidelines, enhance care practices for cesarean deliveries, and ultimately improve neonatal health outcomes and breastfeeding success.

2. Material and Methods

2.1 Study Design

This study will adopt a pragmatic, parallel-design, two-arm randomized controlled exploratory framework. The article's reporting will adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines[6].

2.2 Study Setting, Recruitment and Ethics

This study will be conducted at Qingdao Municipal Hospital in China between July 2022 and June 2024. The hospital is accredited as baby-friendly and adheres to the Ten Steps to Successful Breastfeeding as outlined by the Baby-Friendly Hospital Initiative (BFHI) by UNICEF and WHO[7]. A total of 344 eligible mother-neonate pairs will be recruited and allocated into the experimental group (EG) and control group (CG) at a 1:1 ratio. Written informed consent will be obtained from each participant.

2.3 Inclusion Criteria

Inclusion criteria are as follows: (a) mothers aged 18 years or older with a singleton pregnancy, gestational age between 34+1 and 41+6 weeks; (b) undergoing elective cesarean section with epidural, subarachnoid block, or combined spinal-epidural anesthesia, willing to engage in mother-infant SSC during and after the surgery, without experiencing severe reactions to anesthesia like vomiting or shivering that could affect SSC; (c) having intention to breastfeed with no major contraindications (e.g., hepatitis B, syphilis, HIV, or other infectious diseases); (d) newborns with Apgar scores above 8 at 1 and 5 minutes, a strong sucking reflex, and no critical neonatal conditions requiring transfer.

2.4 Exclusion criteria

Exclusion criteria are as follows: (a) serious pregnancy complications such as placenta previa, placenta accreta spectrum, eclampsia, and grade 3 or higher cardiac issues per NYHA standards; (b) challenges in initiating mother-infant SSC include emergencies such as neonatal asphyxia or respiratory distress, maternal excessive bleeding during surgery, and maternal infectious dermatoses; (c) previous breast

surgeries such as biopsies or augmentations, nipple inversions complicating breastfeeding, or taking medications affecting lactation.

2.5 Randomization and Blinding

A randomization sequence will be generated using Microsoft Excel 2010 with block randomization in blocks of four via a central system. Random distribution cards will be placed in numbered opaque envelopes, each corresponding to a card. As eligible participants enrolled, envelopes will be opened sequentially to assign treatments based on predetermined groupings. The randomization plan will be designed by a public health graduate student specializing in medical statistics, who will not be involved in the clinical phase. Staff performing SSC during and after cesarean will be blinded to the randomization procedure, and data collectors and statistical analysts will be unaware of patient groupings. However, blinding of patients will not be feasible.

2.6 Experimental Group (EG)

2.6.1 Administration of SSC and BF during CS

A multidisciplinary team, including obstetricians, pediatricians, anesthetists, nursing staff, and other personnel, collaborates to implement a SSC and BF during CS (skin-to-skin contact and breastfeeding during cesarean section) protocol for the intervention. Following spinal anesthesia, the gynecologist initiates surgery with double sterile gloves and arm sleeves. The pediatrician remains on standby in the adjacent neonatal resuscitation room to manage any distress in the newborn. As the neonate is delivered, the surgical drape is lowered, allowing the parents to witness the birth. The neonate, facing the parents, is gently placed on the mother's chest by an obstetric nurse. Before resuming the procedure, the surgeon removes one pair of gloves and sleeves, and the sterile barrier is reestablished. If the neonate exhibits no signs of distress, it remains in SSC with the mother for as long as possible, ideally throughout the cesarean. The obstetric nurse monitors the neonate during SSC and assists the mother in holding the newborn. In cases of maternal or neonatal discomfort, the neonate may be handed

to an obstetric nurse or pediatrician. All neonates are examined by the pediatrician within an hour post-delivery in the recovery ward.

2.6.2 Immediate SSC and early breastfeeding initiation

Upon birth, the neonate is promptly placed prone on the mother's chest, with their head turned to one side for optimal skin contact. The drying process begins within 5 seconds and is completed within 20 to 30 seconds while the neonate remains on the mother's chest. Delayed cord clamping is practiced, with the cord clamped approximately 1-3 minutes after birth. Breastfeeding cues such as tongue movements or head turning are monitored, and the obstetric nurse assists the mother in initiating breastfeeding as soon as possible. SSC continues throughout the cesarean procedure, and upon completion, the newborn is temporarily separated from the mother for safety during transfer to the surgical cart. SSC is resumed immediately post-transfer and continues for a cumulative duration of at least 90 minutes. The neonate's skin color, breathing, and feeding responses are continuously observed.

2.6.3 Routine newborn care

Newborn eye care, vitamin K1 administration, immunizations, weighing, and standard examinations are conducted before the neonate is transferred to the ward.

2.7 Control Group (CG)

2.7.1 Delayed SSC and breastfeeding

The neonate is dried within 20-30 seconds after birth, the cord is clamped after 1-3 minutes, and then the neonate is sent to the ward to wait for the mother to complete the surgery. Immediate SSC is initiated within one hour after birth and maintained with the mother for at least 90 minutes post-surgery, during which the neonate's skin color and breathing are continuously monitored. The obstetric nurse supports the mother in initiating breastfeeding at the earliest opportunity.

2.7.2 Routine newborn care

Newborn eye care, vitamin K1 administration, immunizations, weighing, and standard examinations are conducted before the neonate is transferred to the ward.

2.8 Outcome Indicators

2.8.1 Primary outcome

(A) Incidence of neonatal hypoglycemia: Neonatal blood glucose levels will be assessed using the Stat Strip Xpress glucose meter at 1, 3, and 6 hours after birth. Hypoglycemia is categorized as follows: mild hypoglycemia (overall) at <45 mg/dL, moderate-to-severe at <36 mg/dL, and severe at <18 mg/dL. Treatment will be initiated if levels dropped below 25 mg/dL or if symptoms like shakiness, tachycardia, pallor, hypothermia, hunger, sweating, or weakness appeared[8]. In such cases, 10 ml/kg of formula will be administered, followed by a recheck after 0.5 hour. If levels rise above 40 mg/dL, subsequent checks occurs every 3 hours[9]. Persistent levels below 50 mg/dL necessitates continued formula feeding and monitoring, or transferred to neonatal care if needed.

2.8.2 Secondary outcome

(A) Breastfeeding initiation and duration of first breastfeeding, characterized by newborns correctly latching onto the nipple and areola, and establishing regular, effective sucking and swallowing, will be immediately assessed post-operation, with timing recorded to the minute.

(B) Onset of lactogenesis II, approximately 72 hours post-delivery, marked by significant milk secretion perceived by the mother as breast fullness, confirmed by observing and squeezing the areola to assess milk spillage, will be assessed from delivery to pre-discharge, with timing recorded to the hour postpartum.

(C) Exclusive breastfeeding rate during hospitalization, where newborns are exclusively breastfed except for vitamins and minerals. This rate will be calculated for mothers who underwent cesarean delivery in both study groups.

2.9 Data Collection and Management

Researchers will contact all women scheduled for cesarean deliveries within 24 hours before the procedure. Led by the principal investigator and an experienced research assistant, the team will conduct face-to-face interviews to gather demographic and obstetric information. Details regarding the duration of SSC, the initiation and duration of the first breastfeeding session, exclusive breastfeeding

during hospitalization, as well as the infant's safety and blood glucose levels, will be continuously collected and recorded by trained staff during and after elective cesarean sections. All data will be anonymized and de-identified for further evaluation.

2.10 Sample Size

The sample size was determined based on a preliminary trial with 258 participants[5]. In this trial, the Early Essential Newborn Care (EENC) group exhibited a lower incidence of neonatal hypoglycemia compared to the control group receiving conventional care (0 vs. 5.3%, P=0.007). Using G*Power software version 3.1.7, with a two-sided type I error (α) of 0.05, a power (1 - β) of 90%, test family set to 'exact,' and the statistical test 'proportions: inequality, two independent groups,' it was calculated that at least 148 patients were required in each group. To account for an anticipated 20% dropout rate, the total sample size was adjusted to 356 participants, with 178 allocated to each group.

2.11 Statistical Analysis

The data analysis will be performed using SPSS 21.0 (SPSS Inc., Chicago, IL). Quantitative variables will be expressed as mean ± standard deviation. The T-test will be employed for normally distributed data, while the Mann-Whitney U test will be used for non-normally distributed data. Categorical variables will be summarized as frequencies and percentages and analyzed with the Chi-squared test. All statistical tests are two-sided, and a P-value of less than 0.05 is considered significant.

2.12 Ethics

This study will adhere to the ethical standards set by the relevant institutional and national review committees. Approval was granted by the Institutional Research Human or Animal Ethics Committee of Qingdao Municipal Hospital (2023 Lin Shen Zi No. 122), and all procedures complied with the revised 2013 Declaration of Helsinki.

References

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