

Early Skin-to-Skin Contact and Breast-Feeding Behavior in Term Neonates: A Randomized Controlled Trial

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Key Words

Breast feeding · Skin-to-skin contact · Neonatal stress

Abstract

Aim: To evaluate if early skin-to-skin contact (SSC) improves breast-feeding (BF) behavior and exclusive BF (EBF) rates in term infants at 48 h of age. **Methods:** Term infants born by normal delivery were randomized at birth to either early SSC (n = 20) or conventional care (controls; n = 21). SSC was continued for at least 2 h after birth. Subsequently, one BF session of the infants was video recorded at about 48 h of life. The primary outcome, infants' BF behavior at 48 h of life, was assessed using the modified infant Breast-Feeding Assessment Tool (BAT; a score consisting of infant's readiness to feed, sucking, rooting and latching, each item scored from 0 to 3) by three independent masked observers. The secondary outcomes were EBF rates at 48 h and 6 weeks of age and salivary cortisol level of infants at 6 h of age. **Results:** Baseline characteristics including birth weight and gestation were comparable between the two groups. There was no significant difference in the BAT scores between the groups [median: 8, interquartile range (IQR) 5–10 vs. median 9, IQR 5–10; p = 0.6]. EBF rates at 48 h and at 6 weeks were, however, significantly higher in the early-SSC group than in the

control group [95.0 vs. 38.1%; relative risk (RR): 2.5, 95% confidence interval (95% CI): 1.4–4.3 and 90 vs. 28.6%; RR: 3.2, 95% CI: 1.6–6.3]. **Interpretation:** Early SSC did not improve BF behavior at discharge but significantly improved the EBF rates of term neonates.

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Introduction

Early skin-to-skin contact (SSC) refers to the placing of the naked infant prone on the mother's bare chest immediately after birth [1]. It helps in initiating breast feeding (BF) and in reducing infant's stress in the first few hours after birth [1–3]. With the rapid technological advancement in perinatal care, the practice, however, lost its rightful place in most modern-day obstetric units [4]. Recently, with the inclusion of early SSC as a part of the 'routine care' of normal babies, there has been a renewed interest in promoting SSC in the delivery room. Still, there is a huge variation in implementation of this practice in centers across the world [4, 5].

The majority of the studies on SSC have evaluated its effect on the duration and exclusivity of BF during infancy [1]; only a few studies have looked at the success of

BF in the immediate neonatal period [6–9]. While three trials assessed the success of the first breast feed, only one study has so far evaluated the effect at a later age [8]. Carfoot et al. [8] studied the success of BF by using a modified infant Breast-Feeding Assessment Tool (BAT) score before discharge and found no significant difference between the SSC and control groups. However, the study had a major limitation in that only 25% of the infants' feeding sessions were observed by the investigator while the remaining assessments were done by the mothers themselves.

The evidence regarding the effect of SSC on BF behavior before discharge is important from at least two perspectives – (1) with improper sucking at the breast being one of the major reasons for stopping BF in the first week of life [5], a significant improvement noted in rooting and attachment at around the time of discharge could improve exclusive BF (EBF) rates in infancy, and (2) evaluation of BF behavior at a later age, as opposed to assessment at the first breast feed, is less likely to be affected by the mother's nipple protractility. An earlier study by Moore and Anderson [9] has shown that SSC and the mother's nipple protractility contributed equally to the variance in the BAT scores.

The other major effect of SSC in neonates is to reduce the stress levels associated with separation from their mothers [3, 10, 11]. There is some evidence from previous studies that salivary cortisol levels considered as a marker of stress decreased in infants given SSC [10, 11]. Taking these factors into consideration, we designed a randomized controlled trial to evaluate the effect of early SSC on the BAT scores at 48 h and salivary cortisol at 6 h of life in term newborn infants.

Methods

Subjects and Setting

This randomized controlled trial was conducted from August 2008 to September 2009 at All India Institute of Medical Sciences, New Delhi, India. We enrolled term appropriate-for-gestational age infants born by normal delivery between 9 a.m. and 5 p.m. on all working days during the study period. We excluded infants with major congenital anomalies, infants of diabetic mothers and those who required resuscitation beyond the initial steps and/or admission in the intensive care unit.

All term mothers were given the information sheet at the time of admission to the labor room. Written consent was obtained from them after a decision of anticipated vaginal delivery was taken by the obstetrician. The Ethics Committee of the Institute cleared the protocol and the study was registered with the Clinical Trials Registry (clinicaltrials.gov, registration No. NCT00776789).

Table 1. Methods adopted for assigning the BAT scores

Step 1: Creation of standard videos

A team of four reviewers¹ went through the recorded videos and selected the standard videos for each score (0–3) of the four components of the BAT score. These videos were used as the 'reference'

Step 2: Analysis of videos

Three independent outcome assessors², masked to the group allocation then analyzed all the recorded videos by referring to the 'reference' videos. They submitted their scores to the principal investigator (A.T.)

Step 3: Assigning the final scores

The principal investigator assigned the final scores based on the concordance between the three outcome assessors – if the scores given by all three were the same, that score was recorded as the final score. However, if it was different, the three assessors reviewed the videos together to reach a consensus score. This score was then recorded as the final score

¹ The reviewer team (four members) were faculty/fellow level personnel who had prior 10–15 years of experience in assessing BF and related problems.

² The outcome assessment team (three members) included neonatal nurses, neonatology fellows/faculty level personnel with prior experience and competency in managing BF problems and associated issues.

Randomization and Intervention

We randomly allocated the enrolled infants to either the early-SSC group or to the conventional-care group (control group) at birth using computer-generated random sequence numbers. Serially numbered, sealed and opaque envelopes were used to ensure allocation concealment.

Infants randomized to the SSC group were placed prone over the mother's chest immediately after birth. SSC was continued for the next 2 h. The infants who were allocated to the control group were kept by the mother's side and did not receive skin-to-skin care. None of the infants in either of the two groups received SSC at any other point during hospital stay.

Mothers in both groups received support for initiating BF, if required. All mothers, regardless of the group allocation, were advised to give EBF to their infants during the hospital stay and to continue to do so till 6 months of age. They were discouraged from giving supplemental feeds to their infants unless indicated by the duty registrar. Given the nature of the intervention, neither the investigators nor the treating team could be blinded to the study groups. The outcome assessment team responsible for measuring BF behavior was, however, blinded to the group allocation.

Outcome Variables and Their Measurement

The primary outcome measure was the BF behavior of the infants at 36–48 h of age. We video recorded one BF session of the infant between 36 and 48 h (general time of discharge of all non-risk term/near-term infants) and scored the feeding behavior using the modified infant BAT [8].

Table 2. Score for assessment of maternal perception of feeding, breast milk output, and infant's activity¹

Variable	Score		
	1	2	3
Milk output	poor	moderate	good
Breast consistency	rock hard or large lumps	firmer and filling	soft
Assistance for holding	full assistance	minimal assistance	nil
Duration of each feed	takes longer than 15 min to feed	feeds for 10-15 min, few swallows	5-10 min of active nursing with frequent swallows
Activity during feeding	crying, fussy, rooting after feeding	awake, rooting even after feeding sleeps moderately well	awake for feeding, does not require stimulation, then relaxes and falls asleep at breast after feeding

¹ Maternal perception score: very satisfied 13-15, satisfied 9-12, acceptable 7-8, unsatisfied <7.

The BAT tool has four components, namely (1) readiness to feed; (2) sucking; (3) rooting, and (4) latching. Each component is scored from 0 to 3, with 3 being the best possible score. Successful BF was defined as a total score of more than or equal to 8. The methods adopted for scoring the videos are summarized in table 1. To ensure uniformity, we recorded the feeding session only if the infant was alert and had not been fed in the last 2-4 h.

The secondary outcomes included (a) EBF rates at 48 h and at 6 weeks of life; (b) salivary cortisol levels at 6 ± 1 h of age, and (c) maternal perception of milk output, breast consistency, and activity of the infant during feeding at 48 h, and (4) infants' weight at 48 h.

EBF rates were assessed at 48 h and at 6 weeks using the standard WHO definitions [12]. We asked the mothers about the method of feeding and the number and amount of supplemental feeds received in the first 48 h of life. The information was cross-checked by enquiring the nursing staff on duty. EBF rates at 6 weeks were obtained from the mothers at the time of the first vaccination of their infants in the follow-up clinic. Those mothers who did not turn up at the clinic were contacted telephonically to record the method of feeding.

The salivary samples were collected with a salivette device (Sarstedt, Numbrecht, Germany) containing a sterile citric acid-free polyester swab. The infants were allowed to suck on the swab for at least 5 min. To avoid dilution of the saliva by the breast milk, we collected the samples 2 h after the infant was breast fed. The samples were then centrifuged at 2,000 g for 10 min and the filtrate was stored at 2-8°C for 24 h. They were transported to the central laboratory where the samples were stored at -20°C, and later analyzed by electrochemiluminescence assay using a kit (Cobas; Roche Diagnostics, Laval, Qué., Canada) with a high sensitivity (minimum detectable concentration being 0.018 µg/dl) and specificity (about 100%).

Maternal perception (as assessed by mothers at 48 h) was graded as very satisfied, satisfied, acceptable, or unsatisfied on the basis of a scale containing five parameters namely (1) perception of milk output by the mother; (2) consistency of the breast; (3) assistance required for holding the infant during feeding; (4) duration

of each feeding session, and (5) activity of the infant during feeding (table 2). Each parameter was scored from 1 to 3, with 3 being the best possible score.

In addition to the above information, we also recorded the baseline characteristics of infants and mothers, such as gestation, sex, birth weight, Apgar scores, maternal age and previous BF experience. All the infants were monitored for problems in BF and any other concerns as per the unit routine policy discharge.

Statistical Analysis

Analysis was done using Stata 9.1 (Stata Corp, College Station, Tex., US). Data were presented as means and standard deviations (SDs) or numbers and percentages as appropriate. We used the χ^2 test/Fisher's exact test and Student's t test/Wilcoxon rank-sum test for categorical and continuous variables, respectively. A p value <0.05 was considered significant. The analysis was by intention to treat.

To determine the sample size, we performed a pilot study on 15 mothers and evaluated the infants' BF behavior using the BAT. The mean \pm SD BF score in those infants who received conventional care was found to be 7.9 ± 2.2 . To detect a mean difference of 2.1 (i.e. the mean score of 10.0 in the intervention group) with a common SD of 2.2 and a two-sided significance level of 0.05 and a power of 80%, we had to enroll 18 infants in each group.

Results

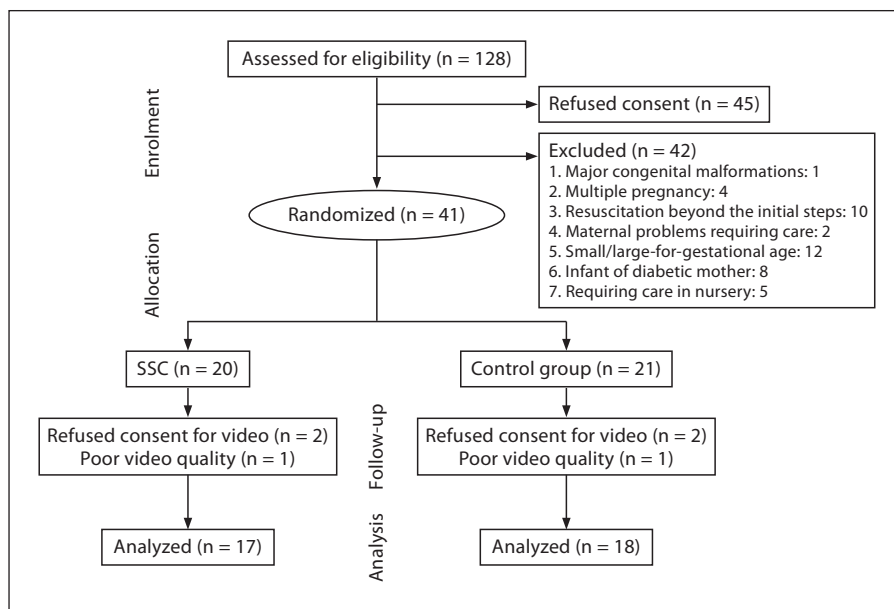
Figure 1 shows the trial flow of the study. Of the 128 maternal infant dyads screened for eligibility, 45 mothers refused to give consent; another 42 dyads were excluded based on the prespecified criteria. The remaining 41 infants were randomly allocated into early SSC and control groups (n = 20 and 21, respectively). All the infants in the intervention group received early SSC for 2 h after birth.

Table 3. Baseline variables

Variable	Early-SSC group (n = 20)	Control group (n = 21)	p
Maternal characteristics			
Age, years	26.2 ± 3.6	25.8 ± 2.8	0.83
Maternal education more than 15 years, n	11 (55%)	15 (71.4%)	0.48
Monthly family income (INR 5,000–10,000), n	9 (45%)	11 (52.4%)	0.50
Nuclear family, n	9 (45%)	14 (66.7%)	0.16
Flat nipples detected at the time of early SSC, n	0	1	0.32
Previous BF experience, n	7 (35%)	7 (33.3%)	0.91
Neonatal characteristics			
Gestation, weeks	38 (38–39)	38 (37–39)	0.94
Male gender, n	10 (50%)	8 (38.1%)	0.44
Birth weight, g	2,841 ± 247	2,755 ± 299	0.32
Apgar at 1 min	9 (9–9)	9 (9–9)	0.28

Figures are median (range) or mean ± SD unless otherwise indicated.

Fig. 1. Trial flow of the study population, indicating the number of subjects screened, the number enrolled and the number of infants for whom primary outcome is available.



Four mothers who gave consent to participate in the study withdrew consent at the time of video recording. Videos of 2 infants were of poor quality and were not included in the final analysis (fig. 1). Baseline variables including gestation, birth weight and maternal prior BF experience and flat nipples were comparable between the two groups (table 3).

We did not find any difference in the primary outcome – BAT score – between the SSC and the control

groups [median: 8, interquartile range (IQR): 5–10 vs. 9 and IQR 5–10, p = 0.6]; nor was there a difference between the two groups in the proportion of infants with BAT scores ≥ 8 (table 4).

Infants in the early-SSC group were more likely to be exclusively breast fed than those in the control group at both 48 h and at 6 weeks [relative risk (RR): 2.5, 95% confidence interval (CI): 1.4–4.3 and 3.2, 95% CI 1.6–6.3, respectively]. The maternal perception scores at 48 h were

Table 4. Outcome variables

Outcome variable	Early-SSC group (n = 20)	Control group (n = 21)	RR/ difference in means ¹	p
Modified infant BAT score ²	8 (5–10)	9 (5–10)	–	0.64
Modified BAT score ≥8, n	10 (50%)	11 (52.4%)	0.9 (0.6 to 1.7)	0.89
EBF at 48 h, n	19 (95%)	8 (38.1%)	2.5 (1.4 to 4.3)	0.001
EBF at 6 weeks, n	18 (90%)	6 (28.6%)	3.2 (1.6 to 6.3)	0.001
Salivary cortisol ³ , µg/dl	0.54 (0.25–0.86)	0.9 (0.3–2.1)	–	0.09
Maternal perception score at 48 h after delivery	12.5 ± 1.9	10.7 ± 1.7	1.7 (0.5 to 2.8)	0.005
Infant's weight at 48 h, g	2,714 ± 220	2,574 ± 275	139 (–18 to 298)	0.11

Figures are median (IQR) or mean ± SD unless otherwise indicated.

¹ 95% CI is shown in parentheses.

² Outcome available for 17 and 18 infants in the early-SSC and control groups, respectively.

³ Outcome available for 19 and 20 infants in the early-SSC and control groups, respectively.

also significantly different between the groups (mean difference 1.7, 95% CI 0.53–2.8).

Salivary cortisol could not be assessed in 2 infants (1 in each group) due to inadequacy of samples. There was no difference in the median cortisol levels between the two groups (table 4). Similarly, we did not find any difference in the weight at 48 h of life between the groups.

Discussion

We did not find any significant difference in the BAT scores at 36–48 h of age between the infants who received early SSC and those who did not. This is in accord with the results of the study by Carfoot et al. [8], which also suggested that the BF success before discharge was similar in the two groups. However, the studies that have evaluated the effect of SSC on first breast feed report higher scores [6, 8] and a better mean sucking competency in the early-SSC group [9]. Notwithstanding the slightly different nature of the outcomes, we assume the following factors to have contributed to the absence of a significant difference in BAT scores in the two groups: (a) improvement in the feeding behavior of the control infants over 48 h following routine BF counseling of mothers; (b) the possibility of missing a true difference in the scores by one-time assessment of a feeding session, and (c) the limited power of the study because of the unexpectedly large variation in the results – while the sample size was calculated based on the assumed SD of 2.2, the SD of the two study groups turned out to be 3.4.

Neonates in the early-SSC group in our study had better EBF rates at both 48 h and 6 weeks of age. The Cochrane systematic review also yielded a significant effect of SSC on EBF rates at 1–4 months after birth [10 trials, odds ratio (OR): 1.82, 95% CI 1.08–3.07] [1]. Improved EBF rates in our study are therefore not surprising. However, the beneficial effect observed at 48 h in the absence of a significant difference in the BF scores is perplexing indeed. Given that EBF rate is a 'true' indicator of the ability to breast feed, the possibility that the BF scores might not adequately measure this ability cannot be ruled out.

Since the BAT score does not take into account the mother's satisfaction or her comfort level, we included the maternal perception score as one of the secondary objectives. The score, yet to be validated, had five parameters. The components of the score emerged out of concerns expressed by the mothers during the immediate postnatal period. Based on these concerns, we attempted to develop a simple score that would help us in comprehensive assessment of the feeding status of the infant. In a pilot study done at our own center prior to the present study, the infants whose mothers scored ≥13 (out of a total score of 15) had improved EBF rates at discharge. Mothers who self-reported of a good output at 48 h felt that the infant slept comfortably and did not require any top-up feeds and/or supplementation during hospital stay, while mothers who reported moderate milk output reported to have given some supplemental feeds during hospital stay. Mothers who reported poor output were found to have taken majority of feeds from the nursery during hospital stay. Breast consistency was ascertained by the mother

prior to her feeding session. In the present study, mothers in the SSC group were found to have a score of 12.5 ± 1.9 versus 10.7 ± 1.7 in the control group. It is possible that the improved maternal satisfaction/perception of mothers in the intervention group resulted in improved EBF rates in their infants at 48 h.

Previous studies [3, 10, 11] including a recently published study [13] have suggested that early SSC might help in reducing the stress levels of the infants during the immediate postnatal period. Our study, underpowered to look at a significant difference between the two groups, also suggested a trend towards lower cortisol levels in the intervention group.

The major strength of our study is the masked evaluation of BF scores using video recording of the infants' feeding sessions. Unlike the previous trials that used either the research assistants or even the mothers to score the infants' feeding ability, we used the scores assigned by three independent outcome assessors to eliminate the measurement bias. The present study had some limitations too – firstly, the study evaluated BF behavior using only one-time assessment of a feeding session at 36–48 h. With so many variables that could affect the latching and other parameters of the score, multiple assessments might have found a difference in the feeding behavior of these neonates. Secondly, the study had limited power to look at a small difference in the scores between the two groups.

Thirdly, we did not measure any physiological or biochemical markers of decreased stress in the mothers.

To conclude, early SSC improved EBF rates at discharge in term neonates without any improvement in their BF behavior as assessed by BAT scores. An adequately powered study with multiple BF sessions of the neonate prior to hospital discharge would be required to provide a definitive answer to this interesting research question.

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Disclosure Statement

None.

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