RESEARCH PAPER

Family-Centered Care to Complement Care of Sick Newborns: *A Randomized Controlled Trial*

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Objective: To assess the impact of family-centered care in delivery of care to sick newborns, on nosocomial infection rate.

Design: Randomized controlled trial

Setting: Tertiary referral nursery (October 2010 to March 2012).

Participants: 295 neonates randomized at the time of hospitalization in neonatal intensive care unit.

Intervention: Parent-attendant of intervention group were trained using an indigenously developed and pretested, culturally sensitive, simple audio-video tool that covered domains of personal hygiene, hand washing, danger signs recognition and feeding of sick neonate. Control group received routine care by nurses and doctors.

Outcome measure: *Primary:* culture positive nosocomial infection rate. *Secondary:* culture negative nosocomial infection rate, duration of hospitalization, mortality and breastfeeding rate.

Results: Two-thirds of family caregivers were fathers/ mothers and about 20% were grandparents. About 60% of family care givers were either illiterate (25%) or primary/middle pass (34%). Incidence of nosocomial episodes of sepsis was not different between groups (incidence rate difference 0.74, 95 % CI -4.21, 5.6, *P* = 0.76). Pre-discharge exclusive breastfeeding rates were significantly higher in intervention group [80.4% *vs* 66.7% (*P*=0.007)].

Conclusions: There was no significant difference in nosocomial infection rate between the two groups. Translating and adapting principles of family-centered care was feasible, and improved the pre-discharge exclusive breastfeeding rates.

Keywords: *Breastfeeding, Capacity building, Caregivers, Cross infection, Patient care team.*

Trial Registration: Clinical Trial Registry of India (CTRI/2013/09/003969)

Family-centered care (FCC) in neonatal intensive care unit (NICU) setting is an approach to develop and nurture the family's role in partnership with that of the healthcare team in care of a sick neonate. Implementation of this strategy has shown to decrease length of stay, improve wellbeing of preterms, allow better allocation of resources and enhance parent infant bonding [1-6]. However, impact of FCC on nosocomial infections has not been evaluated.

We hypothesized that capacity-building and involving parents through a structured training program for a supervised delivery of limited care to their own baby in nursery to complement the conventional care by nurse-doctor will reduce the nosocomial infection rate. This was based on the premise that the parents have more interest than anyone else in their baby's wellbeing. Hence whatever capacity is built for delivery of care to their sick baby during the opportunity of contact during hospitalization is likely to be complied fully not only through the hospital stay but also even likely to be carried at home discharge. While the doctor/nurse continues to be the primary caregiver, involvement of parents leads to sharing of work.

Accompanying Editorial: Pages 451-2.

METHODS

This study designed as a randomized controlled trial was conducted between October 2010 to March 2012 in a setting of 16-bedded referral neonatal unit of Northern India with 2 or 3 nurses and one resident doctor available as care providers round-the-clock. Nursery has an intensive side with provision for tertiary care and a step-down side. Free visitation by mothers/parent attendants is allowed only in the step-down side. The trial was approved by the Institutional Ethical Committee.

The primary objective was to document impact of structured parental participation of parent attendants in delivery of care to their sick neonates on culture-positive

nosocomial infection rate. The secondary objectives were to document effects of this intervention on mortality, median duration of hospital stay, breastfeeding rate and culture-negative nosocomial infection rate. Nosocomial infection was defined as any episode of sepsis developing after 72 hours or more of hospitalization, and the rate was calculated as number of sepsis episodes per 1000 patient-days of admission [7]. A new episode of nosocomial infection was defined in a baby who was doing clinically well and off-antibiotics for at least last 7 days, developing clinical features compatible with sepsis.

Hypothesizing about 50% reduction in nosocomial infection rate from existing rate of about 20 infections/ 1000 patient-days (with ±10% precision) at 80% power and 5% α error, sample size of 2157 patient-days in each group was estimated. Assuming 15 patient-days, we required to enroll about 150 patients in each group.

Participants: All neonates admitted to NICU who were accompanied by at least two attendants (mother/father/ grandparents/relatives) were eligible. After initial assessment, stabilization and appraisal about baby's condition, the accompanying parent/attendants were asked for a written informed consent after they had viewed the research information video.

Neonates whose accompanying attendant refused to consent, or who were critically sick or hemodynamically unstable or had any major malformation incompatible with life or were product of multiple gestation were excluded from the study. The enrolled babies were randomized: control group received care from the nurses and doctors as per routine unit practice and the intervention group in addition to nurses and doctors received a supervised delivery of a package of care by the parent-attendants of the baby who were trained using an indigenously developed audio-visual training module (study tool).

Randomization: Computer generated random number sequence was generated by a person not otherwise involved with the study, using STATA 9.0 version. Allocation concealment was ensured using sequentially numbered, opaque, sealed and stapled envelopes that were opened by the primary investigator at the time of randomization. Given the nature of intervention being clinical care, blinding was not possible.

Intervention: A simplified comprehensive audio-visual training tool was prepared with multidisciplinary technical input from a neonatologist, community medicine specialist, psychologist, nurse, and hindi-language expert. The objective of this module was to make aware, educate, train, and build the capacity of the accompanying parent-attendant in various elementary skills pertaining to sick newborn care. The module content was structured into four sequential parts: Part 1 pertaining to preparing the attendant for entry into nursery (information about dos and don'ts before entry, learning steps of hand washing, wearing gown, change of soiled diapers); Part 2 related to familiarization with nursery environment (information about care under warmer and phototherapy, stability of fixation of warmer/ pulse oximeter probes/orogastric tube/oxygen nasal prongs and intravenous (IV) cannula. Drawing nurses' attention towards monitor-alarms and redness/swelling at IV sites; Part 3 focused on building skills of recognizing and reporting danger signs (noticeable change in colour/ activity/breathing pattern/bleeding rash/gastric aspirates/ vomiting, abdominal distension, altered stool colour), to note frequency of stool/urine passed; and Part 4 on teaching orogastric/*paladay/katori-spoon* feeding. Pre-implementation testing of the tool was done by administering to ten parents from varied religious/ language/socioeconomic/literacy backgrounds and incorporating constructive feedbacks for tool improvement. Tool was re-administered and rechecked for comprehension and clarity, until approved by experts for final implementation. Kangaroo mother care, breastfeeding, milk expression and discharge counselling were taught and practiced in both groups as standard practices of our nursery.

Once enrolled following consent for participation, 2-3 attendants per baby were initiated into daily training between 10 AM to 12 noon. Audio-video module was screened sequentially from part 1 to part 3, respectively from day 1 to day 3 after initiation of the training process for the attendants. Part 4 was screened and training for feeding begun once the infant was considered ready for enteral feeding. This screening was done either individually or in groups. The audio-video training was supplemented with demonstrations as and when required by the principal investigator. Other resident doctors and nurses in the unit were similarly trained to impart training to participating parent-attendants (in case principle investigator was not available). Repeated sequential screening of audio-visual module parts 1-4 were done until the attendants demonstrated satisfactory skill learning as assessed by the investigators. Reinforcement and interactive revision of the module was done each time they viewed next part. Lateral/horizontal learning was encouraged among attendants. The attendant imparted care to their respective babies with these acquired skills (***Table* I**).

Outcomes: The episodes of nosocomial infection (culture positive and negative), duration of stay, final outcome

TABLE I ACQUIRED SKILLS AND THEIR ASSESSMENT: AN OVERVIEW

Part of module	*Skill taught*	*Assessment*
Part 1	Gowning Handwashing Cleaning the soiled baby	Observing the attendant Demonstrating at least 4 out of 6 steps of hand washing correctly
Part 2	Covering eyes/ genitals in phototherapy Checking warmer/ pulse-ox probe stability/fixation Swelling and redness at I/V cannula site	Documentation in nurse's chart
Part 3	Recognition and reporting of danger signs	Monitoring by nurses/ residents
Part 4	Orogastric/paladay/katori-spoon feeding	Supervisory

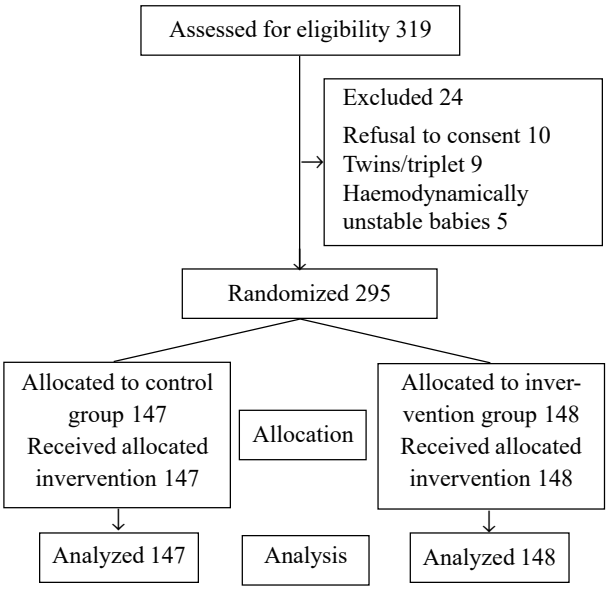

FIG. 1 *Study flow chart.*

(discharge/LAMA/death) and number of babies breastfeeding at the time of discharge were documented as per the pre-set definitions in both groups. Data were recorded in a predesigned performa and managed on an Excel spreadsheet. Actual time spent bedside in previous 24 hours was noted weekly by direct enquiry from attendants.

Statistical analysis: Characteristics of participants in both the groups were compared using Students 't' test (quantitative variables), or Chi-square test (categorical variables). Effect size and its 95% CI were computed for the primary and secondary outcomes. Stratified analysis was done only as exploratory analysis. Analysis was done by 'intention to treat', using STATA 9.0.

RESULT

We randomized 295 out of 319 eligible newborns to either the control group (n= 147) or intervention group (n=148) after 24 exclusions (***Fig.* 1**).

Mean (SD) weight and gestational age in control and intervention groups were 2303 (67) g and 2376 (65) g; 36.4 (3.2) weeks and 36.8 (3.1) weeks, respectively. The baseline characteristics are shown in ***Table* II**.

Majority (37%) of parent-attendants were fathers, 20% were grandparents, mothers were 22% initially and 30% later. One-fourth (25%) were illiterate, 34% were primary/middle school level and only 2% were graduates. 40% were aged 25-35 years, 19% being 36-50 years, and 41% were >50 year-old. Mean (SD) time spent bedside by attendant was 14.7 (1.1) hours/day.

Total nosocomial infection episodes were 75; 38 (culture positive 22, culture negative 16) in control group and 37 (culture positive 23, culture negative 14) in intervention group. No episode of nosocomial infection was reported in step-down side of the nursery. Total nosocomial infection rates (culture positive and culture negative) were 24.72 and 24.02 episodes per 1000 baby days in control and intervention groups, respectively (P=0.7). Culture positive and culture negative nosocomial infection rates between the control and intervention groups were not significantly different (***Table* III** and ***Fig.* 2**). Median (IQR) duration of hospitalization in control and intervention group was 11 (7,18) days and 11.5 (7,17.5) days, respectively (P>0.05). The mortality was 8.8% in control as compared to 6.8% in intervention group. The breastfeeding rate in control group was 66.7 % as compared to 80.4% in intervention group (P=0.007).

DISCUSSION

In this randomized controlled trial evaluating family-centered care of sick newborns admitted in a NICU, we did not find a significant impact on reducing nosocomial infections. The intervention significantly improved breast feeding rates before discharge. This may reflect an easier transition from intensive to the step-down side and better preparedness in this group since mothers were involved through the period of hospitalization of the baby.

Few studies have evaluated impact of various interventions within the ambit of FCC and have shown improved health outcomes for neonates and families. Bhutta, *et al.* [8] had allowed free visitation of mothers in

TABLE II BASELINE CHARACTERISTICS OF ENROLLED BABIES

Characteristics	*Control gp n=147, n (%)*	*Intervention gp n=148, n (%)*
Gestational age (wks)		
<28	9 (3.0)	7 (2.3)
29-34	25 (8.5)	21 (7.1)
35-42	113 (76.8)	120 (81.0)
Gestation* (wk)	36.4 (3.2)	36.8 (3.1)
Weight* (g)	2303 (67)	2376 (65)
Age at admission* (d)	6.9 (7.6)	7.7 (8.9)
SGA	33 (11.2)	27 (9.1)
Male gender	102 (69.4)	101 (68.2)
Home delivery	95 (64.6)	96 (64.8)
Vaginal delivery	118 (80.2)	119 (80.4)
Birth asphyxia	31 (10.5)	27 (9.1)
Previous hospitalization		
Single	22 (14.96)	21 (14.2)
Multiple	10 (6.80)	8 (5.4)
Stability at admission		
Severe hypothermia	1 (0.68)	6 (4.0)
Fever	5 (3.40)	10 (6.7)
#Saturation <85%	20 (13.6)	16 (10.8)
Hypoglycaemia	10 (6.8)	4(2.7)
Invasive procedures		
PICC line *n* (d)	23 (124)	27 (167)
Umbilical cath. *n* (d)	33 (175)	34 (170)
Surgical intervention *n* (%)	1 (0.68)	2 (1.35)
Ventilated *n* (d)	37 (149)	31 (296)

*Values in No. (%) or *mean (SD); #Oxygen saturation; PICC: Peripherally-inserted central catheter.*

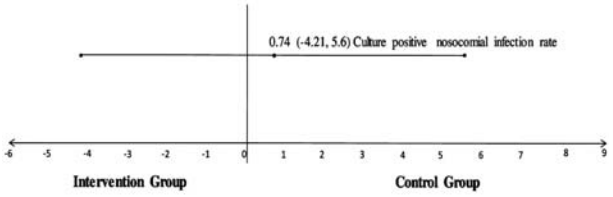

FIG. 2 *Differences in incidence rate of culture positive nosocomial infection.*

step-down area for care of stable very low birth weight (VLBW) infants and found that this was associated with reduced duration of stay and decreased nosocomial infection. Parents in COPE trial had received written and audiotaped information and performed behavioral activities to parent preterms. This reduced their duration of hospitalization [3,9]. In Stockholm Neonatal Family Centered Care Study [10], parents were allowed to stay for 24 hours and this reduced total hospital stay duration in preterm neonates admitted to a level 2 NICU. O'Brien, *et al.* [11] developed a Family Integrated Care model for parental participation in care of preterm babies by getting trained with daily education sessions that improved breast feeding rates and weight gain. Importance of providing peer support to NICU parents, delivered through hospital or community based programs to complement services of NICU staff has been realised. It has been recommended that offering peer support to NICU parents should be an integral part of NICU services [12].

We could not demonstrate a positive impact of FCC in reducing nosocomial infections, our study could be underpowered to detect small differences as we calculated our sample size based on an ambitious 50% reduction. We have not assessed long term outcomes as also perspectives of various stake-holders. It is possible that this intervention that involves competency building of family attendant with respect to essential newborn care has far reaching consequences on post-discharge outcomes.

Broad-based inclusion with limited exclusions and the fact that the trial was conducted on parent attendants with varied characteristics offer a good generalizability. Strict adherence to study protocol with inbuilt quality assurance measures gives a good internal validity to the study.

Possible implication of this trial is that parent attendants could be trained for imparting care to their sick neonates in human resource constrained setting like special care newborn units (SCNUs) and help in strengthening the health care system with better neonatal

TABLE III SUMMARY OF OUTCOMES IN THE TWO GROUP OF SICK NEWBORNS

Outcome variables	*Control group (n=147)*	*Intervention group (n=148)*	*Mean difference (95% CI)*	*P value*
Culture positive nosocomial infection rate	7.17	6.43	0.74 (-4.21, 5.6)	0.76
Culture negative nosocomial infection rate	9.86	10.56	-0.70 (-6.6,5.2)	0.82
Duration of stay, median (IQR)	11 (7,18)	11.5 (7,17.5)		>0.05
Mortality, No. (%)	13 (8.8)	10 (6.8)	(0.042,0.134)	0.5
Breastfeeding rate, No. (%)	98 (66.7)	119 (80.4)	(0.59,0.74)	0.007

WHAT IS ALREADY KNOWN?

- Family-centered care in NICUs favourably impacts outcomes.

WHAT THIS STUDY ADDS?

- Translating and adapting principles of family-centered care to an operational, culturally-sensitive module improved breastfeeding rates before discharge, but did not affect nosocomial infection rates.

outcomes. Translating and adapting principles of family centred care seems to be feasible. Additionally it is believed that empowering and capacity building mothers/ parent-attendants with care giving competencies for their babies would be a cornerstone for providing a continuum of care for these high risk NICU graduates at home after discharge.

While this one as a preliminary study evaluated only few outcomes, and implementation was shown to be feasible, more impact evaluation research may be required including qualitative studies to evaluate the perceptions of the stakeholders as this concept seems to have promising potential to impact newborn care not only during their hospitalization but also likely to impact their outcomes after discharge.

Contributors: ANV: acquisition of data, initial analysis, and interpretation of data, drafted the initial manuscript; AM: conceptualized, designed and supervised the study, reviewed and ensured quality assurance through the study, and revised the manuscript. RMP: designed the study, analysis and interpretation of data, and critically reviewed the manuscript; CH: acquisition of data, interpretation of data, and critically reviewed the manuscript; ARV, FS: analysis and interpretation of data, and drafting the article. All authors approved the final version of manuscript.
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