A Study to Assess the Effectiveness of Developmental Supportive Care Bundle on Neonatal Outcomes of Low Birth Weight Babies at Selected Hospital of Ambala, Haryana

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Abstract

Background: Neonatal period, the first 28 days of life is most vulnerable and crucial time for babies, whose birth weight is less than 2.5 kg. Developmental supportive care is an integrated approach for these babies. The main objectives of the study were to assess and compare neonatal outcomes (physiological, comfort behavior) of LBW Babies before and after implementation of Developmental Supportive Care Bundle in experimental and comparison group and to determine the association of neonatal outcomes of LBW Babies with their selected demographic variables in experimental and comparison group.

Methodology: Quasi-Experimental research design (Non- Equivalent Control Group Pretest Posttest Design) was used. Data was collected from 30 Low Birth Weight Babies (15 in each group) by convenience sampling technique in NICU of MMIMS&R of Ambala, Haryana.

Pre assessment – temperature and pain assessment done before intervention in both group. After that intervention given in only experimental group and post test done on 2 to 5 days. On day 4, the mean post implementation score (36.60) of temperature was found significantly (p=.01*) higher in experimental group. On day 2 to 5, the mean post implementation score (6.80, 6.40, 6.47 and 6.47) of comfort behavior was found to be significantly (p=.006*, .001*, .005* and .002* respectively) higher in experimental group.

Conclusions: The findings of the study concluded that Developmental Supportive Care Bundle (DSCB) was effective in improving neonatal outcomes (temperature and comfort behavior) of Low Birth Weight babies.

Key words: *Effectiveness, Developmental Supportive Care Bundle, Neonatal Outcomes, Low Birth Weight.*

Introduction

Neonatal period, the first 28 days of life is most vulnerable and crucial time for babies, whose birth weight is less than 2.5 kg and their birth takes place before completion of 37 weeks of gestation.[1]Developmental supportive care is an integrated approach for these babies. The core principles of developmental Supportive Care are: Protected sleep, Hearing environment, Family centered care, Activities of daily living, Assessment of pain and stress. [2]

The neonatal mortality is major concern and is not uniform across India. While the other state of Kerala has already attained Single digit NMR (7/1000 live births) where Orissa, Madhya Pradesh, Uttar Pradesh, Rajasthan

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and Chhattisgarh have a higher neonatal mortality rate at 30 or more per 1000 live births. In terms of absolute numbers, 4 state alone- Uttar Pradesh, Madhya Pradesh, Bihar and Rajasthan- contribute to 56% of total neonatal deaths in India and about 14% of the global neonatal deaths that occur every year.[3]

In 2016 main cause of death of neonate occurs due to- birth asphyxia, birth defect and preterm birth. Addressing preterm birth is now an urgent priority. What is reassuring is that more than three- quarters of these premature babies can be saved with simple and cost-effective interventions without the need for sophisticated gadgets and neonatal intensive care. These interventions include antenatal steroid injections, Kangaroo Mother Care, feeding with breast milk, maintaining hygiene, supportive and specific measures to treat newborn infections.[4]

WHO recommends skin-to-skin care immediately after birth for every newborn to ensure that all babies stay warm in the first hours of life helps in early initiation of breast-feeding, so it should be encouraged. KMC satisfies all five senses of the baby. The baby feel mother warm through skin-to-skin contact (touch), listen mother voice and heartbeat (hearing), sucks breast milk (taste) has eye contact with mother (vision) and smell mother's odour (olfaction). KMC can be continued for as long as possible initially in the hospital and then at home. This is desirable until the baby's gestation reaches until term or weight is around 2500 gm.[5]

A cross over clinical trial was conducted to assess the effect of nesting on sleep pattern among preterm infants admitted in NICU. 21 preterm who fulfilled inclusion criteria were enrolled in the study. They were randomly assigned into two groups- for one group nesting was done and other group received routine care. Neonatal sleep assessment scale was used to evaluate the sleep status of preterm babies. This study results supports the use of nesting aids in increase sleep and duration of quiet sleep and aids in stability of physiological parameters. The study suggested further studies needs to recommend nesting.[6]

A systematic review of current research evidence was done to see the effectiveness of non-pharmacological management of pain during needle puncture procedures in infants. Containment is the intervention that limits the movement of infant during painful procedure, promote self-regulation and attenuate physiologic and behavioral stress caused by acute pain. No studies have examined the effect of this intervention in older infants up to a year or the sustained effectiveness of swaddling/ containment over ongoing procedures or across varied procedures. Further research is recommended to fill these knowledge gaps.[7]

The aim of the studyof the study were to assess and compare neonatal outcomes (physiological, comfort behavior) of LBW Babies before and after implementation of Developmental Supportive Care Bundle in experimental and comparison group and to determine the association of neonatal outcomes of LBW Babies with their selected demographic variables in experimental and comparison group.

Methodology

Initially, approval was obtained from the university ethics committee to proceed (approval number: Project no. IEC 1310). The study included LBW babies- were less than 2kg, hemodynamically stable and whose parents give assent for their babies to participate in the study. Tools were formulated and nine experts including three Professor of Pediatric Medicine, one Assistant Professor of Pediatric Medicine, one Doctor (Director Principal) of MMCON, one Professor of Pediatric Nursing and three Assistant Professor of Child Health Nursing were requested to judge the content clarity, relevance, appropriateness and meaningfulness for the purpose of the study and to give their opinion and suggestion on content, its coverage, organization, presentation, language, feasibility of the intervention. A necessary modification in content was done as per expert's suggestions. Intervention was found to be relevant and appropriate.

Description of Tool

1.(a) **Demographic variables sheet for Neonate:** Date and time of birth, date of admission, diagnosis, date of initiating intervention, age (in days), birth weight, gender, gestational age at birth (in weeks), mode of feeding, type of milk, any co- morbid illness, number of

painful procedure and heel prick per day.

(b) **Demographic variables sheet for mother:** Age, religion, educational status of mother, any history of disease during pregnancy, mother's occupation, mode of delivery, gravida of mother, previous experience regarding practice of Kangaroo mother care among low birth weight baby, if yes source of information, previous experience regarding practice of non- nutritive sucking among low birth weight baby, if yes source of information, previous practices regarding care of low birth weight baby.

2**. Development and description of physiological parameters record sheet:** The physiological parameter record sheet was constructed to assess the physiological parameter- Axillary temperature (°C). This tool comprised of a record sheet to record the physiological parameter for 5 days with two observations per day in morning and in evening.

3**. Development and description of COMFORTneo scale:** It was developed from the COMFORTneo scale by Monique van Dijk. The tool comprised of six components that are Alertness, calmness/ agitation, crying, body movement, facial tension, muscle tone. Total score ranges from 6 to 30. High score indicates more pain or more discomfort.

Procedure

Data collection procedure for comparison group-

On the 1st day, Pre Assessment was done by administering the tools. Researcher took 20-25 minutes to complete the sample characteristics performa sheet of neonate and mother, physiological parameter record sheet and COMFORTneo scale (comfort behavior) score of LBW during painful procedure (glucose monitoring).

On the 1st to 5th day, routine care provided to the neonates as per hospital comparison group received policies of Hospital.

On the 2nd to 5th day Post Assessment was done by administering the tools (physiological parameter record sheet and for scoring comfort behavior of LBW during painful procedure.

Data collection procedure for experimental group-

On the 1st day, the Researcher did Pre Assessment and it took 20-25 minutes to complete the demographic sheet of neonate and mother, physiological parameter record sheet and for scoring comfort behavior of LBW during painful procedure (glucose monitoring).

On the 1st to 5th day, implementation of Developmental Supportive Care done. It includes massage, nesting, containment, maternal voice and KMC. Massage done with coconut oil once a day in morning, sterile sheet used for making nest for LBW and baby kept under nest for 12 hours and position was changed every 2 hourly and containment before, during and after the painful procedure in which researcher kept her one hand on head of the baby and other hand either on buttocks or on feet of the baby once a day. These three interventions provided by researcher. Researcher taught the mothers regarding maternal voice benefits and KMC, these two interventions were given by mother twice a day and ensure that mothers were doing the same as told. For that researcher was present in each session of maternal voice and KMC procedure. Each mother talks to their baby and sing lori for 5 min before KMC. Duration for each sitting of KMC was 1 hour. These two interventions was given by mothers daily.

On the 2nd to 5th day Post Assessment was done by administering the tools (physiological parameter record sheet and for scoring comfort behavior of LBW during painful procedure (glucose monitoring).

Data Analysis

Kalmograv- Smirnov test was applied to check the normality of data distribution. Data was normally distributed in both experimental and comparison groups, hence parametric tests were applied.

Descriptive statistics: Frequency, mean, median, standard deviation, chi- square.

Inferential statistics: t- test and one-way ANOVA.

TABLE- 1: Frequency, Percentage Distribution and Chi-Square Showing Comparison of Experimental and Comparison Group in terms of Selected Demographic Variables of LBW Babies

S.No.	Selected variables	Comparison group (n=15) f(%)	Experimental group (n=15) f(%)	Chi square	df	p- value
1	Birth weight (kg) 1.1 1.8-2.0 1.2 1.2-1.79 1.3 <1.2	 5 (33.3) 1 (66.7)	 5 (33.3) 1 (66.7)	-	-	-
2	Gender 2.1 Boy 2.2 Girl	 8 (53.3) 7 (46.7)	 13 (86.7) 2 (13.3)	3.96	1	.04*
3	Gestational age at birth (weeks) 3.1 Less than 32 weeks 3.2 32-34 weeks 3.3 34-36 weeks 3.4 More than 36 weeks	 3 (20.0) 2 (13.3) 6 (40.0) 4 (26.7)	 2 (13.3) 2 (13.3) 6 (40.0) 5 (33.3)	.31	3	.95NS
4	Mode of feeding 4.1 Breast feeding 4.2 Orogastric feeding 4.3 Paladai feeding 4.4 Katori feeding/ cup feeding 4.5 NPO/IV fluids	 0 (0.0) 5 (33.3) 2 (13.3) 4 (26.7) 4 (26.7)	 1 (6.7) 8 (53.3) 0 (0.0) 3 (20.0) 3 (20.0)	3.97	4	.40 NS
5	Type of milk (if not breastfeed directly) 5.1 Expressed breast milk 5.2 Formula milk 5.3 NPO/IV fluids	 6 (40.0) 5 (33.3) 4 (26.7)	 10 (66.7) 2 (13.3) 3 (20.0)	2.42	2	.29NS
6	Any co-morbid illness 6.1 Yes 6.2 No	 15 (100)	 15 (100)			
7	Number of painful procedure and heel prick per day 7.1 1-2 7.2 3-5 7.3 >5	 2 (13.3) 10 (66.7) 3 (20.0)	 2 (13.3) 12 (80.0) 1 (6.7)	1.18	2	.55NS

*Significant ($p < 0.05$) ^{NS} = Not significant ($p>0.05$)

$\chi2(1)= 3.84, \chi2(2)= 5.99, \chi2(3)= 7.82, \chi2(4)=9.49$

Table 1shows that Chi- square was applied to comparison and experimental group with respect to sample characteristics of LBW babies gender gestational age at birth ($\chi2=.95$), mode of feeding ($\chi2=.40$), type of milk ($\chi2=.29$), number of painful procedure and heel prick per day ($\chi2=.55$) which were found not significant at 0.05 level of significance except for gender ($\chi2=.04$) which was found to be significant. Thus, it can be inferred that both the groups were homogenous and comparable

at baseline in terms of all sample characteristics except for gender.

TABLE-2: Mean, Mean Difference, Standard Deviation of Mean Difference, Standard Error of Mean Difference and 't' Value of Mean Post Test of Temperature of LBW Babies.

N=30

Temperature (°C)	Group	Mean	MD	SD	SEMD	t	df	p-value
Day-2	Experimental group	36.58	0.02	.51	.13	.23	28	.81 NS
	Comparison group	36.60						
Day-3	Experimental group	36.70	0.3	.52	.13	1.13	28	.29 NS
	Comparison group	36.40						
Day-4	Experimental group	36.60	0.4	.41	.01	2.9	28	.01*
	Comparison group	36.20						
Day-5	Experimental group	36.71	0.18	.53	.13	.91	28	.36 NS
	Comparison group	36.53						

*Significant ($p < 0.05$) ^{NS} = Not significant ($p>0.05$) $t(2)=4.30, t(3)=3.18, t(1)=12.71$

Table 2 data concludes that there is significance difference in mean temperature of LBW babies after the implementation of DSCB as evident by p value<0.05on day 4.

TABLE-3: Mean, Mean Difference, Standard Deviation of Mean Difference, Standard Error of Mean Difference and't' Value of Mean Post Test of Comfort Behavior of LBW Babies.

N=30

Comfort behavior	Group	Mean	MD	SD	SEMD	t	df	p-value
Day-2	Experimental group	6.80	2.8	1.55	0.4	4.27	28	.006*
	Comparison group	9.60						
Day-3	Experimental group	6.40	3.13	4.72	0.48	3.76	28	.001*
	Comparison group	9.53						
Day-4	Experimental group	6.47	2.66	0.79	0.50	3.06	28	.005*
	Comparison group	9.13						
Day-5	Experimental group	6.47	2.6	1.71	0.44	3.51	28	.002*
	Comparison group	9.07						

*Significant ($p < 0.05$) ^{NS} = Not significant ($p>0.05$)

$t(4)=2.78$, $t(3)=3.18$

Table 3 data concludes that there is significance difference in mean comfort behavior score of LBW babies after the implementation of DSCB as evident by $p<0.05$on day-2 to day-5. Thus, it indicates that this difference was a true difference not by chance with experimental and comparison group. Hence it can be stated that DSCB was effective in reducing the discomfort of LBW Babies during painful procedure.

Discussion

Nearly two third of LBW babies in both group (66.7%) weight falls between 1.2-1.79 kg. More than half of LBW babies in comparison group (53.3%) and majority of LBW babies in experimental group (86.7%) were boys. More than one third of LBW babies in both groups (40%) fall in the gestational age of 34-36 weeks. Present study was found contradictory with study conducted by AyseKahraman et al (2017), involved 33 preterm infants, with an average gestational age of 33.03±1.31 weeks. The mean birth weight of the infants was 1757 g±316, 57.6% were female. [8]

Present study results are consistent with systematic review of current research evidence to see the effectiveness of non-pharmacological management of pain during needle puncture procedures in infants. Containment is the intervention that limits the movement of infant during painful procedure, promote self-regulation and attenuate physiologic and behavioral stress caused by acute pain. No studies have examined the effect of this intervention in older infants up to a year or the sustained effectiveness of swaddling/ containment over ongoing procedures or across varied procedures. Further research is recommended to fill these knowledge gaps.[7]

In the present study pre implementation scores of physiological parameters and comfort behavior of LBW babies were independent of all the selected variables included in the study (birth weight, gender, gestational age, mode of feeding, type of milk, any co- morbid illness, number of painful procedure and heel prick per day, maternal age, religion, educational status of mother, mother's occupation, gravid of mother, any history of disease during pregnancy, mode of delivery and previous practices regarding care of LBW baby). The findings of the study was consistent with the findings of Nashwa M. Samra et al, there was no significance association of the demographic variables (mode of delivery, gender, gestational age, birth weight, mode of delivery) with the physical parameter scores. [9]

Conclusion

Based on the findings of the study, it can be concluded that DSCB was effective in improving neonatal outcomes (temperature and comfort behaviour) of LBW babies. DSCB outcomes can be more effective if it is continued for long time even at home.

Conflict of Interest: None

Funding Sources: None

Ethical approval: The ethical clearance was obtained from university research ethics committee of Maharishi Markandeshwar (Deemed to be University), Mullana, Ambala (MMU/IEC/1310) and the study was carried out in accordance with the guidelines laid by Indian Council of Medical Research ICMR. The permission was taken to conduct the study from the Medical Superintendent of selected Hospital. The written assent from the parents were collected prior to the study. The purpose for carrying out research project was explained and assurance of confidentiality was given to the parents.

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