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Original Article

Paediatrics Section

Clinical Outcome in Newborns after Omission of Heart Rate Counting Step vs Standard Neonatal Resuscitation: A Randomised Controlled Trial

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ABSTRACT

Introduction: In all Neonatal Resuscitation Program (NRP) scenarios, Heart Rate (HR) counting is essential to assess the response to resuscitation. Undue delay in initiating Positive Pressure Ventilation (PPV) due to the time taken in HR counting may increase the risk of hypoxic injury and infant mortality.

Aim: To observe whether omitting the HR counting step in the First Golden Minute (FGM) and early initiation of PPV affects outcomes.

Materials and Methods: The present Randomised Controlled Trial (RCT) was conducted in the Special Newborn Care Unit (SNCU), GSVM Medical College, Kanpur, Uttar Pradesh, India, from September 2020 to March 2022. A total of 67 newborns were included, with 34 in the control group (group 1) and 33 in the intervention group (group 2). In the control group, neonatal resuscitation was performed according to Facility-based Newborn Care (FBNC) guidelines, while in the intervention group, only the HR counting step was omitted from the FGM. Both groups of newborns were assessed for outcomes including normal baby, baby developing Hypoxic Ischaemic Encephalopathy (HIE) stage I, II and III, and death. Data was compiled and analysed using percentages for categorical variables. Continuous variables were analysed using mean and standard deviation of Z score and Student's t-test. A p-value less than 0.05 was considered statistically significant.

Results: The mean gestational age was 38.3±5.8 weeks in group 1 and 37.9±6.1 weeks in group 2. Gender distribution was almost equal, with 19 (56%) female newborns in group 1 and 17 (52%) female newborns in group 2. The mean total time from birth to the end of PPV (in seconds) was significantly lower in group 2 (63.47±7.09) compared to group 1 (78.18±8.36), with a p-value of <0.001. Clinical outcomes in group 1 included 10 (29.41%) normal babies, 12 (35.29%) with HIE-I, 5 (14.71%) with HIE-II, 5 (14.7%) with HIE-III, and 2 (5.88%) deaths. In group 2, the outcomes were 14 (42.42%) normal babies, 6 (18.18%) with HIE-I, 8 (24.24%) with HIE-II, 4 (12.12%) with HIE-III, and 1 (3.03%) death.

Conclusion: The present study demonstrated that even after omitting the HR counting step from the FGM, the outcomes in terms of HIE and death are similar to those observed after following the standard NRP protocol.

Keywords: Asphyxia, Brain hypoxia-ischaemias, Cerebral hypoxia-ischaemia, Heart rate determination, Hypoxic ischaemic encephalopathy, Neonate

INTRODUCTION

The goal of neonatal resuscitation is to prevent the morbidity and mortality associated with hypoxic-ischaemic tissue (brain, heart and kidney) injury and to re-establish adequate spontaneous respiration and cardiac output [1,2]. Guidelines for neonatal resuscitation have been issued by the American Heart Association (AHA) and the American Academy of Pediatrics (AAP). These guidelines help to remember the sequence for resuscitation, and failure to follow them has resulted in poor outcomes [1,3]. Despite an increase in skilled assistance during deliveries over the past years and various training modules for neonatal resuscitation, there has not been a significant change in the incidence of perinatal asphyxia. The incidence of HIE is 1.5 per 1000 live births in developed countries and varies between 2.3 and 26.5 per 1000 live births in developing countries [4,5]. Globally, birth asphyxia is estimated to account for 920,000 neonatal deaths every year and is associated with another 1.1 million intrapartum stillbirths [6,7]. Out of the total affected infants, 15-20% die in the early neonatal period, and 25-30% of survivors have severe neurological impairment, including cerebral palsy, epilepsy, visual and hearing impairment, cognitive impairment, intellectual, behavioural and social disorders [8].

This lack of improvement in outcomes may be due to the complexity of the teaching modules for neonatal resuscitation that must be followed within the time limit of the FGM, leading to poor outcomes, if not adhered to. In the FGM of resuscitation, valuable time is lost in assessing the HR of the newborn despite the baby's poor condition after the initial steps of resuscitation. This assessment usually takes more than six seconds for any trained person, making the baby more prone to hypoxic injury. Additionally, in resource-poor settings, there may only be one skilled person available to resuscitate the baby at birth.

Furthermore, it is challenging for Auxiliary Nurse Midwives (ANMs), nurses, midwives, Traditional Birth Attendants (TBAs), as well as, doctors to follow the same resuscitation steps within the time limit due to the complexity of the protocol. According to the current AAP NRP protocol, the use of Electrocardiogram (ECG) for HR monitoring and preductal Saturation of peripheral Oxygen (SpO_2)monitoring for guided oxygen therapy during resuscitation is not a feasible option in most places in India.

The current protocol instructs the use of a stethoscope to count the HR, which is counted for six seconds and then multiplied by 10

to determine the HR. However, in reality, this procedure often takes more than six seconds (usually 11-19 seconds), and there may also be interobserver variability. This observation was supported by a study by Johnson PA and Schmölzer GM [9].

In neonates at birth, a decline in HR to less than 100 per minute is almost always secondary to respiratory insufficiency. Therefore, ventilating the lungs at the earliest becomes the most important step during resuscitation, which should be done within the FGM. According to our current protocol, the initial steps should be completed within 30 seconds of birth, and the response to these steps is assessed by evaluating two parameters: HR and breathing. If the HR is below 100 or the child is apnoeic or gasping, PPV using a bag and mask should be initiated. Even if the HR is above 100 and the baby is apnoeic or gasping, PPV should be administered. After the initial steps of resuscitation, counting the HR by stethoscope for six seconds is either not universally practiced or, if done, it often takes longer than six seconds, which wastes precious time during the FGM. This is why the authors planned the present study to evaluate whether omitting the HR counting step during the FGM and initiating early bag and mask ventilation in babies who remain apnoeic or have gasping respiration after the initial steps of resuscitation at birth improves outcomes or decreases the chance of hypoxic injury.

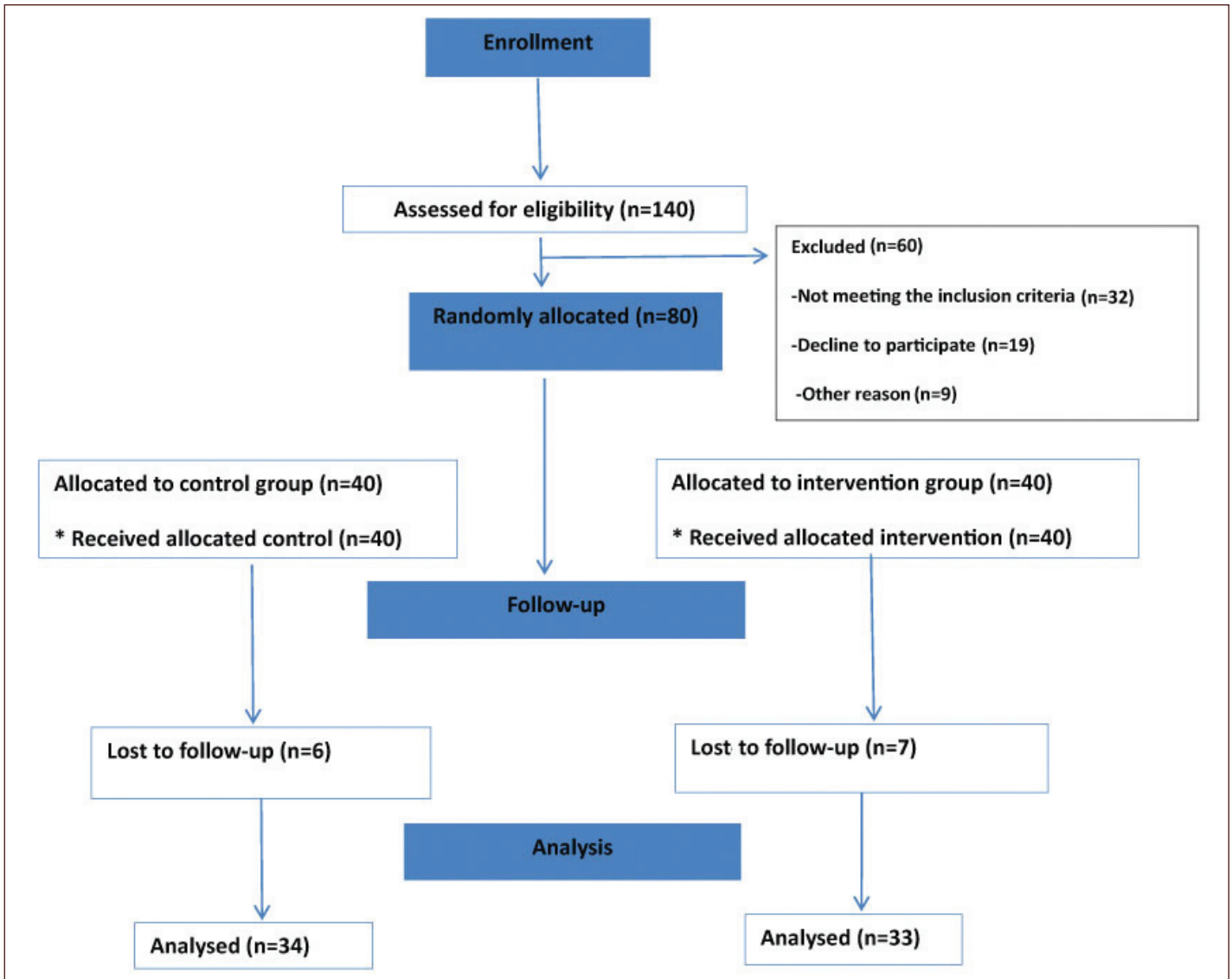
The objective of the present study was to assess the impact of omitting the HR counting step during the FGM in NRP on neonatal outcomes in terms of normal babies, HIE-I, HIE-II, HIE-III, and death.

MATERIALS AND METHODS

This RCT was conducted in the SNCU, GSVM Medical College, Kanpur, Uttar Pradesh, India, from September 2020 to March 2022. The study design was parallel with an allocation ratio of 1:1. Institutional Ethics Committee approval was obtained (Ref no: EC/150/Sept/2020). Only anticipated high-risk deliveries were enrolled in the present study, and consent was obtained from parents before delivery.

Sample size calculation: A pilot study was conducted on 10 subjects who were randomly assigned to control and intervention groups. The total number of days of hospital stay was assessed in both groups. In the control group, the mean number of days was 7.8, while in the intervention group, it was 6.9. The standard deviation was 1.3. Using the formula for comparing means, the sample size was calculated to be 33 in each group, with a power of 80% and a significance level of 5%.

A total of 140 newborns were initially enrolled in the present study, of which 60 newborns were excluded for not meeting the inclusion criteria (n=32), parents declining to participate (n=19), and other reasons (n=9). The remaining 80 newborns were randomised into the control group (n=40) and intervention group (n=40). In the control group, six newborns were lost to follow-up, and the remaining 34 newborns were analysed for the study. In the intervention group, seven newborns were lost to follow-up, and the remaining 33 newborns were analysed for further study [Table/Fig-1].



[Table/Fig-1]: Study flow diagram.

Inclusion criteria: All newborns, irrespective of the mode of delivery, delivered at the study site, who were not breathing or crying at birth, and whose parents had given prior written informed consent were included in the study.

Exclusion criteria: Newborns with major heart, CNS, or respiratory system anomalies, congenital heart block, those needing chest compression, or whose parents refused to give consent for the study were excluded.

A balanced block randomisation technique was used to assign the newborns into two groups. The randomisation codes for each group were computer-generated, with a block size of four. The randomisation code was assigned to each newborn in sequence in the order of enrollment, and then the newborn received the respective intervention. The principal investigator generated the codes from the computer software and also assigned newborns to the two groups. All attendants of newborns were masked for treatment allocation. The two groups were:

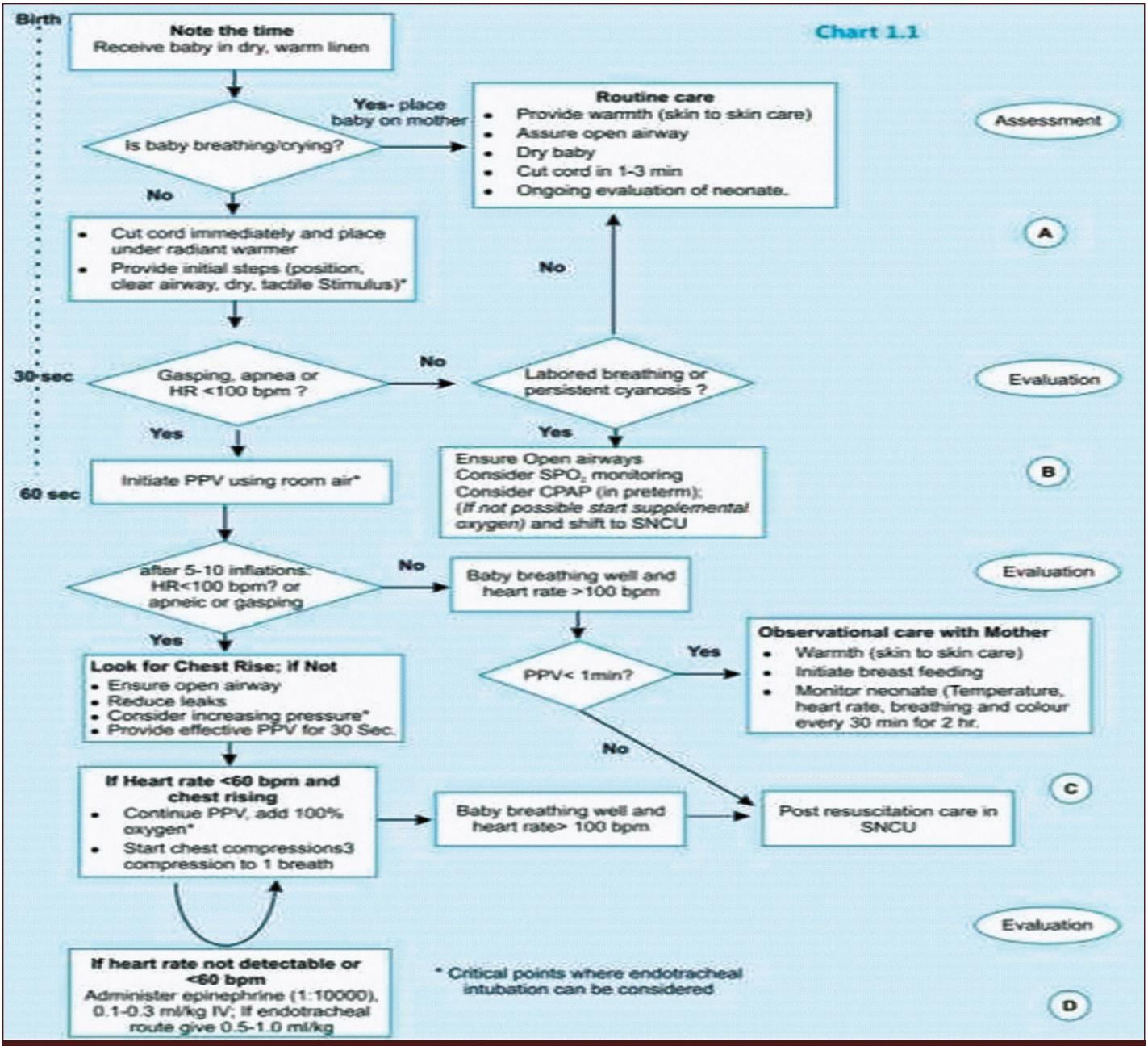
Group 1: Control group. Here the FBNC NRP algorithm [Table/Fig-2] was followed [10].

Group 2: Intervention group. In this group, the FBNC protocol was followed except, immediately after the initial steps, HR was not assessed, only breathing or crying was assessed to decide whether PPV was to be given or not. HR was assessed after doing PPV for 30 seconds. PPV was stopped when the baby gained spontaneous breathing and maintained it. In both groups, immediately after the initiation of PPV, the baby was put on Pulse Oximetry (PO). A Goldway GS20 monitor with a neonatal probe was used to read SpO_2 (the average time taken to display SpO_2 is around 12 seconds). The pulse oximeter sensor was placed on the right hand/wrist. The whole resuscitation process was noted on a time scale with the help of a stopwatch by a third person/observer. The same three-member team attended all deliveries to avoid any interobserver variability. In both groups, newborns were followed-up until discharge from the health care facility. In both groups, newborns were assessed for the following outcomes:

-Normal baby;

-Baby developing HIE stage I, II and III [11];

-Death;



[Table/Fig-2]: Facility Based Newborn Care (FBNC) NRP Algorithm. (Adapted frrom Facility Based Newborn Care Operational Guide. Guidelines for planning and implementation 2011).

-Any other complications of hypoxia and/or ischaemia like renal or cardiac involvement, etc.

STATISTICAL ANALYSIS

Independent variables were gestational age, birth weight, Appearance, Pulse, Grimace, Activity and Respiration (APGAR) score (at 1 minute and 5 minutes after birth), maternal co-morbidities and use of antenatal corticosteroids. Dependent variables were the mean total time taken from birth to the end of PPV (in seconds), duration of hospital stay, and outcome (Normal baby, HIE-I, HIE-II, HIE-III and death). Statistical Package for the Social Sciences (SPSS) version 22.0 software was used. Data was compiled and analysed using percentages for categorical variables. Continuous variables were analysed using the mean and standard deviation of the Z score and Student's t-test. A p-value less than 0.05 was considered statistically significant.

RESULTS

A total of 67 neonates were included in the current study during the study period. Out of 67, a total of 34 (50.75%) patients in the control group and 33 (49.25%) in the Intervention group were included. Distribution according to gender was also almost equal, with 19 (56%) female newborns in group 1 and 17 (52%) female newborns in group 2. In group 1, the mean gestational age (in weeks) was 38.3±5.8, and in group 2, it was 37.9±6.1 (p-value=0.784). In group 1, the mean birth weight (in kg) was 2.61±0.5, and in group 2, it was 2.63±0.4 (p-value=0.283) [Table/Fig-3].

Gestational age	Group 1 (n=34)		Group 2 (n=33)		[1]p-value
	n	%	n	%	
<28 weeks (extremely preterm)	0	0	1	3.03	0.306
28-<32 weeks (early preterm)	2	5.88	2	6.06	0.975
32-34 weeks (moderate preterm)	6	17.65	5	15.15	0.783
35-36 weeks (late preterm)	8	23.53	8	24.24	0.945
37-42 weeks (term)	17	50	13	39.39	0.383
>42 weeks (post-term)	1	2.94	4	12.12	0.153
Birth weight					
Birth weight	**Group 1 (n=34)**		**Group 2 (n=33)**		
	n	%	n	%	[1]p-value
<1.5 kg	0	0	1	3.03	0.306
1.5-2.5 kg	21	61.76	14	42.42	0.113
2.6-3.5 kg	10	29.41	14	42.42	0.267
>3.5 kg	3	8.82	4	12.12	0.659
Maternal Co-morbidities					
Maternal co-morbidities	**Group 1 (n=34)**		**Group 2 (n=33)**		
	n	%	n	%	[1]p-value
No	13	38.24	15	45.45	0.549
CNS	2	5.88	0	0	0.157
CVD	5	14.71	3	9.09	0.478
Endocrinological	5	14.71	7	21.21	0.487
Respiratory disease	4	11.76	4	12.12	0.964
Renal disease	1	2.94	0	0	0.320
Obstetrics events	3	8.82	2	6.06	0.667
BMI >=30 kg/m^2	1	2.94	2	6.06	0.537
APGAR score					
Time	**Group 1 (n=34)**		**Group 2 (n=33)**		**t**	**[2]p-value**
	Mean	**±SD**	**Mean**	**±SD**	
Baby response (APGAR score at 1 min.)	7.24	0.82	7.42	0.71	-1.009	0.317
Baby response (APGAR score at 5 min.)	8.97	1.27	8.88	1.02	0.326	0.746
Use of antenatal corticosteroids					
Antenatal corticosteroid used	**Group 1 (n=34)**		**Group 2 (n=33)**		**[1]p-value**
	n	%	n	%	
Yes	7	20.5	7	21.2	0.952
No	27	79.4	26	78.7	

[Table/Fig-3]: Distribution of study population according to gestational age, birth weight, maternal co-morbidities, APGAR score and use of antenatal corticosteroids in group 1 and group 2.
CNS: Central nervous system; CVD: Cardiovascular disease; BMI: Body mass index; [1]Z test; [2]Students's t-test

The mean time elapsed in the initial step (in seconds) before the initiation of PPV without counting HR was significantly lower in group 2 (25.12±1.47) as compared to group 1 (40.29±1.70). The mean total resuscitation time (in seconds) was significantly lower in group 2 (63.47±7.09) as compared to group 1 (78.18±8.36) [Table/Fig-4].

Parameters	Group 1 (n=34)		Group 2 (n=33)		t	[1]p-value
	Mean	±SD	Mean	±SD		
Time taken in the initial step (in sec) before initiation of PPV without counting HR	40.29	1.70	25.12	1.47	39.02	<0.001*
Time taken from birth to end of PPV (in sec)	78.18	8.36	63.47	7.09	7.682	<0.001*

[Table/Fig-4]: Comparison of the mean total time taken in the initial step (in sec) before initiation of PPV without counting HR and time taken from birth to end of PPV (in sec) in group 1 and group 2.
[1]t test; *The p-value <0.05 was considered statistically significant

The mean duration of hospital stay (in days) was significantly lower (5.9±1.6) in group 2 as compared to group 1 (11.6±2.4) (p-value <0.001). The p-value for a hospital stay of less than 7 days was 0.035, and the p-value for a hospital stay duration between 15-21 days was 0.036 [Table/Fig-5].

Hospital stay duration	Group 1 (n=34)		Group 2 (n=33)		[1]p-value
	n	%	n	%	
<7 days	9	26.47	17	51.51	0.035*
7-14 days	10	29.41	10	30.30	0.936
15-21 days	10	29.41	3	9.09	0.036*
>21 days	5	14.71	3	9.09	0.478

[Table/Fig-5]: Comparison of study population according to hospital stay in group 1 and group 2.
[1]Z test; *The p-value <0.05 was considered statistically significant

The number of deaths was higher in group 1 (5.88%) as compared to group 2 (3.03%), p-value=0.572. Moreover, the final clinical outcomes were not significantly different between group 1 and group 2 [Table/Fig-6].

Outcome	Group 1 (n=34)		Group 2 (n=33)		[1]p-value
	n	%	n	%	
Normal baby	10	29.41	14	42.42	0.389
HIE-I	12	35.29	6	18.18	0.114
HIE-II	5	14.71	8	24.24	0.323
HIE-III	5	14.71	4	12.12	0.756
Death	2	5.88	1	3.03	0.572

[Table/Fig-6]: Comparison of study population according to outcome in group 1 and group 2.
[1]Z test

DISCUSSION

The goal of the present study was to simplify the steps of NRP for low-resource settings in different regions around the world, where ECG and PO are costly and inaccessible. In addition, the availability of clinical staff, their levels of training, and the competency of healthcare professionals may also influence the success of the resuscitation. During observation, it was found that birth attendants were taking more than a minute during resuscitation, so we emphasised the FGM.

Annual deliveries at the present study hospital are approximately 3000-3500 per year, where the authors have observed 1-1.25% of newborns require extensive resuscitation. Similar studies emphasising on FGM have been done in the past. Money N et al., evaluated the accuracy of auscultation according to NRP HR target ranges and identified the overestimation of HR 100 beats per minute (bpm) as a common tendency for participants [12]. Another study by Kamlin CO et al., who compared auscultation and umbilical cord palpation with ECG, reported that both auscultation and umbilical cord palpation underestimated HR with a mean HR difference of 14 bpm and 21 bpm compared to ECG [13].

During resuscitation, the assessment of HR using auscultation remains challenging. Resuscitators need to assess HR while working under high-stress levels, high cognitive load and varying surrounding noise levels [9]. A long latency ranging from 1-2 minutes for sensor attachment and reliable signal display following birth is reported for PO, indicating that HR is not detected within the Golden Minute [14,15]. In a study by Gulati R et al., failure to detect HR within one minute occurred in 30%, 54% and 20% of infants by ECG, PO and either of the devices, respectively [16].

The present study showed that there is no significant difference in outcomes in terms of HIE in both groups. The duration of hospital stay and total resuscitation time were significantly less in group 2, in which the HR counting step was omitted in the FGM. Thus, the authors are saving precious time during the FGM. TBAs/Dais/first-level responders are uneducated and poorly skilled, so saving even around 15 seconds and preventing the delay of the initiation of PPV can make a huge difference in the clinical outcome. A similar conclusion was drawn in a study by Voogdt KG et al. They found that the mean time to estimate HR in neonatal resuscitation varied between 7.8 and 17.0 s and 28% of all HR assessments would have prompted incorrect management during resuscitation or stabilisation [17]. Boon W et al., concluded from their study that timeliness, communication and accuracy of house officers' HR determination are suboptimal, particularly for HR 60-100 bpm, which might lead to inappropriate decision-making and neonatal resuscitation care [18]. By omitting the HR counting step in the FGM before the initiation of PPV, the decision to initiate PPV will be simplified as only the breathing/crying of the baby will need to be assessed.

The strength of this trial was minimal interobserver variability as the same three-member team was present during the resuscitation of all study subjects.

Limitation(s)

However, the timing of events by a third member/observer of the resuscitation team was not video recorded and measured independently, which can be a source of measurement bias and is one of the limitations of the current study. Another limitation was the short duration of the present study. A multicentric study with a large sample size and a longer study duration is recommended in the future.

CONCLUSION(S)

The present study shows that even after omitting the HR counting step from the FGM in NRP, the clinical outcome in terms of HIE and the death rate is similar to that after following the standard FBNC NRP. In resource-poor countries like India, where grassroot level health workers are not highly skilled, there can be difficulty in efficiently assessing HR by auscultation within the stipulated time. Availability of PO/ECG is also limited. Therefore, omitting the HR counting step from the FGM will simplify the decision-making process before the initiation of PPV, so that the delay in the initiation of PPV is minimised. However, larger, multicentric RCTs are needed to justify the authors suggestion.

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