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Original Research Article

T-PIECE RESUSCITATOR VERSUS SELF-INFLATING BAG FOR NEONATAL POSITIVE PRESSURE VENTILATION: EFFECT ON THE DELIVERY ROOM STABILISATION AND RESPIRATORY OUTCOME

Neeli Hari Kiran[1], Abhijeet Shrivastava[2], Maheswari[3]

[1]Resident, Department of Paediatrics, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry, India.
[2]Professor, Department of Paediatrics, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry, India.
[3]Professor & Head, Department of Paediatrics, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry, India.

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Corresponding Author:
Dr. Maheswari,
Professor & Head, Department of Paediatrics, Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry, India.
Email: maheswarijipmer@gmail.com

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ABSTRACT

Background: Neonatal resuscitation is one of the life-saving methods in the delivery room. Moreover, about 10% of the neonates were found to need some form of assistance at the time of birth for the smooth transition from intrauterine to extrauterine life. Moreover, positive pressure ventilation (PPV) is an effective method in resuscitation for those who fail to establish spontaneous breathing. Moreover, most of the time, the PPV was delivered via the self-inflating bag (SIB). However, this was found to be associated with many disadvantages. Moreover, the newly designed T-piece resuscitator had been used in the delivery of the PPV to the newborns. The aim is to find the efficacy of the T-piece resuscitator versus the self-inflating bag in neonatal positive pressure ventilation.

Materials and Methods: This prospective comparative study was conducted in the department of paediatrics in a tertiary care centre in Puducherry. Moreover, all neonates who required resuscitation were included in the study. After the initial assessment, all participants were randomised into two groups. All the neonates in one group had received self-inflating bag resuscitation, and in another group, all the patients received T-piece resuscitation. Moreover, the patient's outcomes, including PPV duration, resuscitation in the room, intubation in the delivery room, and neonatal outcomes, were evaluated. Moreover, all the data had been entered into Excel and analysed using SPSS version 25.

Results: A total of 90 neonates were included in the study. Moreover, they were randomly and equally divided into two groups. The mean gestational age of the patients in the SIB and TPR groups was 36.2 ± 1.3 weeks and 37.4 ± 1.2 weeks, respectively. The mean duration of the positive pressure ventilation among the SIB and TPR group was found to be 55.4 + 6.6 and 25.6 + 5.9 ($p < 0.001$), and about 80% of the patients with TPR were found to have resuscitation in room air when compared to only 31.1% in the SIB group ($p < 0.001$). The intubation rate in the delivery room was higher in the SIB group (44.4%). The TPR group showed an overall favourable outcome in neonatal parameters, including NICU admission ($p=0.001$), APGAR score ($p < 0.001$), and duration of mechanical ventilation ($p=0.016$).

Conclusion: The study concluded that resuscitation with TPR decreased PPV and reduced the need for intubation during delivery room resuscitation. Moreover, the study noted that the TPR also reduces the need for invasive ventilation.

Keywords: neonatal resuscitation; outcome; t-piece- self inflating bag.

INTRODUCTION

Acute pediatric emergencies were found to arise from diverse etiologies. Moreover, at the time of delivery, the newly delivered infants were found to experience many critical events, which are often presented in the form of apnea, bradycardia, hypotension and central cyanosis secondary to the incomplete cardiopulmonary transition.[1] Moreover, studies reported that about 90% of newborns required some assistance to transition from intrauterine to extrauterine life successfully. Moreover, about 10% of infants required assisted ventilation, and less than 1% required extensive resuscitation for a successful transition. The essential step in the resuscitation of a newborn in the delivery room is to establish good ventilation.[2,3]

Effective positive pressure ventilation was found to be an important resuscitation manoeuvre in neonates who fail to establish spontaneous breathing at the time of resuscitation.[4] However, the studies have shown that prolonged or increased positive pressure ventilation is found to be associated with an increased risk of overdistension, and this is more commonly demonstrated in animal models secondary to the development of the inflammatory response and histological injury to the lungs.[5] Moreover, the various determinants of effective ventilation were found to be improvements in heart rate, muscle tone, the need for endotracheal intubation, and the APGAR score. Moreover, the most common method for delivering positive-pressure ventilation was the Self-inflating bag (SIB).[6,7]

The self-inflating bag is the most commonly used piece of equipment for delivering positive-pressure ventilation to patients. However, the main disadvantage of this device is that it is not designed to deliver positive end-expiratory pressure (PEEP) unless a special valve is attached. On the other hand, the T-piece resuscitator is an alternative device used for positive-pressure ventilation and provides PEEP.[8,9] And the studies showed that the T-piece resuscitator helped deliver a more accurate and consistent peak inspiratory pressure. Moreover, to date, only a limited number of studies have compared the efficacy of the two devices in delivery room resuscitation. And so this study was planned to find the efficacy of the T-piece resuscitator versus the self-inflating bag in the neonatal positive pressure ventilation.

MATERIALS AND METHODS

Study design: This prospective comparative study was conducted among neonates who required assisted ventilation at the time of delivery at the Sri Lakshmi Naraya Institute of Medical Sciences in Puducherry, India. The study was conducted for 24 months, from May 2024 to May 2026.

Sampling: The patients were selected using convenience sampling. The study by Thakur A et al.[10] found that the mean durations of positive pressure ventilation with the self-inflating bag and the T-piece resuscitator were 81.6 and 50.2 seconds, respectively. With 95% confidence and 90% power, the minimum sample size per group was 40.

Inclusion and Exclusion criteria

All neonates who required positive pressure ventilation at birth were included in the study. Moreover, the mother with chorioamnionitis, neonates with meconium-stained and the neonates with major congenital anomalies were excluded from the study.

Data collection: After obtaining approval from the Institute Ethics Committee and informed written consent, neonates requiring positive-pressure ventilation were included in the study. The block randomisation technique had been used to divide the neonates into two groups. Moreover, all neonates in the first group received resuscitation ventilation via a self-inflating mask, and those in the other group received resuscitation via a T-piece resuscitator. During TPR, the initial PIP and PEEP were established at 20 cm H2O and 5 cm H2O, respectively. In all groups, positive pressure ventilation (PPV) was administered at a rate of 40–60 breaths per minute, with the inflation pressure calibrated to ensure observable chest elevation. Neonates were resuscitated according to the 2005 NRP guidelines, which were in effect during the study period. 9PPV commenced with ambient air, and oxygen was administered according to established recommendations.[11]

The primary outcome of the study includes the duration of the positive pressure ventilation during the delivery room resuscitation, and the secondary outcomes, which are evaluated in the study, include the intubation rates in the delivery room, development of the respiratory distress, need for the change of mechanical ventilation and the need for the initiation of the surfactant therapy. Moreover, in patients in whom the PPV failed, the neonates were immediately changed to endotracheal intubation. Moreover, all the events occurring in the delivery room had been recorded.

Data analysis: Data entry was conducted using Epi-Data software, and analysis was performed using Statistical Package for the Social Sciences (SPSS) version 25 (IBM Corp., Armonk, NY, USA).

Ethical Approval: The study procedure was approved by the Internal Human Ethics Committee of Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry, under reference number 8/SLIMS/IEC/0833.

RESULTS

A total of 90 neonates participated in the study. Among them, about 45 patients were randomised to the SIB group, and another 45 to the TPR group. Upon exploring the demographic details of the patients, about 64.4% of neonates in the SIB group

and 55.6% in the TPR group had a birth weight of less than 2.5 Kg. 66.7% of patients in the SIB group and 62.2% in the TPR group were male. Moreover, the mean gestational age of the patients in the SIB group was 36.2 ± 1.3 weeks, and in the TPR group, 37.4 ± 1.2 weeks. In the study, 48.9% in the SIB group and 44.4% in the TPr group were primigravida. Moreover, among the comorbidities of the patients, in the SIB group GDM was noted in 42.2%, followed by hypertension in 24.4%; in the TPR group, GDM was noted in 44.4%. Oligohydramnios was noted in 28.9% of patients, as shown in [Table 1].

Table 1: Demographic details of the study participants

Characteristics	SIB (n=45)	TPR (n=45)	p-value
Birth weight			
<2.5 Kg	29 (64.4)	25 (55.6)	0.741
>2.5 Kg	16 (35.6)	20 (44.4)	
Gender			
Male	30 (66.7)	28 (62.2)	0.659
Female	15 (33.3)	17 (37.8)	
Mean Gestational age(weeks)	36.2 + 1.3	37.4 + 1.2	<0.001
Antenatal steroids			
Given	19 (42.2)	20 (44.4)	0.831
Not given	26 (57.8)	25 (55.6)	
Gravida			
Primi	22 (48.9)	20 (44.4)	0.672
Multi	23 (51.1)	25 (55.6)	
Comorbidities			
Hypertension	11 (24.4)	9 (20)	0.612
GDM	19 (42.2)	20 (44.4)	0.831
Oligohydramnios	10 (22.2)	13 (28.9)	0.468
Antepartum hemorrhage	7 (15.6)	8 (17.8)	0.777
ARED	2 (4.4)	4 (8.9)	0.393

Outcomes of the neonates in the delivery room had been shown in the following [Table 2], the mean duration of the positive pressure ventilation among the SIB and TPR group was found to be 55.4 + 6.6 and 25.6 + 5.9 (p-<0.001) and about 80% of the patients with TPR were found to had resuscitation in room air when compared to only 31.1% of the patients in the SIB group (p-0.001). Moreover, the intubation rate in the delivery room was higher in the SIB group (44.4%) than in the TPR group (8.9%) (p < 0.001). Moreover, neonates in the TPR group had higher APGAR scores at 1 min (p < 0.001) and 5 min (p < 0.001) than those in the SIB group. and the study also showed that the NICU admission rate was higher among neonates in the SIB group (66.7%; p=0.001) than in the TPR group (24.4%). The respiratory parameters, including the maximum mean arterial pressure and the FiO2, showed significant differences between the two groups. Moreover, the study found no significant differences in surfactant administration (p=0.113) or mortality (p=0.306) between the groups.

Table 2: Outcomes of the study participants during the study period

Characteristics	SIB (n=45)	TPR (n=45)	p-value
Delivery room			
Duration of PPV (s)	55.4 + 6.6	25.6 + 5.9	<0.001
Resuscitation in room air			
Present	14 (31.1)	36 (80)	0.001
Absent	31 (68.9)	9 (20)	
Intubation in DR			
Present	20 (44.4)	4 (8.9)	0.001
Absent	25 (55.6)	41 (91.1)	
APGAR score at 1 min	4.2 + 1.2	6.5 + 1.5	0.001
APGAR score at 5 mins	6.3 + 1.1	8.4 + 1.5	<0.001
NICU Stay			
NICU admission	30 (66.7)	11 (24.4)	0.001
Respiratory distress	19 (42.2)	14 (31.1)	0.274
Mechanical ventilation	26 (57.8)	7 (15.6)	0.001
Invasive ventilation	20 (44.4)	4 (8.9)	0.001
CPAP only	6 (13.3)	3 (6.7)	0.292
Max MAP	8.4 + 1.4	9.9 + 1.2	<0.001
Max FiO2	46.9 + 20.8	29.6 + 12.8	<0.001
Duration of MV (h)	45.6 + 11.2	40.2 + 9.5	0.016
Surfactant administration			
Present	12 (26.7)	6 (13.3)	0.113
Absent	33 (73.3)	39 (86.7)	
Mortality	3 (6.7)	1 (2.2)	0.306

DISCUSSION

This prospective comparative study was conducted to evaluate the efficacy of the self-inflating bag versus the T-piece resuscitator in delivering positive-pressure ventilation during delivery room resuscitation. In our study, a significant difference in PPV duration was observed. The study showed that the duration of PPV in the TPR group was significantly shorter than in the SIB group. We further evaluated the clinical significance of the finding by comparing it with successful resuscitation in the room air and intubation in the delivery room. Moreover, both outcomes were found to be favourable in neonates in the TPR group compared with SIB neonates. Moreover, a smaller proportion of patients had intubation in the delivery room in the TPR group (8.9%) than in the SIB group (44.4%). Moreover, the study by Carpio ALM et al,[12] showed that the use of PEEP in the TPR was associated with reduced intubation rates and shorter PPV duration among neonates. The study by Satosh D et al,[13] showed that applying PEEP during resuscitation enhances FRC formation and improves oxygenation. Also, the study by O'Donnell, CPF et al,[14] reported that, in the absence of PEEP, most fetal lung fluid, which is expelled during inspiration, re-enters the airways during expiration.10 to 13 This may delay the transition and increase the need for resuscitation. Furthermore, another possible reason for the increase in benefit was the delivery of more consistent inspiratory pressure with the TPR system than with the other models.

And our study showed that the APGAR score differed significantly between the groups. The APGAR score was higher in TPR group neonates at both the 1st and 5th minutes compared with SIB group neonates. Similar to our study, Thakur A et al,[10] Also found that the APGAR score was higher among patients who received T-piece resuscitation than among those who received self-inflation bag ventilation. However, the study by Siripattanapipong P et al,[15] reported the opposite result to our study, with the SIB group having a higher APGAR score than the TPR group.

Our study showed that the intubation rate was higher among neonates in the SIB group than in the TPR group. In our study, about 57.8% of patients in the SIB required mechanical ventilation, compared with 15.6% in the TPR group. Szyld et al,[16] Conducted a recent multicenter cluster-randomised two-period crossover experiment to examine the efficacy and safety of these devices in neonates gestationally ≥26 weeks who required resuscitation at birth. The self-inflating bag group had a considerably higher intubation rate than the T-piece group (26% vs 17%). The fractional inspired oxygen was found ot be lower in the TPR when compared to the TPR group. The study by Thakur A et al,[10] showed that the FiO2 level was lower in the TPR group compared with the SIB group. Moreover, the study by Kumar H et al,[17] showed that TPR was more efficacious than SIB in providing better SpO2 at 5 minutes, especially in preterm neonates. The duration of mechanical ventilation in the TPR group was significantly shorter than in the SIB group. Moreover, the study by Kumar J et al,[18] showed that the TPR had a shorter duration of mechanical ventilation and PPV ventilation compared to the Sib group, due to higher PEEP and better oxygen delivery.

In our study, 13.3% of patients in the TPR group and 26.7% in the SIB group received surfactant. The study by Siripattanapipong P et al,[15] showed that the rate of surfactant administration was higher in the TPR group (19.4%) than in the SIB group (18%). However, the difference was not statistically significant. Moreover, the study by Thakur A et al,[10] showed that the proportion of neonates receiving surfactant was equal in both the TPR and SIB groups. Moreover, our study found that the mortality rate did not differ significantly between the groups. Moreover, similar results were noted in the study by Thakur A et al,[10] where the mortality among patients with TPR was 7.5%, and in the SIB group was 6%. Moreover, the study by Kumar J et al,[18] also showed no significant difference in neonatal mortality between the TPR and SIB groups.

Limitations of the study

The study was conducted with a smaller sample size; if it had been conducted with a larger sample size and in a multicentre setting, it would be helpful to generalise the findings to the whole population.

CONCLUSION

Neonatal resuscitation is one of the life-saving measures for many newborns, which helps in progressing the life from the intrauterine life to the outside world. Moreover, our study showed that resuscitation with TPR decreased PPV and reduced the need for intubation during delivery room resuscitation. Moreover, the study noted that the TPR also reduces the need for invasive ventilation. So, the study recommends using the TPR in neonatal resuscitation to achieve better outcomes with fewer complications.

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