EFFECTIVENESS OF T-PIECE RESUSCITATOR VERSUS SELF-INFLATING BAG DURING BIRTH RESUSCITATION IN VERY LOW BIRTH WEIGHT INFANTS

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Abstract. T-piece resuscitator (TPR) and self-inflating bag (SIB) are two different devices used for positive-pressure ventilation (PPV) during birth resuscitation. However, the effectiveness of TPR has not been clearly demonstrated. The aim of this study was to compare the rate of endotracheal intubation between TPR and SIB for PPV during birth resuscitation in very low birth weight (VLBW) infants. This retrospective cohort study was conducted in infants born with either gestational age <33 weeks or birth weight <1,500 grams and who received PPV during birth resuscitation at Siriraj Hospital during the 2014 and 2016 study period. Medical charts were reviewed to identify type of device and respiratory outcome. A total of 128 infants were included 67 infants received PPV via TPR and 61 received PPV via SIB. The TPR group had lower gestational age and lower birth weight than the SIB group (28.6 *vs* 30.2 weeks; $p<0.001$ and 1,061.1 *vs* 1,288.3 g; $p<0.001$). There was no significant difference in intubation rate between groups (adjusted odds ratio=0.83, 95% confidence interval: 0.38-1.80). However, incidence of mortality or oxygen requirement at 36 weeks postmenstrual age was significantly higher in the TPR group (44.8% *vs* 25.4%; $p=0.02$). In conclusion, use of TPR for PPV in VLBW infants did not improve intubation rate during birth resuscitation when compared with SIB.

Keywords: birth resuscitation, positive-pressure ventilation, self-inflating bag, T-piece resuscitator, very low birth weight infants

INTRODUCTION

Preterm infants are born with several physiological limitations that adversely affect their ability to establish effective ventilation, such as poor respiratory control, compliant chest wall, surfactant deficiency, and large amount of lung fluid (Polin *et al*, 2011). One of the challenges faced by clinicians during birth resuscitation of preterm infants is to promoting ventilation with minimal lung injury. Strategies to promote lung recruitment in preterm infants with breathing difficulty at birth in order to avoid intubation have been accepted in modern neonatal practice (te Pas and Walther, 2007; te Pas *et al*, 2009; Lista *et al*, 2011; Grasso *et al*, 2015). However, infants with severe lung conditions may require positive-pressure ventilation (PPV). PPV provides forced ventilation and oxygenation into the respiratory system. As a result, there is some associated risk of inflicting lung damage. Experimental studies have shown that aggressive ventilation during birth resuscitation triggers a process of lung injury that can last for several weeks (Bjorklund *et al*, 1997; Wilson *et al*, 2003; Hillman *et al*, 2007).

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Among recommended PPV devices, self-inflating bag (SIB) is commonly used due to several recognized advantages (Perlman *et al*, 2010; John, 2011). However, the use of T-piece resuscitator (TPR) has been increasing over the past several years especially during preterm resuscitation, because it provides constant pressure delivery throughout the maneuver (Hoskyns *et al*, 1987; Finer *et al*, 2001; Bennett *et al*, 2005; Oddie *et al*, 2005).

American Academy of Pediatrics (AAP) 2011 guidelines and International Liaison Committee on Resuscitation (ILCOR) guidelines (John, 2011) recommend either device for PPV during birth resuscitation. Some controlled trials reported higher efficacy in TPR than in SIB (Dawson *et al*, 2011b; Szyld *et al*, 2014; Thakur *et al*, 2015). However, few studies have demonstrated the superiority of TPR over SIB in real-life clinical practice.

The primary aim of this study was to compare the rate of endotracheal intubation between TPR and SIB for PPV during birth resuscitation in very low birth weight infants. The secondary objective was to compare other short-term outcomes between groups.

MATERIALS AND METHODS

This retrospective cohort study was conducted in infants born with either gestational age less than 33 weeks or birth weight less than 1,500 grams and who received PPV during birth resuscitation at Siriraj Hospital from January 2014 to March 2016. Siriraj Hospital is tertiary referral center. The protocol for this study was approved by the Siriraj Institutional Review Board (SIRB), Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand.

Medical records were reviewed for prenatal history, type of PPV device used, and respiratory outcomes. Infants who did not require PPV, and those who had major congenital malformation that could affect respiratory outcomes at birth were excluded. Included infants who received PPV during birth resuscitation were allocated into either the T-piece resuscitator (TPR) group or the self-inflating bag (SIB) group.

As a tertiary care center and a teaching hospital, the Department of Obstetrics and Gynecology manages 7,000 to 9,000 deliveries each year, including both normal and high-risk pregnancies. Obstetric practices for preterm delivery at our center follow American College of Obstetrics and Gynecology (ACOG) and institutional guidelines, including antenatal corticosteroid administration, intrapartum antibiotic prophylaxis, and tocolytic treatment for the management of preterm labor (ACOG Committee on Obstetric Practice, 2011a; ACOG Committee on Obstetric Practice, 2011b; ACOG Committee on Practice Bulletins - Obstetrics, 2012). All preterm deliveries are attended and resuscitated by a dedicated team that includes a neonatal fellow, a pediatric resident, and at least one experienced nurse following the AAP/ILCOR guidelines (2011) (John, 2011). We routinely attempt non-invasive ventilation in newly born infants who develop signs of respiratory distress. Intubation is considered only in infants who develop significant respiratory distress despite nasal continuous positive-airway pressure or severely depressed conditions, such as perinatal asphyxia.

Both TPR and SIB are available for resuscitation in the delivery rooms at our center. TPR can take of form of a mobile device (Neopuff®; Fisher & Paykel Healthcare, Auckland, New Zealand) or a TPR system that is a component part of a comprehensive resuscitation system. According to policy at our center, PPV is initiated in infants with less than 30 weeks gestation using a TPR with an initial peak inspiratory pressure (PIP) setting of 20 cm H_2O and a positive end-expiratory pressure (PEEP) of 5 cm H_2O. The SIB system uses a 280 ml MR-100™ Silicone Manual Resuscitator (GaleMed, Taipei, Taiwan). The self-inflating bag was not routinely connected to a PEEP valve.

Oxygen administration during study period was initiated at FiO_2 of 0.4, and was adjusted according to pre-ductal target saturation.

Sample size calculation

The sample size was calculated using intubation rate data from a previous study (52% *vs* 69% in the TPR group and SIB group, respectively) (Szyld *et al*, 2014). Using a significance level of 0.05 (2-sided) and a power of 80%, a total of 258 infants (129 infants per group) was calculated. However a strict preterm resuscitation protocol was established at our center in 2013, we decided to include only infants that were born in 2014 and later.

Statistical analysis

Data analysis was performed using PASW Statistics version 18.0 (IBM, Armonk, NY). Categorical variables are presented as number and percentage. Normally distributed continuous variables are presented as mean ± standard deviation, and non-normally distributed continuous variables are presented as median and interquartile range. Continuous variables were compared using Student's *t*-test or Mann-Whitney *U* test, depending on their distribution pattern. Categorical variables were compared using chi-square test or Fisher's exact test. A *p*-value <0.05 was considered statistically significant. Adjusted odds ratios for protective factors or risk factors

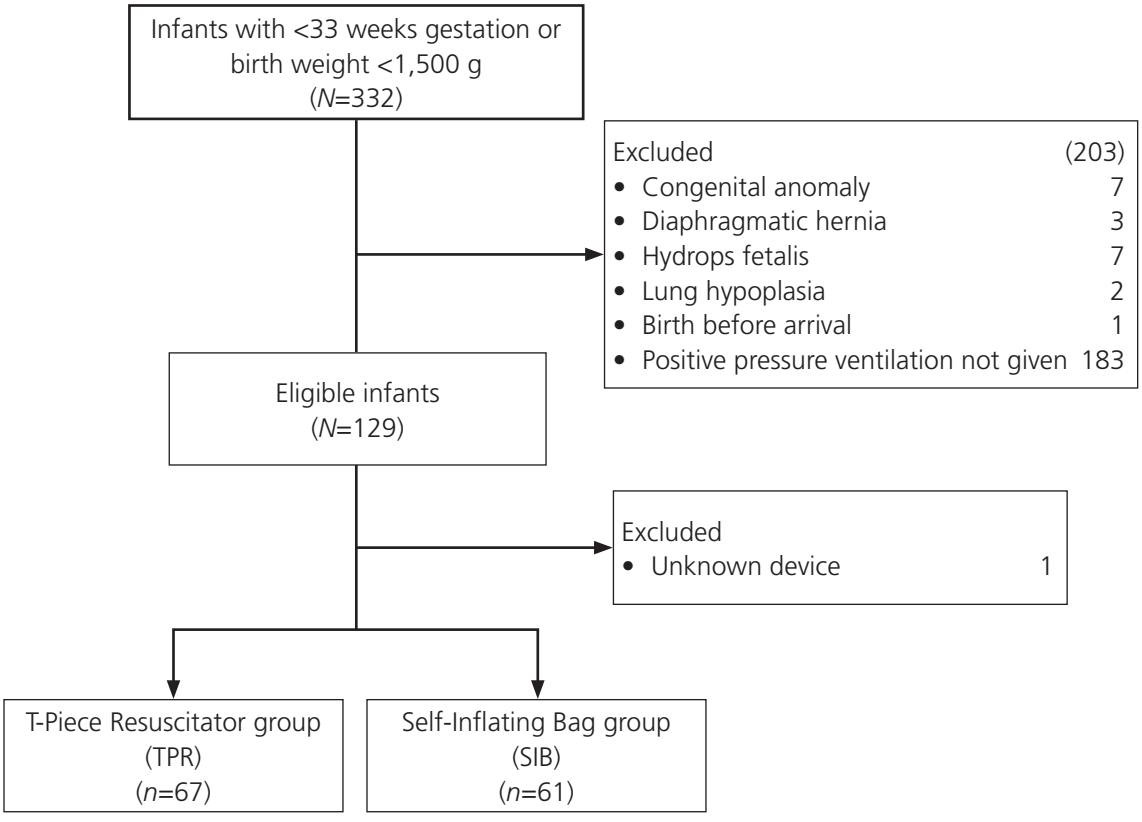

Fig 1– Flow diagram of very low birth weight infants who required positive-pressure ventilation during birth resuscitation (*N*=128).

for endotracheal intubation were derived from binary logistic regression analysis.

RESULTS

Of 332 eligible preterm infants, 128 infants (38.9%) that required PPV during birth resuscitation were included in the final analysis. Of those 128 infants, 67 received PPV via T-piece resuscitator (TPR group) and 61 received PPV via self-inflating bag (SIB group). A flow diagram of the infant selection and allocation process is shown in Fig 1.

Demographic and clinical characteristics of mothers and infants are presented in Table 1. TPR group infants had lower gestational age and lower birth weight than SIB group infants (28.6 *vs* 30.2 weeks; $p<0.001$ and 1,061.1 *vs* 1,288.3 g; $p<0.001$, respectively). TPR group mothers had significantly more fetal distress than SIB group mothers ($p=0.02$). Median 1-minute Apgar score was similar between groups.

A comparison of infant outcomes between groups is given in Table 2. There was no significant difference in intubation rate between groups (58.2% *vs* 54.1% for the TPR and SIB groups, respectively; $p=0.64$). Infants in the TPR group had a higher rate of chest compression, but the difference between groups did not reach statistical significance. Importantly – although respiratory outcomes, including respiratory distress syndrome (RDS), requirement for surfactant administration, and air leak syndrome were similar, the incidence of mortality or oxygen requirement at 36 weeks postmenstrual age (PMA) was higher in the TPR group than in the SIB group (44.8% *vs* 25.4%; $p=0.02$). Using binary logistic regression model and adjusted for birth weight, gender, singleton, fetal distress, and maternal

Table 1
Demographic and clinical characteristics of mothers and infants.

Characteristics	TPR group	SIB group	*p*-value
Mothers, *n*	62	60	
Age (years), mean±SD	29.9±7.6	29.7±8.3	0.725
Hypertensive disorder, *n* (%)	20 (32.3)	14 (23.3)	0.272
Diabetes, *n* (%)	4 (6.5)	9 (15)	0.151
Preterm labor, *n* (%)	39 (62.9)	47 (78.3)	0.062
Antepartum hemorrhage, *n* (%)	5 (8.1)	6 (10)	0.709
Fetal distress, *n* (%)	57 (91.9)	46 (76.7)	0.020[a]
Antenatal corticosteroids, *n* (%)	61 (91.0)	49 (80.3)	0.082
Cesarean delivery, *n* (%)	47 (75.8)	36 (60)	0.061
Infants, *n*	67	61	
Gestational age (weeks), mean±SD	28.6±2.3	30.2±2.7	<0.001[a]
Birth weight (grams), mean±SD	1,061.1± 312.5	1,288.3±321.4	<0.001[a]
Male gender, *n* (%)	30 (44.8)	22 (36.1)	0.316
Singleton, *n* (%)	47 (70.1)	45 (73.8)	0.649
Intrauterine growth retardation, *n* (%)	9 (13.4)	8 (13.1)	0.958

[a]$p< 0.05$, statistically significant. SIB, self-inflating bag; TPR, T-piece resuscitator.

corticosteroid administration, the adjusted odds ratio for intubation in the TPR group was 0.83 (95% confidence interval: 0.38-1.80; p=0.63).

DISCUSSION

T-piece resuscitator (TPR) is increasingly used for PPV during birth resuscitation. TPR is a pressure limiting device that has been documented as an alternative device in the Neonatal Resuscitation Program (NRP) guideline since 2011(John, 2011). The device comes with an adjustable PEEP and controlled PIP. Although it is a simple device, experienced staff are needed to effectively set-up and adjust all necessary parameters during resuscitation (McHale *et al*, 2008; Hawkes *et al*, 2010; Roehr *et al*, 2010). The potential advantages of lung protection and lung recruitment at birth in preterm infants has influenced the increased popularity of TPR among clinicians. Experimental studies reported that pressure delivered by the TPR is more accurate and consistent than SIB throughout the PPV maneuver (Finer *et al*, 2001; O'Donnell *et al*, 2005; Oddie *et al*, 2005; Dawson *et al*, 2011a). Three major RCT studies compared efficacy between TPR and SIB. A relatively small RCT (Dawson *et al*, 2011a) conducted in very preterm infants found no difference in resuscitation outcomes between devices. The other two studies (Szyld *et al*, 2014; Thakur *et al*, 2015) reported more favorable outcomes, including intubation rate in the delivery room, in the TPR group than the SIB group. It should be noted that the latter two studies recruited only a small proportion of very low birth weight infants, and their results are more likely to represent late preterm infants than very preterm infants.

This study focused on very low birth weight infants, because they are more likely to develop respiratory compromise at birth and chronic lung disease later in life. Interestingly, our intubation rate in both study groups was higher than rates published in other reports. One potential explanation is that over three quarter of our population had history of fetal distress (92% and 77% in the TPR- and SIB groups, respectively), which was reflected in the median Apgar score at 1 minute of only 4 in both groups. This indicates that our study population was a high-risk population that had not only respiratory issues, but also perfusion problems. This population is commonly encoun-

Table 2
Comparison of infant outcomes between groups.

Outcome measure	TPR group (n = 67)	SIB group (n = 61)	p-value	OR	95% CI
1-minute Apgar score[a]	4 (1,5)	4 (3,5)	0.210	-	-
5-minute Apgar score[a]	7 (5,8)	8 (5,9)	0.149	-	-
Intubation in delivery room, n (%)	39 (58.2)	33 (54.1)	0.640	1.18	0.59-2.38
Chest compression, n (%)	8 (11.9)	3 (4.9)	0.212	2.62	0.66-10.37
Diagnosis of RDS, n (%)	20 (29.9)	16 (26.2)	0.649	1.19	0.55-2.60
Surfactant administration, n (%)	13 (19.4)	11 (18)	0.843	1.09	0.45-2.67
Air leaks, n (%)	8 (11.9)	6 (9.8)	0.703	1.24	0.41-3.81
Mortality/use of oxygen at 36 week-PMA, n (%)	30 (44.8)	15 (25.4)	0.024[b]	2.38	1.11-5.08

[a]Apgar scores are presented as median (interquartile range). CI, confidence interval; OR, odds ratio; PMA, post-menstrual age; RDS, respiratory distress syndrome; SIB, self-inflating bag; TPR, T-piece resuscitator. [b]$p< 0.05$, statistically significant.

tered in real-life clinical practice, which may be in contrast to relatively well preterm infants that were included in previous RCT studies (Szyld *et al*, 2014; Thakur *et al*, 2015). We also found no significant difference in intubation rate between the TPR and SIB groups. This finding is consistent with a previous RCT study in preterm infants (Dawson *et al*, 2011b).

More importantly, the TPR group had significantly higher rate of composite outcome of mortality or oxygen dependence at 36 weeks PMA. However, this finding should be interpreted with caution because birth weight, which is an important confounder, could not be adjusted due to the limited number of infants that had a composite outcome. Morbidity and mortality in preterm infants might also be influenced by other factors, including necrotizing enterocolitis, sepsis, and severe intraventricular hemorrhage. These factors were not accounted for in this study, because the relatively small sample size could lead to invalid results and conclusions. The involvement of these factors should be investigated in future study with a larger sample size.

Our study reflects similar effectiveness between T-piece resuscitator and self-inflation bag in a more practical and real-life situation profile. We did not find any different in either intubation rate or incidence of respiratory morbidities between the groups. Therefore, the resuscitation team can select the PPV device upon availability and user preference. Nevertheless, we realize several limitations of the study. Our sample size is only half of the required number which consequently undermined the power to detect differences. This problem has been diluted by a higher than expected rate of intubation, therefore the power of our study may not be very much disturbed. The other issue is the alternation of types of PPV devices in between the resuscitation process when a team leader believed better ventilation can be achieved. In this situation, the influence of both types of PPV devices on infant outcomes cannot be separated. Once again, we want to report the setup of using device rather than the efficacy of the device itself.

In conclusion, use of T-piece resuscitator for PPV in preterm infants less than 33 weeks gestation or in very low birth weight infants did not improve intubation rate in a real-life clinical setting when compared to self-inflating bags. Other short-term respiratory morbidities, including respiratory distress syndrome, surfactant administration, and air leak syndrome, were also similar between devices. However, infants who were resuscitated with a T-piece resuscitator had a significantly higher rate of either mortality or oxygen dependence at 36 week post-menstrual age. Further study with an appropriate sample size is needed to confirm this outcome.

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