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Title:

T-piece Resuscitator versus Self-Inflating Bag for Preterm Resuscitation – an Institutional Experience

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Abstract

Background: Positive pressure ventilation (PPV) is provided by manual ventilation devices such as self-inflating bags (SIB), flow inflating bags and T-piece resuscitators. The objective of this study is to compare the effect of type of manual ventilation device on overall response to resuscitation among preterm neonates born < 35 weeks gestation.

Methods: Retrospective data were collected in 2 time periods. Primary outcome was overall response to resuscitation as measured by Apgar score. Secondary outcomes were incidence of airleaks, need for chest compressions/epinephrine, need for intubation and surfactant use.

Results: 294 resuscitations requiring PPV were identified. 135 neonates had SIB used and 159 neonates had T-piece used to provide PPV. There was no significant difference in 1 and 5 minute Apgar scores between devices (P=0.770, P=0.105 respectively) nor were there significant differences in secondary outcomes. The rate of rise of Apgar scores was higher by 0.47 for the T-piece compared to the SIB (95% CI=0.08, 0.87, P=0.019)

Conclusion: Although some manikin studies favor the T piece device in providing reliable and consistent pressures, our experience did not indicate significant differences in effectiveness of resuscitation between the T piece and SIB in preterm resuscitations .

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Introduction

Positive pressure ventilation (PPV) during neonatal resuscitation is provided by various manual ventilation devices such as self-inflating bags (SIB), flow inflating bags (FIB) and T-piece resuscitators. Each device has its own advantages and disadvantages. The SIB despite inability to provide CPAP and oxygen reliably is still used commonly. T-piece resuscitator delivers desired pressure more accurately but may have disadvantage of longer time to set up and delivers hazardous pressures with changes in gas flow rates (1-4). Studies on manikins indicate that the T piece guarantees reliable pressure irrespective of operator dependent variables. Although studies compare the three devices on manikins, there is not much literature comparing the T-piece with other devices during neonatal resuscitations. The objective of this study is to test the hypothesis that premature infants less than 35 weeks resuscitated with T-piece may have better response to PPV as demonstrated by better Apgar scores compared to those resuscitated with SIB.

Methods

Subjects

Retrospective data were collected from the Children's Hospital of Richmond of VCUMC Neonatal Intensive Care unit (NICU) database after IRB approval. The T-piece (Neopuff) was introduced at our facility for neonatal resuscitations in April 2009 prior to which SIB with manometer were used for all neonatal resuscitations. Due to emerging data from manikin studies regarding potential advantages of providing consistent pressures (1,2,4), the decision was made to switch to the T-piece in the delivery rooms and during transport from the delivery room to the NICU. Allowing for a transition period of 6 months where in all providers attending the delivery room were trained in the use of the T-piece , all resuscitations of NICU admissions between Sept 2009 – Aug 2011) were included. A similar number of records were reviewed in the period prior to the introduction of the T-piece (Jan 2007 – Jan 2009). The

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inclusion criteria consisted of NICU admissions less than 35 weeks gestation for whom PPV was required. Neonates born with congenital and lethal abnormalities were excluded. There were 7 and 6 delivery room deaths due to unsuccessful resuscitation during the SIB and T piece periods, respectively. During the period when SIBs were used, no definite pressure guidelines were in place. Pressures required to see a response in heart rate and chest rise were used based on the compliance felt by the provider. There were 'default' pressure guidelines in place for use of T piece resuscitator (PIP of 20 cmH20 and PEEP of 5 cmH20) and these could be altered by the provider based on the response to resuscitation. During both periods either a respiratory therapist, Neonatal Nurse Practitioner or Neonatal Fellow/Neonatologist were responsible for providing positive pressure ventilation. NRP 5th edition guidelines for resuscitation and oxygen use were followed in both time periods. Per recommendations at that time, 'color' was assessed by the resuscitation team to guide with supplemental oxygen provision. Although saturation monitors were available for use starting in mid-2010, its use was sporadic and random until definite recommendations came out in the 6th edition of NRP (2011).During both periods all infants less than 30 weeks GA were intubated in the delivery room and received prophylactic surfactant per unit policy at that time. Those > 30 weeks GA were intubated only if clinical picture necessitated intubation.

Measures

A neonate's overall response to resuscitation is measured by the Apgar score at one and five minutes after birth. The gestational age (weeks), birth weight (grams), and sex of the neonate were included to account for any changes in the Apgar scores due to these biologic factors. The use of antenatal steroids (either complete or incomplete course) and type of delivery were also recorded.

Due to high correlation between gestational age and birth weight, a surrogate variable was created that reflects the physical development of each of the neonate. This score, termed the physical development score (PDS), is a summation of the standardized gestational age and birth weight variables. Large positive values of this score indicate higher physical development present with older, heavier babies while large

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negative values indicate a neonate is less developed seen with younger and smaller babies. Accounting for age and body weight in this manner permits a larger sample size to be used for the comparison of the manual ventilation devices while still adjusting for the results for the expected effect of these variables on the Apgar scores.

Secondary outcomes analyzed were i) occurrence of airleaks (pneumothorax, pneumomediastinum, pulmonary interstitial emphysema) within 24 hours of life, ii) need for chest compressions/epinephrine in the delivery room, iii) need for intubation in the delivery room and iv) surfactant use in neonates between 30 and 35 weeks, as it was our unit guidelines to give prophylactic surfactant to all < 30 weeks GA.

Statistical Analysis

All variables were summarized by means, standard deviations, frequencies and percentages, separately for each cohort. Independent t-test or Pearson tests of association were performed to determine if there are any marginal differences between the variables for each cohort. A linear mixed-effects model was used to test the primary hypothesis with the physical development score (PDS), sex, delivery type, antenatal steroids use, time, and the interaction of the breathing device with each of these variables. This model explicitly models the mean Apgar scores at each time point for each device. Using this information, the mean rate of increase of the mean Apgar scores can be calculated and compared for each device. The same predictor variables, except for time, were used in a logistic regression with the secondary response variables of airleaks, chest compressions/epinephrine, surfactant use and intubation. The SAS Statistical Software was used for all analyses. A Type-I error rate of 0.05 was used for all analyses.

Results

A total of 294 neonates were identified. 135 neonates had SIB used and 159 neonates had T-piece used to provide PPV. 123 were between 30-35 weeks Gestational Age (GA), with 48 being resuscitated with SIB and 75 with T-piece. Mean Apgar score at 1 minute and 5 minutes were 4.2 and 6.0 for the SIB group and 4.0 and 6.2 for the T-Piece group. A summary of the variables is presented in Table 1. The

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T-piece group was more likely to have received antenatal steroids and was slightly heavier compared to the SIB group. No other statistically significant differences were observed between the groups. Four observations (The sex and 5-minute Apgar score from two different neonates, and the antenatal steroids use from two neonates) were excluded from the analysis due to missing covariates.

Neonates resuscitated with the T-piece showed a 2.23 point (Standard Error (SE) = 0.14, 95% Confidence Interval (CI): 1.96, 2.50) increase from the one- to five-minute Apgar score (P<0.001), while those resuscitated with the SIB had Apgar scores increased by 1.76 points (SE=0.15, 95%CI: 1.47, 2.04) between the two time points (P<0.001). This results in a 0.47 (SE=0.20, 95%CI=0.08, 0.87) higher increase for the T-piece group compared to the SIB group (P=0.019). The Apgar scores were not different between the devices at either one or five minutes (P=0.771, P=0.105, respectively) (Fig. 1).

The use of antenatal steroids also had an effect on the overall mean Apgar scores that was moderated by the breathing device. Apgar scores were 0.67 points (SE=0.30, 95%CI: 0.07, 1.27) higher in the neonates who received antenatal steroids in the SIB group (P=0.029) compared to those that did not receive steroids. No such difference was observed between the neonates who received and did not receive antenatal steroids in the T-piece group (difference=0.32, SE=0.39, 95% CI=-0.45, 1.09, P=0.415).There were no differences observed between the SIB and T-piece devices with respect to the overall mean, sex and delivery type. The PDS for each neonate was an important predictor of the 1 and 5 minute Apgar scores, in that older and heavier neonate had higher Apgar scores at each time point; and this effect was the same for both groups. Furthermore, the secondary analyses revealed no significant differences between devices for any of the response variables.

Discussion

The T piece resuscitator, although offers the theoretical advantage of being able to provide consistent PEEP as proven by manikin studies (2 , 4), there is insufficient evidence from neonatal studies to attest to

this benefit (7). It appears that widespread use of PEEP during neonatal resuscitation is derived from animal models and observational studies (8, 9).This study shows that neonates resuscitated with T-piece device increased their one-minute to five-minute Apgar score more rapidly than the SIB. Although a statistically significant difference in rate of rise was seen between the 2 devices, since the Apgar score at 5 minutes were not found to be different, the conclusion that the T piece is superior cannot be definitively stated. The observation of a more rapid rate of rise in the T-piece group may indicate that this group could perhaps demonstrate a superior outcome at some point beyond 5 minutes. Neonates who did not receive antenatal steroids and were resuscitated with SIB had a lower Apgar score than those who received both the SIB and antenatal steroids. This decrease based on antenatal steroids was not observed in the neonates that were resuscitated with the T-piece. We can only speculate that this observation may be due to more consistent delivery of PEEP with the T piece resuscitator and therefore better maintenance of Functional Residual Capacity (FRC) even in the absence of antenatal steroid benefit.

The secondary analyses indicated that there are no differences between the devices for the combined incidence of airleaks occurring within 24 hours of life, or the need for use of chest compressions or epinephrine in the delivery room. Among neonates with GA between 30 and 35 weeks, neither surfactant use nor need for intubation in the delivery room showed any differences between the devices. Our results support similar findings by Dawson et al (1) who compared 5 minute SpO2 in preterm infants that were resuscitated with SIB or T-piece and did not find any significant difference (5).

A limitation of this study is the retrospective nature with a convenience sample, and therefore lacks randomization which makes it difficult to control for operator experience. Since this is a retrospective, single-center study, it also makes it difficult to generalize the results. This study was designed primarily to look at differences in overall Apgar scores which has some limitations for use in extremely preterm population (10), but is widely used none the less; rather an improvement in heart rate may have been a better indicator of response to resuscitation. It would have been also useful to examine the effectiveness

of resuscitation by analyzing Apgar scores beyond 5 minutes as the faster rise that was observed with the T piece may have been more obvious and shown a significant difference. Because of the infrequency of outcomes such as airleaks and CPR in the delivery room, the study was most likely underpowered for many of the secondary analyses.

Although the T piece resuscitator offers advantages over the SIB in terms of ability to provide continuous positive distending pressure and consistent pressures, in our experience PPV in the delivery room is feasible with both SIB and T piece resuscitator with no significant difference in effectiveness of resuscitation or in immediate clinical outcomes. If future recommendations are to clearly favor one device over the other, larger randomized neonatal studies comparing the use of different devices for PPV during neonatal resuscitations are needed.

Figure 1 Legend

1 and 5 minute Apgar scores for each of the manual ventilation devices for all neonates aged 23-35 weeks. The T-piece (dashed line) has a faster rise between the 1 and 5 minute Apgar scores than the SIB (solid line), with no mean differences at either the 1-minute or 5-minute scores.

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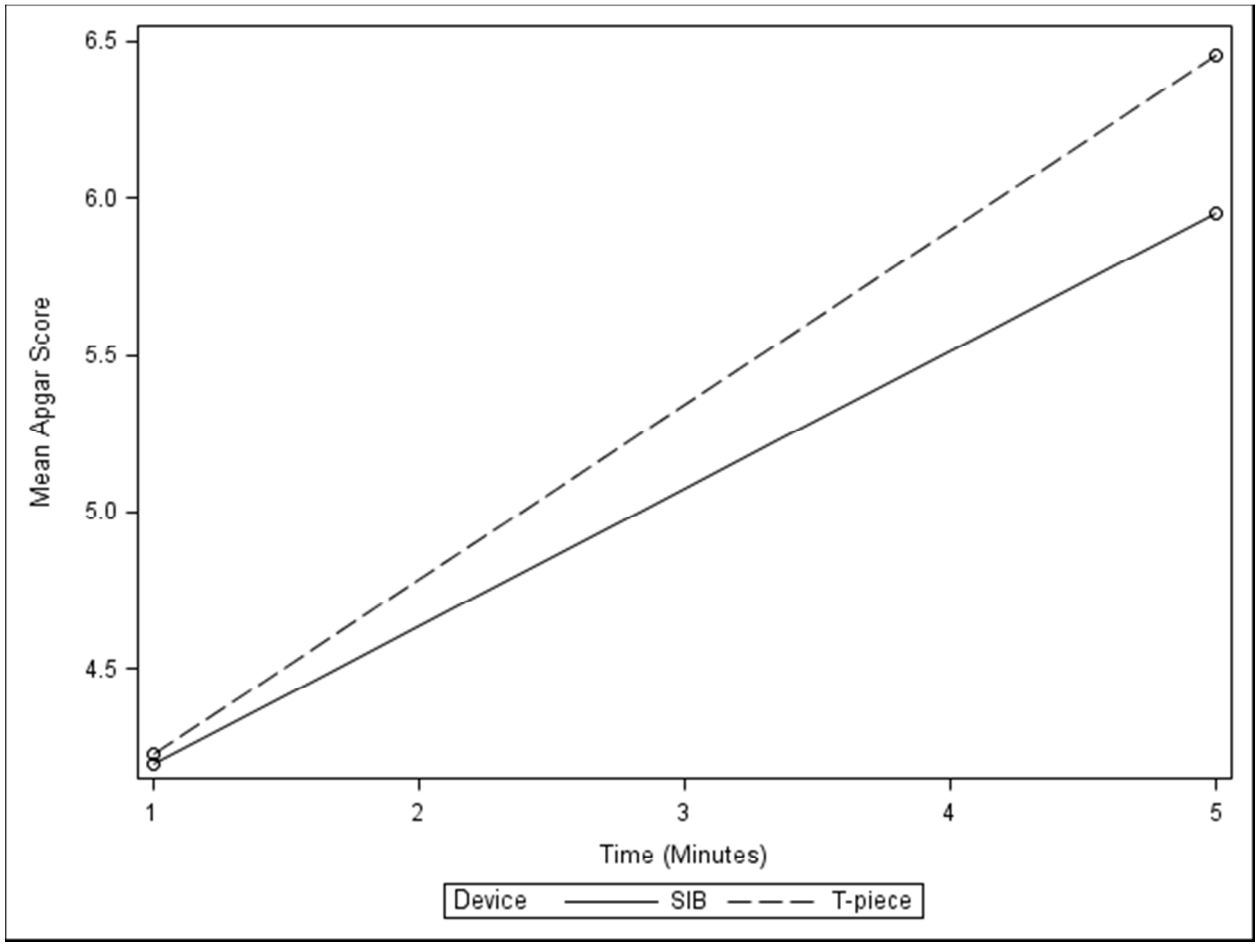
Figure.1



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Variable	23-35 wks Gestational Age			30-35 wks Gestational Age		
	SIB (n=135)	T-piece (n=159)	P	SIB (n=48)	T-piece (n=75)	P
Apgar Score (1 minute)	4.2 (1.9)	4.0 (2.3)	0.349	4.2 (1.7)	4.3 (2.3)	0.796
Apgar Score (5 minute)	6.0 (1.9)	6.2 (1.8)	0.258	6.4 (1.8)	6.7 (1.6)	0.276
Gestational Age (wks)	28.2 (3.2)	28.8 (3.6)	0.129	31.9 (1.1)	32.1 (1.5)	0.323
Birth Weight (g)	1152 (512)	1299 (603)	0.027	1674(413)	1798 (449)	0.125
Sex						
Female	66 (48.9%)	62 (39.2%)	0.097	24 (50.0%)	28 (37.3%)	0.165
Delivery Type						
C-Section	84 (62.2%)	103 (64.8%)	0.650	27 (56.3%)	52 (69.3%)	0.140
Antenatal Steroid						
Yes	73 (54.1%)	128 (81.5%)	<0.001	24 (50.0%)	54 (74.0%)	0.007
Chest Compressions / Epinephrine						
Yes	8 (5.9%)	16 (10.1%)	0.197	1 (2.1%)	5 (6.7%)	0.250
Air leak						
No	8 (5.9%)	5 (3.1%)	0.248	0 (0.0%)	1 (1.3%)	0.422
Intubation*						
Yes	-	-	0.840	25 (52.1%)	28 (37.3%)	0.107
Surfactant*						
Yes	-	-	0.804	12 (25.0%)	11 (14.7%)	0.153

Table 1: Summary statistics for all variables included in the study. Variables are summarized by mean (SD) or n (%). P < 0.05 reflects significant differences between the self-inflating bag (SIB) and T-piece groups.

*** All infants <30 wks were intubated and received prophylactic surfactant per unit guidelines**