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T-Piece Resuscitator or Self Inflating Bag for Positive Pressure Ventilation during Neonatal Resuscitation: A Randomized Controlled Trial

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Abstract: *Effective positive pressure ventilation (PPV) is the key to successful resuscitation in neonates who fail to establish spontaneous breathing.Thestudy was designed with an objective to evaluate the efficacy of Positive pressure ventilation with T-piece resuscitator & self-inflating bag during neonatal resuscitation. Objective of this study was to test the hypothesis that newborns resuscitated with T-piece resuscitator may have better response to manual ventilation as demonstrated by 1) Better APGAR scores2) Lesser duration of PPV 3) Lesser rate of intubation & barotrauma as compared to those resuscitated with SIB. Primary objective was to compare the mean duration of PPV,to compare the improvement in APGAR score & the intubation rate in delivery room*

Material and methods *Prospective, Randomized controlled & non-blinded trial was conducted in Newborn corners in Government MultiSpecialty Hospital, Sector 16 (GMSH-16), Chandigarh on Newborns≥28 weeks of gestation requiring PPV at 30 sec of birth.For study purpose sample size was increased to 25 subjects in each group* ***Group 1:****This group was consist of those newborns in which PPV willbe provided by TPR (T-piece resuscitator).****Group 2:****This group was comprise of newborns in which PPV was provided by SIB (self-inflating bag).*

Result: *Mean duration of positive pressure ventilation was significant lesser in TPR group: TPR and SIB 71.48±19.00 versus 88.48±19.28 secs;(p = 0.003), respectively and significant higher proportion of newborns achived better APGAR score at 1 min, those were enrolled in TPR as compared to SIB 5.08±1.07 versus 4.40±0.91; (p = 0.02)*

Conclusion: *study suggested that T-pieceresuscitator is better device compared to SIB as it reduces the duration of positive pressure ventilation & helps to achieve better APGAR score. Large sample sized multicenter randomized controlled trials are needed in future for the recommendation for use of T-piece resuscitator device for neonatal resuscitation.*

Key words: *T-piece resuscitator (TPR),Self inflating bag (SIB) ,APGAR score, Positive pressure ventilation (PPV)*

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I. Introduction

About 4 to 10% of neonates require assistance at birth for smooth transition from intrauterine life to extra-uterine life.[1]Only 10% require some assistance at birth for this transition. Effective positive pressure ventilation (PPV) is the key to successful resuscitation in neonates who fail to establish spontaneous breathing.[2]The most important & effective action in neonatal resuscitation is effective positive pressure ventilation that can be provided with T-piece resuscitator and self inflating bag. T-piece resuscitator provides PEEP that helps in better resuscitator outcome Effective ventilation leads to improvement in heart rate, blood pressure & pulmonary blood flow.[3,4]

The common determinants of effective resuscitation are improvement in heart rate, muscle tone & APGAR scores. However it has not been established whether duration of PPV during delivery room resuscitation affects subsequent pulmonary outcomes.[4]There is a strong association between a low FRC & subsequent respiratory distress syndrome requiring ventilation.[5,6]FRC is better achieved when we use PEEP during early resuscitation of newborn with positive pressure ventilation. Increasing the PEEP lowers expiratory resistance, conserves surfactant, & reduces hyaline membrane formation, alveolar collapse & the expression of

pro inflammatory mediator.[7]Previous studies have shown that the application of PEEP during the mechanical ventilation of premature infants with respiratory distress improves blood oxygenation.[8-9]

PEEP helps in better alveolar recruitment; improve lung compliance & functional residual capacity.

The optimal ventilation strategy immediately after birth, when the lungs are still fluid-filled, may be different from that later in life. Studies showed that a sustained inflation (2–5 s) helped to improve functional residual capacity during resuscitation of asphyxiated term infants.[10-11]

If newly born infants require positive pressure ventilation (PPV)to assist with breathing in the delivery room (DR), this can be provided with T piece resuscitator, a self-inflating bag or aflow-inflating 'anesthetic' bag. The addition of positive endexpiratory pressure (PEEP) with PPV has been shown toimprove oxygenation in a preterm animal model. The T piece& flow-inflating bag provide PEEP. The addition of a PEEPvalveto the self-inflating bag allows delivery of some PEEP.

Why T-Piece or Self Inflating Bag Was Chosen For Positive Pressure Ventilation

Several manual ventilation devices, including self-inflating bags (SIB), flow-inflating bags & T-pieces are recommended for positive pressure ventilation (PPV) in the delivery room.

Self-inflating bag (SIB) is a commonly used device but this device is not designed to deliver positive end expiratory pressure (PEEP). Addition of PEEP during resuscitation has been shown to improve oxygenation. T-piece resuscitator (TPR) is an alternative device for positive pressure ventilation, which intrinsically provides most consistent PEEP. In addition, it has been shown to deliver more accurate & consistent peak inspiratory pressure (PIP).

Need For This Study

Few trials (RCT / Cohort) studies have demonstrated a benefit of PEEP for reducing need for mechanical ventilation. However no benefit was found for reduction of mortality, broncho-pulmonary dysplasia or air leak. One cohort study suggested that the need for intubation was less after using PEEP during PPV in neonatal resuscitation. There is insufficient data so far &studies are underpowered to have sufficient confidence in a significant-difference conclusion. We designed this study with an objective to evaluate the efficacy of Positive pressure ventilation of T-piece resuscitator & self-inflating bag during neonatal resuscitation objective of this study was to test the hypothesis that newborn resuscitated with T-piece resuscitator may have better response to manual ventilation as demonstrated by 1) Better APGAR scores2) Lesser duration of PPV 3) Lesser rate of intubation & barotrauma as compared to those resuscitated with SIB primary objective was to compare the mean duration of PPV,to compare the improvement in APGAR score &the intubation rate in delivery room

II. Material and Methods

Prospective,Randomized controlled & non-blinded trial conducted in Newborn corners in Government MultiSpecialty Hospital, Sector 16 (GMSH-16), Chandigarh on Newborns≥28 weeks of gestation requiring PPV as apnea, gasping, heart rate less than 100 at 30 sec of birth and oxygen saturation below the target range despite free flow oxygen and CPAP as per inclusioncriteria and newborns with gross congenital malformation, antenatal diagnosed congenital heart disease, congenital diaphragmatic hernia are excluded.

Sample size: 50 cases; Sample size was calculated to be 14 subject in each of the 2 groups at an alpha error 0.05 & study power of 90% assuming the difference in mean duration of PPV to be 30±10 sec (as per study of Anup Thakur et al.). For study purpose sample size was increased to 25 subjects in each group.

Inclusion Criteria were Newborns ≥ 28 weeks of gestation, those requires PPV at 30 sec of birth as per NRP guideline- apnea, gasping, heart rate less than 100 at 30 sec of birth and oxygen saturation below the target range despite free flow oxygen and CPAP.

Exclusion Criteria were Newborn with gross congenital malformations**&**Antenatal diagnosed/ suspected case of congenital diaphragmatic hernia/ Antenatal diagnosed congenital heart disease were excluded.

III. Methodology

After taking an informed/written consent from the relatives or guardians, newborn ≥ 28 weeks of gestation requiring PPV at birth were randomized in 2 groups. Groups were allocated by employing computer generated random numbers which was placed in sealed envelopes & after enrollment of patient, one envelope was opened & respective treatment was started. Twins & triplets were randomized as individuals. Caregiverswere not masked to the allocated device. All other resuscitative measures (ex. intubation, cardiac massage, & administration of oxygen or other drugs) were at the discretion of the clinical staff involved,

following a standardized protocol. The alternative device was also be available when there is a failure of the allocated device.

Group 1: This group was consisted of those newborns in which PPV willbe provided by TPR (T-piece resuscitator). T-piece resuscitator was preset with attachment of inlet & outlet tubing. Inlet flow meter was fixed at 10 L/min. There are 2 controlled dials to set desired pressure. PIP max was fixed at 30 cm of H_2O. PIP that was delivered to baby fixed at 20 cm of H_2O & outlet tubing was attached to appropriate mask size to deliver PPV. Every breath was delivered by using a finger to alternatively occlude & release a gas escape opening on the top of T-piece cap. Initially respiratory rate was kept at 40-60 breaths per min, PIP 20 cm H_2O & PEEP kept at 5cm of H_2O, then increased according to response. Initially we used 21% oxygen (compressed air) at flow rate 10L/min. An assistant was place a pulse oximeter sensor on the right hand or wrist as soon as possible after PPV is started. Once the oximeter is reading reliably, we compared the baby's pre-ductal oxygen saturation with the range of target values & adjust the oxygen concentration as needed.

Group 2: This group was comprised of newborns in which PPV was provided by SIB (self-inflating bag). Self-inflating bag is attached to an oxygen source. PIP in SIB is controlled by how hard the bag is squeezed.We was squeeze the bag just enough to see the chest rise. PIP was not monitored by manometer & PEEP was not provided with SIB. Bag has a pressure release valve also called pop-off valve which limit peak pressure at 30-40 cm H_2O pressure. SIB squeezed at the rate of 40-60/min, provides breathe 40-60/min. Initially room air was used. An assistant should place a pulse oximeter sensor on the right hand or wrist as soon as possible after PPV is started & does SpO_2 monitoring. Oxygen concentration was adjusted to achieve time targeted baby's pre-ductal oxygen saturation.
The most important indicator of successful PPV is a rising heart rate. Baby's heart rate response was monitored with a stethoscope & pulse oximeter. We made separate assessments of the baby's heart rate response to PPV first after 15 sec, second after 30 sec and then at 1 min, 5 min and at 10 min.

First Heart Rate Assessment: after 15 seconds of positive-pressure ventilation.

If the heart rate is increasing we were continue PPV & second assessment of baby's heart rate wasdone after 15 seconds. But if heart rate not increasing &chest is moving we werwcontinued PPV for another 15 seconds that moves the chest.

If heart rate is not increasing & chest is not moving necessary ventilation corrective steps toachieve chest movement with ventilation [Mask adjustment, Reposition head, Suction airway, Open mouth, Pressure increase, & Alternative airway] were taken. Once chest movement is achieved PPV were continued for 30 seconds & assess the baby's heart rate response.

Second Heart Rate Assessment: **after 30 seconds of ventilation that inflates the lungs.**

If heart rate is greater than or equal to 100 bpm we were continue ventilating at a rate of 40 to 60 breaths per minute. We were monitor the baby's chest movements, heart rate, & respiratory efforts. Positive-pressure ventilation were discontinued when the baby has a heart rate continuously over 100 bpm & sustained spontaneous breathing. After PPV is stopped, we were continue to monitor the baby's oxygen saturation & breathing. Free-flow oxygen or CPAP may be required & can be weaned, as tolerated, based on pulse oximetry.

If heart rate is between 60 to 100 bpm we were continue to administer PPV (40-60 breaths per minute) as long as the baby is showing steady improvement. Oxygen saturation were monitored & oxygen concentration were adjusted to meet the target saturation. If the heart rate remains at least 60 bpm, but less than 100 bpm & is not improving, then we were adjust the oxygen concentration to meet the target saturation & insertion of endotracheal tube. ButIf the baby's heart rate remains less than 60 bpm despite 30 seconds of PPV that inflates the lungs (chest movement), through an invasive airway, increase the oxygen concentration 21% to 100% & begin chest compressions& inj. Adrenaline were used according to standard protocol.Baby were monitored for APGAR SCORE & SpO_2continuously.Trialwere registered with the Clinical Trial Registry of India before enrollment of the first patient.

Statistical analysis was performed with the SPSS, Trial version 23 for Windows statistical software package (SPSS inc., Chicago, il, USA)& Primer for the generation of descriptive & inferential statistics. The Categorical data were presented as numbers (percent) & were compared among groups using Chi square test. The quantitative data were presented as mean & standard deviation& were compared using by students t-test. Probability P value <0.05 was considered statistically significant.

IV. Results and Observation

Out of birth cohort of 3591 deliveries during study period, 50 newborns enrolled, were randomized in two groups, 25 each in TPR group &SIB group, respectively.

General characteristics of both the groups were comparable. Mean gastetion age was comparable in both TPR and SIB group 38.88 ± 1.56 versus 38.28±1.95 weeks; (*P* =0.23) respectively.Out of total 50 study subjects, most were term babies, 22(88%) in TPR group & 20 (80%) in SIB group. Preterm were 3(12%) in TPR with the gestation of 35 weeks to 36 weeks &4(16%) were in SIB group with gestation 34weeks to 36 weeks, respectively. There was only one post term baby, in SIB group with gestation of 43 weeks. No significant difference was observed according to maturity levels of newborns in the two groups. According to sex distribution in TPR group 17(68%) were males& 8(32%) were females, while SIB group included 12(48%) males & 13(52%) females, (*P*=0.25). TPR had a male preponderance though both groups were comparable according to sex distribution.

Heart rate was recorded after birth at 30 sec, 1 min, 5 min & 10 min with auscultation along with continuous monitoring by pulse-oximeter. Majority of newborns had heart rate more than 100 bpm, out ofthem 17(68%) in TPR group & 21(84%) in SIB group, respectively. Newborns were having heart rate varying between 60 -100 bpm, 20%(5)of them in TPR group and12%(3) in SIB group. There were12%(3)newborns in TPR &4%(1) newborns in SIB group had a heart rate of less than 60 bpm. But no significant difference was observed in study groups in comparison of initial heart rate (*P*=0.38). At 1 min of life, newborns inboth groups achieved the heart rate more than 100 bpm. Heart rate at 5 min was also comparable in two groups though there was no significant difference.At birth all enrolled newborns were showing no respiration, after 30 sec of starting of positive pressure ventilation (at 1 min of life), newborns those were ventilated with TPR had improvement in respiratory outcome as compared to SIB group. In TPR group 16(64%) started showing improvement in respiration as compared to 7(28%)in SIB group; (P= 0.02). At 1 min 9(38%) babies in TPR group &18(72%) in SIB group had no respiration but developed some improvement in color, tone, reflexes, continued with positive pressure ventilation till babies developed regular respiration & targeted SpO_2 achieved. Except one casein each group did not show any improvement in APGAR score after 30 sec of positive pressure ventilation, those were intubated & given positive pressure ventilation. These babies did not developed spontaneous breathing even after 10min of invasive positive pressure ventilation shifted to NICU & given ventilator support.

One minuteAPGAR score (Mean ±SD) in TPR group was 5.08±1.07 while in SIB groupit was 4.4±0.91; *P*=0.02. This difference was statistically significant. Minimum APGAR in both group at 1 min was 2.APGAR score achieved at 5 min& 10min in TPR group & SIB group were 8.64±1.2 versus 8.08±1.2; (*P*=0.11) &8.84±1.2 versus 8.84±1.2; (*P*= 1.0), respectively. Minimum APGAR score at 5 min was 3 & at 10 min was 4 in both group. APGARscore at5 min & 10 min were not statistically significant.The mean±SD, improvement in APGAR score achieved between 1min to 5 min in TPR group was 3.60±0.913 compared to SIB group in which mean ±SD improvement in APGAR score was 3.72±0.737; (*P*=0.61), respectively.

In TPR group, the mean duration of positive pressure(71.48 sec) with median (IQR)of 68 (58-82) seconds was much lesser as compared to (88.48 sec) with median(IQR) of 85(77-92) seconds in SIB group. There was a significant difference in two group with *P* =0.003. Two babies, one in each group those were intubated at 2 min due tono response to positive pressure ventilation,they had no spontaneous respiration even after 10 min were shifted to NICU on intermittent positive pressure ventilation then put on ventilator support.

In TPR group 14(56%) newborns required oxygen supplementation to achieve targeted oxygen saturation according to time as compared to SIB group 17(68%), in which high proportion of newborn required oxygen supplementation to achieve targeted oxygen saturation. Although this finding was not significant (*P* = 0.56).There were 11(44%) newborns in TPR group & 8(32%) in SIB group who did not require oxygen supplementation& were resuscitated at room air.Mean oxygen saturation at 1min, 5 min & 10 min was comparable & statisticallyinsignificant in both groups.

The mean time needed to achieve SpO_2 >90% in TPR & SIB groups were 10.08±1.222 min versus 9.96 ±1.098 min with non-significant (*P* = 0.71)i.eBoth groups have comparable mean time.Comparison between two study groups according to need for intubation, chest compression have no significant differences. There was one subject (4%) in each group which required intubation & chest compression during neonatal resuscitation. These two subjects were intubated & invasive positive pressure ventilation given.

In our study population 14(56%) newbornsin TPR group & 8(32%) in SIB group respectively, did not show any complications in immediate post resuscitation period.Respiratory distress including tachypnea, retraction & use of accessory muscles was the most common complication in post resuscitation period. 28% (7) newborns those were resuscitated with TPR had relatively lesserrespiratory distress as compared to 60% (15) in SIB group;(*P*=0.04), significant difference was present in two groups. Hypoxic ischemic encephalopathy also present in both groups, 3 babies had HIE stage 1&one baby had HIE stage 3 in TPR groupwho hadsevere fetal distress with fetal breadycardiaantenatally, with APGAR score 2,3,4 at 1 min, 5min & 10 min respectively, after birth required chest compression& intubation during resuscitation for intermittent PPV &never achieved targeted oxygen saturation. That baby shifted to NICU on bag & tube ventilation & kept on ventilator support, during NICU stay baby had cardio respiratory arrest & died within 2 hours of life. While in SIB group 2 babies developed hypoxic ischemic encephalopathy,one baby had HIE stage 2, was post term baby having antenatal

history of prolonged rupture of membrane & fetal distress with APGAR score of 3,7,9 at 1min, 5min & 10 min respectively&second baby was with HIE stage 3 had breech presentation & fetal breadycardiaantenatally with APGAR score 2,3,4 at 1 min, 5 min & 10 min respectively, required chest compression & intubated during resuscitation, that baby achieved targeted oxygen saturation at 12 min of life, shifted to NICU on IPPV & ventilator support given, that baby developed bronchopulmonary dysplasia (chronic lung disease) during NICU admission. In this study not a single case of air leak/ pneumothorax was observed in any group.

There was no significant difference in both groups according to final outcome. In TPR group out of 25 newborns, 21(84%) improved & discharged from neonatal ICU, 3(12%) newborns hadsequelae like hypoxic ischemic encephalopathy & chronic lung disease (bronchopulmonary dysplasia) at the time of discharge. There was one severely asphyxiated newborn in TPR group which required chest compression &endo- tracheal intubation, died during NICU stay within 24 hrs of life. There was one sever birth asphyxiate baby in SIB group that was intubated during resuscitation developed HIE stage 3.

V. Discussion

Currently there islimited data available that supports effectiveness of one device over the other which provides positive pressure ventilation during neonatal resuscitation. Some devices can provide PEEP with PIP in positive pressure ventilation like T-piece resuscitator & anesthetic flow inflating bag. Self-inflating bag is the most commonly used device in neonatal resuscitationbut thatis not able to provide PEEP during positive pressure ventilation.Recent updated NRP guidelines 2016 recommended the use of PEEP in positive pressure ventilation during resuscitation of preterm newborns. Many studies are available that show a role of PEEP in effective resuscitation & early achievement of FRC that leads to smooth transition from intrauterine to extrauterine life.

In our study we compared the efficacy of two devices – TPR & SIB during neonatal resuscitation. Our primary outcome was to compare duration of positive pressure ventilation required in each group. Our secondary outcome was to evaluate the improvement in APGAR score & intubation rate in newborn resuscitation.Out of birth cohort of 3591 deliveries we studied 50 newborns, 25 newborns randomly allocated to TPR group & SIB group each.

A known disadvantage of TPR is that it is technically more difficult to set, takes more time to set pressures& it is difficult to change pressures during resuscitation. In our study we assembled the TPR before every high risk delivery with anticipation of birth asphyxia. TPR was preset with a flow rate at 10L/min, PIP was 20 cm H_2O & PEEP was at 5 cm H_2O to avoid any delay in starting of resuscitation. As about 90% newborns included in the study were term, it was safe to use the above mentioned pressures during resuscitation. Flow rate was set as per recommendation of **C P Hawkes et al[12]at** 10 L/min that can provide adequate pressure, even if there is 50% gas leak & also added a safety mechanism as less pressures cause less barotrauma / volutrauma that was very important factor for lung injury during resuscitation specially in preterm babies.**Colin P H et al[13]** also suggested that flow rates should be on lower side as PEEP valve also is more sensitive at lower flow rates & desired precise PEEP can be provided. In addition to that resuscitation provider was trained in use of both devices during resuscitation & accustomed to use them. During resuscitation for recording of eventsastop clock was used by the person assisting the resuscitation.

Our primary outcome in this study was duration of positive pressure ventilation that was recorded with stop clock. We found themean duration of positive pressure ventilation significantly less in TPR group compared to SIB group. These findings are consistent with a recent RCT conducted by **Anup Thakur et al[5]** that showed that the median (IQR) duration of positive pressure ventilation in delivery room was significantly less in TPR as compared to SIB;30(30-60)secs versus 60(30-90)secs respectively;(P=<0.001).This significant difference is possibly due to use of PEEP with PPV during neonatal resuscitation in TPR group resulting in faster establishment of FRC.

There was no significant differencein establishing successful ventilation, as assessed by improving heart rate in both groups. This finding was consistent withone randomized trial that was conducted by **Szyldetal[8]**on 1032 newborns ≥ 26 weeks.Their analysis showed that outcome as heart rate ≥ 100 bpm at 2 min with TPR versus SIB was 94% versus 90% respectively, OR=0.65(0.41,1.05), CI=95%, P= 0.08. There was no significant difference between TPR group& SIB group in establishing ventilation, as assessed by improving heart rate.

This study found that newborn resuscitated with TPR showed significantly better APGAR score improvement compared to SIB group.The Mean ±SD of APGAR score which was achieved at 1min after using TPR was 5.08±1.07 wassignificantly much better than using SIB for resuscitation, that was 4.4±0.91; P=0.02. Also the APGAR score achieved at 5 min & 10 min in TPR group & SIB group, 8.64±1.2 versus 8.08±1.2; (P=0.11) & 8.84±1.2 versus 8.84±1.2; (P= 1.0), respectively was statistically insignificant . APGAR score achieved at 5 min & 10 min were comparable in both groups. Our finding supported that PEEP helps in early development of FRC & rapid resuscitation can be achieved after use of PEEP during resuscitation. Results were

comparablewith the study of **Archana et al[14]**,a comparative & retrospective study on preterm ≤ 35 weeks gestation, they studied 294 resuscitations requiring PPV. SIB was used in 135 newborns & TPR used in 159 neonates. The results of this study showed that the rate of rise of APGAR score was higher by 0.47, with T-piece compared to SIB (95% CI 0.08–0.87, *P* = 0.02). But these results showed that there were no significant differences between the 1 min & 5 min APGAR score between the TPR group & SIB group; (*P*= 0.77).

We compared the need of oxygen supplementation in both groups to achieve targeted SpO_2 as per **NRP guidelines 2016,** A small proportion which required oxygen supplementation were 14(28%) in TPR group compared to 17(34%) in SIB group. Rest 19(38%) newborns were successfully resuscitated at room air. This study showed that the newborns needing oxygen supplementation in both groups (TPR & SIB) was comparable; (*P* =0.56).

The mean oxygen saturation ± SD at 1 min in TPR group was 60.6±4.2 % compared to SIB group was 60.2±3.3 %; *P*=0.65. At 5min it was 78.3±4.5 % in TPR group versus 79.6±3.7 % in SIB group; (*P*=0.26). We also monitored the oxygen saturation till 10 min, which was also comparable in both TPR group & SIB group (93.4±3.7 % versus 93.2±3.8 %; *P*=0.85), respectively. These results are consistent with a prospective randomized controlled study by **Dawson J A et al[8]** on 80 infants ≤ 29 weeks gestation who received PPV in delivery room in first 5 min. Their results showed that there were no significant differences between the median oxygen saturations in TPR & SIB groups at 5 min after birth (61% versus 55% respectively; *P*=0.27). They also concluded that more infants in TPR group received oxygen during delivery room resuscitation (100% versus 90%; *P*= 0.04).

But mean duration to achieve SpO_2 >90 % in TPR group& SIB group was 10.08 min versus 9.96min respectively. This result was comparable with a recommended time to achieve ≥ 90% oxygen saturation as per NRP. The probable reason for this observation was term newborns were in higher proportion in our study & they were able to generate FRC through their own respiratory efforts.

We also compared the rate of intubation, need of chest compressions& medications in delivery room. This parameter did not show any significant difference between both groups. Although it was anticipated that application of PEEP in TPR group would decrease the need of intubation in delivery room but we did not find any difference. The possible explanation of this could be higher proportion of the term newborns were enrolled in both groups with the mean gestation in TPR & SIB being (38.88±1.56 versus 38.28±1.95) respectively. Term babies were able to maintain FRC without need of PEEP. Our study supports the similar finding of **ArchanaJayaramet al[14]and Dowson et al[8]**who also observed that rate of intubation did not show any significant difference in two groups i.e TPR & SIB.

According to complications or morbidity after resuscitation observed that respiratory distress was higher in proportion in SIB group compared to TPR, 60% versus 28%; *P*= 0.04), respectively. It may be due to the use of PEEP with PPV which is better to establish FRC. On other side **Anup Thakur et al[5]**did not show any significant difference in this outcome in TPR & SIB group 38% versus 47.5%; *P*= 0.36).

VI. Limitations

Our study had certain limitations as it was a non-blinded study. We also did not measure PIP & PEEP pressure in case of SIB group. In case of TPR we gave preset PIP & PEEP but actual delivered pressure to newborn, time needed to achieve PIP & inflation time were not measured. At time of birth & during resuscitation heart rate was calculated by auscultatory method instead of ECG, this may affect accuracy in measurement of heart rate. Newborns which needed oxygen requirement to achieve targeted saturation were given 100% FiO_2; titration of oxygen requirement (FiO_2) was not done. This may cause no significant difference in SpO_2 at 1 min, 5min & 10 min. We did not follow the newborn which required resuscitation at birth& admitted in NICU for post resuscitation care like requirement of CPAP, duration of positive pressure ventilation, required duration of oxygen, intubation rate within 24 hours, scoring of respiratory distress etc. We observed the complication at the time of NICU discharge only.

VII. Conclusion

Our study suggest that T-piece resuscitator is better device compared to SIB as it reduces the duration of positive pressure ventilation & helps to achieve better APGAR score. Large sample sizedmulticenter randomized controlledtrials are needed in future forthe recommendation for use of T-piece resuscitator device for neonatal resuscitation.

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Table 1: General characteristics of study subjects

		TPR group n=25 (%)	**SIB group n=25 (%)**	*P* value
GESTATION (weeks); mean ± SD		38.88 ± 1.56	38.28 ± 1.95	0.23
MATURITY	**Preterm**	3(12%)	4(16%)	0.538
	Term	22(88%)	20(80%)	
	Posterm	0(0%)	1(4%)	
SEX	**Male**	17 (68%)	12 (48%)	0.25
	Female	8 (32%)	13 (52%)	
FETALRISK FACTORS	**IUGR**	2 (8%)	2 (8%)	0.6
	FETAL DISTRESS	22(88%)	20(80%)	0.07
	MSL	11(44%)	10(40%)	1.00
	PROM	4(16%)	5(20%)	1.00
MATERNALRISK FACTORS	**PIH**	3 (12%)	1 (4%)	0.6
	APH	1 (4%)	0	1.00
	OLIGO	1 (4%)	1 (4%)	0.47
	ANAEMIA	6 (24%)	8 (32%)	0.75
	HYPOTHYROIDISM	3 (12%)	1 (4%)	0.6
GROWTH STATUS	SGA	2 (8%)	2 (8%)	0.35
	AGA	21 (84%)	23 (92%)	
	LGA	2 (8%)	0	
MODE OF DELIVERY	NVD	7 (28%)	14 (56%)	0.011
	LSCS	14 (56%)	11 (44%)	
	Forceps	3(12%)	0	
	Vacuum	1(4%)	0	
DRUGS STATUS	No drug	21 (84%)	23 (92%)	0.58
	Thyroxin	3 (12%)	1 (4%)	
	Antihypertensive	1 (4%)	1 (4%)	

Table No 2: Heart Rate and Respiratory rate among the groups at different time

Time	**HR**	**TPR group n=25 (%)**	**SIB group n=25 (%)**	***P* value**
At 30 sec	**< 60 bpm**	3 (12%)	1 (4%)	0.38
	60-100bpm	5 (20%)	3 (12%)	
	>100 bpm	17 (68%)	21 (84%)	
At 1 min	**>100 bpm**	25 (100%)	25 (100%)	-
At 5 min	**>100 bpm**	25 (100%)	25 (100%)	-

Time	**Respiration**			
At 30 sec	No respiration	25 (100%)	25 (100%)	-
At 1 min	No respiration	9 (36%)	18(72%)	0.02
	Poor respiratory effort	16(64%)	7(28%)	
At 5 min	No respiration	1 (4%)	1 (4%)	0.47
	Spontaneous respiration	24 (96%)	24 (96%)	

Table 3 : Distribution of various complications in study groups

Complication	**TPR group n(%)**	**SIB group n (%)**	**Total N (%)**	**P value**
NONE	14 (56%)	8(32%)	22 (44%)	0.15
RD	7(28%)	15(60%)	22(44%)	0.046
MAS	2(8%)	0	2 (4%)	0.47
HIE-1	3 (12%)	0	3 (6%)	0.23
HIE-2	0	1 (4%)	1 (2%)	1.00
HIE-3	1 (4%)	1 (4%)	2 (4%)	0.47
CLD	0	1 (4%)	1 (2%)	1.00
RF	1(4%)	1(4%)	2(4%)	0.47
PNEUMOTHORAX	0(0%)	0(0%)	0(0%)	

Table No 4: Outcome variables among the groups

APGAR	**TPR(n=25)**	**SIB(n=25)**	***P* value**
At 1min	5.08±1.07	4.4±0.91	0.02
At 5min	8.64±1.2	8.08±1.2	0.11
At 10 min	8.84 ±1.02	8.84±1.02	1
IMPROVEMENT IN APGAR SCORE BETWEEN 1 MIN TO 5 MIN	3.60±0.913	3.72±0.737	0.61
Duration of positive pressure ventilation (secs)	71.48±19.28	88.48±19.00	0.003S
Need for oxygen supplementation	14 (56%)	17 (68%)	0.56
OXYGEN SATURATION (%)			
at 1 min	60.6 ± 4.2	60.2 ± 3.3	0.65
at 5 min	78.3 ± 4.5	79.6 ± 3.7	0.26
at 10 min	93.4±3.7	93.2± 3.8	0.85
Time needed to achieve Spo2 > 90% Mean time (mins)	10.08±1.222	9.96 ±1.098	0.71
Needed Intubation	1 (4%)	1 (4%)	0.47
Needed chest compression	1(4%)	1 (4%)	0.47
Final Outcome			
Improved	21 (84%)	23 (92%)	
Sequelae	3 (12%)	2 (8%)	
Death	1 (4%)	0	0.52

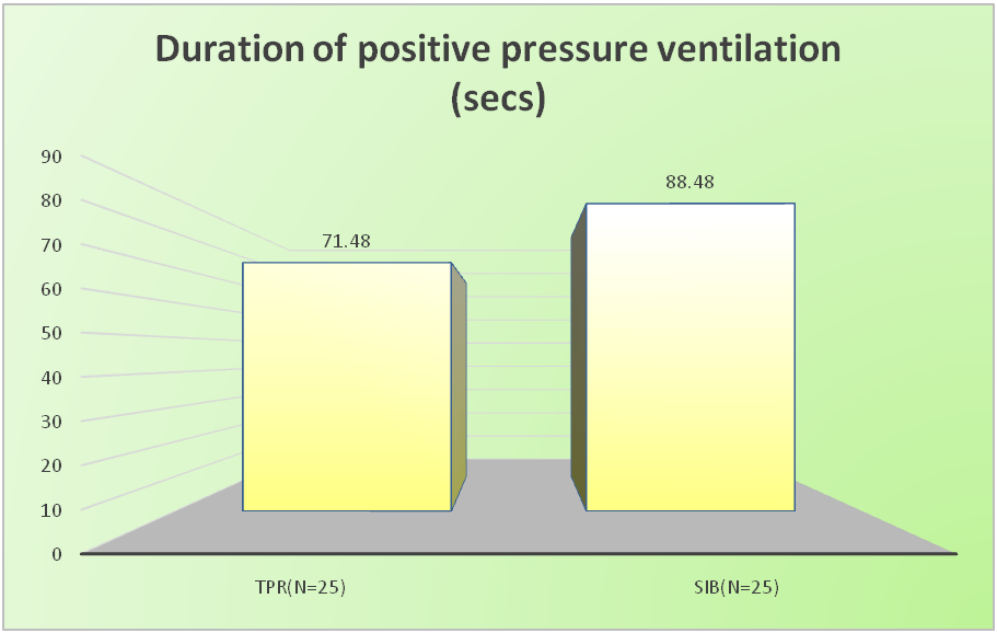

Figure 1: Duration of positive pressure ventilation (secs) among the TPR and SIB

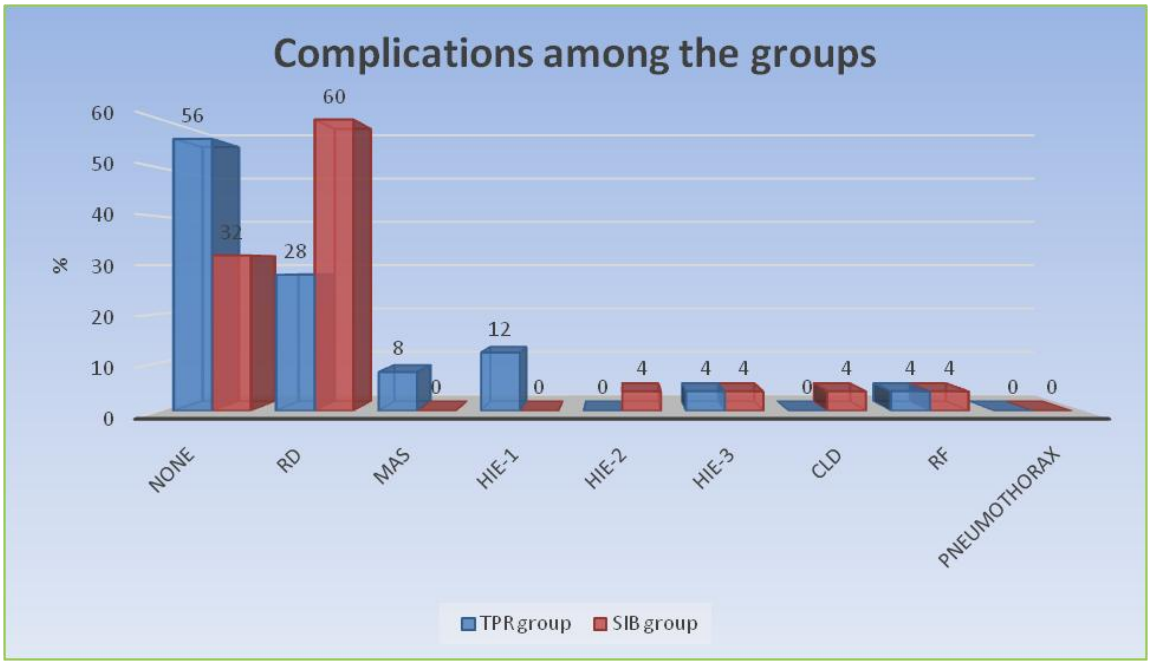

Figure 2: complications among the groups.

Suryalata kookna. "T-Piece Resuscitator or Self Inflating Bag for Positive Pressure Ventilation during Neonatal Resuscitation: A Randomized Controlled Trial." IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 18, no. 5, 2019, pp 66-74.