EFFICACY OF T PIECE RESUSCITATOR VERSUS SELF INFLATING BAG AND SELF INFLATING BAG WITH PEEP VALVE IN NEWBORN RESUSCITATION – A RANDOMISED CONTROL TRIAL

Dissertation submitted to

THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY

In partial fulfillment of the requirements

for the award of the degree of

D.M. (NEONATOLOGY)

2011-2014

THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY

CHENNAI

APRIL 2014

CERTIFICATE

This is to certify that the dissertation entitled **"EFFICACY OF T PIECE RESUSCITATOR VERSUS SELF INFLATING BAG AND SELF INFLATING BAG WITH PEEP VALVE IN NEWBORN RESUSCITATION – A RANDOMISED CONTROL TRIAL"** is a bonafide work done by **Dr.Sathyan.V.K** under my guidance and supervision during the period between November 2013 – March 2014 towards the partial fulfillment of requirements for the award of **D.M. (Neonatology)** degree examination to be held in August 2014 by the Tamil Nadu Dr.M.G.R. Medical University, Chennai.

Prof. Dr. J.KUMUTHA,MD.,DCH.,
Prof. and H.O.D. of Neonatology,
Institute of Child Health,
Madras Medical College,
Chennai.

Prof. Dr.M. KANNAKI MD., DCH.,
Director & Superintendent,
Institute of Child Health,
Madras Medical College,
Chennai.

Dr.R.VIMALA.,MD.,
Dean,
Madras Medical College,
Chennai – 600003.

CERTIFICATE

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Name and Signature of Guide :

Prof.Dr.J.Kumutha, MD.,DCH.,
Professor & H.O.D. of Neonatology,
Institute of Child Health,
Madras Medical College,
Chennai.

Name and Signature of the Head of Department :

Prof.Dr.J.Kumutha, MD.,DCH.,
Professor & H.O.D. of Neonatology,
Institute of Child Health,
Madras Medical College,
Chennai.

Name and Signature of the Dean :

Dr.R.Vimala.MD.,
Dean,
Madras Medical College,
Chennai - 600003

DECLARATION

I solemnly declare that this study titled **"EFFICACY OF T PIECE RESUSCITATOR VERSUS SELF INFLATING BAG AND SELF INFLATING BAG WITH PEEP VALVE IN NEWBORN RESUSCITATION – A RANDOMISED CONTROL TRIAL"** was my original work in the Department of Neonatology, Madras Medical College, Chennai under the guidance and supervision of Prof.Dr.J.Kumutha MD., DCH., Professor & Head of the Department, Department of Neonatology, Institute of Child health and Hospital for Children, Egmore, Chennai. This dissertation is submitted to The Tamil Nadu Dr.M.G.R. Medical University, Chennai in partial fulfillment of the university requirements for the award of the degree of D.M.(Neonatology).

Place: Chennai

Date: **Dr.SATHYAN.V.K**

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INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE , CHENNAI- 3

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CERTIFICATE OF APPROVAL

To
Dr. Sathyan.V.K
PG in DM Neonatology
Institute of Child Health and Hospital for Children
Madras Medical College , Chennai – 3

Dear Dr. Sathyan.V.K ,

The Institutional Ethics Committe of Madras Medical College reviewed and discussed your application for approval of the proposal entitled **"Efficacy of T piece resuscitator versus self inflating bag and selfinflating bag with PEEP valve in Newborn Resuscitation – A Randomised control trial"** No.31112013

The following members of Ethics Committee were present in the meeting held on 13.11.2013 conducted at Madras Medical College , Chennai – 3 .

1. Dr. G. Sivakumar, MS FICS FAIS	-- Chairperson
2. Prof. R. Nandini, MD Director ,Instt of Pharmacology , MMC , Ch-3	-- Member Secretary
3. Prof. Ramadevi , Director i/c , Instt. Of Biochemistry, MMC , Ch- 3	-- Member
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5. Prof. Kalaiselvi ,MD Prof. of Pharmacology , MMC , Ch-3	-- Member
6. Thiru. S. Govindasamy, BABL	-- Lawyer
7. Tmt. Arnold Saulina, MA MSW	-- Social Scientist

We approve the proposal to be conducted in its presented form.

Sd / Chairman & Other Members

The Institutional Ethics Committee experts to be informed about the progress of the study , and SAE occurring in the course of the study , any change in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

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anticipation, adequate preparation, accurate evaluation and prompt initiation. The first minute of 18

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positive pressure ventilation (PPV) is taken at the end of 7

30 seconds of starting resuscitation when the neonate is apneic

or gasping or with heart rate less than 100/min. 19

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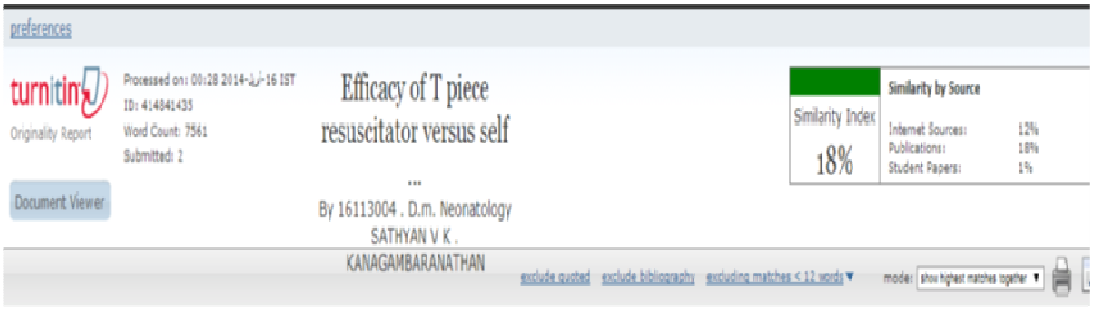

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INTRODUCTION

1

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INTRODUCTION

The American Academy of Paediatrics formulated the Neonatal resuscitation guidelines and published it in 2010 and suggested modification based on local needs[1] .These guidelines primarily apply to neonates undergoing transition from intrauterine to extrauterine life with difficulty. About 1 in 10 neonates require some form of resuscitation and fewer than 1% require extensive resuscitation [2].

Ventilation of the lungs is the most important step for successful resuscitation. Ineffective ventilation is an important cause of prolonged or unsuccessful resuscitation. Effective resuscitation needs proper anticipation, adequate preparation, accurate evaluation and prompt initiation. The first minute of neonatal resuscitation is known as the **golden minute** where active steps are taken to ventilate the newborn lungs.

Each step in resuscitation is performed for 30 seconds along with assessment of heart rate, respiration and oxygen saturation at the end of every step. The decision to administer positive pressure ventilation (PPV) is taken at the end of 30 seconds of starting resuscitation when the neonate is apneic or gasping or with heart rate less than 100/min. [1]

The purpose of PPV is to provide an adequate tidal volume, establish functional residual capacity (FRC), facilitate gas exchange and stimulate breathing, while minimizing lung injury. To establish FRC immediately after birth and to prevent lung collapse positive end expiratory pressure (PEEP) or continuous positive airway pressure (CPAP) should be provided. However, more attention is usually paid to the peak inflating pressure rather than PEEP during neonatal resuscitation.

Lung injury is one of the important factors leading to the development of Bronchopulmonary dysplasia (BPD) in neonates. PEEP helps to keep the lungs of neonates partially expanded at the end of expiration, thereby preventing their complete deflation.[2] PEEP reduces atelectotrauma and volutrauma thereby reducing lung injury.[3] PEEP provided during resuscitation of newborns results in more rapid correction of oxygen and carbon dioxide levels and less damage to the lungs.

Current guidelines in neonatal resuscitation recommend three devices for positive pressure ventilation; self inflating bag with or without PEEP valve, Flow inflating bag and T-piece resuscitator. The most commonly used device is self inflating bag without PEEP valve which does not provide PEEP.[1] T piece resuscitators, Flow inflating bag and

Self inflating bag with PEEP valve are the devices which can provide PEEP during resuscitation.

Leone et al [11] in a survey of delivery room practices in America found that 76% of programs attempt to provide continuous positive airway pressure(CPAP) or positive end expiratory pressure (PEEP) during resuscitation, and the most commonly used device was flow-inflating bag (58%), followed by a self-inflating bag with PEEP valve (19%) and T-piece resuscitator (16%). A PEEP of 5 cm H2O was used by 55% of programs.

Self inflating bags are the commonly used ventilation devices in neonatal resuscitation but their major drawback is that they deliver inconsistent pressures depending on the squeeze applied by the physician and they do not provide PEEP.

The T Piece resuscitator is a flow controlled, pressure limited neonatal ventilation device. The peak inspiratory pressure (PIP) and positive end expiratory pressure (PEEP) are set manually with adjustable controls. Its main advantages[4] are the delivery of consistent pressures, control of PIP and PEEP and the ability to adjust inspiratory time but an important drawback[8] is that it requires a compressed gas source.

Self-inflating bag with a PEEP valve has the ability to deliver PEEP[9]. The self-inflating bag can be fitted with a Laerdal PEEP valve which is connected via an expiratory diverter .When the self-inflating

device is squeezed, gas is pushed past the one-way fish-mouth valve. Passive exhalation occurs as the pressure falls and the expired gas flows via the expiratory diverter through the expiratory valve of the PEEP device. PEEP is generated by adjusting the tension spring, using the markings to set the desired level of PEEP. When set to provide 7 cm H_2O of PEEP, the mean PEEP delivered is 5.4 cm H_2O when the bag is squeezed at the rate of 60 per minute.[9]

Devices which do not have provision for delivery of PEEP like self inflating bags are the ones still being used in the labor rooms for newborn resuscitation in many institutions in India.

Although there exists biological explanation for the use of PEEP and many institutions in western world are using devices providing PEEP to resuscitate neonates, randomised clinical trials comparing positive pressure ventilation with and without PEEP at neonatal resuscitation are limited in number.

There is no recommendation from ILCOR regarding the preferred neonatal ventilation device in delivery room. There are very few studies comparing the available ventilation devices in delivery room.

REVIEW OF LITERATURE

The International Liaison Committee on Resuscitation (ILCOR) and various National resuscitation guidelines recommend equipment and techniques for neonatal resuscitation. Positive pressure ventilation (PPV) is the basis of respiratory support immediately after birth.[1,2] PPV helps deliver an adequate tidal volume and to establish functional residual capacity (FRC) to facilitate gas exchange and stimulate breathing .

Early use of delivery room CPAP/PEEP [23], in both preterm and term-gestation infants, has been advocated by many clinicians but there is a paucity of clinical studies supporting this approach. More attention is usually paid to the peak inflating pressure rather than PEEP.

Physiological effects of PEEP in neonates:

The use of PEEP of at least 5 cm H_2O in the delivery room has been advocated to help in lung expansion at the time of extrauterine transition.[22,23]

PEEP provides the following advantages.

Increases the functional residual capacity of lungs [24]

Helps in improving oxygenation of the neonates.[25]

Increases the compliance of stiff lungs. [3,24]

Reduces the inspiratory resistance.[25]

Increases the mean airway pressure. [24]

Decreases ventilation perfusion mismatch.[3] and also conserves surfactant on the alveolar surface.[3]

Delivery room PEEP in preterm neonates:

The role of PEEP or CPAP in delivery room has been studied in preterm neonates less than 28 weeks in large RCTs.

In the COIN trial [12] conducted from 1999 to 2006, 610 neonates of 25 to 28 weeks gestation who had signs of respiratory distress at 5 minutes of life were randomised to receive either CPAP or endotracheal intubation. The primary outcome, risk of mortality or treatment with oxygen at 28 days of life was lower among neonates who received CPAP (odds ratio of 0.63; 95% CI 0.46–0.88; p value of 0.006). But they could not find any difference in the proportion of infants who had died or were treated with oxygen at 36 weeks' corrected gestational age between the two groups (CPAP 33.9% vs intubation 38.9%). Those neonates in the CPAP group required fewer days of ventilation and the use of surfactant was reduced by half. However the investigators found that more infants treated with nasal CPAP developed pneumothorax (9% vs 3%).

In the SUPPORT trial [13] conducted from 2005 to 2009, 1316 neonates of gestational age between 24 to 28 weeks were randomised to 2 groups either CPAP or endotracheal intubation and surfactant. Mortality and Bronchopulmonary dysplasia (BPD) rates (47.8% and 51%,

respectively) were comparable between the CPAP and the surfactant group. Neonates who received CPAP required intubation less frequently, required shorter duration of ventilation, and received postnatal corticosteroids for BPD less frequently. There was no difference in the rate of pneumothoraces between the 2 groups (CPAP 6.8% vs intubation 7.4%).

Finer at al [16] conducted a study to determine the feasibility of providing delivery room CPAP. They randomised 104 neonates less than 28 weeks' gestation to either CPAP/PEEP or no CPAP/PEEP during resuscitation after delivery. Neonates treated with CPAP were intubated only when they required FiO2 greater than 0.3 or had a PaCO2 more than 55 mm Hg, or had episode of apnea requiring positive pressure ventilation. 47 neonates required intubation in the delivery room of which 49% were in the CPAP group and 41% were in the control group. Only 4 of the 43 infants with birth weight of less than 700 g, and 3 of the 37 neonates less than 25 weeks' gestation were resuscitated successfully without positive-pressure ventilation, and no difference was observed between the treatment groups. 80% of the neonates were intubated within the first 7 days of life. The rates of intubation, death, and BPD were similar in both groups.

In a study conducted by Vermont oxford network[26] 648 preterm neonates of 26–29 weeks gestation were randomised to either of 3 treatment strategies ; prophylactic surfactant(PS) followed by ventilation, intubation and surfactant followed by rapid extubation to nasal CPAP(ISX) or nasal CPAP. Lesser number of neonates in the nasal CPAP group received surfactant or ventilation during the first week of life. But the investigators did not find any difference in the outcomes of death or bronchopulmonary dysplasia. Relative risk of BPD or death was 0.78 (95% CI 0.59 –1.03) for the ISX group and 0.83 (95% CI 0.64 – 1.09) for the nCPAP group when compared to prophylactic surfactant group.

These studies focussed on CPAP in delivery room in preterm <29 weeks and they did not include larger gestational age babies.

Delivery Room PEEP in Term neonates:

Though PEEP has beneficial effects in neonates there are no clinical trials as of now studying the effects of providing PEEP in delivery room in term neonates. Inspite of known beneficial effects of PEEP it has not been made mandatory in resuscitation guidelines due to lack of larger number of studies.

Mannequin studies of Ventilation devices:

Bennet et al [7] compared the ability to deliver desired peak inspiratory pressures (PIP), positive end expiratory pressures (PEEP), prolonged inflations and the length of time to transition between different pressures between the three devices. The T-piece resuscitator delivered the desired pressures with more accuracy, but required greater time to increase the PIP from 20 to 40 cmH2O. With the Self inflating bag it was difficult to maintain a prolonged inflation and deliver the desired PEEP even with the PEEP valve in place. They suggested improvement in the design and function of manual resuscitation devices and suggested prospective trials to evaluate the optimal method of PPV during resuscitation of the neonate.

Roehr et al [11] conducted a mannequin study comparing the delivered tidal volume and Peak inspiratory pressure (PIP) provided by the ventilation devices. One hundred and twenty medical professionals were involved in the study. They used a self-inflating bag and a T-piece resuscitator to ventilate an intubated mannequin. Tidal volume and PIP delivered was significantly higher in self inflating bags, compared to T-piece resuscitator. The interpersonnel variability of tidal volume and PIP delivery was distinctly higher in self inflating bags, compared to T piece resuscitator. Use of T-piece resuscitator enables to provide consistent

tidal volume and PIP regardless of individual, operator dependent variables.

Delivery room studies of Ventilation devices

Mannequin studies comparing the ventilation devices have concluded that T piece resuscitator delivers consistent pressures when compared to either self inflating bag or self inflating bag with PEEP valve but there is a paucity of published randomised controlled trials comparing the various ventilation devices in newborn resuscitation in delivery room.

The only published RCT comparing various ventilation devices in delivery room neonatal resuscitation available was done by Dawson et al[14] who randomized 80 preterm neonates less than 29 weeks' gestation to receive PPV with either a T-piece resuscitator or a self-inflating bag without a PEEP valve. The primary outcome which was analyzed was oxygen saturation at 5 minutes of life. Forty-one infants received PPV with a T-piece and 39 infants received PPV with a Self inflating bag. At 5 minutes after birth, there was no significant difference between the median (interquartile range) oxygen saturation in the T-piece 61% (13% to 72%)and self inflating bag group 55% (42% to 67%) with p value of 0.27. They could not find a significant difference in either oxygen saturation or heart rate at 5 minutes after birth or in mortality, rate of intubation, or BPD between the two groups.

A retrospective study by Archana et al [15] in Children's Hospital Richmond compared the effect of different type of manual resuscitation devices on overall response to resuscitation among preterm neonates born < 35 weeks gestation. Primary outcome which they analysed was Apgar score from retrospective data. They identified 294 neonates requiring PPV of which Self inflating bag was used for resuscitating 135 neonates and T piece resuscitator for 159 neonates. They could neither find significant difference in 1 and 5 minute Apgar scores between the two groups nor any difference in other outcomes such as need for intubation, chest compression and air leaks within 24 hours.

An unpublished study [18] conducted in Gangaram hospital New Delhi compared T piece resuscitator with self inflating bag during delivery room neonatal resuscitation. All neonates requiring positive pressure ventilation (PPV) were included in the study. Forty neonates received PPV with T piece resuscitator and fifty neonates with self inflating bag. Duration of PPV was the primary outcome. Mean duration of PPV was 30 seconds in T piece resuscitator group compared to 60 seconds in self inflating bag group. PPV with T piece resulted in shorter duration of PPV compared to self inflating bag.

A multicenter cluster randomized controlled trial (Alabama)[17] conducted in neonates more than 26 weeks gestational age requiring positive pressure ventilation (PPV) for resuscitation in the delivery room

compared T piece resuscitator device versus Self inflating bag. The primary outcome which they analysed was proportion of infants reaching HR $\geq$ 100 at 2 minutes of life. Study has been completed in November 2012 but results of the study are awaited.

Study Justification:

Currently there is no evidence based guideline mandating the use of PEEP during resuscitation in delivery room and there is no recommendation on the use of any one particular effective device for provision of PPV. The benefit of PEEP in higher gestational age is yet to be studied.

Research Question:

Is T piece resuscitator more effective than self inflating bag without PEEP valve and self inflating bag with PEEP valve in delivery room resuscitation in neonates more than 28 weeks gestation in improving short term outcomes?

HYPOTHESIS & OBJECTIVES

HYPOTHESIS

T piece resuscitator will be more effective than Self inflating Bag and Self inflating bag with PEEP valve in Delivery room resuscitation of neonates more than 28 weeks gestation.

OBJECTIVES

PRIMARY OBJECTIVE:

To compare the effectiveness of T Piece resuscitator with Self inflating Bag and Self inflating bag with PEEP valve in reaching Heart rate ≥ 100bpm in depressed newborns more than 28wks gestation after initiation of Positive Pressure Ventilation

SECONDARY OBJECTIVES:

1) To Study the time taken to reach a Heart rate ≥ 100 bpm measured using a Stop clock.
2) To determine the Oxygen saturation at 5 minutes of life measured by continuous pulse oximetry using Futura pleth pulse oximeter.
3) To assess the need for intubation and chest compressions and drugs in the delivery room

4) To assess the need for mechanical ventilation in NICU and air leaks within 7 days of life.

5) To Study mortality before discharge.

OUTCOMES

Primary Outcome:

Proportion of newborn babies achieving a Heart rate $\geq$ 100 bpm at 2 minutes of life.

Secondary Outcomes:

1. Time taken to reach a Heart rate $\geq$ 100 bpm.
2. Oxygen Saturation (SpO_2) value at 5 minutes of life.
3. Number of neonates who were intubated after failure of PPV in the Delivery room.
4. Number of neonates needing chest compression and/or medications in Delivery room.
5. Number of neonates requiring mechanical ventilation.
6. Number of babies developing air leaks in NICU in less than 7 days.
7. Mortality before discharge.

MATERIAL AND METHODS

Study Design:

Open labelled Randomised control trial

Study site:

This randomised control trial was conducted in the Labor room and Operation theatre of Institute of Obstetrics and Gynaecology, Egmore, Madras Medical College, Chennai.

Time frame:

November 2013 to March 2014

Subjects:

Newborn babies more than 28 weeks gestation with HR<100/min requiring Positive Pressure Ventilation according to NRP guidelines.

Inclusion Criteria:

All newborn babies more than 28 weeks gestation with HR<100/min requiring Positive Pressure Ventilation at birth according to NRP guidelines.

Exclusion criteria:

1. Non vigorous meconium stained babies
2. Newborns < 28 weeks gestation
3. Newborns with major congenital malformation

Study consent

The study was explained to the father or the mother in the delivery room in the local language and consent was obtained prior to delivery and the baby was enrolled in the study if he/she met the inclusion criteria.

Ethics clearance

The study protocol was submitted to the Institutional ethical committee and approval obtained on November 11, 2013 No.31112013.

Sample size:

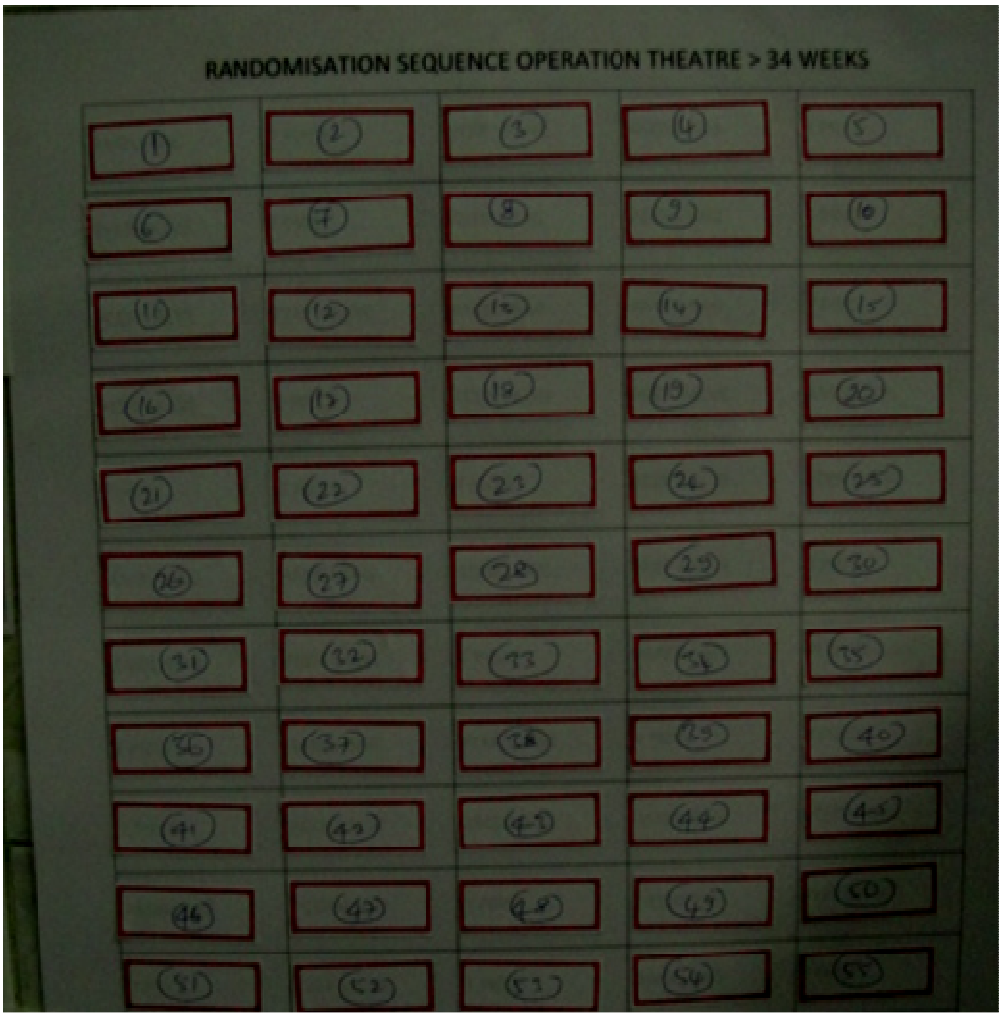
The sample size was determined from baseline proportion of newborn babies achieving HR $\geq$ 100 at 2 minutes of age determined from a pilot study done in our Institute. With an effect size of 14% and an alpha error of 0.05 and 80% power, sample size calculated was a total of 168 babies with 56 babies in each Group.

Stratification and Randomisation:

The newborns were stratified based on the place of delivery (Labor room/ operation theatre) and based on the gestational age (less than 34 weeks and more than 34 weeks) and block randomisation of the babies was done by generating random numbers of varying blocks of three and six. The random number sequence was made into a table which was enlarged and laminated and allocation concealment was ensured by pasting a label with the number over the intervention sequence. The label was peeled off at the time of resuscitation when a baby is enrolled and

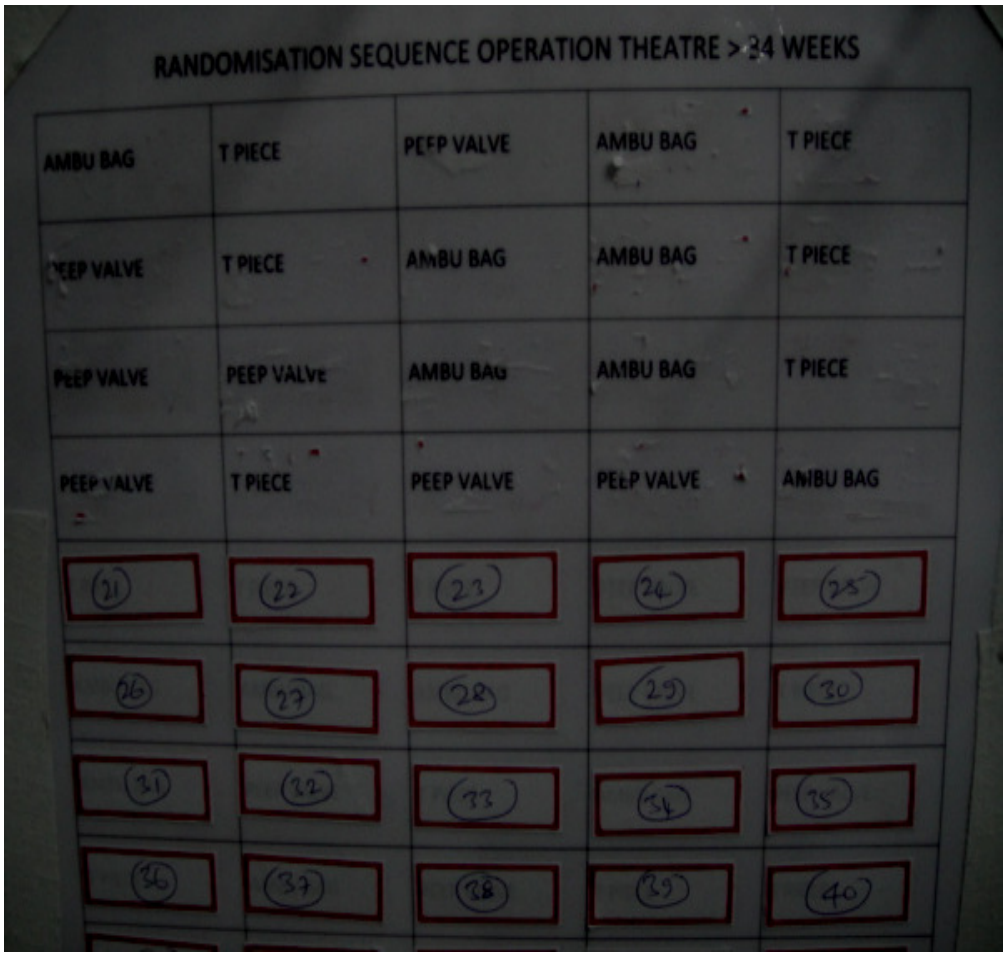
resuscitation device corresponding to the random number was used. The investigator was blinded to the random number sequence.

RANDOM NUMBER TABLE USED IN THE STUDY WITH OVERLYING LABEL FOR ALLOCATION CONCEALMENT



RANDOM NUMBER TABLE WITH LABEL PEELED OFF

SHOWING THE RESUSCITATION DEVICE



Intervention:

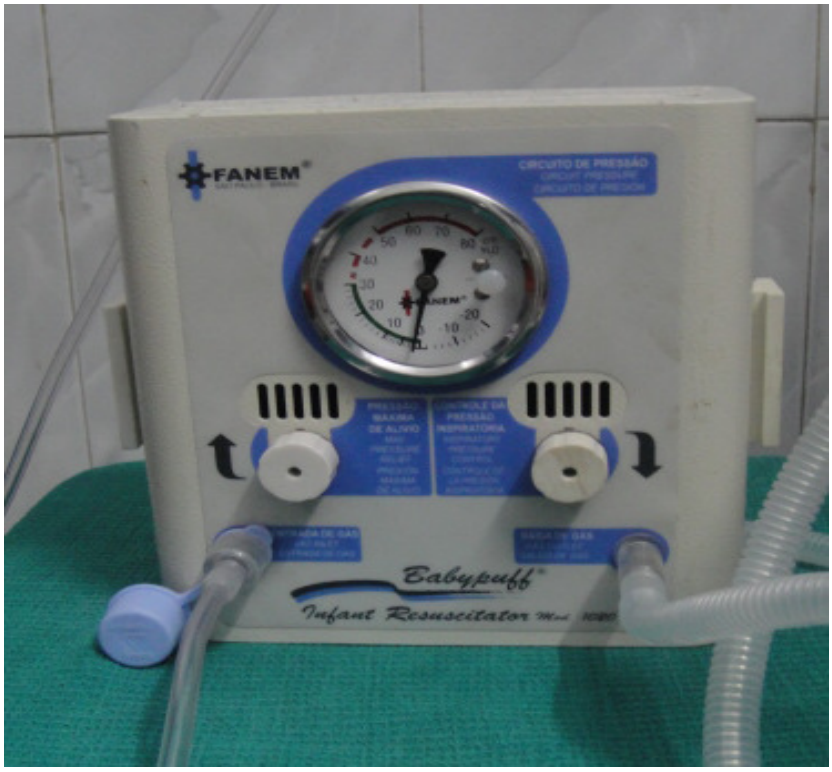
Newborn Babies more than 28weeks gestation requiring positive pressure ventilation in delivery room according to current NRP recommendation were eligible for this study. If they did not have any exclusion criteria they were enrolled into the study. Two trained persons were present for the deliveries one was involved in randomization and other resuscitated the baby. Randomisation was done by peeling off the label in the random number table which was presented in the labor room and operation theatre and the appropriate device was used for resuscitation. Pulse oximeter probe was attached to the neonate's right hand. Heart rate achieved at 2 minutes of age was recorded by use of Stop clock and pulse oximeter. The time taken for the baby to reach a Heart rate $\geq$ 100 and the oxygen saturation at 5 minutes of age were recorded.

Number of babies requiring delivery room intubation and chest compressions/drugs were noted. Any need for oxygen therapy and mechanical ventilation in NICU was noted. The study proforma was filled up and all findings duly recorded. The baseline characteristics of the baby and mother were noted.

Training on the appropriate use of the 3 devices was imparted by the principal investigator to all the Pediatric residents posted in the unit. The Fanem T piece resuscitator was used with a starting PIP of 25 cm H2O and PEEP of 5 cm H2O. The Laerdal disposable PEEP valve was

used and PEEP of 5 cm H2O was set. Futura pleth pulse oximeter was used in this study. Instructions were displayed through posters in the delivery room and was also personally conveyed to the pediatric residents on duty regarding the study.

Fanem T Piece Resuscitator

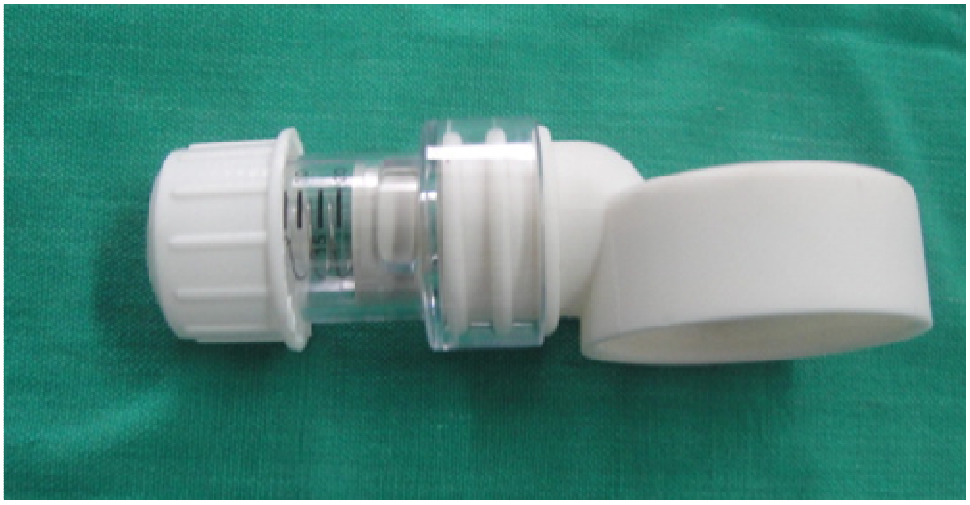


Stopclock

Self inflating bag

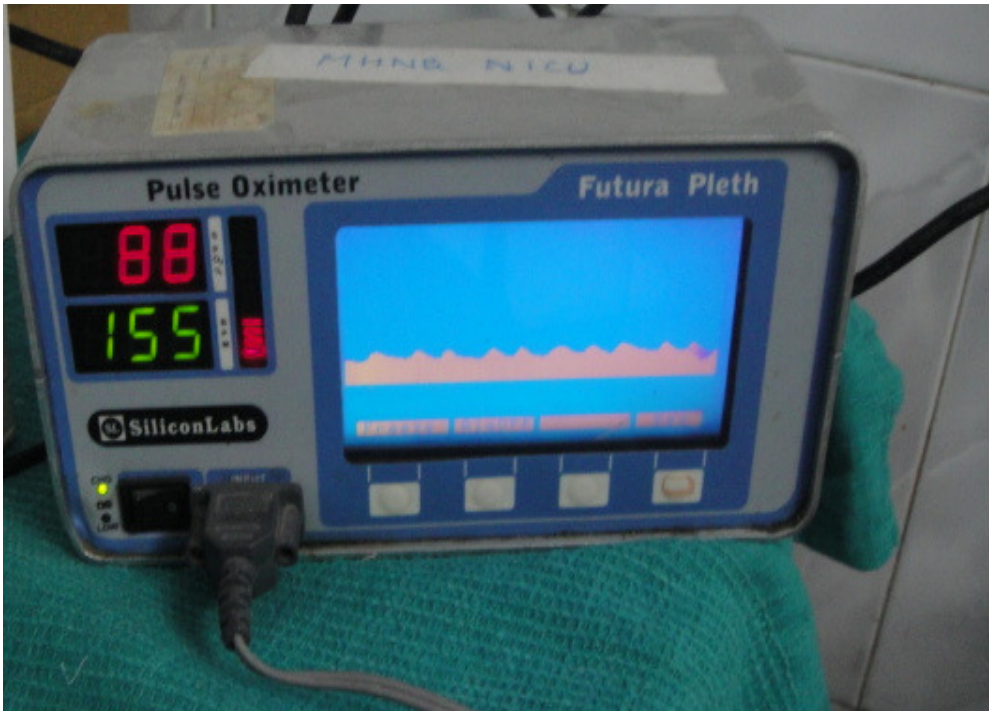
Self inflating bag with PEEP valve

Laerdal PEEP valve with Expiratory Diverter



Newborn Resuscitated with T Piece resuscitator

Futura Pleth Pulse Oximeter



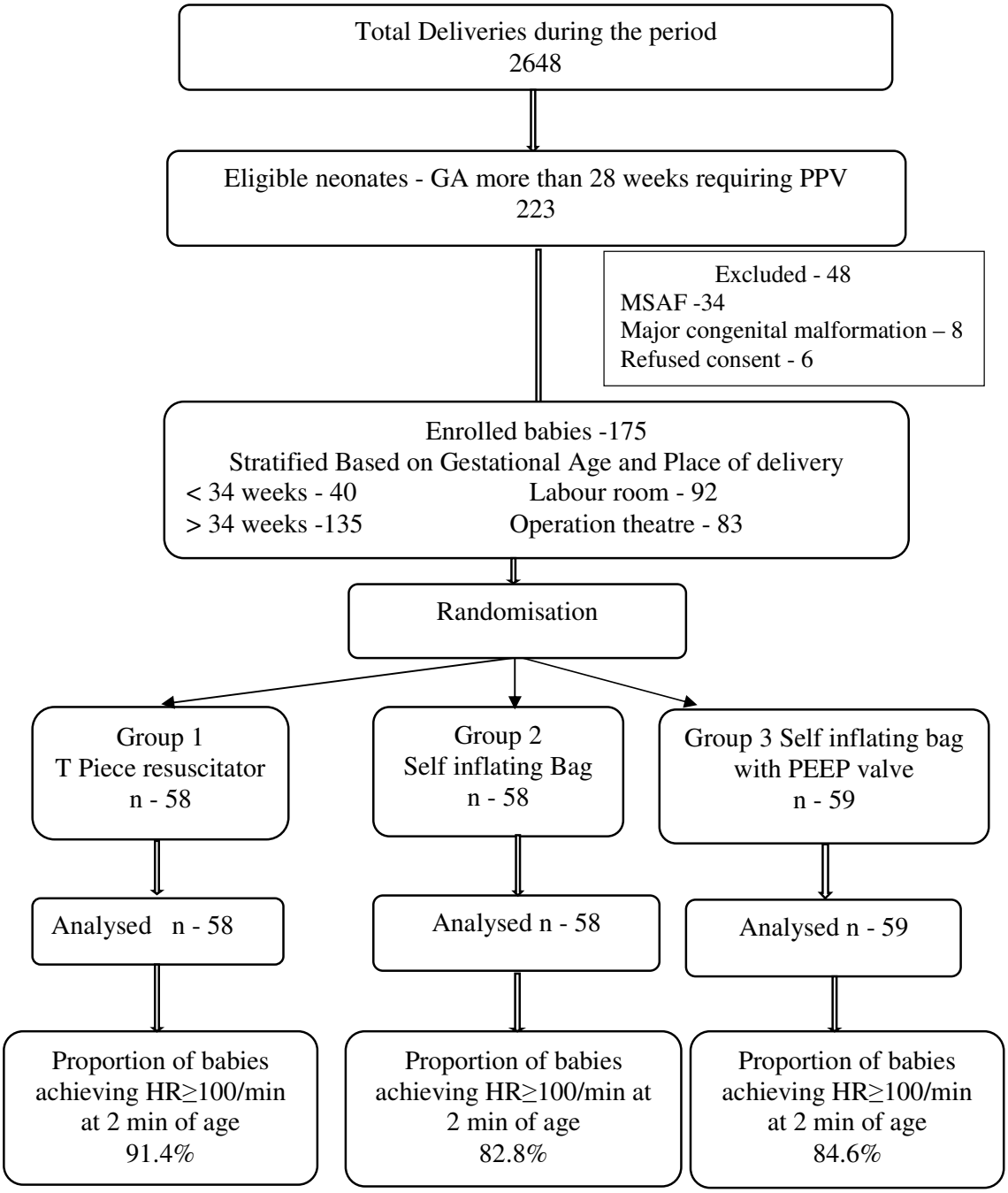
DATA COLLECTION:

The baseline maternal and neonatal characteristics were entered in the proforma. The primary and secondary outcomes were recorded and entered in the study proforma. All the data were later transferred to Microsoft Excel sheet.

STATISTICAL ANALYSIS:

The data was analysed using SPSS 17.0. The baseline clinical characteristics and outcome variables were compared with the ANOVA for parametric and Kruskal-Wallis test for non-parametric comparisons for continuous variables, and chi square test for categorical variables. A p value <0.05 was considered statistically significant. The data is presented as numbers (percentage) for categorical variables, or means (SD) for normally distributed continuous variables and median (IQR) when the distribution was skewed.

STUDY FLOW


Total Deliveries during the period
2648
Eligible neonates - GA more than 28 weeks requiring PPV
223
Excluded - 48
MSAF -34
Major congenital malformation – 8
Refused consent - 6
Enrolled babies -175
Stratified Based on Gestational Age and Place of delivery
< 34 weeks - 40
> 34 weeks -135
Labour room - 92
Operation theatre - 83
Randomisation
Group 1
T Piece resuscitator
n - 58
Group 2
Self inflating Bag
n - 58
Group 3 Self inflating bag with PEEP valve
n - 59
Analysed n - 58
Analysed n - 58
Analysed n - 59
Proportion of babies achieving HR≥100/min at 2 min of age
91.4%
Proportion of babies achieving HR≥100/min at 2 min of age
82.8%
Proportion of babies achieving HR≥100/min at 2 min of age
84.6%

RESULTS & ANALYSIS

Total number of deliveries during our study period were 2648. Out of 223 eligible neonates, 48 neonates who met the exclusion criteria were excluded (34 MSAF neonates, 8 neonates with major congenital malformation and 6 refused consent).

175 neonates were enrolled in the study and they were stratified based on gestational age (less than 34 weeks and more than 34 weeks) and Place of delivery (Labor room and Operation theatre) and then randomised to one of the 3 groups.

Out of 175 babies 58 neonates received positive pressure ventilation with T piece resuscitator, 58 with self inflating bag and 59 with self inflating bag with PEEP valve. In less than 34 weeks gestational age stratum 13 neonates received PPV with T piece resuscitator, 13 neonates with self inflating bag and 14 neonates received PPV with self inflating bag with PEEP valve. In more than 34 weeks gestational age stratum there were 45 neonates in each group. Babies more than 34 weeks constituted a majority (77%) of the study population. Babies weighing more than 2500 gms constituted 59% of the study population.

Table 1: Baseline maternal characteristics of the 3 groups:

	T Piece resuscitator n - 58	Self inflating Bag n - 58	Self inflating Bag with PEEP valve n - 59	p value
Maternal Age	25.0(24.2-25.8)	25.0(24.3-25.7)	24.4(23.7 - 25.3)	0.56
Primi	27(46.6)	32 (55.8)	38 (64.4)	0.15
Anemia*	28 (48.3)	33 (56.9)	35 (59.3)	0.45
Diabetes*	9 (15.5)	11 (18.9)	8 (13.6)	0.57
Hypothyroidism*	4 (6.9)	6(10.3)	6 (10.2)	0.77
Heart Disease*	2 (3.5)	2 (3.5)	1 (1.7)	0.81
PIH*	11 (18.9)	13 (22.4)	10 (16.9)	0.75
APH*	2 (3.5)	5 (8.6)	4 (6.8)	0.51
Oligohydramnios*	13(22)	15(26)	12(20)	0.77
Polyhydramnios*	4 (7)	3(5)	5 (8)	0.78
Antenatal Steroid(<34 weeks)*				0.24
Full course	10 (76.9)	6 (46.4)	6 (42.9)	
Partial Course	2 (15.4)	3 (23.1)	3(21.4)	
No steroids	1(7.7)	4(30.7)	5(35.7)	
Received MgSo4*	5 (8.6)	7 (12.1)	5 (8.5)	0.76
PROM > 24hrs*	8 (13.8)	5 (8.6)	3 (5.1)	0.26
Intrapartum Fever*	6 (10)	4(7)	3(5)	0.56
Abnormal CTG*	5(9)	8(14)	8(14)	0.625

*Numbers in brackets are expressed as percentages

Perinatal risk factors like maternal anemia, heart disease, hypothyroidism, PIH, Abruption, oligohydramnios, maternal intrapartum fever, PROM, CTG abnormalities and maternal magnesium sulphate administration were equally distributed between the 3 groups.

Table 2: Baseline characteristics of the enrolled neonates

	T Piece resuscitator N=58	Self inflating Bag N=58	Self inflating Bag with PEEP valve N=59	p value
Male*	32 (55.2)	36 (62.1)	34 (57.6)	0.75
Mean Gestational Age (GA)	36.41± 2.74	36.84 ± 3.29	36.78 ± 3.17	0.73
GA distribution*				
28-30wks	2 (3)	4 (7)	3 (5)	
31-34wks	11(19)	9(16)	11(19)	0.88
35-37wks	14(24)	11(19)	9(15)	
>37wks	31(53)	34(59)	36(61)	
Birth Weight	2427.93 ± 737.18	2523.71 ± 820.49	2464.24 ± 659.37	0.78
Weight Distribution*				
<1000gms	1 (2)	1 (2)	1 (2)	
1000-1500gms	10 (17)	11(19)	8(14)	
1500-2000gms	7(12)	4(7)	6(10)	0.97
2000-2500gms	9(16)	6(10)	8(14)	
>2500gms	31(53)	36(62)	36(61)	
Foetal distress*	10 (17)	12(21)	13(22)	0.80
Mode of Delivery*				
Normal Vaginal	25 (43)	25(43)	27(46)	
Instrumental	5(9)	6(10)	4(7)	0.90
LSCS	28(48)	27(47)	28(47)	
Growth status*				
AGA	46 (79)	49 (84)	51(86)	0.54
SGA/IUGR	11(19)	7(12)	7(12)	
LGA	1(2)	2(3)	1(2)	

*Numbers in brackets are expressed as percentages

The baseline characteristics of the babies like gestational age, gender, weight, mode of delivery, growth status and foetal distress were equally distributed between the 3 groups and comparable (Table 2)

PRIMARY OUTCOME

Table 3: Proportion of neonates achieving HR≥100/min at 2 minutes of age

	T piece Resuscitator n=58	Self-Inflating bag n=58	Self-inflating Bag with PEEP valve n=59	p value
Reached HR≥ 100/min at 2 min age*	53 (91.4)	48 (82.8)	50 (84.8)	0.37

Chi square test

*Numbers in brackets are expressed as percentages

A higher proportion of babies (91.4%) achieved a HR≥100/min at 2 minutes of age in the T piece resuscitator group compared to self-inflating bag (82.8%) and self-inflating bag with PEEP valve (84.8%). But the difference was not statistically significant.

SECONDARY OUTCOMES

Table 4: Time taken for reaching HR≥100/min after positive pressure ventilation (PPV)

	T Piece Resuscitator n=58	Self inflating Bag n=58	Self inflating Bag with PEEP valve n=59	p value
Time taken for reaching HR≥100/min after PPV (seconds)*	45(30-60)	60(45-75)	60(45-77)	0.01

Kruskal-Wallis test

*Median (IQR)

Newborns resuscitated with T piece resuscitator took a significantly lesser median time (45 seconds) to achieve a Heart rate ≥100/min compared to those resuscitated with self inflating bag (60 seconds) and self inflating bag with PEEP valve (60 seconds).

Intergroup analysis

	T piece resuscitator	Self inflating bag	P value
Time taken to reachHR≥100	45 (30-60))	60 (45-75)	0.009

	T piece resuscitator	Self inflating bag with PEEP valve	P value
Time taken to reachHR≥100	45 (30-60)	60(45-77)	0.012

	Self inflating bag	Self inflating bag with PEEP valve	P value
Time taken to reach HR≥100	60 (45-75)	60(45-77)	0.770

There is significant difference between T piece resuscitator and self inflating bag ($p<0.017$) (adjusted by Bonferroni's method) in the time taken for reaching HR≥100 and significant difference between T piece resuscitator and self inflating bag with PEEP valve ($p<0.017$) (adjusted by Bonferroni's method) and no statistical significance between self inflating bag and self inflating bag with PEEP valve ($p=0.77$) which implies that the time taken by neonates resuscitated with T piece for reaching HR≥100 is significantly less compared to Self inflating bag and Self inflating bag with PEEP valve .

Table 5: Oxygen Saturation (SpO_2) at 5 minutes of age

	T Piece Resuscitator n=58	Self inflating Bag n=58	Self inflating Bag with PEEP valve n=59	p value*
SpO2 at 5 min of age (%) **	87(85-88)	85(84-87)	87(84-88)	0.002

Kruskal Wallis test

* $p<0.05$ considered statistically significant

**Median (IQR)

The median oxygen saturation was 87 in neonates resuscitated with T Piece resuscitator and self inflating bag with PEEP valve with IQR being 85-88 for the former and 84-88 for the latter. This was significantly higher than the median oxygen saturation achieved by neonates resuscitated with self inflating bag 85(84-87).

Intergroup Analysis

Mann Whitney U test

	T piece resuscitator	Self inflating bag	p value
Spo2 at 5 min	87 (85-88)	85 (84-87)	0.001

	T piece resuscitator	Self inflating bag with PEEP valve	p value
Spo2 at 5 min	87 (85-88)	87(84-88)	0.170

	Self inflating bag	Self inflating bag with PEEP valve	p value
Spo2 at 5 min	85 (84-87)	87(84-88)	0.015

When intergroup analysis was performed between the 3 devices for median oxygen saturation, there was significant difference between T piece resuscitator and self inflating bag ($p<0.017$ adjusted by Bonferroni's method) and also between Self inflating bag with PEEP valve and Self inflating bag ($p<0.017$ adjusted by Bonferroni's method). There was no significant difference between T piece Resuscitator and Self inflating bag with PEEP valve ($p=0.170$). This implies that the oxygen saturation at 5 minutes of age in neonates resuscitated with T piece resuscitator or Self inflating bag with PEEP valve group is significantly higher than those neonates resuscitated with self inflating bag.

Table 6: Need for Delivery room Intubation, Chest compressions and Medications

	T Piece n=58	Self-inflating Bag n=58	Self-inflating Bag with PEEP valve n=59	p value
Need for Delivery room Intubation*	5 (8.6)	10 (17.2)	8 (13.5)	0.39
Need for Chest compression*	1 (1.7)	4 (6.9)	2 (3.4)	0.21
Need for medications*	1(1.7)	2(3.5)	1(1.7)	0.78

*Numbers in brackets expressed as percentages

The need for Delivery room intubation and chest compressions and medications was less in the T piece resuscitator group compared to the self inflating bag and selfinflating bag with PEEP valve group but the difference was not statistically significant.

Table 7: Need for Invasive ventilation in NICU / Air leaks in NICU and mortality

	T Piece Resuscitator n=58	Self-inflating Bag n=58	Self-inflating Bag with PEEP valve n=59	p value
Need for Mechanical ventilation*	7 (12.1)	13 (22.4)	11 (18.6)	0.34
Air Leaks*	1 (1.7)	3 (5.2)	1 (1.7)	0.43
Mortality*	5 (8.6)	10 (17.2)	9 (15.3)	0.37

*Numbers in brackets expressed as percentages

The number of neonates who required mechanical ventilation in NICU were less in T piece resuscitator group compared to those in self inflating bag and self inflating bag with PEEP valve group but the difference was not statistically significant. Neonates who developed air leaks in NICU within 7 days were comparable between the 3 groups. Mortality in neonates resuscitated with T piece resuscitated was less compared to those resuscitated with self inflating bag and self inflating bag with PEEP valve though not statistically significant.

SUBGROUP ANALYSIS

Table 8: Less than 34 weeks

Primary outcome: Proportion of babies achieving Heart rate ≥100/min at 2 min age

	T piece Resuscitator n=58	Self-Inflating bag n=58	Self-inflating Bag with PEEP valve n=59	P value
Reached HR≥100 at 2 min age	10 (77)	9 (69)	11 (78.6)	0.84

The proportion of neonates less than 34 weeks who achieved a Heart rate ≥ 100 at 2 minutes of age was almost equal in T piece resuscitator and self inflating bag with PEEP valve group and it was higher than those in the self inflating bag group but it is not statistically significant.

Table 9: More than 34 weeks

Primary outcome: Proportion of babies achieving Heart rate ≥100/min at 2 min age

	T piece Resuscitator n=58	Self-Inflating bag n=58	Self-inflating Bag with PEEP valve n=59	P value
Reached HR≥100 at 2 min of age	43(96)	39(87)	39(87)	0.28

In more than 34 weeks a higher proportion of neonates achieved a Heart rate ≥100 at 2 min of age in T piece resuscitator group compared to self inflating bag and self inflating bag with PEEP valve group but the difference was not significant statistically.

Subgroup analysis: Secondary outcomes

Table 10 : Less than 34 Weeks

	T piece Resuscitator n=13	Self-Inflating bag n=13	Self-inflating Bag with PEEP valve n=14	P value
Time taken for reaching HR≥100 /min after PPV (sec)	60.0 (30-70)	75.0 (45-95)	72.0 (45-77)	0.14
SpO2 at 5 min of age (%)	84.0 (83-87)	84.0 (80-87)	84.5 (80-87)	0.59

The time taken for reaching Heart rate ≥ 100/min after PPV and oxygen saturation at 5 minutes of age was comparable between the 3 groups in less than 34 weeks gestational age.

Table 11: More than 34 Weeks

	T piece Resuscitator n=45	Self-Inflating bag n=45	Self-inflating Bag with PEEP valve n=45	P value
Time taken for reaching HR≥100/min after PPV (sec)	45.0 (30-60)	60.0 (45-88)	60.0 (45-72)	0.07
SpO2 at 5 min of age (%)	88.0 (87-89)	86.0 (85-87)	87.0 (86-88)	<0.001

In more than 34 weeks stratum neonates who were resuscitated with T piece resuscitator took median time of 45 seconds to reach a HR more than 100/min compared to median time of 60 seconds in self inflating bag and self inflating bag with PEEP valve group but it was not statistically significant. Oxygen saturation at 5 min of age was significantly higher in the T piece resuscitator group compared to self inflating bag and self inflating bag with PEEP valve.

DISCUSSION

Our single centre randomised control trial was designed to compare the efficacy of T piece resuscitator versus self inflating bag and self inflating bag with PEEP valve in delivery room resuscitation of neonates more than 28 weeks gestation.

We enrolled neonates more than 28 weeks gestation in our study since the baseline mortality in our unit in less than 28 weeks was higher and we desired to study the effects of PEEP in higher gestational age groups also. Dawson et al[14] had enrolled only babies less than 28 weeks gestation and they had compared the efficacy of T piece resuscitator and self inflating bag. In our study we also included self inflating bag with PEEP valve as the third group since it could also deliver PEEP though at a variable level. As ours was a study in neonatal resuscitation blinding of the resuscitation device was practically not possible but the principal investigator was blinded to the randomisation sequence.

Primary outcome: Proportion of babies achieving a HR≥100/min at 2 minutes of age

In our study the proportion of babies achieving a HR≥100/min at 2 minutes of age was used as the primary outcome since increase in heart rate is a good indicator of effectiveness of neonatal ventilation. We found that a higher proportion of babies achieved a HR≥100/min at 2 minutes of

age when resuscitated with T piece resuscitator compared to self inflating bag and self inflating bag with PEEP valve. But the difference was not statistically significant. This could be due to the reason that our study was only 80% powered if we had designed our study with 90% power with more neonates we might have been able to pick up a statistically significant difference. As there are no published studies with similar outcome we could not compare it with other studies. An unpublished study done in Alabama [17] had used the increase in heart rate as their primary outcome which is similar to ours but their results are yet to be published.

When we did a subgroup analysis with gestational age we found that in less than 34 weeks the proportion of babies who achieved a HR ≥100/min at 2 minutes of age was similar in T piece resuscitator and Self inflating bag with PEEP valve (77% and 78.6%). In this subgroup where self inflating bag was used lesser proportion achieved HR ≥100/min at 2 minutes (69%). But the difference was not statistically significant. In more than 34 weeks a higher proportion of babies achieved a HR≥100/min at 2 minutes of age when resuscitated with T piece resuscitator (96%). The proportion was similar in self inflating bag and self inflating bag with PEEP valve (87% and 87%). Again the difference was not statistically significant.

Secondary outcomes

Time taken for reaching HR≥100/min after PPV

In our study neonates in the T piece resuscitator group took significantly lesser time after positive pressure ventilation to reach a HR≥100/min compared to those in the self inflating bag and self inflating bag with PEEP valve group. The median time taken in the T piece resuscitator group was 45 seconds compared to 60 seconds in the Self inflating bag and self inflating bag with PEEP valve group.

This was lesser than that observed in Yam et al [19] where median time taken was 73 seconds but the study population was neonates less than 30 weeks gestation. But our study population was newborns more than 28 weeks gestation with a predominance of more than 34 weeks. There are no other studies taking into account the time taken to reach HR ≥100 which are available for comparing with our results.

In subgroup analysis based on gestational age we observed that in less than 34 weeks gestation neonates resuscitated with T piece resuscitator took less time (median of 60 seconds) to achieve a HR≥100/min compared to those with self inflating bag and self inflating bag with PEEP valve (median of 75 and 72 seconds respectively) which was not statistically significant . In more than 34 weeks gestation newborns resuscitated with T piece resuscitator took a significantly lesser time (median 45 seconds) to achieve a HR≥100 compared to those with

self inflating bag and self inflating bag with PEEP valve (median of 60 and 60 seconds respectively).

Oxygen saturation at 5 minutes of age

The oxygen saturation at 5 minutes of age was significantly higher in the T piece resuscitator group (87%) and self inflating bag with PEEP valve group (87%) compared to those in the self inflating bag group (median of 85%). On doing multiple comparison between pairs of devices oxygen saturation in T piece group and self inflating bag with PEEP valve group was significantly higher than self inflating bag group but the oxygen saturations between T piece resuscitator group and self inflating bag with PEEP valve group were similar.

Our median oxygen saturation was higher than those observed in Dawson et al[14] who observed a median oxygen saturation of 66% in T piece group but they included only neonates <28 weeks. Dawson et al did not find any difference in oxygen saturation between T piece resuscitator and self inflating bag. The higher than expected oxygen saturation in our study could be possibly explained by the higher gestational age group neonates in our study and use of 100% oxygen in our study.

When we did a subgroup analysis based on gestational age we found that in less than 34 weeks gestation median oxygen saturation at 5 minutes of age was similar with all the three devices (84%). In more than 34 weeks babies resuscitated with T piece resuscitator achieved a

significantly higher oxygen saturation (88%) compared to self inflating bag (86%) and self inflating bag with PEEP valve (87%).

Need for delivery room intubation, chest compression and drugs:

We observed a lesser delivery room intubation rate of 8.6% in the T piece resuscitator group compared to 17.2% in self inflating bag group and 13.5% in self inflating bag with PEEP valve group but it was not statistically significant. Our intubation rates in T piece group were less compared to Dawson et al[14] but that could be due to gestational age difference since Dawson et al recruited only < 28 weeks gestation neonates. Our delivery room intubation rates were lesser compared to a unpublished study from Gangaram Hospital [18] where the 15% neonates were intubated in T piece resuscitator group compared to 34% in self inflating bag group.

Number of neonates who resuscitated with T piece resuscitator who required Chest compression in delivery room were less (1.9%) compared to those in self inflating bag and self inflating bag with PEEP valve group (6.9% and 3.4% respectively) but it was not statistically significant. Less neonates required drugs in delivery room when resuscitated with either T piece resuscitator or self inflating bag with PEEP valve (1.7%) than those with self inflating bag (3.5%) but it was not significant statistically.

Need for mechanical ventilation:

In our study number of neonates requiring mechanical ventilation in NICU were less in T piece resuscitator group (12.1%) compared to those in the Self inflating bag (22.4%) and self inflating bag with PEEP valve (18.6%) group which was not statistically significant.

Air leaks in NICU less than 7 days

We did not observe any delivery room air leaks in the three groups but air leaks were observed in the NICU in all three groups but was comparable between 3 groups (1.7% when resuscitated with T piece resuscitator or self inflating bag with PEEP valve and 5.2% in self inflating bag group)

Mortality before discharge:

Mortality was less in T piece resuscitator group (8.6%) compared to self inflating bag with PEEP valve (15.3%) and self inflating bag group (17.2%) but the difference was not statistically significant .

Strengths of our study:

1. Our study is the first study which compared the three resuscitation devices in newborn resuscitation.
2. We attempted to study the benefit of PEEP in term gestation in addition to preterm neonates.
3. We used block randomisation with varying blocks and allocation concealment.
4. Primary outcome we used was an increase in heart rate which is the best indicator of effective ventilation.

Limitations of our study:

1. Our study was only 80% powered. Perhaps 90% powered study with larger sample size could have yielded statistically significant results.
2. We used 100% oxygen for resuscitation of all babies for want of similarity between groups (contrary to the current NRP recommendations).
3. We did not include neonates less than 28 weeks gestation who would have benefited more from early administration of PEEP.

CONCLUSIONS

1. Use of T piece resuscitator resulted in higher number of neonates achieving a Heart rate ≥ 100/min at 2 minutes of age when compared to self inflating bag and self inflating bag with PEEP valve. Hence T piece resuscitator seems to be more effective than self inflating bag and self inflating bag with PEEP valve in delivery room newborn resuscitation of babies more than 28 weeks gestation. This was statistically insignificant. A larger sample size may be needed to clearly demonstrate the advantage of T piece resuscitator over self inflating bag and self inflating bag with PEEP valve.
2. Resuscitation with T piece resuscitator achieves a Heart rate ≥ 100 at a significantly lesser time than self inflating bag and self inflating bag with PEEP valve .
3. T piece resuscitator and self inflating bag with PEEP valve enables a newborn to achieve significantly higher oxygen saturation at 5 minutes of age than self inflating bag. The effect is more pronounced in more than 34 weeks gestational age.
4. T piece reduces the number of babies requiring delivery room intubation, chest compressions and medications compared to self

inflating bag and self inflating bag with PEEP valve though statistically insignificant.

5. T piece resuscitator reduces the number of babies requiring invasive ventilation but the effect is not significant statistically.
6. There is no difference in complications like air leaks between the three devices.
7. Provision of PEEP by T piece resuscitator or self inflating bag with PEEP valve improves the short term outcomes in neonatal resuscitation but requires further adequately powered studies with higher sample size to test for statistical significance if any.
8. In settings where T piece resuscitator may not be available use of self inflating bag with PEEP valve could be an alternative resuscitation device in newborn resuscitation.

Implications for practice:

Ventilation devices which deliver PEEP such as T piece resuscitator and Self inflating bag with PEEP valve may be used in delivery room resuscitation wherever it is feasible till we conclusively establish the benefits of delivery room PEEP through further studies.

Implications for research:

Further large multicentre randomised trials with a larger sample size are needed to conclusively prove the need for mandatory use of resuscitation devices which can provide PEEP in delivery room. Outcomes like bronchopulmonary dysplasia and long term neurodevelopmental outcomes should be included in further studies.

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Annexure 1

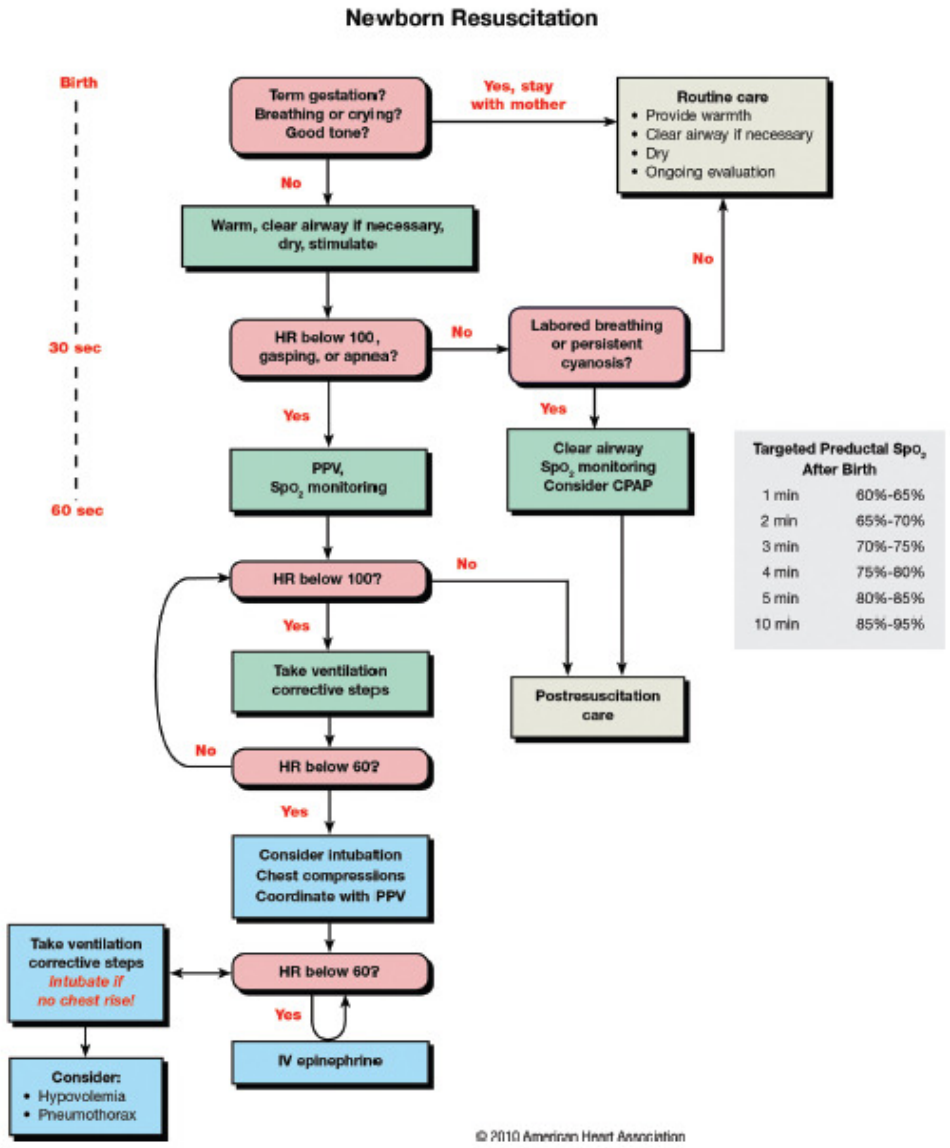

Figure. Newborn Resuscitation Algorithm.

Annexure 2

STUDY PROFORMA

Name	:	
Place of delivery	:	Labor Room/Operation theatre
Mode of delivery	:	Labor natural/Instrumental/LSCS
Gestational age	:	<34wks / >34wks
Randomisation number	:	
Gestational Age	:	
Sex	:	
Weight	:	
Growth status	:	AGA/SGA/LGA

Parents Name and Address:

Mother Details:

Age	:	
Parity	:	
LMP	:	
EDD	:	
Scan EDD	:	

Medical History

Anemia: Yes / No

Diabetes: Yes / No

PIH: Yes /No

APH: Yes / No

Oligohydramnios/ Polyhydramnios

Heart disease: Yes / No

Antenatal Steroids: Full course/Partial course/Nil

Drugs: MgSo4 / sedatives

PROM; Yes/No

Intrapartum Fever: Yes/No

Abnormal CTG: Yes/No

BABY RESUSCITATION DETAILS

Device Used For Resuscitation:

T piece resuscitator/Self inflating bag/Self inflating bag with PEEP valve

Primary outcome:

Reached HR >100/min at 2 minutes of age: Yes / No

Secondary Outcomes:

- Time the newborn takes to reach a HR > 100 bpm :
- SpO2 value at 5 minutes of life :
- Delivery room Intubation : Yes / No
- Chest compression and/or medications : Yes / No
- Oxygen treatment beyond the delivery room : Yes / No
- Need for mechanical ventilation or CPAP: Yes / No
- Air leaks : Yes / No
- Mortality before discharge : Yes / No

Annexure 3

PATIENT INFORMATION SHEET

Title: "Efficacy of T piece resuscitator versus self inflating bag and self inflating bag with PEEP valve in Newborn Resuscitation – A Randomised control trial"

Neonatal resuscitation is required by 5 to 10% of the babies at birth for survival. It is done by various devices. The commonly used device is self inflating bag. A new device which has been found to be more effective in mannequin studies is T piece resuscitator. It has been found to deliver more consistent pressures and also delivers PEEP which is very useful in lung inflation at birth. Another device is Self inflating bag with PEEP valve attached to it

Hence we are conducting this study to see if T Piece resuscitator is more effective than self inflating bag and self inflating bag with PEEP valve in newborn resuscitation. If your baby requires resuscitation at birth for breathing then one of these devices would be used for your baby.

We would be happy if could make your baby a part of this study. We assure you that we would take utmost care to see that your baby is not harmed in any way throughout the study.

There is no compulsion. You can withdraw your baby from the trial at any time during the study. Your baby will continue to receive routine care given as per the hospital protocol. During the study, during the analysis of the results and during the publication of the study your identity will not be revealed.

The outcome of the study will be revealed to you after the completion of the study if requested for.

Signature of the Investigator Signature of the Parent

Date:

Chennai - 8

Annexure 4

STUDY CONSENT FORM

Title: **"Efficacy of T piece resuscitator versus self inflating bag and Self inflating bag with PEEP valve in Newborn Resuscitation – A Randomised control trial "**

I Ms/Mr._____ M/O/F/O, B/O_____Sex_____Hosp.No._____ delivered in Institute of Obstetrics and Gynaecology, Egmore on _____ was explained to by the doctor that my baby is being enrolled in Efficacy of T piece resuscitator versus self inflating bag and Self inflating Bag with PEEP valve in Newborn Resuscitation study.

I have received the Patient Information Sheet from the doctor regarding the study. I am willing for my child to be enrolled in this study. The doctors have explained to me the nature and the purpose of the trial.

I have given my consent only after completely understanding the details that were explained to me. I am willing for my baby to be enrolled in this study without any ones compulsion.

I am fully aware that I can withdraw from the trial at any time during the study and routine care will be continued. I have given consent for Resuscitation by one of these devices.

The rare complications which can arise was explained to me.

I have given this consent to be enrolled in this study with my full consciousness.

Signature of the Investigator Signature of the Parent

Date:

Place: Chennai -8

Annexure 5

ஆராய்ச்சி தகவல் தாள்

தலைப்பு : பச்சிளம்குழந்தைகளுக்கு உயிர் சுவாசம் அளிக்கும் மூன்று கருவிகளுக்கு இடையிலான திறனாய்வு.

பிறக்கும்பொழுது 5 முதல் 10% பச்சிளம்குழந்தைகளுக்கு உயிர் சுவாசம் தேவைப்படுகிறது. உயிர்சுவாசம் அளிப்பதற்கு பல்வேறு கருவிகள் உள்ளன. இதில் தற்பொழுது தானே விரிவடையும் சுவாசப்பை அதிகஅளவில் பயன்படுத்தப்படுகிறது. இது அல்லாமல் பீப் வால்வு பொருத்திய சுவாசப்பை மற்றும் T வடிவ சுவாச கருவியும் உபயோகத்தில் உள்ளன. T வடிவ சுவாச கருவி மற்றும் பீப் வால்வு பொருத்திய சுவாசப்பை நுரையீரலை விரிவடைய செய்வதில் அதிக திறன் உள்ளதாக பல்வேறு ஆய்வுகளில் தெரியவந்துள்ளது.

இந்த ஆராய்ச்சி பச்சிளம் குழந்தைகளுக்கு உயிர்சுவாசம் அளிக்கும் இந்த மூன்று கருவிகளுக்கு இடையிலான திறனாய்வு ஆகும். உங்கள் குழந்தைக்கு பிறக்கும்பொழுது உயிர்சுவாசம் தேவைப்பட்டால் இம்மூன்று கருவிகளில் ஏதேனும் ஒன்று பயன்படுத்தப்படும்.

இந்த ஆய்வில் கலந்து கொள்ள உங்கள் குழந்தை தகுதி உள்ளதாக இருந்தால், உங்கள் விருப்பத்தின்படி நீங்கள் சம்மதிக்கலாம். இந்த ஆய்வில் தங்கள் குழந்தைக்கு எவ்வித பாதிப்பும் நேராது என நாங்கள் உறுதி கூறுகிறோம். நீங்கள் இந்த ஆய்விலிருந்து விலக நினைத்தால் தாராளமாக விலகலாம். உங்களின் இந்த முடிவானது குழந்தையின் மருத்துவ சிகிச்சையில் எந்தவித பாதிப்பையும் ஏற்படுத்தாது என்று உறுதி அளிக்கிறோம். இந்த ஆய்வின் முடிவில் தங்களுக்கு ஆய்வின் இறுதியில் தெரிவிக்கப்படும். ஆய்வு நிகழும்போது ஏதேனும் மாறுபாடு இருந்தால் குழந்தையின் சிகிச்சைக்கு உதவும் பொருட்டு முடிவுகள் உங்களுக்குத் தெரிவிக்கப்படும்.

ஆய்வாளர் கையொப்பம்
பெயர் :
நாள் :

பெற்றோர்/பாதுகாப்பாளர் கையொப்பம்
பெயர் :
நாள் :

Annexure 6

ஆராய்ச்சி ஒப்புதல் சான்று

தலைப்பு : பச்சிளம்குழந்தைகளுக்கு உயிர் சுவாசம் அளிக்கும் மூன்று கருவிகளுக்கு இடையிலான திறனாய்வு.

பெயர் :
த/பெ :
பால் :

தேதி :
உள்நோயாளி எண் :
ஆராயச்சி சேர்க்கை எண்:

பச்சிளம்குழ்நதைகளுக்கு உயிர்சுவாசம் அளிக்கும் மூன்று வெவ்வேறு கருவிகளுக்கு இடையிலான திறனாய்வில் பங்கு பெற முழு சம்மதத்தை தெரிவிக்கிறேன்.

இந்த ஆய்வு குறித்த தகவல் தாளை மருத்துவர்மூலம் பெற்றுக்கொண்டேன். இந்த ஆய்வின் நோக்கமும் ஆய்வு குறித்த விளக்கமும் மருத்துவரால் எனக்கு தெளிவாக விளக்கப்பட்டது. இந்த ஆய்வு பற்றிய விவரங்களை முழுமையாகப் புரிந்து கொண்ட பிறகே இந்த ஆய்வில் பங்கு பெற சம்மதிக்கிறேன்.

நான் இந்த ஆய்வில் எவரின் கட்டாயமும் இன்றி முழு சுதந்திரத்துடன் பங்கு பெற சம்மதிக்கிறேன். இந்த ஆய்வின் எந்த நிலையிலிருந்தும் எனது குழந்தையை ஆய்விலிருந்து விலக்கிகொள்ளலாம் என்பதை நான் அறிவேன்.

மூன்று வகையான சுவாச கருவிகளில் எந்தவொரு கருவியினாலும் எனது குழந்தைக்கு உயிர்சுவாசம் அளிக்கப்படலாம் என நான் அறிவேன். இந்த ஆய்வினால் விளையும் அரிதான பக்கவிளைவுகளை மருத்துவர் மூலம் அறிவேன். நான் என்னுடைய முழு சுதந்திரத்துடன் இந்த ஆய்வில் என் குழந்தை பங்குபெற சம்மதிக்கிறேன்.

ஆய்வாளர் கையொப்பம்
பெயர் :
நாள் :

பெற்றோர்/பாதுகாப்பாளர் கையொப்பம்
பெயர் :
நாள் :

S.No	Random	Deliv	Mod	Gesta	Group	Name	Gestat	Gest A	Sex	Weig	Weight	Grow	Matern	Parit	Anen	Diabe	PIH	APH	Heart D	Hypo	Oligoh	Polyh	Fetal Dis	Abno	Antena	Mag.S	Materna	PROM>2	HR>100 at 2 m	Time Taken	SpO2 at 5	DR Int	Chest co	Apgar 1	Apgar	Oxygen	CPAP	Mecha	Air leak	HIE	Mortality
1	LRA1	1	1	1	1	B/o Kalpana	2	32	2	3	1610	1	20	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	45	83	2	2	5	7	1	1	2	2	1	2
2	LRA2	1	1	1	3	B/o yasmin	1	30	1	2	1420	1	23	1	1	2	2	2	1	2	2	2	2	2	1	2	2	2	1	73	86	2	2	5	7	1	1	1	2	1	1
3	LRA3	1	1	1	2	B/o Suganthi	2	33	1	3	1530	1	28	2	1	2	1	2	2	2	1	2	2	2	1	2	2	2	1	30	85	2	2	6	8	1	1	2	2	1	2
4	LRA4	1	1	1	1	B/o Veronika	2	33	1	3	1680	1	26	2	1	2	2	2	2	2	2	2	2	2	1	2	2	1	1	60	86	2	2	5	8	1	1	2	2	1	2
5	LRA5	1	1	1	3	b/o Devipriya	2	32	2	3	1600	1	26	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	108	80	1	2	5	7	1	2	1	2	1	1
6	LRA6	1	1	1	2	B/o Bharathi	1	30	1	2	1130	1	21	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	114	80	1	2	5	7	1	2	1	2	1	1
7	LRA7	1	1	1	2	B/o Mahadevi	2	32	1	2	1475	1	28	1	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	108	74	1	1	3	6	1	2	1	1	1	1
8	LRA8	1	1	1	3	B/o Vidhya	1	29	1	2	1070	1	20	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	60	84	2	2	5	7	1	1	1	2	1	1
9	LRA9	1	1	1	1	B/o Komala	2	32	2	2	1400	1	30	2	1	2	2	2	2	2	2	2	2	2	1	2	2	1	2	104	80	2	2	5	8	1	1	1	2	1	1
10	LRA10	1	1	1	1	B/o Vimala	1	30	1	2	1270	1	23	1	1	2	2	2	2	2	2	2	2	2	1	2	1	1	2	96	80	1	2	5	7	1	1	1	1	1	1
11	LRA11	1	1	1	2	B/o Ammu	2	33	1	2	1330	1	24	1	1	2	1	2	2	2	1	2	2	2	1	1	2	2	1	60	84	2	2	5	8	1	1	1	2	1	1
12	LRA12	1	1	1	3	B/o Saritha	2	32	2	2	1400	1	23	1	2	2	2	1	2	2	2	2	2	2	2	2	2	2	1	73	85	2	2	5	7	1	1	2	2	1	2
13	LRA13	1	1	1	2	Bo Kushboo	2	33	1	2	1420	1	27	2	2	2	2	2	2	2	2	2	2	2	1	2	2	2	1	75	83	2	2	5	8	2	2	2	2	1	2
14	LRA14	1	1	1	2	B/o Janaki	1	29	2	1	890	1	25	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	2	113	75	2	2	5	7	1	1	1	2	1	1
15	LRA15	1	1	1	3	B/o Suganya	2	33	2	3	2000	1	28	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	30	87	2	2	6	8	2	2	2	2	1	2
16	LRA16	1	1	1	3	B/o Rathammal	1	28	2	2	1115	1	23	1	1	2	1	2	2	2	1	2	2	2	2	1	2	2	2	117	77	1	2	5	7	1	2	1	2	1	1
17	LRA17	1	1	1	1	B/o Sujatha	2	31	2	2	1400	1	26	2	1	2	2	2	1	2	2	2	2	2	2	2	2	2	1	60	84	2	2	5	8	1	1	1	2	1	1
18	LRA18	1	1	1	1	B/o Kalaiarasi	2	32	1	3	1530	1	31	2	1	2	1	2	2	2	1	2	2	2	1	2	2	2	1	30	85	2	2	6	8	2	2	2	2	1	2
19	LRA19	1	1	1	3	B/o Deepa	2	34	1	3	1910	1	24	2	2	2	2	2	2	2	2	2	2	2	1	2	2	2	1	60	88	2	2	5	8	2	2	2	2	1	2
20	LRA20	1	1	1	1	B/o Kaliammal	2	33	2	1	995	2	25	2	1	2	1	2	2	2	1	2	2	2	1	2	2	2	1	45	83	2	2	5	8	1	1	2	2	1	2
21	LRA21	1	1	1	3	B/o Chitra	2	33	2	2	1465	1	24	1	1	2	1	2	2	2	1	2	2	2	1	2	2	2	1	86	86	2	2	5	8	1	1	2	2	1	2
22	LRA22	1	1	1	2	B/o Subbulaxm	1	29	2	2	1280	1	20	1	1	2	1	2	2	2	1	2	2	2	1	2	2	2	1	60	84	2	2	5	8	1	1	2	2	1	2
23	LRB1	1	1	2	1	B/o Karpagam	3	35	1	4	2180	1	28	2	1	2	2	2	2	2	1	2	2	2	2	2	2	2	1	30	88	2	2	5	8	2	2	2	2	1	2
24	LRB2	1	1	2	2	B/o Kokila	4	40	2	5	3130	1	25	1	2	1	2	2	2	2	2	2	2	2	2	2	2	2	1	30	86	2	2	6	8	2	2	2	2	1	2
25	LRB3	1	2	2	3	B/o Sundari	4	38	2	5	2550	1	26	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	30	86	2	2	6	8	1	2	2	2	1	2
26	LRB4	1	1	2	2	B/o Soundarya	4	38	1	2	1300	2	23	1	1	2	1	2	2	2	1	2	2	2	2	2	2	2	1	50	84	2	2	5	8	1	2	1	2	1	1
27	LRB5	1	1	2	1	B/o Hajeera	3	36	1	3	1980	2	21	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	1	40	87	2	2	6	8	2	2	2	2	1	2
28	LRB6	1	1	2	3	B/o Rajalaxmi	4	38	1	4	2450	2	25	2	1	1	2	2	2	2	2	1	2	2	2	2	2	2	2	30	87	2	2	6	9	2	2	2	2	1	2
29	LRB7	1	2	2	2	B/o Selvi	4	40	2	5	3090	1	20	1	2	2	2	2	1	2	1	2	2	2	2	2	2	2	1	73	85	2	2	5	8	2	2	2	2	1	2
30	LRB8	1	1	2	3	B/o Sujatha	3	37	1	5	2890	1	30	2	1	2	2	2	2	2	1	2	2	2	2	2	2	2	1	50	89	2	2	5	8	2	2	2	2	1	2
31	LRB9	1	1	2	1	B/o Premakuma	4	40	1	5	3500	1	27	1	1	2	2	2	2	2	2	2	2	2	2	2	1	1	1	60	90	2	2	5	8	2	2	2	2	1	2
32	LRB10	1	1	2	1	B/o Dhanalaxm	4	40	2	4	2370	2	20	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	45	90	2	2	5	8	2	2	2	2	1	2
33	LRB11	1	1	2	3	B/o sowmya	4	38	2	5	2750	1	20	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	108	83	2	2	5	7	1	2	2	2	3	2
34	LRB12	1	1	2	2	B/o Sudha	3	37	1	5	2800	1	24	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	78	86	2	2	5	8	1	2	2	2	1	2
35	LRB13	1	2	2	2	B/o Pracilla	4	40	1	5	3700	1	28	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	50	88	2	2	5	8	2	2	2	2	1	2
36	LRB14	1	1	2	3	B/o Shanthi	4	39	1	5	2700	1	27	2	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	60	88	2	2	5	8	2	2	2	2	2	2
37	LRB15	1	2	2	1	B/o Dhanalaxm	4	38	1	5	3800	1	28	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	50	89	2	2	5	8	2	2	2	2	1	2
38	LRB16	1	1	2	3	B/o Gomathy	4	40	2	5	2655	1	23	1	1	2	2	2	2	2	2	2	2	2	2	2	1	1	1	45	87	2	2	5	9	2	2	2	2	1	2
39	LRB17	1	2	2	2	B/o Akhila	4	38	2	5	3000	1	23	1	1	2	2	2	2	2	1	2	2	2	2	2	2	2	1	74	86	2	2	5	8	2	2	2	2	1	2
40	LRB18	1	1	2	1	B/o Mexoleena	3	37	1	4	2500	1	24	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	30	90	2	2	6	8	2	2	2	2	1	2
41	LRB19	1	1	2	3	B/o Sarmila	4	38	1	5	3700	3	20	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	60	87	2	2	5	8	1	2	2	2	1	2

42	LRB20	1	1	2	1	B/o Venda	3	35	1	3	1650	2	22	1	2	2	2	2	2	2	2	2	2	2	2	1	1	1	30	85	2	2	6	8	2	2	2	2	1	2
43	LRB21	1	1	2	2	B/O Uma mahe	4	39	1	5	3100	1	27	2	1	1	1	1	1	1	1	2	2	2	1	1	1	1	1	50	87	2	2	5	8	2	2	2	2	1	2
44	LRB22	1	1	2	1	B/o Pavithra	3	35	2	4	2130	1	24	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	45	88	2	2	5	8	2	2	2	2	1	2
45	LRB23	1	1	2	3	B/o Pandiselvi	4	38	1	5	2690	1	26	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	30	88	2	2	6	8	2	2	2	2	1	2
46	LRB24	1	1	2	2	B/o Chitra	4	40	2	5	2850	1	27	1	2	1	2	2	2	2	2	2	2	2	2	2	2	2	1	30	86	2	2	6	8	2	2	2	2	1	2
47	LRB25	1	1	2	3	B/o Sumithra	4	38	1	5	3400	1	31	1	2	2	2	2	2	1	2	2	2	2	2	2	2	2	1	30	87	2	2	5	8	1	2	2	2	1	2
48	LRB26	1	1	2	1	B/o Deepa	4	38	2	3	1560	2	24	2	2	2	1	2	2	2	1	2	2	2	2	2	2	2	1	30	88	2	2	6	8	2	2	2	2	1	2
49	LRB27	1	1	2	2	B/o Divya	4	40	2	5	2550	2	32	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	45	87	2	2	5	8	2	2	2	2	1	2
50	LRB28	1	2	2	2	B/o Divya Ranjit	4	38	2	5	2750	1	24	1	2	1	2	2	2	2	2	2	2	2	2	2	2	2	1	60	88	2	2	5	8	1	2	2	2	1	2
51	LRB29	1	1	2	3	b/o Vanishree	4	40	1	4	2250	2	24	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	102	83	1	2	5	7	1	2	1	2	3	2
52	LRB30	1	1	2	3	B/o Deepa	3	37	1	5	2755	1	22	1	1	2	2	2	2	2	2	2	2	2	2	1	1	1	45	84	2	2	5	8	1	2	2	2	1	2
53	LRB31	1	1	2	1	B/o Rekha	4	38	1	2	1350	2	23	1	2	2	1	2	2	2	1	2	2	2	2	2	2	2	1	30	88	2	2	6	9	1	2	2	2	1	2
54	LRB32	1	1	2	2	Bo Jothiswar	4	39	1	5	2750	1	26	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	60	87	1	2	4	7	1	2	1	2	3	2
55	LRB33	1	1	2	1	B/o Prema	3	37	1	4	2150	2	23	1	1	2	1	2	2	2	1	2	2	2	2	1	2	2	1	45	86	2	2	5	8	1	2	2	2	1	2
56	LRB34	1	1	2	1	B/o Divya	4	38	2	4	2250	2	23	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	60	86	2	2	5	8	2	2	2	2	1	2
57	LRB35	1	1	2	3	B/o Tamilselvi	4	40	1	5	3250	1	22	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	45	87	2	2	5	8	2	2	2	2	1	2
58	LRB36	1	2	2	2	B/o Mala	4	40	1	5	3250	1	21	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	117	70	1	1	3	5	1	2	1	2	4	1
59	LRB37	1	1	2	3	B/o mahalaxmi	4	40	1	5	3000	1	23	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	60	85	2	2	5	8	2	2	2	2	1	2
60	LRB38	1	1	2	2	B/o Amala	4	38	1	4	2470	2	25	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	60	87	2	2	5	8	2	2	2	2	1	2
61	LRB39	1	1	2	1	B/o Gowthami	4	39	1	4	2400	2	28	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	30	88	2	2	6	8	1	2	2	2	1	2
62	LRB40	1	1	2	3	B/o Mythili	3	37	1	5	2600	1	24	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	45	89	2	2	5	8	1	2	2	2	1	2
63	LRB41	1	1	2	1	B/o Shakila	3	36	2	4	2400	1	20	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	30	88	2	2	7	9	1	2	2	2	2	2
64	LRB42	1	1	2	2	B/o Thamirasi	4	39	1	5	2905	1	31	2	2	1	2	2	2	2	2	1	2	2	2	2	2	2	1	30	85	2	2	6	8	1	2	2	2	1	2
65	LRB43	1	1	2	2	B/o Anjali	4	38	1	5	2770	1	28	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	30	86	2	2	6	8	2	2	2	2	1	2
66	LRB44	1	1	2	3	B/o Ponnamma	4	39	1	5	3300	1	27	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	114	81	1	2	5	6	1	2	1	2	4	1
67	LRB45	1	1	2	1	B/o Kalaiselvi	4	38	1	5	2825	1	27	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	45	88	2	2	5	8	1	2	2	2	1	2
68	LRB46	1	1	2	2	B/o Selvi	4	38	2	5	2950	1	28	1	2	2	2	2	2	1	2	2	2	2	2	2	2	2	2	70	85	2	2	5	8	2	2	2	2	1	2
69	LRB47	1	1	2	1	B/o Mohanasur	4	38	1	5	3250	1	19	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	30	89	2	2	7	8	2	2	2	2	1	2
70	LRB48	1	2	2	1	B/o Megala	4	39	1	5	3700	1	28	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	30	86	2	2	7	9	2	2	2	2	1	2
71	LRB49	1	1	2	3	B/o Dhanapriya	4	40	1	5	3240	1	27	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	1	77	87	2	2	5	8	1	2	2	2	1	2
72	LRB50	1	1	2	2	B/o Anusha	3	36	1	3	1900	2	22	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	50	87	2	2	5	8	2	2	2	2	1	2
73	LRB51	1	2	2	3	B/o Kalaiselvi	4	40	1	5	3450	1	24	2	2	1	2	2	2	2	2	1	2	2	2	2	2	2	1	30	87	2	2	6	8	1	2	1	2	1	2
74	LRB52	1	2	2	1	B/o Vijayalaxmi	4	40	1	5	3420	1	27	2	1	1	2	2	2	2	2	1	2	2	2	2	2	2	1	30	85	2	2	7	9	2	2	2	2	1	2
75	LRB53	1	1	2	3	B/o Revathy	4	38	1	5	2640	1	22	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	30	87	2	2	6	8	2	2	2	2	1	2
76	LRB54	1	1	2	2	B/o Kirupa jasm	3	37	2	5	3000	1	29	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	74	86	2	2	5	8	2	2	2	2	1	2
77	LRB55	1	1	2	1	B/o Saranya	4	38	2	5	2820	1	23	1	1	2	2	2	2	1	2	2	2	2	2	2	2	2	1	70	84	2	2	5	8	2	2	2	2	1	2
78	LRB56	1	1	2	3	B/o Nazeema	4	39	1	5	3000	1	19	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	50	87	2	2	5	8	2	2	2	2	1	2
79	LRB57	1	1	2	2	B/o Parvathy	4	38	1	5	2800	1	22	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	60	86	2	2	5	8	1	2	2	2	1	2
80	LRB58	1	2	2	3	B/o Suganya	4	38	1	5	3500	1	29	1	2	1	2	2	2	2	2	1	2	2	2	2	2	2	1	60	87	2	2	5	8	1	2	2	2	1	2
81	LRB59	1	2	2	1	B/o Kokila	4	38	1	5	3350	1	28	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	50	87	2	2	5	8	2	2	2	2	1	2
82	LRB60	1	1	2	2	B/o Thulasi	4	40	2	5	3250	1	24	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	30	85	2	2	6	8	2	2	2	2	1	2
83	LRB61	1	1	2	1	B/o Priya	4	40	2	5	2800	1	24	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	76	87	2	2	5	8	2	2	2	2	1	2

84	LRB62	1	1	2	3	B/o Revathy	4	40	1	5	2935	1	29	2	2	2	2	2	2	1	2	2	2	2	2	2	2	2	1	50	84	2	2	5	8	1	2	2	2	1	2
85	LRB63	1	1	2	2	B/o Nandini	3	37	2	5	2860	1	24	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	60	85	2	2	5	8	2	2	2	2	1	2
86	LRB64	1	2	2	1	B/o Janaki	4	38	2	5	3700	1	28	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	97	85	1	2	5	6	1	2	1	2	3	2
87	LRB65	1	1	2	2	B/o Uma	4	38	2	4	2380	2	23	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	60	84	2	2	5	8	2	2	2	2	1	2
88	LRB66	1	2	2	3	B/o Vidhya	4	40	2	5	3120	1	20	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	30	84	2	2	6	8	2	2	2	2	1	2
89	LRB67	1	1	2	3	B/o AnuChristin	4	38	1	5	2705	1	27	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	80	87	2	2	5	8	2	2	2	2	1	2
90	LRB68	1	2	2	2	B/o Anandhi	4	40	1	5	2800	1	26	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	114	83	1	2	4	6	1	2	1	2	3	2
91	LRB69	1	1	2	1	B/o Saranya	4	39	2	5	3045	1	24	2	2	2	2	2	2	1	2	2	2	2	2	2	2	2	1	50	87	2	2	5	8	2	2	2	2	1	2
92	LRB70	1	1	2	2	B/o Premalatha	4	40	1	5	3100	1	27	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	30	86	2	2	7	9	2	2	2	2	1	2
93	OTA1	2	3	1	1	B/o Vinothini	2	33	2	3	1930	1	27	2	1	2	2	1	2	2	2	2	2	2	1	2	2	2	1	30	86	2	2	6	8	2	2	2	2	1	2
94	OTA2	2	3	1	2	B/o Kavitha	2	31	1	2	1100	1	27	2	1	2	2	2	2	2	2	2	2	2	2	2	1	1	1	45	85	2	2	6	8	2	2	2	2	1	2
95	OTA3	2	3	1	3	B/o Dhanalaxm	2	32	2	2	1400	1	24	2	1	2	2	1	2	2	2	2	2	2	2	2	2	2	1	84	78	1	2	5	8	1	1	1	1	1	1
96	OTA4	2	3	1	2	B/o Anitha	2	32	1	2	1120	1	24	1	1	2	1	2	2	2	1	2	2	2	1	1	2	2	1	60	85	2	2	5	8	1	1	2	2	1	2
97	OTA5	2	3	1	3	B/o Malathi	2	34	1	3	1910	1	24	1	2	2	1	2	2	2	1	2	2	2	1	1	2	2	1	30	86	2	2	6	8	2	2	2	2	1	2
98	OTA6	2	3	1	1	B/o Vishnupriya	2	32	2	3	1900	1	29	2	1	1	2	2	2	2	2	2	2	2	1	2	2	2	1	45	85	2	2	5	8	1	1	2	2	1	2
99	OTA7	2	3	1	1	B/o Shakila	1	30	2	2	1345	1	20	1	1	2	1	2	2	2	1	2	2	2	1	1	2	2	2	116	75	1	2	4	7	1	2	1	2	1	1
100	OTA8	2	3	1	3	B/o Sofiya Mary	2	31	1	2	1160	1	19	1	1	2	1	2	2	2	1	2	2	2	1	1	2	2	1	60	87	2	2	5	8	1	1	2	2	1	2
101	OTA9	2	3	1	2	B/o Karthika sel	1	28	1	2	1195	1	27	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	84	85	2	2	5	7	1	1	1	2	1	1
102	OTA10	2	3	1	2	B/o Abhirami	2	32	1	2	1460	1	24	2	1	2	1	2	2	2	1	2	2	2	2	1	2	2	1	75	85	2	2	5	8	1	1	2	2	1	2
103	OTA11	2	3	1	3	B/o Bhama	2	31	2	2	1165	1	22	1	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	114	7	1	2	4	6	1	2	1	2	1	1
104	OTA12	2	3	1	1	B/o Rajeswari	2	33	1	3	1840	1	29	2	1	2	2	1	2	2	2	2	2	2	2	2	1	1	1	60	84	2	2	5	8	1	1	2	2	1	2
105	OTA13	2	3	1	1	B/o Thangaman	2	33	1	3	1700	1	27	2	1	2	1	2	2	2	1	2	2	2	1	2	2	2	1	30	82	2	2	6	8	1	1	2	2	1	2
106	OTA14	2	3	1	2	B/o Dhanalaxm	2	34	1	3	1900	1	23	1	1	2	2	1	2	2	2	2	2	2	2	2	2	2	1	86	84	2	2	5	8	1	1	2	2	1	2
107	OTA15	2	3	1	3	B/o Muthumath	2	33	2	3	1920	1	23	2	2	1	2	2	2	2	2	1	2	2	1	2	2	2	1	72	83	2	2	5	8	1	1	2	2	1	2
108	OTA16	2	3	1	1	B/o Hemalatha	2	33	1	3	1790	1	22	1	2	2	1	2	2	2	1	2	2	2	1	1	2	2	1	60	81	2	2	6	8	2	2	2	2	1	2
109	OTA17	2	3	1	3	B/o Kamala	2	32	2	2	1500	1	21	1	1	2	2	1	2	2	2	2	2	2	2	2	2	2	1	60	80	2	2	5	7	1	1	2	2	1	2
110	OTA18	2	3	1	2	b/o Chithra	2	32	1	2	1070	2	28	2	1	2	2	1	2	2	2	2	2	2	2	2	1	1	2	118	73	1	1	4	7	1	2	1	1	1	1
111	OTB1	2	3	2	2	B/o Shabana	4	39	1	5	3430	1	23	2	1	2	2	2	2	1	2	2	1	1	2	2	2	2	1	60	87	2	2	5	8	2	2	2	2	1	2
112	OTB2	2	3	2	1	B/o Mangalaxm	4	38	2	4	2100	2	24	1	1	2	1	2	2	2	1	2	2	2	2	2	2	2	1	30	89	2	2	6	9	2	2	2	2	1	2
113	OTB3	2	3	2	3	B/o Rekha	4	40	2	4	2260	2	22	1	2	2	2	2	2	1	2	2	2	2	2	2	2	2	1	30	88	2	2	6	9	2	2	2	2	1	2
114	OTB4	2	3	2	2	B/o Keerthiga	3	37	2	5	3000	1	20	1	2	2	1	2	2	2	1	2	1	2	2	1	2	2	1	30	88	2	2	6	8	1	2	2	2	1	2
115	OTB5	2	3	2	1	B/o Saranya	4	40	2	5	3100	1	25	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	73	87	2	2	5	8	2	2	2	2	1	2
116	OTB6	2	3	2	3	B/o Beena	4	39	1	4	2140	2	26	2	1	2	1	2	2	2	1	2	2	2	2	2	2	2	1	60	88	2	2	5	8	2	2	2	2	1	2
117	OTB7	2	3	2	1	B/o Shanthi Por	4	38	2	5	3000	1	24	1	2	1	2	2	2	2	2	2	2	2	2	2	2	2	1	60	89	2	2	5	8	2	2	2	2	1	2
118	OTB8	2	3	2	2	B/o Laxmi	3	37	1	5	3070	1	24	2	1	2	2	2	2	2	2	2	2	2	2	2	1	1	2	106	82	1	2	4	6	1	1	1	2	3	1
119	OTB9	2	3	2	2	B/o Deivanai	4	39	1	5	3100	1	26	2	2	1	2	2	2	2	2	2	1	1	2	2	2	2	1	30	88	2	2	5	8	2	2	2	2	1	2
120	OTB10	2	3	2	1	b/o Sathya	4	38	2	5	3340	1	20	1	2	2	2	2	2	2	2	2	1	2	2	2	2	2	1	30	88	2	2	6	9	2	2	2	2	1	2
121	OTB11	2	3	2	3	B/o Subashini	3	37	1	5	3290	1	32	1	2	2	2	2	2	1	2	2	2	2	2	2	2	2	1	78	87	2	2	5	8	2	2	2	2	1	2
122	OTB12	2	3	2	3	B/o Kumari	4	41	2	5	2680	1	26	1	1	2	2	2	2	2	2	2	1	2	2	2	2	2	1	60	88	2	2	5	8	2	2	2	2	1	2
123	OTB13	2	3	2	2	B/o Laxmi	4	40	1	5	2955	1	24	1	2	2	2	2	2	2	2	2	1	2	2	2	2	2	1	73	85	2	2	5	8	1	2	2	2	1	2
124	OTB14	2	3	2	2	B/o Prasanna	4	39	1	5	3530	1	27	1	2	2	2	2	2	1	2	2	2	2	2	2	2	2	1	45	86	2	2	5	8	2	2	2	2	1	2
125	OTB15	2	3	2	1	B/o Saraswathi	4	38	1	5	3200	1	23	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	50	88	2	2	5	8	2	2	2	2	1	2

126	OTB16	2	3	2	3	B/o Sathiya	4	41	1	5	3390	1	22	1	2	2	2	2	2	2	2	2	1	2	2	2	2	2	1	45	87	2	2	5	8	1	2	2	2	2	2
127	OTB17	2	3	2	1	B/o Mahalaxmi	4	39	1	5	3300	1	25	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	75	89	2	2	5	8	2	2	2	2	1	2
128	OTB18	2	3	2	3	B/o Banumathi	4	38	1	5	2680	1	20	1	1	2	1	2	2	2	1	2	2	2	2	2	2	2	1	72	88	2	2	5	8	2	2	2	2	1	2
129	OTB19	2	3	2	3	B/o Gomathi	3	36	1	5	2630	1	24	2	1	2	2	2	2	1	2	2	1	1	2	2	2	2	2	108	85	2	2	5	7	2	2	2	2	1	2
130	OTB20	2	3	2	2	B/o Vasantha	4	38	1	5	2565	1	22	1	2	2	1	2	2	2	1	2	1	1	2	1	2	2	1	73	86	2	2	5	8	2	2	2	2	1	2
131	OTB21	2	3	2	1	B/o Prathiba	4	40	1	4	2200	2	26	1	2	2	2	2	2	2	2	2	1	1	2	2	2	2	1	60	88	2	2	5	8	1	2	2	2	1	2
132	OTB22	2	3	2	1	B/o Devi	4	38	1	5	3550	1	24	1	2	1	2	2	2	2	2	2	2	2	2	2	2	2	1	45	87	2	2	5	8	2	2	2	2	1	2
133	OTB23	2	3	2	1	B/o Mallika	4	38	1	5	2540	1	26	2	2	2	2	2	2	2	2	2	1	2	2	2	2	2	1	30	88	2	2	6	9	2	2	2	2	1	2
134	OTB24	2	3	2	3	B/o Rajathi	4	40	2	5	2770	1	32	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	60	88	2	2	5	8	2	2	2	2	1	2
135	OTB25	2	3	2	3	B/o gracy	3	37	2	4	2300	1	24	1	1	2	2	2	2	2	2	2	1	1	2	2	2	2	1	45	87	2	2	5	8	1	2	2	2	2	2
136	OTB26	2	3	2	2	B/o Selvi	4	40	1	5	4400	3	24	1	2	1	2	2	2	2	2	2	2	2	2	2	2	2	1	30	88	2	2	6	9	2	2	2	2	1	2
137	OTB27	2	3	2	2	B/o Suguna	4	38	2	5	3030	1	24	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2	113	78	1	1	3	5	1	2	1	1	4	1
138	OTB28	2	3	2	2	B/o Veni	4	40	2	5	4350	3	26	1	2	1	2	2	2	2	2	2	1	1	2	2	2	2	1	60	87	2	2	5	8	1	2	2	2	1	2
139	OTB29	2	3	2	3	B/o Vijaya	4	40	2	5	2530	1	28	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	72	88	2	2	5	7	1	2	2	2	1	2
140	OTB30	2	3	2	1	B/o Susin	4	38	1	5	3175	1	31	1	2	1	2	2	2	1	1	2	1	2	2	2	2	2	1	30	89	2	2	6	9	2	2	2	2	1	2
141	OTB31	2	3	2	2	B/o Devaki	4	40	2	5	3325	1	25	1	1	2	2	2	2	2	2	2	1	2	2	2	2	2	1	30	87	2	2	6	9	1	2	2	2	1	2
142	OTB32	2	3	2	3	b/o Mariyarekh	4	38	1	5	3240	1	28	1	1	2	2	2	2	2	1	2	1	1	2	2	2	2	2	104	71	1	1	4	6	1	2	1	2	4	1
143	OTB33	2	3	2	1	B/o Dilllirani	4	38	1	3	1585	1	23	1	2	2	1	2	2	2	1	2	2	2	2	1	2	2	1	75	88	2	2	5	8	2	2	2	2	1	2
144	OTB34	2	3	2	2	B/o Maheswari	3	37	1	5	2640	1	23	2	1	1	2	2	2	2	2	2	2	2	2	2	2	2	1	60	84	2	2	5	8	1	2	2	2	3	2
145	OTB35	2	3	2	3	B/o Pavithra	3	37	2	4	2370	1	19	1	2	2	1	2	2	2	1	2	2	2	2	1	2	2	1	50	87	2	2	5	8	2	2	2	2	1	2
146	OTB36	2	3	2	1	B/o Sasirekha	3	36	1	4	2250	1	27	1	2	2	2	2	2	1	2	2	1	1	2	2	2	2	1	60	88	2	2	5	8	1	2	2	2	1	2
147	OTB37	2	3	2	2	B/o kamatchi	4	38	1	4	2500	1	23	1	1	2	2	2	2	2	1	2	1	1	2	2	2	2	1	84	80	1	2	5	7	1	2	2	2	3	2
148	OTB38	2	3	2	3	B/o Selvi	4	40	2	5	2850	1	23	1	2	2	2	2	2	2	2	2	1	1	2	2	2	2	1	60	88	2	2	5	8	2	2	2	2	1	2
149	OTB39	2	3	2	1	b/o Asma	3	35	1	4	2000	1	24	2	2	2	1	2	2	2	1	2	2	2	2	1	2	2	1	50	87	2	2	5	8	2	2	2	2	1	2
150	OTB40	2	3	2	1	B/o Nagajothy	3	36	2	4	2300	1	23	2	2	1	2	2	2	2	2	2	1	1	2	2	2	2	1	30	87	2	2	6	9	2	2	2	2	1	2
151	OTB41	2	3	2	1	B/o Revathy	3	37	2	4	2350	1	28	2	2	1	2	2	2	2	2	1	2	2	2	2	2	2	1	60	86	2	2	5	8	1	2	2	2	1	2
152	OTB42	2	3	2	3	B/o Amsavalli	4	39	2	5	2675	1	28	2	1	2	2	2	2	2	2	2	1	2	2	2	2	2	1	30	88	2	2	6	9	2	2	2	2	1	2
153	OTB43	2	3	2	2	B/o Murugajoth	3	37	2	4	2450	1	28	1	2	1	2	2	2	2	2	1	1	1	2	2	2	2	2	96	84	1	2	4	7	1	2	1	2	1	2
154	OTB44	2	3	2	2	B/o Ammu Ven	3	36	1	5	2700	1	24	1	2	2	1	2	2	2	1	2	2	2	2	2	2	2	1	45	88	2	2	5	8	2	2	2	2	1	2
155	OTB45	2	3	2	3	B/o Semparuthi	4	40	2	5	3240	1	29	2	2	1	2	2	2	2	2	1	1	2	2	2	2	2	1	60	86	2	2	5	8	2	2	2	2	1	2
156	OTB46	2	3	2	2	B/o Tamilselvi	4	38	1	5	3290	1	24	1	1	2	2	2	2	2	2	2	1	2	2	2	2	2	1	73	88	2	2	5	9	1	2	2	2	1	2
157	OTB47	2	3	2	3	B/o Vanitha	4	38	1	5	2600	1	24	2	2	2	2	2	2	2	2	2	1	1	2	2	2	2	1	45	87	2	2	5	8	2	2	2	2	1	2
158	OTB48	2	3	2	1	B/o maheswari	4	39	2	5	2600	1	27	2	1	2	2	2	2	1	2	2	1	2	2	2	2	2	1	30	87	2	2	6	8	1	2	2	2	1	2
159	OTB49	2	3	2	2	B/o Kavitha	4	38	2	5	3050	1	30	1	2	2	2	2	2	1	2	2	2	2	2	2	2	2	1	30	87	2	2	6	8	2	2	2	2	1	2
160	OTB50	2	3	2	3	B/o Dhanalaxm	3	36	1	5	2700	1	27	2	2	1	2	2	2	2	2	1	2	2	2	2	2	2	1	60	87	2	2	5	8	2	2	2	2	1	2
161	OTB51	2	3	2	1	B/o Durgadevi	4	38	1	4	2350	1	24	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	106	75	1	1	4	6	1	2	1	2	4	1
162	OTB52	2	3	2	3	B/o Bapitha	3	37	2	4	2350	1	23	1	1	2	2	2	2	2	2	2	1	2	2	1	2	2	2	112	80	1	2	4	6	1	2	1	2	4	1
163	OTB53	2	3	2	1	B/o Aitha	3	36	1	4	2350	1	24	2	2	1	2	2	2	2	2	1	1	1	2	2	2	2	1	76	84	1	2	4	7	1	2	1	2	3	2
164	OTB54	2	3	2	2	B/o Parvathy	4	40	2	5	2800	1	29	2	1	2	1	2	2	2	1	2	1	1	2	2	2	2	1	45	87	2	2	5	8	2	2	2	2	1	2
165	OTB55	2	3	2	1	b/o Urmila	3	37	2	5	3060	1	28	2	2	1	2	2	2	2	2	1	2	2	2	2	2	2	1	30	88	2	2	5	9	1	2	2	2	1	2
166	OTB56	2	3	2	3	B/o Sivagami	4	38	1	5	2585	1	22	1	2	2	1	2	2	2	1	2	1	1	2	2	2	2	1	60	88	2	2	5	8	1	2	2	2	1	2
167	OTB57	2	3	2	2	B/o Indhumath	4	40	1	4	2400	1	23	1	2	2	1	2	2	2	1	2	1	1	2	2	2	2	1	30	86	2	2	6	9	2	2	2	2	1	2

168	OTB58	2	3	2	3	B/o Subashini	4	38	1	4	2085	2	25	1	1	2	1	2	2	2	1	2	2	2	2	2	2	2	1	84	87	2	2	5	8	1	2	2	2	1	2
169	OTB59	2	3	2	1	B/o Vijayalaxmi	4	38	2	5	2600	1	28	2	2	2	2	2	2	2	2	2	1	2	2	2	2	2	1	45	88	2	2	5	8	1	2	2	2	1	2
170	OTB60	2	3	2	3	B/o Geetha	4	38	2	3	1780	2	25	1	1	2	1	2	2	2	1	2	1	1	2	1	2	2	1	30	87	2	2	6	8	2	2	2	2	1	2
171	OTB61	2	3	2	1	B/O Sangeetha	4	40	1	5	2750	1	24	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	60	87	2	2	5	8	1	2	2	2	1	2
172	OTB62	2	3	2	2	B/o Nalini	3	36	2	4	2285	1	26	2	2	1	2	2	2	2	2	1	2	2	2	2	2	2	1	60	86	2	2	5	8	2	2	2	2	1	2
173	OTB63	2	3	2	2	B/o Deepa	3	36	2	3	1850	2	21	1	2	2	1	2	2	2	1	2	2	2	2	1	2	2	1	60	85	2	2	5	8	1	2	2	2	1	2
174	OTB64	2	3	2	1	B/o Malathy	3	37	2	5	3600	3	24	2	1	2	2	2	2	2	2	2	1	1	2	2	2	2	1	30	87	2	2	6	9	1	2	2	2	1	2
175	OTB65	2	3	2	3	B/o Venda	4	38	2	5	2550	2	25	1	1	2	2	2	2	2	2	2	1	1	2	2		2	1	45	88	2	2	5	8	1	2	2	2	1	2