"EFFICACY OF CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) ADMINISTRATION IN DELIVERY ROOM FOR NEONATES WITH RESPIRATORY DISTRESS : A RANDOMISED CONTROL TRIAL"

BY

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ETHICAL CLEARANCE

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Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"OUTCOME OF CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) ADMINISTRATION IN DELIVERY ROOM FOR NEONATES WITH RESPIRATORY DISTRESS: A RANDOMISED CONTROL TRIAL",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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LIST OF ABBREVIATIONS

NVD	:	Normal vaginal delivery
LSCS	:	Lower segment caesarean section
PROM	:	Premature rupture of membranes
PV Bleed	:	Per vaginal bleed
FGR	:	Foetal growth restriction
AVD	:	Assisted vaginal delivery
MSL	:	Meconium stained liquor
PPV	:	Positive pressure ventilation
CPAP	:	Continuous positive airway pressure
FFO	:	Free flow oxygen
LR	:	Labour room
DR CPAP	:	Delivery room CPAP
DR FFO	:	Delivery room FFO
PE	:	Pre-eclampsia
CPD	:	Cephalo-pelvic disproportion
MSAF	:	Foetus born through Meconium stained liquor
TTN	:	Transient tachypnea of newborn
CONS	:	Coagulase negative staphylococci
GA	:	Gestational age
LBW	:	Low birth weight
NRP	:	Neonatal Resuscitation Program
HBB	:	Help Baby Breathe

ABSTRACT

Background and objectives

With the advent of CPAP and its assimilation in the 6th Edition of NRP guidelines since 2011,the use of delivery room CPAP (DR CPAP) has been under evaluation world wide for neonates developing respiratory distress in the labour room.Establishing its evidential benefit in preterm neonates,the benefit of DR CPAP amongst late preterm & term neonates has always been questioned.

The objective of this randomised control trial was to evaluate the efficacy of delivery room CPAP delivered via T-piece based infant resuscitator via face mask , in reducing the severity and duration of respiratory distress for neonates delivered at >35 weeks of gestation.The study also analyses the effect of CPAP on the early neonatal outcome and NICU admissions.

Material & methods

The study was a hospital based,single centre,open label,parallel group,randomised control trial.Neonates with a gestation of > 35 weeks ,with no known congenital anomaly developing respiratory distress in the form of laboured breathing or not maintaining the target saturation level were randomised and subjected either to CPAP via T-piece of FFO via face mask in the labour room,as per the NRP guidelines.

Results

A total of 131 neonates were enrolled into the trial.Out of the total newborns enrolled ,62 (47.32 %) were randomised to DR CPAP while 69 (52.67 %) to DR FFO group.The DR CPAP group showed improvement in 55 (87.3 %) whereas DR FFO

showed improvement in 58 (84.05 %) neonates ,with no statistical significance within the results.A total of 18 (13.74 %) neonates were shifted to NICU , with 15 (83.33 %) being admitted in view of respiratory distress , requiring some amount of respiratory support in the NICU.Out of those requiring respiratory support in the NICU, 9 (60 %) belonged to DR FFO group while 6 (40 %) belonged to the DR CPAP group with no statistical significance associated (p-value > 0.05).No infant in the study required any form of mechanical ventilation ,no death was recorded and no incidence of any air leak syndrome was documented.

Conclusion

Our randomised control trial shows no significant difference in the labour room or early neonatal outcome amongst the late preterm or term neonates presenting with respiratory distress after randomisation to delivery room CPAP or delivery room FFO.Both the groups i.e interventional and control, show no significant difference in the transitional adaptation when subjected to the delivery room CPAP and delivery room FFO.

Key words : Neonatal resuscitation program, delivery room CPAP , pressure leak syndromes

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INTRODUCTION

Why focus on resuscitation at birth :

The first few minutes after birth can influence the entire life of a neonate.

For centuries the focus of medical interventions has been upon the mother without whom the newborn had no chance of survival.[1]

With the inception of APGAR score in 1953, the focus shifted on the physiologic transition of the newborn infant [2] But even with extensive research in neonatal medicine, perinatal asphyxia continued to be a leading cause of neonatal mortality.

Recognition of perinatal asphyxia as a major public health problem evoked the leaders in medical research and public health in the United States of America to begin an initiative to improve the science and practice of newborn resuscitation[3].

Over the years neonatology grew as a subspeciality branch ,and the importance of having at least one trained person present at every delivery was recognised.

With the global aim of improving the neonatal survival rates ,the art of neonatal resuscitation has been a pivotal point of consideration.Supporting a safe birth thus protects the health of families and communities.

Resuscitation Programs :

In 1987 the Neonatal Resuscitation Program (NRP) was established with an aim of increasing the awareness regarding the initial management of newborns requiring transfer to NICU care.

For over more than 20 years , NRP has set a standard for training of healthcare providers in neonatal resuscitation.With an ever evolving formulation, the NRP has been changing as per the latest evidence and as per the need of the resuscitator in each corner of the world.

In its 6th edition of the NRP in 2011 ,the American Academy of Paediatrics introduced CPAP via T-piece resuscitator as a mode of intervention for spontaneously breathing neonates without apnea,gasping ; presenting with laboured breathing or persistent cyanosis & heart rate of > 100/min ,regardless of gestational age.[15]

The interventional modality has gained popularity amongst preterm neonates ever since,with decreasing the proportion of intubations and the need for surfactant [27.]

The application was however questioned amongst the late preterm and term neonates ,possessing a more mature lung physiology.

It was William Smithhart and et al who performed a retrospective cohort study to determine the association of DR CPAP with symptomatic pneumothorax [11] .

The study found a raised proportion of pneumothorax after the execution of 2011 NRP guidelines,from 0.4 % to 0.6 %.

An increased proportion of pneumothorax was thus attributed directly proportional to gestational age and oxygen administration.

With a sample size of over 2 lakhs, the study triggered multiple researchers to look further for the implications of DR CPAP in the late preterm and term neonates.

Indian scenario :

According to the 'million death' report by the WHO in 2018, 19% of the neonatal deaths were related to birth asphyxia. Indian Academy of Paediatrics currently recommends NRP guidelines for training of healthcare personnel in the act of Neonatal Resuscitation.[43]

No thorough evaluation has been done on the use of Labour room CPAP in the Indian scenario ,thereby lacking data on the safety & efficacy of the newly introduced modality of intervention.

Moreover,there's a significant paucity in the infrastructure required for the basic training in application of labour room CPAP with a significant deficit of CPAP instruments available as well.

It is necessary to perform a thorough evaluation before the implementation of any new interventions that require specialised training and equipment in a resource limited country like India.

Need of the study :

The study addresses the key issue of lacking data/evidence over the application of the labour room CPAP in late preterm and term neonates.The study also helps in determining the early neonatal outcome in newborns subjected to DR CPAP.

Studies addressing the short and long term outcome of DR CPAP in a limited resource country like India are very few to be enumerated.Studies addressing the issues faced in late preterm neonates and term newborns are even lesser.

We thus hereby try to add some contribution in determining if the use of DR CPAP as per the NRP guidelines make a significant difference in the neonatal outcome in the hospital.

BACKGROUND

The Birth of Resuscitation Programs :

In 1987 the Neonatal Resuscitation Program (NRP) was established with an aim of increasing the awareness regarding the initial management of newborns requiring transfer to NICU care.

The genesis of NRP took place to emphasise that in "Every area where a delivery might occur , there be at least one person available who has acquired the basic and/or advanced resuscitation skills" [4.]

Keeping in mind the goal of improving neonatal survival rates NRP was conceptualised with a certain key principles embodied in the framework of the program :

1. Best practice recommendations on the best available evidence.
2. Recognise the different types of skills necessary for successful neonatal resuscitation
3. Understand the importance of self-education for the adult learner
4. Adequately prepare the instructors
5. Regionalise training

A consensus of neonatal delegation would hence assemble and identify all the important questions pertaining to the neonatal resuscitation every 5 years.

The delegation would then review the best available evidence and reach a consensus to form the finest evidence based answers to all the queries.

For over more than 20 years , NRP has set a standard for training of healthcare providers in neonatal resuscitation.The ability of the program to adapt and improvise as per the ever evolving needs of the instructors and trainees forms the crux for the success of the program[19].

Evolution of HBB :

It was Dr.Vinod K Paul, from All India Institute of Medical Sciences who said "The current system of teaching neonatal resuscitation is overly complex, and at the same time misses meeting the needs of many babies born around the world.A program that targets providers in the low-resource settings and focuses on core neonatal resuscitation skills should be developed and scaled up. This will transform our approach to reduce neonatal mortality worldwide."

Inception of HBB was thus based upon targeting the developing nations ,trying to bridge the educational gap with a goal of reducing the perinatal mortality and morbidities.

HBB relies on the same science as NRP, however the words, illustrations used are simple and consistent to facilitate translation and understanding for the use by low-literacy resuscitation providers.

The persistent implementation of global HBB training demonstrated that timely initiation of basic resuscitation interventions reduced a big proportion of infants from developing morbidities and mortalities [42,43].

Understanding the Foetal-Neonatal physiology :

Neonatal resuscitation efforts are designed to help the neonate make the necessary respiratory and circulatory transition required for extrauterine survival immediately after birth.This very principle forms the framework of the Neonatal Resuscitation Program since its inception more than 30 years ago [14].

To be able to provide optimum support to the newborn infant, it's imperative to understand the physiology that forms the basis of the neonatal resuscitation.

Adult and foetal physiology are very different from each other & the foetal system is very well suited for its in utero development.This system needs to go under a rapid change so the neonate can adapt to the external environment with a smooth transition .

The aeration of lungs is thus vital for the gaseous exchange to switch from the placenta to lungs , restructuring the circulation pattern ,thereby increasing the pulmonary blood flow.[20]

A) **Neonatal transition :**

The time period required by the newborn for the transition from the intrauterine life to an extrauterine environment with minimal or no assistance can be termed as Neonatal Transition.A delayed transition can even take up to 48 hours , whereas an immediate transition is seen within 1 to 3 hours. The lungs must switch from secretory mode to an absorptive mode to accommodate the transition of breathing air at the birth.

This transition is thought to be facilitated by the maternal-foetal hormonal changes , including the surge in glucocorticoids , catecholamines observed at the end of the birthing process.

B) **Principle of Resuscitation :**

The pulmonary system thus progresses through 2 different phases of transition, each of which require a different approach in order to provide a suitable respiratory support.

The lung aeration amidst the liquid-filled airways comprises the first phase.

All the interstitial lung fluid pools up in the perivascular cuff tissue and the interlobar fissures ,which is then cleared into the pulmonary capillaries along with the lymphatics.Aerating the distal airways ensures a proper gaseous exchange, and therefore this phase should be pivoted upon optimising the clearance of airways .

Any delay in the clearance of the lung fluid in the newborn leads to transient pulmonary oedema.

In the next stage of transition ,the fluid expended from the airways accumulates in the lung parenchyma.Accumulated fluid further leads to compression of the compliant airways resulting in airway obstruction,air trapping and ventilation-perfusion mismatch.

The resultant obstruction leads to reduction in the functional residual capacity whereas the air trapping results in increase in thoracic gas volume of the lung ,the next stage of resuscitation should hence focus upon alleviating the ill effects of the parenchymal fluid accumulation [16].

It is important to note here that labour associated with the vaginal delivery helps in clearance of the fluid from airways even before birth.The postural changes experienced during the delivery of the head via vaginal delivery leads to increase in the transpulmonary pressures which force the fluid to leave the lungs via trachea,but not via the caesarean section without labour.[21]

The respiratory support should thus change as per the dynamics of airway experienced during the lung aeration .Initially a higher airway pressure can be applied when the resistance is expected to be high and then modify as the airway compliance increases to avert any lung damage owing to over inflation.[22,23]

Majority of the neonates tide over the transition phase with ease ,it is only a small proportion ,specifically the preterm or few term infants with a compromised materno-foetal milieu owing to any reason,who require a certain amount of assistance.

This assistance can be broadly termed as 'Neonatal Resuscitation'.

The successful transition of a newborn from the in utero foetal circulation and placental respiration to the neonatal pulmonary circulation & respiration forms the very basis of Neonatal Resuscitation.

Now that the principle physiology behind Neonatal Resuscitation is delineated, the role of CPAP can be understood.

Advent of CPAP :

Early use of CPAP mode of ventilation via T-piece ,in labour rooms was introduced around the year 2009 by Fisher-Paykel ™.

New guidelines were published in 2010 and in its 6th edition of the NRP ,the American Academy of Paediatrics introduced CPAP via T-piece resuscitator as a mode of intervention for spontaneously breathing neonates without apnea,gasping ; presenting with laboured breathing or persistent cyanosis & heart rate of > 100/min ,regardless of gestational age.[15]

C**o**ntinuous positive airway pressure (CPAP) maintains a continuous distending pressure support throughout the respiratory cycle, thus preventing alveolar collapse.It splints air-ways ,improving the lung compliance,conserving surfactant and thereby reduces the work of breathing overall.

In order to maintain the functional residual capacity within the alveoli ,preventing atelectasis , CPAP delivers a constant positive pressure to the airways.This also helps in improving gaseous exchange of oxygen and carbon dioxide in the pulmonary circulation.[17,18]

CPAP bears the advantage of providing the necessary distending airway pressures via the T-piece without the hazards associated with full endotracheal intubation and the mechanical ventilation.

But the preterm pulmonary physiology distinctively differs in the matter of surfactant levels thus decreasing the lung compliance.With this principle , a large number of trials studied the effect of early CPAP / delivery room CPAP in the preterm infants, thereby guiding resuscitation practices more efficiently for this group [7,8,9,10].

It's noteworthy, the same delivery room CPAP has not been evaluated with the same rigour for the case of late preterm and term neonates.

P Srinivasan and et al conducted a trial on full term neonates born via elective LSCS, providing them prophylactic CPAP in the delivery room itself .The study found no adverse or beneficial effects providing prophylactic CPAP in the delivery room to term neonates [34].Evidence was thus lacking and inconclusive for the use of CPAP in the late preterm and term neonates.

If no study indicated obvious benefit to the group,adverse effects were soon found to be reported amongst term newborns provided with DR CPAP [11,12,13].

A need for a study to ascertain norm guide-lines for the use of CPAP in the late preterm and term neonates can hence be vouched for.

Working of T-piece resuscitator :

T-piece resuscitator was introduced by Fisher-Paykel [TM] Healthcare systems in 2006 for neonatal resuscitation.

T-piece resuscitators are gas powered and capable of delivering a preset,consistent and controllable peak inspiratory pressure (PIP) and positive end expiratory pressure (PEEP).The controlled delivery of PIP and PEEP ,helps in protecting the lungs from injury and also establish and maintain the functional residual capacity (FRC).

The operator can set the PIP and PEEP as per the need, and the T-piece will not deliver PEEP or PIP above the set pressures if the flow of gas remains constant.

The operator can control the length of the inspiratory time by varying the occlusion of the PEEP cap.

Key mechanisms of the T-piece resuscitators include the following :

1. Designed to deliver a controlled set of PIP and PEEP,thereby preventing any lung injury.
2. Establishes and maintains FRC during the transition phase of birth.

Incidence of respiratory distress in newborns owing to delayed transition of respiratory physiology :

Incidence of respiratory distress is noted in 0.6% of term and 6.5% of preterm neonates,immediately after birth.[5]

OBJECTIVES

Primary objective:

1. To study the efficacy of delivery room continuous positive airway pressure (CPAP), delivered using a T-piece-based infant resuscitator via a face mask, in reducing the severity and duration of respiratory distress

Secondary objective:

To study the effect of delivery room CPAP on NICU admissions and the early neonatal outcome.

REVIEW OF LITERATURE

The Neonatal Resuscitation Program (NRP), launched in 1987,is a learning program through which the primary goal of achieving at least one skilled person at every delivery was sought.[26]

The NRP has been evolving ever since its inception based on the best available current evidence providing the ever evolving resuscitation guidelines.

Most infants don't need any assistance to transit from foetal to neonatal mode of respiration to survive in the external gaseous environment.

Approximately 10% of such neonates require some form support to smoothen the process which can be broadly termed as neonatal resuscitation.

It is mostly preterm neonates which require assistance to traverse over the transitory phase while term infants ,owing to a much mature system tide over with ease.

It was in its 2011 consensus guidelines that NRP included CPAP via T-piece resuscitator as a mode of intervention for spontaneously breathing neonates without apnea,gasping ; presenting with laboured breathing or persistent cyanosis & heart rate of > 100/min ,regardless of gestational age.[15]

CPAP as a mode of intervention proved to be a boon for the preterm neonates, with many studies reporting a beneficial outcome as compared to the current in practice conventional interventions.

Although its place in term physiology was ever since questioned , subsequent studies delineate its overall outcome.

A systematic review was performed by Bedwell Susan et al concerning the modalities of management in case of respiratory distress observed in late preterm and term infants experiencing a delayed neonatal respiratory transition using prophylactic CPAP [35].

The study outlined following inferences ;

1.Two randomised trials ,both using the prophylactic CPAP ,showed significant reduction in the NICU admission rates amongst neonates exclusively delivered via caesarean section.

2.A single study using sustained lung inflation recorded no substantial difference for the need of any respiratory support or NICU admission.

The review thus concluded that subsequent studies are needed before early prophylactic CPAP can be advised .

The lack of any safety or efficacy data for CPAP precludes either of the methods for current use in prevention of respiratory distress in late preterm or term infants demonstrating a slow transition into the extrauterine life.

Both studies were conducted at a single centre and exclusive to newborns born by caesarean delivery .

3.A single study using sustained lung inflation proved no substantial difference in the need of NICU admission or respiratory assistance.

4.A single study using adrenaline also showed no benefit in averting the respiratory distress related to delayed transition.

Multicenter randomised controlled trials are needed furthermore before the broad adoption of CPAP in delivery rooms for any late preterm and term infants presenting with respiratory distress.

Colleen C. Claassen et al conducted a study challenging the safety of CPAP in term and late preterm neonates [36].

The study addresses the key physiology of newborn transition,the crucial step being the establishment of FRC of the lungs.

CPAP functions to increase the intra-alveolar pressure and assist with establishing FRC and ventilation-perfusion matching in spontaneously breathing infants.

The investigators do address CPAP being useful in preterm infants as a result of the low levels of surfactant leading to a low lung compliance.

Term infants on the other hand have a higher surfactant level and hence a higher lung compliance.Owing to the inequivalent distribution of fluid across the lung tissue , the compliance varies across different lung spaces during resuscitation.

The resuscitator's impatience may trigger us to provide an early , unnecessary CPAP to the neonate.

The term lung is thus at an increased risk of acute injury owing to the increased compliance and unequal distribution of the lung fluid.

An association between CPAP and air leaks within late preterms and term neonates was established in this study amongst many others.[37]

A retrospective birth cohort study of newborns was conducted by Wiilam Smithhard and et al for newborns delivered from 2001 to 2015 , and a nested cohort for neonates delivered from 2005 to 2015.The aim of the study was to determine the association of DR CPAP with symptomatic pneumothorax amongst neonates delivered within a gestational age of 32 to 35 weeks [11].

The study came to the following conclusion :

With a p-value of < 0.05,the study found a raised proportion of pneumothorax after the execution of 2011 NRP guidelines , from 0.4% to 0.6 % .Use of DR CPAP was associated with pneumothorax (Odds ratio : 5.5 with confidence interval of 95%). An increased proportion of pneumothorax was thus attributed directly proportional to gestational age and oxygen administration.

Since its introduction into the resuscitation guidelines most of the studies carried out with delivery room CPAP have been on premature/preterm neonates.

The study carried out by Smithart et al raised the question of safety of CPAP in the term and late preterm population.

Smithhart's study was one of the many trials reporting the association of early CPAP and air leak syndromes.

The study however was significant in terms of the sample size with a cohort for > 9000 subjects with a statistical adjustment to reduce the bias from all the retrospective studies.

With the advent of CPAP in the delivery room , this mode of intervention has been studied with a lot of vigour amongst the premature/preterm neonates.[11]

In a study conducted by Saumil A Desai and et al at a tertiary care hospital , all the spontaneously breathing preterm neonates (<34 weeks of gestation) were primarily evaluated for the proportion of need of surfactant therapy and the need of mechanical ventilation.

The hypothesis proposed was that delivery room CPAP reduces the necessity of surfactant and mechanical ventilation during the first 7 days of the newborn period.

The study reported a reduction in the need for mechanical ventilation from 86 % to 30%.[10]

In a study conducted by W.A.Goncalves-Ferri & F.E.Martinez at University of Sao Paulo, prophylactic CPAP was administered to neonates weighing 500g to 1000g.

The objective of the study was to evaluate the use of labour room CPAP for neonates with extremely low birth weight, to prevent the need for mechanical ventilation or surfactant therapy.

The objective of the study could not be attained as most of the neonates were intubated in the labour room itself.

47.3% of neonates weighing 750 g-1000 g and 85.7 % of neonates weighing 500g -750g were intubated.Thus no CPAP could be administered for 63.6 % of neonates weighing < 1000g.

As a result CPAP in the delivery room was not possible in 63.6% of infants weighing <1000g.

Goncalves concluded that antenatal steroids and prenatal monitoring are fundamental for the success of DR CPAP amongst this group of neonates.To the withstand the effort of respiration without the need of intubation it is necessary for the preterm babies to be more prepared at the point of delivery and this can only be better achieved with the help of antenatal steroids and prenatal monitoring.[8]

Matteo Bruchettini et al, evaluated interventions for the management of TTN reviewing the systematic reviews.Assessing the various benefits and adversaries of different modalities used in the management of TTN [37].

Six Cochrane reviews , addressing 1134 infants enrolled in 18 different trials on the management of TTN in the term and the late preterm neonates.

Seven trials assessed Salbutamol , epinephrine in one trial , budesonide in one ,Two trials with budesonide, fluid restriction in 4 trials and non-invasive respiratory support within 3 trials.

The overview summarises :

1. The duration of tachypnea may be reduced by Salutamol ,but uncertain with need for mechanical ventilation.
2. Very limited evidence to determine if epinephrine,cotricosteroids,fluid restriction or diuretics reduce the need for mechanical ventilation.
3. Lacks data on possible harms [38]

The impact of early CPAP i.e. Labour Room CPAP was studied in the preterm babies in a single center study conducted by Naveen Jain et al, in Kerala,India [7].

It was found that the number of babies requiring intubation was reduced by over 50% of the preterm babies who received early CPAP ie. delivery room CPAP as compared to the controls.Moreover, preterms from the early CPAP group were even extubated earlier (Median 45 % by 12 hours and 70 % by 36 hours)

The study did conclude ,stating early CPAP (delivery room CPAP) decreases the need for respiratory support without decrease in survival.[7]

Nicole T.Spillane and et al in their retrospective study of neonates born at 35 weeks of gestation and studied the outcome of DR CPAP with respect to risk for neonatal morbidities amongst the group.

It was a single centre study consisting of all the neonates born at 35 weeks of gestation presenting with laboured breathing or persistent cyanosis who were given DR CPAP as per the NRP guidelines.

Eighty percent of the neonates receiving labour room CPAP were admitted to NICU.Early CPAP/ Delivery room CPAP was associated with maximum NICU admission risk ; 9.300 times more than those without delivery room positive pressure and respiratory ailments .[38]

P.Srinivasan et al devised a very unique study giving prophylactic DR CPAP to prevent TTN amongst neonates delivered via elective LSCS ; a prospective RCT .

The aim of study was to see if prophylactic DR CPAP could reduce the incidence of TTN and NICU hospitalisation rates amongst those neonates born via

elective LSCS who have a higher propensity of developing respiratory distress on account of delayed clearance of foetal lung fluid.

No significant difference was found amongst the interventional and control group.No adverse or beneficial effects were seen of prophylactic CPAP in the delivery room.[34]

A similar study was designed by Miray Yilmaz et al ; studying the effects of prophylactic CPAP administration to infants born at 34 to 38 wks of gestation via elective LSCS [33.]

Out of the total 259 neonates enrolled for the study,134 received prophylactic CPAP and 125 served as control group.It was found that the NICU admission rates were significantly lower amongst the CPAP group (p-value =0.045) ; but no significant difference was found in the incidence of Transient tachypnea of Newborn.

The study concluded that prophylactic CPAP decreases the NICU admission rates amongst the late preterm and early term neonates without any significant adverse effects.[33]

Birju A. Shah et al conducted a systematic review to study the effects of early CPAP (DR CPAP) among neonates > 34 weeks of gestation as well as term newborns [39].

The meta-analysis studied two randomised control trials which showed that(323 newborns delivered by LSCS) likelihood of NICU admission was substantially reduced by labour room CPAP (RR-95% ; p-value: <0.0005) and respiratory support required at the NICU level(RR-95% ; p-value :0.005) .At the same time two other

before-after study (8476 neonates) reported an increased risk of pneumothorax with labour room CPAP.

The systematic review concluded that the level of evidence for supporting the use of DR CPAP amongst term & ≧ 34 weeks of gestation having the risk of developing respiratory distress was very low.

Jyothi. K et al studied the outcome of the early use of bubble CPAP in labour with respect to need for mechanical ventilation, duration of the stay in the hospital and mortality at the NICU [9].

The study observed that the administration of CPAP in the labour room in preterms reduces the need of the mechanical ventilation amongst those developing respiratory distress.The duration of the stay in the hospital with labour room CPAP was considerably less as well.

Although no significant data was obtained over the mortality proportions in both the groups.[9]

Laura Clevenger and et al tried to assess the association between the labour room CPAP (DR CPAP) and the pneumothorax in term neonates [12].

The team assessed two studies conducted at community hospitals and the data was obtained from computerised records.The case control study showed neonates with pneumothorax more likely to have received DR CPAP (16.8% vs 40.2% ,p-value <0.05) as compared to the control group.Logistic regression revealed DR CPAP and Gestational age to be independent risk factors for pneumothorax.

The cohort study observed that 4.8 % of neonates receiving DR CPAP and 0.1% of the control group developed pneumothorax.Logistic regression analyses showed that DR CPAP significantly predicted pneumothorax.[12]

Kenji Hishikawa and et al assessed the effect of CPAP on term birth and its association with pulmonary leak. The Japanese Resuscitation council (JRC) formulated new guidelines in 2010 for neonatal resuscitation provisioning CPAP in labour room, the study tries to evaluate the outcome of the new introduced intervention for term deliveries.

The study analysed a total of 5038 infants.It was observed that the use of CPAP via t-piece increased after the introduction of new guidelines in 2010.Proportion of pneumothorax also increased amongst the early terms.[13]

MATERIAL AND METHODS

The study was conducted at Paediatrics Department of KLE Prabhakar Kore Hospital and Medical research centre Belgaum from January 2021 to December 2021

Study design :

The study was a hospital based, single-centre, open-label, parallel-group, randomised control trial.

Study duration and period :

This study was carried out from January 2021 to December 2021.

Place :

The research was carried out in the Department of Paediatrics at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, a tertiary care teaching hospital affiliated with J.N Medical College, Belagavi.

Source :

Neonates born in the labour room of Dr.Prabhakar Kore Hospital and Medical Research Centre, Belagavi,

Sample size :

A total of 130 newborns developing respiratory distress were studied.

Selection criteria :

Inclusion criteria

1. Neonates delivered with gestational age >35 weeks by Normal Vaginal delivery(NVD)/Lower segment Caesarean Section(LSCS) who
2. Develop laboured breathing in the delivery room or unable to maintain saturation (SPO2) in target range.

Exclusion criteria-

1. Neonates with gestation < 35 weeks
2. Neonates with antenatally or immediate postnatally detected life threatening congenital anomalies
3. Neonates needing prolonged positive pressure ventilation (PPV) or intubation as per NRP algorithm
4. If the treating physician decides to change the mode of resuscitation based on clinical scenario.

Ethical clearance :

The study was approved by the J.N Medical College, Belagavi, Ethical and Research Committee (Annexure III). Clinical trial registration done.

Informed Consent :

The parents of the neonates who met the inclusion criteria were briefed on the nature of the study and written informed consent was obtained from the parents before the enrollment into the study (Annexure I).

Method of collection :

Babies delivered at the labour room of KLEs Dr Prabhakar Kore Charitable Hospital & Medical Research Centre, which is affiliated with KLE Academy of Higher Education and Research & Medical College, Belagavi developing respiratory distress , meeting the inclusion criteria were chosen.

After explaining the goal of the study to the parents of neonates who met the inclusion criteria written consent was obtained. The data from the participants was entered into a structured proforma (Annexure II).

A total of 130 babies developing respiratory distress after birth were randomised into two groups by a computer spawned sequence into the two modes of intervention group and control group by the physician attending the delivery

Children with gestational age of <35 weeks ,antenatally detected life threatening congenital anomalies , those requiring prolonged positive pressure ventilation (as per NRP guidelines) or intubation were excluded.

Group 1 (Interventional group) received continuous positive airway pressure (CPAP) via a T-piece resuscitator and group 2 (control group) received only free flow oxygen.

All the physicians attending the resuscitation were trained as per the Neonatal Resuscitation Program (NRP) guidelines outlined by the American Academy of Paediatrics.

Newborns with persistent respiratory distress at the end of one hour of resuscitation in the form of laboured breathing, unable to maintain target saturation or

worsening of the distress at any point of time,were shifted to NICU for further management.The newborns shifted to NICU were observed for the early neonatal outcome.

Outcome of the neonates at the end of 1 week of neonatal ICU stay was followed up.

Instrument :

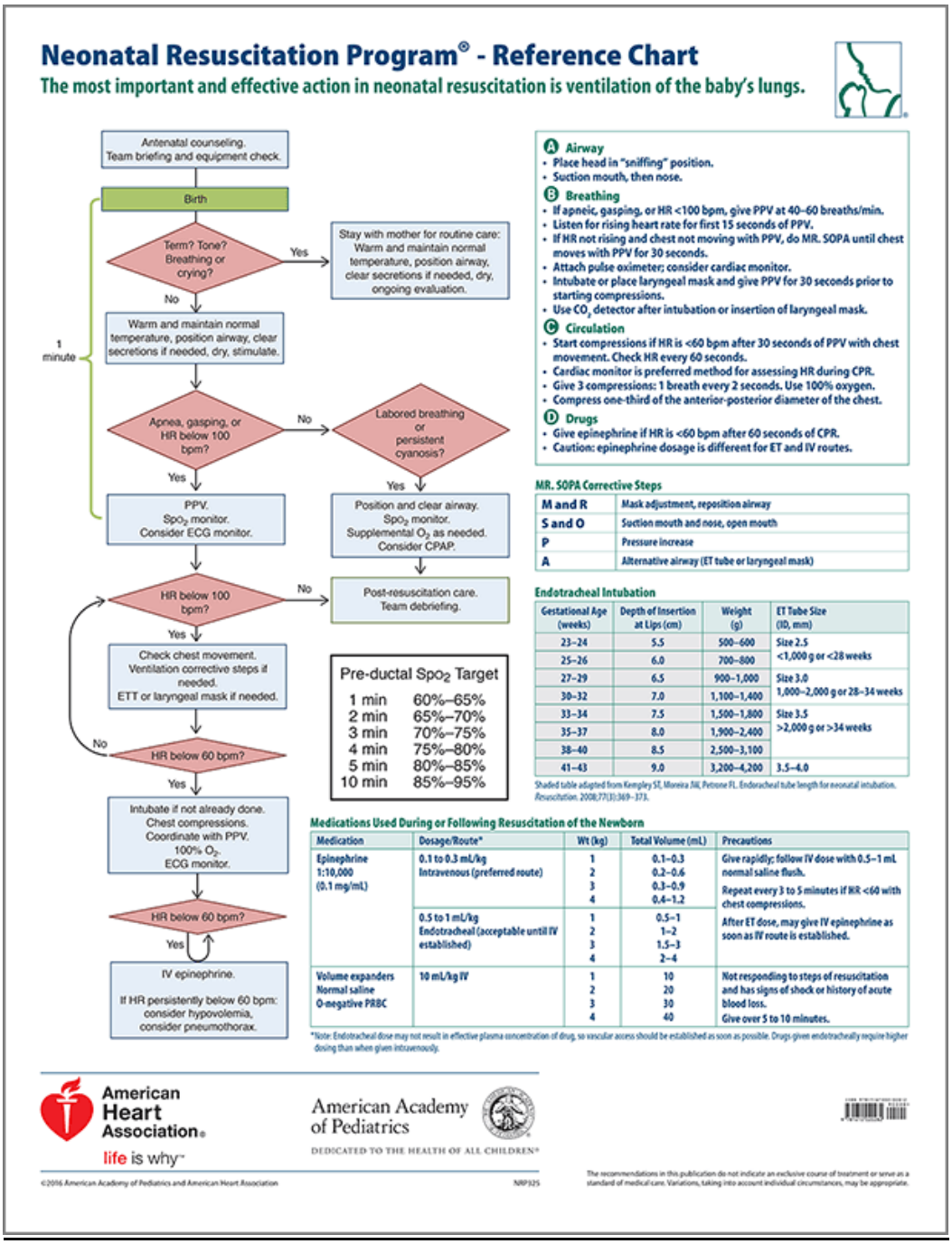
The T-piece resuscitator :

The T-piece resuscitator is device designed to deliver Continuous Positive Airway Pressure via facemask.

Outcome variables :

1. Neonates improving with the administered mode of resuscitation i.e CPAP via T-piece resuscitator or Free flow oxygen,thereby getting shifted to the mother side for routine care.

2. Neonates with persistent respiratory distress in the form of laboured breathing,not maintaining target saturation or worsening at any point of time during the resuscitation getting shifted to NICU for further management.



NRP Algorithm

RESULTS

METHODS:

Data was analysed using R software version 4.2.1 and Excel. Categorical variables are presented in the form of a frequency table. Continuous variables are presented as Mean ± SD/ Median (Min, Max) form. A Chi-square test was applied to find the association of attributes. Mann Whitney U test is used to compare distributions of variables over group. P-value less than equal to 0.05 was considered statistically significant.

RESULTS:

Data contains measurements on 131 subjects. Out of these, 63 belonged to CPAP and 68 belonged to FFO. The following table gives the comparison of different variables over groups.

Demography :

Mother details :

Table 1: Distribution of age of mother over the groups

Variables	Sub Category	CPAP	FFO	Total	p-value
Age of mother	Mean ± SD Median (Min, Max)	24.91 ± 4.97 24 (18, 42)	24.88 ± 4.33 24 (19, 42)	24.9 ± 4.65 24 (18, 42)	0.8156^{MW}

Antenatal risk factors :

Table 2 : Comparison of various antenatal risk factors over the groups

Variable	Category	CPAP	FFO	Total	p-value
Antenatal Risk Factors	Acute GE	1(1.59%)	0	1(0.76%)	0.4928[MC]
	Anaemia	2(3.17%)	2(0.29%)	4(3.05%)	1[MC]
	Gestational Diabetes mellitus	4(6.35%)	3(0.44%)	7(5.34%)	0.7226[MC]
	COVID+	0	1(0.15%)	1(0.76%)	1[MC]
	PROM	6(9.52%)	8(1.17%)	14(10.69%)	0.7966[MC]
	Foetal macrosomia	1(1.59%)	0	1(0.76%)	0.4928[MC]
	FGR	3(4.76%)	3(0.44%)	6(4.58%)	1[MC]
	HBsAg +	0	1(0.15%)	1(0.76%)	1[MC]
	Gestational Hypertension	9(14.29%)	5(0.73%)	14(10.69%)	0.2759[MC]
	Oligohydramnios	2(3.17%)	1(0.15%)	3(2.29%)	0.6087[MC]
	Preeclampsia	2(3.17%)	1(0.15%)	3(2.29%)	0.6087[MC]
	Rh Negative	1(1.59%)	3(0.44%)	4(3.05%)	0.6222[MC]
	Antepartum Haemorrhage	0	2(0.29%)	2(1.53%)	0.5067[MC]
	Short stature	0	2(0.29%)	2(1.53%)	0.5067[MC]
	Hypothyroid	0	5(0.73%)	5(3.82%)	0.069[MC]

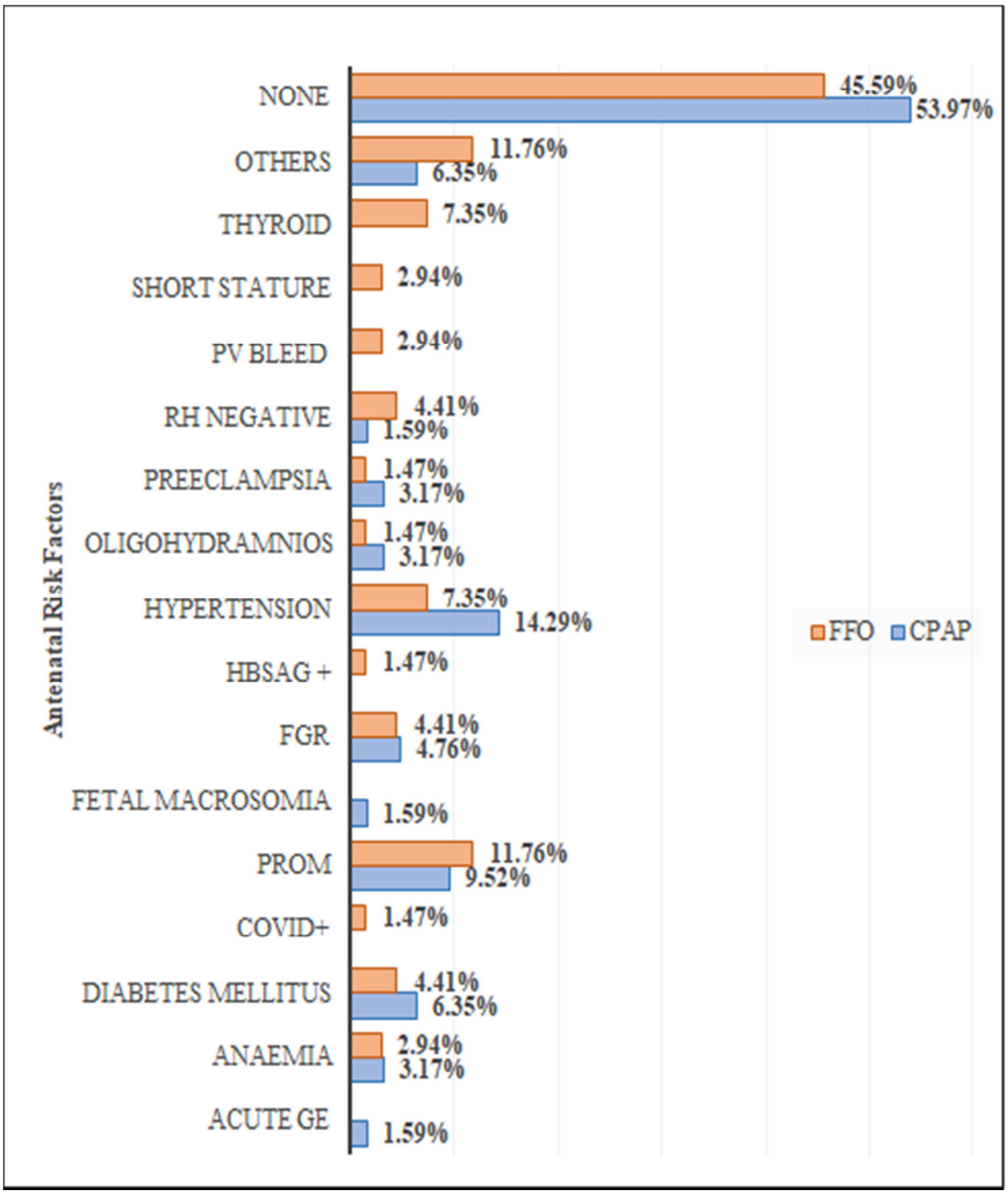


Figure 1: Distribution of antenatal risk factors over groups.

Delivery details :

Table 3 : Distribution of Mode of delivery,status of liquor over the groups

Variable	Sub-category	CPAP	FFO	Total	p-value
Mode of delivery	AVD	1(1.59%)	3(4.48%)	4(3.08%)	0.2694[MC]
	LSCS	34(53.97%)	43(64.18%)	77(59.23%)	
	NVD	28(44.44%)	21(31.34%)	49(37.69%)	
Liquor	Clear	47(74.6%)	54(80.6%)	101(77.69%)	0.412[C]
	MSL	16(25.4%)	13(19.4%)	29(22.31%)	

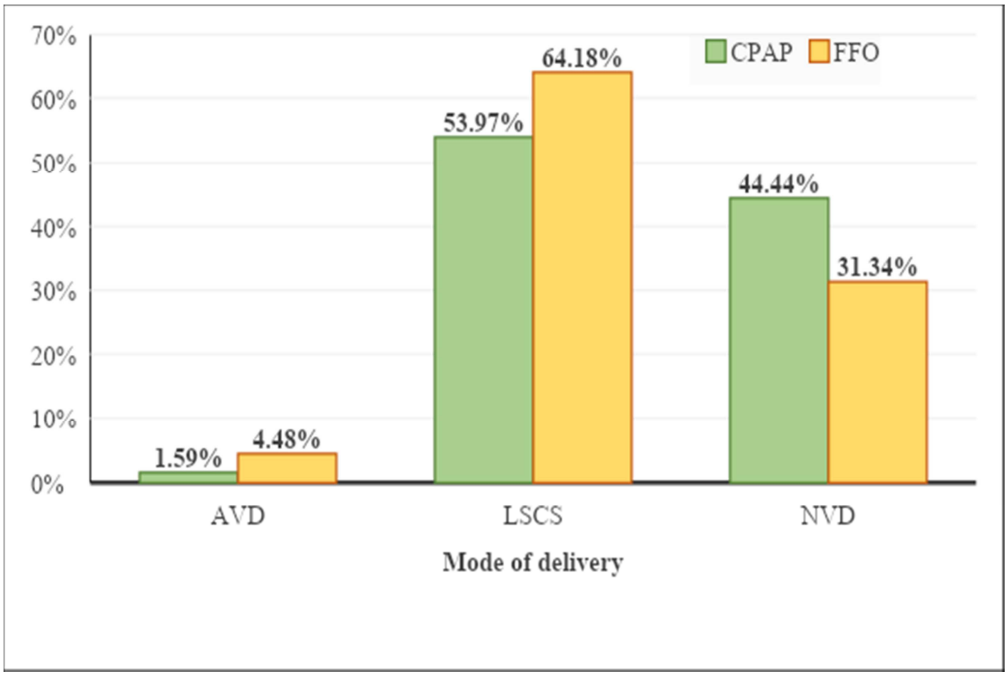


Figure 2: Distribution of mode of delivery over groups.

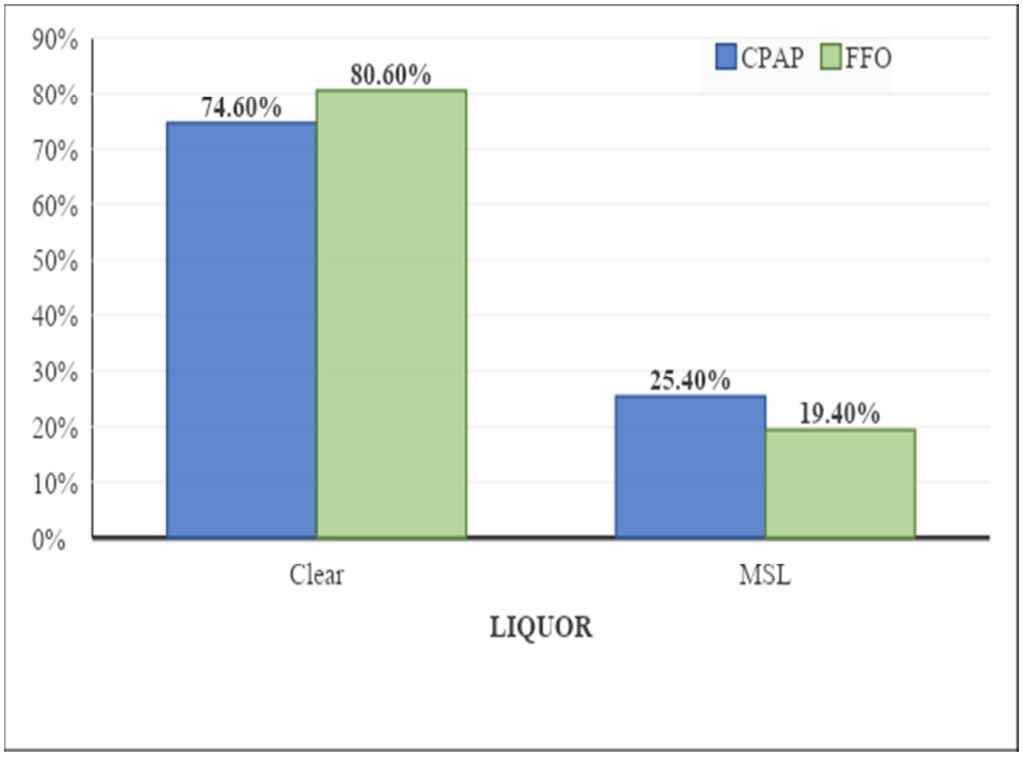


Figure 3: Distribution of status of liquor over groups.

Resuscitation details :

Table 4: Distribution of status of first cry at birth details over the groups

Variable	Sub-category	CPAP	FFO	Total	p-value
Cried at birth	No	2(3.17%)	3(4.41%)	5(3.82%)	1[C]
	Yes	61(96.83%)	65(95.59%)	126(96.18%)	

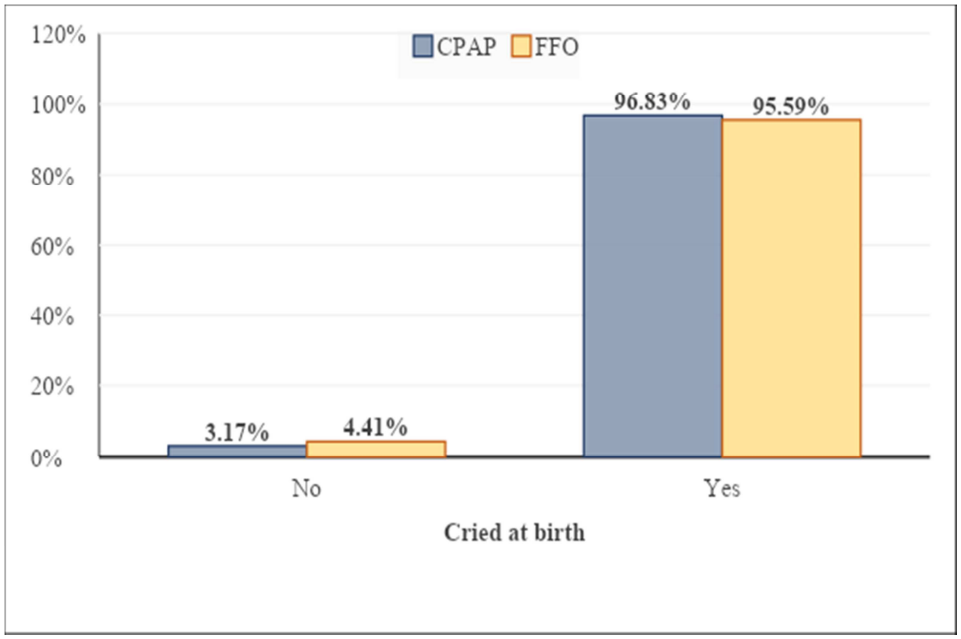


Figure 4: Distribution of status of first cry details at birth over the groups.

Table 5: Duration of CPAP and FFO over the groups

Variables	Mean ± SD	Median (Min, Max)	p-value
LR CPAP duration (min)	12.34 ± 5.02	10 (5, 30)	0.802^{MW}
LR FFO duration (min)	13.82 ± 8.56	10 (5, 45)	

Abbreviation: MW – Mann Whitney U test.

From Mann Whitney U test, we observe that, there is no significant difference in the duration of CPAP and FFO required over groups.

Table 6 : Comparison of Labor room outcome over the groups :

Variable	Subcategory	CPAP	FFO	Total	p-value
LR outcome	Improved	55(87.3%)	58(84.05%)	113(86.25%)	0.5485[C]
	Shifted to NICU	8(12.7%)	10(14.7%)	18(13.74%)	

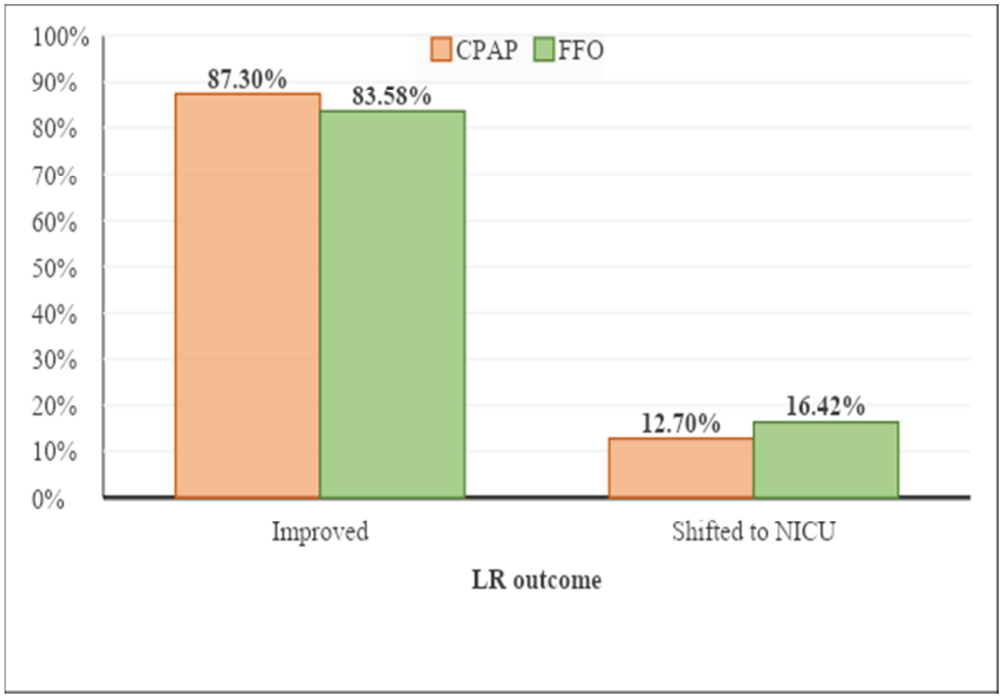


Figure 5: Distribution of LR outcome over group.

Baby details :

Table 7 : Distribution of various neonatal details over the groups :

Variable	Sub-category	CPAP	FFO	Total	p-value
Gestational age (weeks)	Late preterm (< 37 weeks)	6(9.52%)	5(7.46%)	11(8.46%)	0.673[C]
	Term (≥ 37 weeks)	57(90.48%)	62(92.54%)	119(91.54%)	
	Mean ± SD	38.44 ± 1.4	38.27 ± 1.35	38.35 ± 1.37	0.5623[MW]
	Median (Min, Max)	38 (36, 42)	38 (35, 41)	38 (35, 42)	
Birth weight (Kg)	Mean ± SD	2.8 ± 0.49	2.78 ± 0.49	2.79 ± 0.49	0.951[MW]
	Median (Min, Max)	2.7 (2, 4)	2.8 (1.6, 4.5)	2.8 (1.6, 4.5)	
Gender	Female	31(48.39%)	27(38.81%)	58(44.27%)	0.2727[C]
	Male	32(51.61%)	41(61.19%)	73(55.72%)	

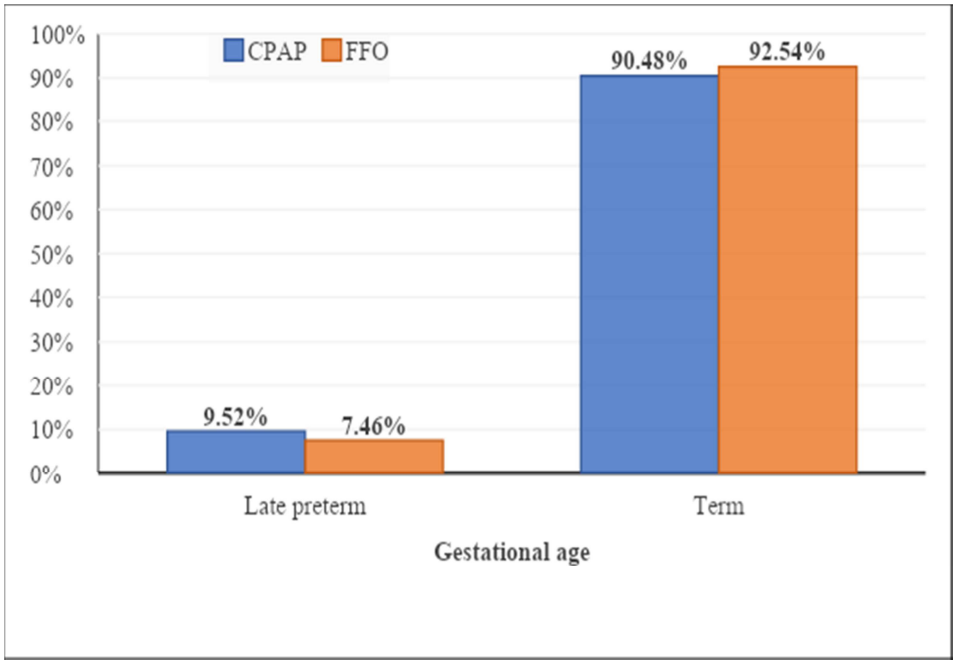


Figure 6: Distribution of gestational age over group

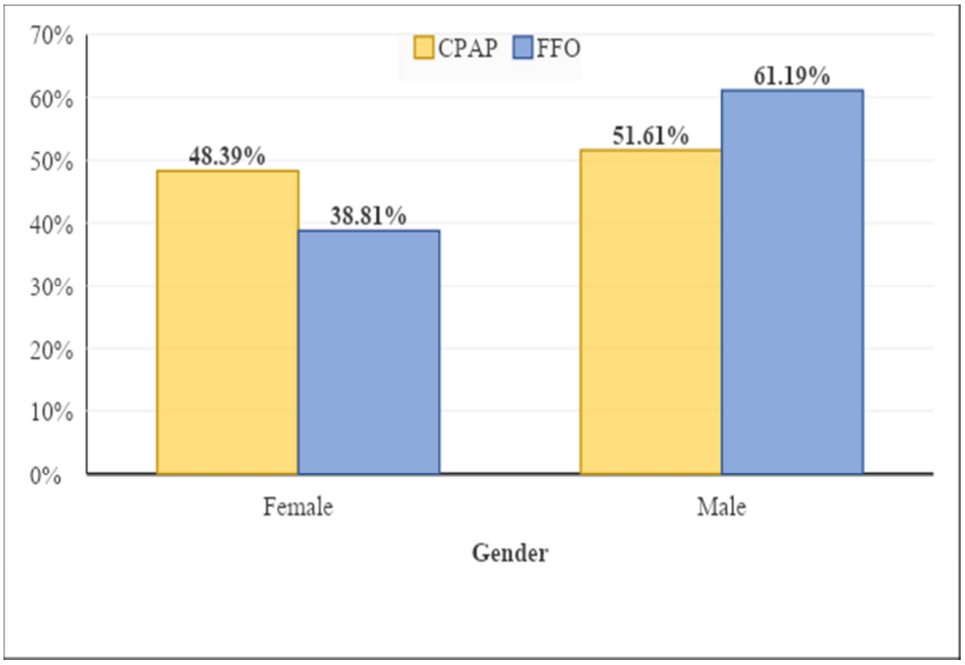


Figure 7: Distribution of gender of baby over group.

Abbreviation: C – Chi square test, MC – Chi square test with Monte Carlo simulation, MW – Mann Whitney U test.

From Mann Whitney U test, we observe that, there is no significant difference in the distribution of age of mother, gestational age and birth weight over groups.

The following table gives the comparison of LSCS indication with groups.

Table 8: Comparison of LSCS indication with groups.

LSCS indication	CPAP	FFO	Total	p-value
Anamnios	1(2.94%)	1(2.33%)	2(2.6%)	1^{MC}
CPD	4(11.76%)	1(2.33%)	5(6.49%)	0.1784^{MC}
Deep transverse arrest	1(2.94%)	0	1(1.3%)	0.4578^{MC}
Failed induction	1(2.94%)	6(13.95%)	7(9.09%)	0.1369^{MC}
MSL	8(23.53%)	14(32.56%)	22(28.57%)	0.4683^{MC}
Oligohydramnios	2(5.88%)	2(4.65%)	4(5.19%)	1^{MC}
Pre-eclampsia	4(11.76%)	0	4(5.19%)	$\mathbf{0.0365^{MC}*}$
Previous LSCS	11(32.35%)	18(41.86%)	29(37.66%)	0.4918^{MC}
Twin pregnancy	2(5.88%)	1(2.33%)	3(3.9%)	0.5807^{MC}

*Abbreviation: MC – Chi square test with Monte Carlo simulation, * indicates statistical significance.*

From Chi square test, we observe that, only preeclampsia has significant association with group.

NICU details :

The following table gives the comparison of respiratory distress at the point of admission to NICU with groups.

Table 9: Comparison of Presence of respiratory distress at the point of admission to NICU within groups.

Respiratory Distress at the time of NICU admission	CPAP	FFO	Total	p-value
No	1(14.29%)	2(18.18%)	3(16.67%)	1^{MC}
Yes	6(85.71%)	9(81.82%)	15(83.33%)	

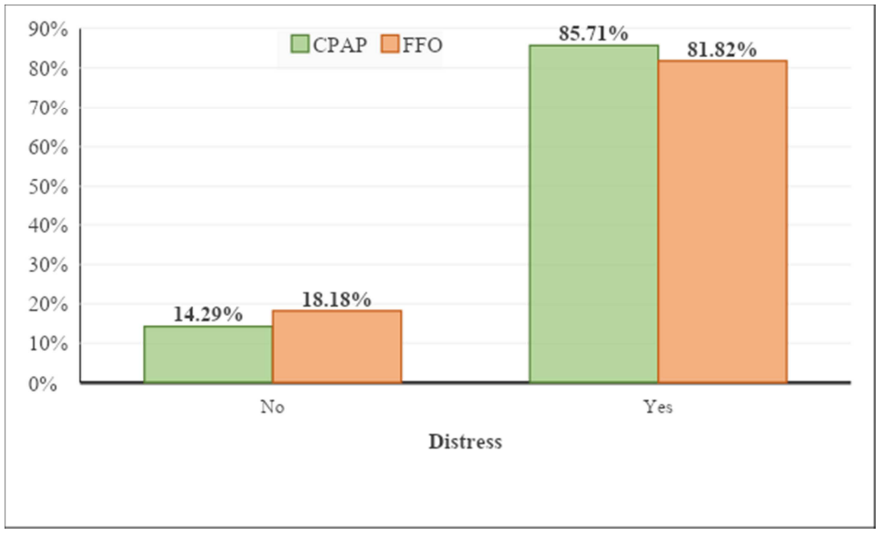


Figure 8: Distribution of presence respiratory distress at the point of admission to NICU with groups.

Abbreviation: MC – Chi square test with Monte Carlo simulation.

From Chi square test, we observe that, there is no significant association of distress with group.

The following table gives the comparison of Modified Downe's score with groups.

Table 10: Comparison of Modified Downe's score with groups.

Modified Downe's score	CPAP	FFO	Total	p-value
0	1(14.29%)	3(27.27%)	4(22.22%)	0.3938[MC]
1	1(14.29%)	5(45.45%)	6(33.33%)	
2	3(42.86%)	2(18.18%)	5(27.78%)	
3	2(28.57%)	1(9.09%)	3(16.67%)	

Abbreviation: MC – Chi square test with Monte Carlo simulation.

From Chi square test, we observe that, there is no significant association of Modified Downe's score with group.

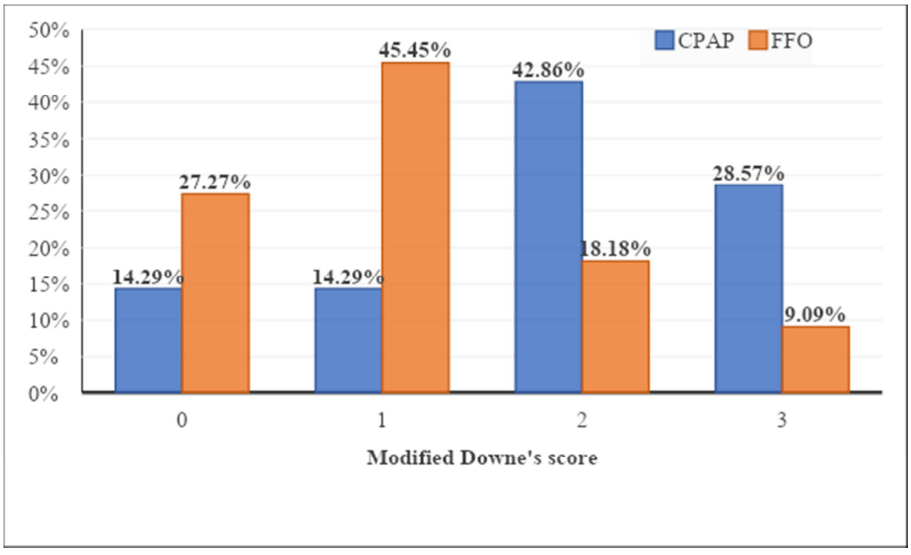


Figure 9: Distribution of Modified Downe's score over group.

The following table gives the comparison of respiratory support in NICU with groups.

Table11: Comparison of Respiratory Support in NICU with groups.

Respiratory Support in NICU	CPAP	FFO	Total	p-value
Nasal CPAP	2(28.57%)	1(9.09%)	3(16.67%)	0.5392^{MC}
O2 by nasal prongs	4(57.14%)	8(66.66%)	12(61.11%)	1^{MC}

Abbreviation: MC – Chi square test with Monte Carlo simulation.

From Chi square test, we observe that, there is no significant association of Nasal CPAP and Nasal prongs with group.

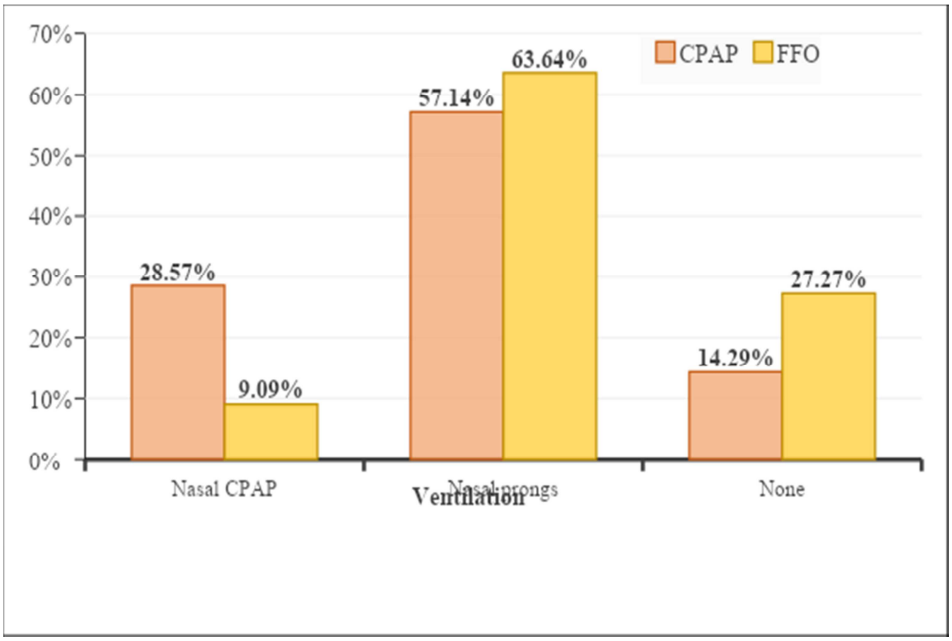


Figure 10: Distribution of respiratory support in NICU over group.

The following table gives the comparison of final diagnosis with groups.

Table 12: Comparison of final diagnosis with groups.

Final diagnosis	CPAP	FFO	Total	p-value
Late Preterm/LBW	0	2(18.18%)	2(11.11%)	
MSAF Birth	3(42.86%)	2(18.18%)	5(27.78%)	
Perinatal asphyxia with respiratory distress	2(28.57%)	0	2(11.11%)	
Perinatal depression	1(14.29%)	1(9.09%)	2(11.11%)	0.1079^{MC}
Perinatal depression with sepsis	1(14.29%)	0	1(5.56%)	
Transient tachypnea of newborn	0	4(36.36%)	4(22.22%)	
Perinatal asphyxia with sepsis	0	2(18.18%)	2(11.11%)	

Abbreviation: MC – Chi square test with Monte Carlo simulation.

From Chi square test, we observe that, there is no significant association of final diagnosis with group.

The following table gives the comparison of improvement rate over groups in different conditions.

Table 13: Comparison of improvement rate over groups in different conditions.

Variables	Sub Category	CPAP	FFO	p-value
Mode of delivery	LSCS	31 (91.18%)	36 (83.72%)	0.5212^{MC}
	NVD	24 (85.71%)	17 (80.95%)	0.7226^{MC}
Liquor	Clear	43 (91.49%)	46 (85.19%)	0.3893^{MC}
	MSL	12 (75%)	10 (76.92%)	1^{MC}
Gestational age (weeks)	Late preterm (< 37 weeks)	4 (66.67%)	2 (40%)	0.5732^{MC}
	Term (≥ 37 weeks)	51 (89.47%)	54 (87.1%)	0.7956^{MC}

Abbreviation: MC – Chi square test with Monte Carlo simulation.

From Chi square test, it is observed that, there is no significant difference in the improvement rate over groups in different modes of delivery, liquor type and gestational age.

DISCUSSION

This study was conducted at the Department of Paediatrics of KLES Prabhakar Kore Hospital & Medical Research Centre,Belgaum from January 2021 to December 2021

All neonates delivered with gestational age >35 weeks by Normal Vaginal delivery(NVD) or Lower segment Cesarean Section(LSCS) AND developing laboured breathing in the delivery room or requiring respiratory support to maintain saturation (SPO2) in target range , were included in the study.

All the neonates of gestation more than >35 wks of gestation with known congenital anomalies ,or requiring prolonged positive pressure ventilation were excluded from the study.

It was in the mid 1960s that the subspeciality of neonatology grew with the advent of NICUs in each major district of the United States of America.The presence of at least one person trained in basic resuscitation skills at the place of delivery was emphasised at that point of time.

Keeping that in mind,Neonatal Resuscitation Program (NRP) and Helping Babies Breathe (HBB) these two educational programs have proven to be indispensable towards the global goal of having at least one trained personnel available at the birth of every neonate.[24]

Based upon the best evidence available, the NRP was designed to standardise the approach to resuscitation and provide not only knowledge but the skills required at the delivery of a newborn.

With over 2 decades of its inception , the NRP has had to evolve perpetually to stay valid and provide an optimal resuscitation to the newborn babies.[25,26]

One of the best examples of such evolution, which we try to evaluate in our study is the delivery of CPAP via T-piece in the labour room in neonates developing respiratory distress.

It was in its 2011 consensus guidelines that NRP included CPAP as a mode of intervention for spontaneously breathing neonates without apnea,gasping ; presenting with laboured breathing or persistent cyanosis & heart rate of > 100/min ,regardless of gestational age.[15]

Over the years the use of CPAP in delivery room became the norm for preterm newborns, with multiple studies reporting a reduced need of surfactant and endotracheal intubation amongst the group [27].

Questioning its application in the late preterm and term neonates , our study tries to evaluate the efficacy of delivery room CPAP as per the guidelines suggested by NRP in its 6th edition .

To start with the demographic details of our study ; The mean age of mothers of neonates enrolled into the study was 24.9 +/- 4.65 years (table 1), with a mean gestational age of 38.44 ± 1.4 weeks in the DR CPAP group while 38.27 ± 1.35 weeks in the DR FFO group (table 7).

Osman and et al in their study of providing DR CPAP noted a mean gestational age of 37.6 +/- 0.7 weeks & 37.7 ± 0.7 weeks in the control group , while Hishikawa and et al noted it to be same i.e 38.7± 1.1 in both the groups[13].

The study by William Smithart and et al which is noted to be groundbreaking in the study over DR CPAP notes a mean gestation of 38 ± 2 weeks in both arms of the study[11].

Our study consisted of a total 131 neonates recording a total of 73 (55.72 %) males and 28 (44.27 %) females randomised amongst both arms ; DR CPAP consisting of 32 males & 41 females ; whereas DR FFO consisting of 31 & 27 males and females respectively (table 7).

Smitharth and et al documented 3123 ± 669 g as the mean weight in the interventional group and 3123 ± 729 g in the control group , while Hishikawa and et al document 3003 ± 374 g & 3000 ± 386 g neonatal weight in interventional and control groups respectively [11.]

Our study documents a mean weight of 2800 ± 490 g in the DR CPAP group and 2780 ± 490 g in the DR FFO group , with no statistical difference being noted (table 7).

With the demographic details compared with the notable studies, our study also observed different antenatal risk factors associated with neonates developing respiratory distress.

Antenatal risk factors such as anaemia,gestational diabetes mellitus,gestational hypertension,premature rupture of membranes ,FGR,preeclampsia, were observed ,but no statistical significant association could be found for any of the factors analysed.

No comparable data was obtained from any of the similar studies .

A total of 3 % of mothers had anaemia while , 5.34 % had GDM , 10.69 % with PROM and PIH, and 4.58 % of the neonates suffered from FGR (table 2).

The use of CPAP grew popular ,especially in the preterm neonates ,with multiple studies reporting less proportion of dreadful complications such as bronchopulmonary dysplasia and even death, as compared to the conventional endotracheal intubation.[27]

Naveen Jain et al conducted a trial to analyse the impact of early CPAP (DR CPAP) on preterm babies.The study found a decrease in intubations by 50% as compared to the control group and also a reduction in the median time on invasive ventilation to be reduced to 14 hours from the median of 48 hours with respect to the control group.The study concluded that early CPAP (DR CPAP) decreased the need for respiratory support (intubation + CPAP time) with no decrease in survival of preterm babies.[7]

Jyothi K et al studied the outcome of the early use of bubble CPAP in labour with respect to need for mechanical ventilation, duration of the stay in the hospital and mortality at the NICU.

The study found statistical significance within the interventional group i.e DR CPAP. 29.63 % of interventional group needed mechanical ventilation with comparison of 50.91% of the control group.The duration of NICU stay was lower in the DR CPAP group, while no significant difference was observed with respect to mortality within the groups.[9]

W.A.Goncalves and et al tried the same strategy of providing extremely low birth weight infants with labour room CPAP .Goncalves concluded that antenatal steroids and prenatal monitoring are fundamental for the success of DR CPAP amongst this group of neonates.To the withstand the effort of respiration without the need of intubation it is necessary for the preterm babies to be more prepared at the point of delivery and this can only be better achieved with the help of antenatal steroids and prenatal monitoring.[8]

An Indian study by S.A.Desai and et al at a tertiary care centre evaluated the potency of labour room CPAP in neonates with gestational age of < 34 weeks in a resource limited setting.The outcome was compared with similar group in the past for whom CPAP was initiated in the NICU.

The trial found out that there was an absolute reduction in the need of surfactant by 36% and the need for mechanical ventilation by 56 % in the interventional DR CPAP group.[10]

CPAP significantly improves the oxygenation in the preterm infants with respiratory distress syndrome (RDS), it also improve the gaseous exchange,functional residual capacity and the respiratory work.As the gestational age increases, the pressure required to distend the alveoli decreases ,with proportionate increase in the surfactant amount present in the lung.

The use of DR CPAP was thus established amongst the preterm group of neonates and well justified as well.It was thus thoroughly evaluated for the preterm infants and found to be of great benefit.

But a series of further research was warranted for its use amongst term and late preterm neonates with a well established pulmonary system ,prepared for the change from in-utero to external air exchange transition.

Resuscitation bags or t-piece devices are the most routinely used instruments for respiratory assistance in India.These provide no means to measure the changing lung pressures thus providing a very little opportunity to modify the ventilation parameters as per the needs of each particular neonate.[28,29]

A sustained inflation required in first positive ventilation after birth is justified as different lung regions aerate at different rates.Its important to note this principle as during the subsequent inflations , air would rapidly flow into the expanded aerated lung regions.The aerated regions are thus prone for over expansion if the duration of inflation is kept short ,dispersing the entire tidal volume only to these regions. Moreover an optimum gas exchange would take place only when the distal alveolar regions aerate.[30,31,32]

Now keeping this in mind , it is necessary to understand that with increased compliance ergo a decreased need of pressure to distend the alveoli, the term lungs are predisposed to injury when CPAP is applied.

Subsequently trials were conducted of using prophylactic DR CPAP amongst neonates born via caesarean section anticipating a certain hindrance in the transition of term,late preterm neonates.

Miray Yilmaz and et al conducted a trial to study the effect of prophylactic CPAP on TTN and NICU admissions in neonates delivered via elective LSCS.The study concluded that NICU admission rates can be reduced with the use of

prophylactic CPAP in the late preterm and the early term neonates without any side-effects.The study thus promoted the use of DR CPAP amongst late-preterms born via elective LSCS [33].

P. Srinivasan and et al on the other hand ,found different results.A prospective RCT conducted by the team amongst Full term neonates born via elective LSCS found no adverse or beneficial effects of providing prophylactic CPAP in the delivery room .

The data was thus lacking and inconclusive for the use of CPAP on late-preterm and term infants in the delivery room.

Gaining popularity amongst the preterm neonates, with a justified principle targeting the preterm physiology , the use of delivery room CPAP (DR CPAP) was still to be evaluated specifically for the late preterm & term newborns.

Subsequent studies reporting the adverse effects of delivery room CPAP amongst the term neonates can then be found causing pressure leak syndromes.[11,13,36]

A retrospective birth cohort study of newborns was conducted by Wiilam Smithhart and et al was deemed to be groundbreaking in evaluating DR CPAP for term neonates. Study evaluated newborns delivered from 2001 to 2015 , and performed a nested cohort for neonates delivered from 2005 to 2015 [11].

All the newborns requiring resuscitation, but not any form of positive pressure ventilation progressing to NICU care were included in the study.

Determining the association of DR CPAP with symptomatic pneumothorax amongst neonates delivered within a gestational age of 32 to 35 weeks was the aim of the study.

With a p-value of < 0.05,the study found a raised proportion of pneumothorax after the execution of 2011 NRP guidelines , from 0.4% to 0.6 % .Use of DR CPAP was associated with pneumothorax (Odds ratio : 5.5 with confidence interval of 95%)

An increased proportion of pneumothorax was thus attributed directly proportional to gestational age and oxygen administration.

This study was a benchmark in questioning the application of the DR CPAP amongst term neonates.With sample size of over 2 lakh, the study triggered multiple researchers to look for further adverse implications of the DR CPAP .

Laura Clevenger and et al extracted data from the computerised records of two neonatal studies performed in community hospitals.

The aim of the study was to determine an association between early CPAP/ Labour room CPAP and pneumothorax amongst term infants.

Infants receiving any form of positive pressure ventilation in the DR were excluded from both the studies.In the case control study ,as compared to the controls ,neonates with pneumothorax were more likely to have received DR CPAP. In the cohort study , DR CPAP reported 4.8 % of pneumothorax while control group 0.1%.

The study thus concluded that any respiratory condition treated with labour room CPAP is associated with increased propensity of causing a pneumothorax.[12]

Our study thus tries to ascertain the exact guidelines for the use of CPAP in neonatal resuscitation amongst the late preterm and term neonates presenting with respiratory distress.

Out of the total of 130 deliveries attended by the physician , 77 (59.23%) were LSCS, 49 (37.69%) were delivered normally via vaginal delivery while 4 were assisted vaginal deliveries (table 3).

With randomisation , 68 (52.30%) out of the total 130 subjects were given FFO , while 63 (47.49 %) were subjected to DR CPAP.

Over 58 (84.05 %) of neonates belonging to the FFO group and 55(87.3 %) of the CPAP group improved ,while 8(12.7 %) neonates belonging to CPAP & 10 (14.7%) of FFO group were shifted to NICU (table 6).

Thus no significant difference in the outcomes of both the groups was observed (p-value :0.548) .

Our study documented the time required by each of the modality to alleviate the respiratory distress in the neonate.

The time required for DR CPAP to alleviate the distress was documented to be 12.34 ± 5.02 mins while DR FFO required 13.82 ± 8.56 mins , thus it could be postulated that CPAP offers no advantage in helping the neonatal transition, although no statistical difference was noted , hence requiring further evaluation (table 5).

It should be noted that , out of the total 18 newborns shifted to NICU , 3 (16.67 %) were shifted with no signs of respiratory distress : 1 (14.29 %) from DR CPAP and 2 (18.18 %) from FFO respectively.Furthermore,to have an objective

assessment, Modified Downes score was documented for the neonates shifted in view of respiratory distress at the point of admission to NICU.Reviewing table 10,it can be seen that no statistical significance can be observed over the distribution over both the groups.

In the single centre retrospective study conducted by Nicole T.Spillane et al it was observed that neonates born at 35 weeks of gestation who received CPAP were more likely to be born via LSCS.[39]

They also noted a significant proportion of the neonates administered DR CPAP to be shifted to NICU ,9.3 times the risk of those who did not receive positive pressure in the labour room.Respiratory distress was the most common cause of NICU admissions in this group.

With an intention of determining the exact application of using the DR CPAP, we further analysed certain perinatal risk factors that could influence the foetal pulmonary transition.

It was observed that 32 (94.11 %) of neonates subjected to DR CPAP post LSCS mode of delivery improved while 36 (83.72 %) within the FFO group.With no statistical difference obtained ,any superiority of DR CPAP over the FFO group was ruled out.

P.Srinivasan and et al in their study of providing prophylactic DR CPAP to newborns delivered via elective LSCS found similar results with no significant benefits or adverse effects seen amongst the control and interventional groups.[30]

Although a similar study by Miray Yilmaz Celebi and et al of providing prophylactic CPAP to newborns yielded strikingly different results.They noted that

the percentage of infants with TTN was lower in the prophylactic CPAP group than the control group, and so were the NICU admission rates (p value =0.045).[33]

Approximately 13% of the newborns are delivered through meconium-stained amniotic fluid, out of these 5-12 % are prone to develop meconium aspiration syndrome.Meconium can be aspirated in-utero or postnatally , it can have direct toxic effects on the lung parenchyma itself, and the resulting meconium aspiration syndrome may result in the need of considerable respiratory support.

Our study recorded a total of 29 (22.31%) of deliveries with meconium stained liquor.With randomisation 16 (25.4 %) were subjected to DR CPAP while 13 (19.4 %) to FFO. 12 (75 %) neonates improved with DR CPAP , 10 (76.92 %) with FFO , but no statistical significance was observed (table 13).

Studies document the incidence of the respiratory distress in almost 7% of the term neonates and 9% of the late preterms.CPAP use in the neonates with gestation of < 33 weeks has been known to decrease the need for surfactant therapy or even the need of mechanical ventilation with a decrease the risk of death or any other chronic lung ailment.

It is amongst late preterm and term neonates that the use of labour room CPAP is being questioned.Our study comprised a total 119 (91.4 %) term , while 11 (8.46 %) late preterm neonates.

A comparative study of both the interventional groups showed no statistical significance in the improvement rates of the neonates.

It is noteworthy that no neonate was mechanically ventilated, no death nor any case of air leak syndrome was documented in the entire sample size of the study.

LIMITATION AND SCOPE OF THE STUDY

- As the study included a limited population from a single centre, results cannot be extrapolated to the whole population.
- A study with a large sample size from different geographical areas should be conducted to have reliable results.
- This study was conducted at a tertiary care hospital with trained paediatric postgraduate students conducting the resuscitation at the delivery room with substantial resources at their behest.

It is necessary to perform a thorough evaluation before the implementation of interventions like delivery room CPAP for late preterm and term neonates, which would require specialised training and equipment in a resource limited country like India.

CONCLUSION

Our randomised control trial shows no significant difference in the labour room or early neonatal outcome amongst the late preterm or term neonates presenting with respiratory distress after randomisation to delivery room CPAP or delivery room FFO.

Both the groups ,i.e interventional and control, show no significant difference in the transitional adaptation when subjected to the delivery room CPAP and delivery room FFO.

No significant difference was seen in the requirement of respiratory support in the NICU setting between the two groups in those neonates shifted for NICU care ,at the end of the labour room resuscitation.

SUMMARY

One year randomised control trial was conducted from January 2021 to December 2021 in the Department of Pediatrics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi. A total of 131 neonates with gestation more than or equal to 35 weeks presenting with respiratory distress were included in the study. The salient findings of the study are summarised below:

- The average gestational age of neonates presenting with respiratory distress in our study was 38.35±1.37 weeks.
- A total of 59.23 % of neonates developing distress were delivered via LSCS and 37.69 % via NVD.
- 77.69 % of the neonates developing respiratory distress had clear liquor while 22.31 % had MSL.
- 96.18 % of neonates cried immediately after birth ,3.82 % required brief positive pressure ventilation.
- In our study 44.27 % were female and the remaining 55.72 % male.
- The average birth weight of neonates in our study was 2.79±0.49 Kg.
- A total of 52.67 % neonates received DR FFO while remaining 47.32 % received DR CPAP as per the randomisation method.Total 84.05% of the neonates receiving DR FFO group improved,while 15.94 % were shifted to NICU, comparatively 87.3 % of DR CPAP group improved and 12.7 % were shifted to NICU.No statistical significance could be established ,disapproving any advantage

of DR CPAP over DR FFO.Similarly the mean time required by DR CPAP group to alleviate the respiratory distress was noted to be 12.34±5.02 mins while DR FFO group documented a time 13.82 ± 8.5 mins ,with no statistical significance.

- Certain specific antenatal risk factors presumed to alter the transitory course of the neonate were analysed in the trial as well.In neonates delivered via LSCS ,91.8 % of the neonates subjected to DR CPAP showed improvement whereas DR FFO group showed an improvement in 83.72 %.

- Total of 22 Neonates were documented to have MSL, the DR CPAP group showed an improvement in 75 % of the neonates while 76.92 % in DR FFO.No significant advantage of DR CPAP over any of the presumed risk factors could be demonstrated in our study.

- Our study had a total of 131 neonates, 8.39% belonging to the late preterm group , and 91.6% of term neonates,DR CPAP showed an improvement of 89.47 % in the term neonates and 66.67% amongst late preterm, while DR FFO showed improvement rates of 87.1% in term and 40% amongst late preterm.

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ANNEXURE I – CONSENT FORM

"EFFICACY OF CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) ADMINISTRATION IN DELIVERY ROOM FOR NEONATES WITH RESPIRATORY DISTRESS : A RANDOMISED CONTROL TRIAL"

CONSENT FOR PARTICIPATION IN RESEARCH

Project title: Efficacy Of Continuous Positive Airway Pressure Administration In Delivery Room For Neonates With Respiratory Distress : A Randomised Control Trial

Name of principal investigator: _____

Contact address: Junior resident, Department of Paediatrics, JNMC, KLE,Belagavi

The content of the provided information sheet, has been carefully read by me/explained to me in detail , in a language that I comprehend and have understood its content. I confirm that I have had the opportunity to ask questions.

The nature and purpose of study and its potential risks/benefits and expected duration of study, and relevant details of study have been explained to me in detail. I understand that the participation of my newborn in this study is voluntary and that I am free to withdraw at any time without giving reasons, without my medical care or legal rights being affected.

I understand that information collected about me from my participation in this research and section of any of my medical notes, may be looked at by responsible individuals from regulatory authorities where relevant.I give permission for these individuals to have access to my records.

Signature/left thumb impression

Signature of the subject/left thumb impression & date: _____

Place: _____

Name of the participant: _____

Name of the parent/guardian: _____

Son/daughter/spouse of: _____

This is to certify that above consent has been obtained in my presence.

Name of principal investigator	Signature of principal investigator
Name of witness 1:	Name of witness 2 :
Signature of witness 1	Signature of witness 2:
Address:	Address :

ANNEXURE II – PROFORMA

"EFFICACY OF CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) ADMINISTRATION IN DELIVERY ROOM FOR NEONATES WITH RESPIRATORY DISTRESS : A RANDOMISED CONTROL TRIAL"

IP Number :

Name :

1.Age of mother : ……

2.Antenatal risk factors :DM/HTN/Thyroid/PV leak/PV bleed

3.Mode of delivery : NVD/LSCS/Assisted : Ventouse/Forceps

Indication :

4.Liquor : Clear/ Meconium Stained

5.Infant's details:

Gestational Age :

Birth weight : ..... Sex: Male/Female/Ambiguous

Resuscitation Details :

1-Cried at birth : Yes/No

2-Initial steps of resuscitation : a)Placed under warmer

b)Suction

c)Drying & stimulation

d)Repositioning

3-Status of the baby at the end of initial steps of resuscitation :

Breathing well □ Labored breathing □

4-In case of PPV : Duration .....

5-Status at the end of PPV :

Breathing well □ Labored breathing □

6-Randomised to CPAP :

Duration : ..... FiO2 : .....% Pressure : .....mmhg

Outcome :

Improved □ FFO given □ Restarted PPV □

Shifted to mother's side □ Shifted to NICU □

7- **Randomised to FFO :**

Duration : ……. Flow : .....L/min

Outcome :

Improved □ Started on CPAP □ Restarted PPV □

Shifted to mother's side □ Shifted to NICU □

8. Early neonatal Outcome :<u>Modified Downe's scoring system</u>(On admission)

Date : .../.../20 Time :

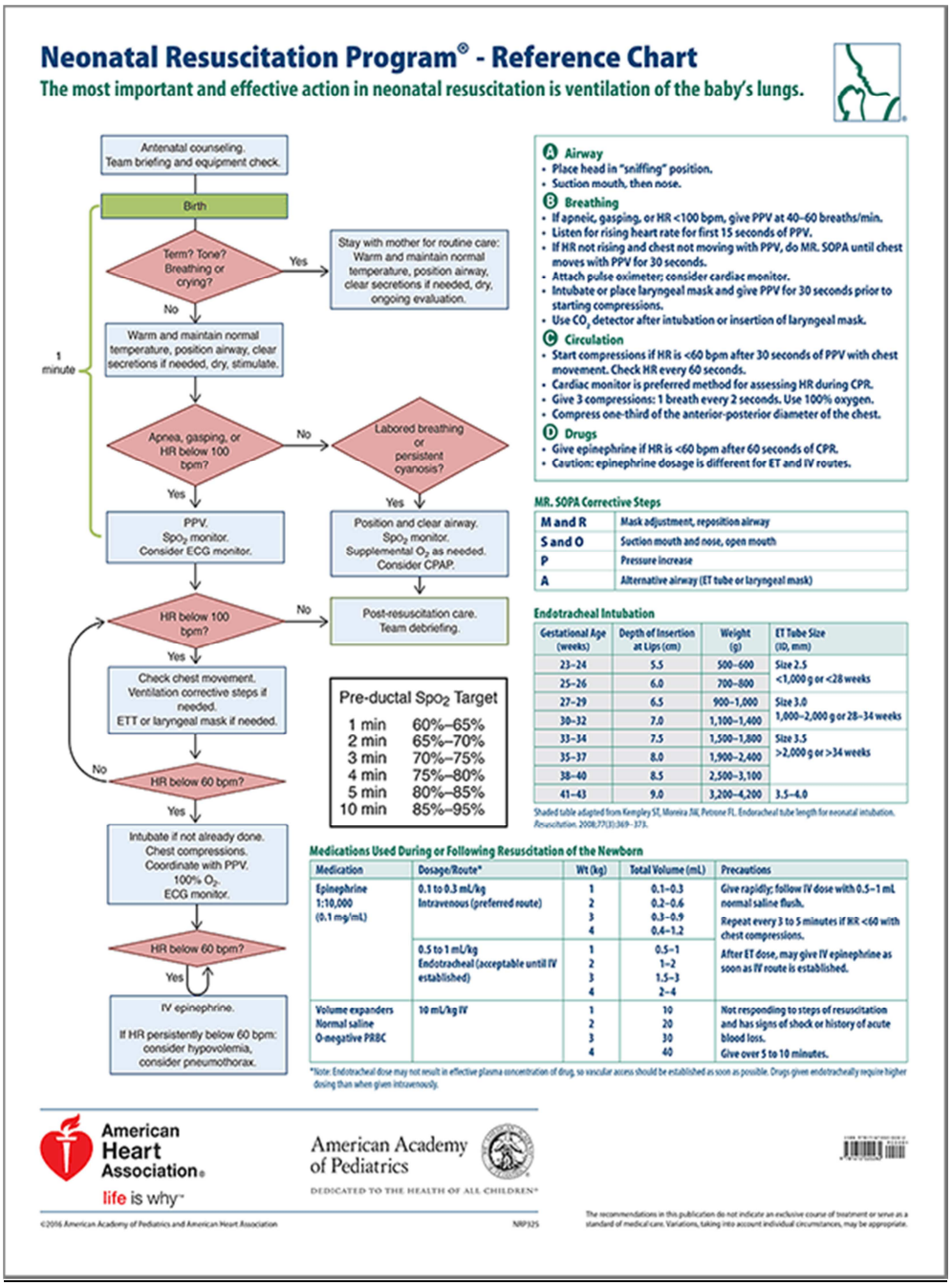
Score	0	1	2
Respiratory rate (rate/min)	<60	60-80	>80
Cyanosis	None in room air	No cyanosis on oxygen support	Cyanosis in spite of oxygen support
Retractions	None	Mild	Moderate to severe
Grunting	None	Audible with stethoscope	Audible without stethoscope
Air entry	Good	Decreased	Barely audible

Total Score : .....

Early neonatal outcome (<7Days) of NICU admissions

Date	Problem	Intervention	Outcome

NRP Algorithm Table :



Neonatal Resuscitation Program® - Reference Chart

The most important and effective action in neonatal resuscitation is ventilation of the baby's lungs.

Pre-ductal Spo_2 Target

1 min	60%–65%
2 min	65%–70%
3 min	70%–75%
4 min	75%–80%
5 min	80%–85%
10 min	85%–95%

A Airway
- Place head in "sniffing" position.
- Suction mouth, then nose.

B Breathing
- If apneic, gasping, or HR <100 bpm, give PPV at 40–60 breaths/min.
- Listen for rising heart rate for first 15 seconds of PPV.
- If HR not rising and chest not moving with PPV, do MR. SOPA until chest moves with PPV for 30 seconds.
- Attach pulse oximeter; consider cardiac monitor.
- Intubate or place laryngeal mask and give PPV for 30 seconds prior to starting compressions.
- Use CO_2 detector after intubation or insertion of laryngeal mask.

C Circulation
- Start compressions if HR is <60 bpm after 30 seconds of PPV with chest movement. Check HR every 60 seconds.
- Cardiac monitor is preferred method for assessing HR during CPR.
- Give 3 compressions: 1 breath every 2 seconds. Use 100% oxygen.
- Compress one-third of the anterior-posterior diameter of the chest.

D Drugs
- Give epinephrine if HR is <60 bpm after 60 seconds of CPR.
- Caution: epinephrine dosage is different for ET and IV routes.

MR. SOPA Corrective Steps

M and R	Mask adjustment, reposition airway
S and O	Suction mouth and nose, open mouth
P	Pressure increase
A	Alternative airway (ET tube or laryngeal mask)

Endotracheal Intubation

Gestational Age (weeks)	Depth of Insertion at Lips (cm)	Weight (g)	ET Tube Size (ID, mm)
23–24	5.5	500–600	Size 2.5 <1,000 g or <28 weeks
25–26	6.0	700–800	
27–29	6.5	900–1,000	Size 3.0 1,000–2,000 g or 28–34 weeks
30–32	7.0	1,100–1,400	
33–34	7.5	1,500–1,800	Size 3.5 >2,000 g or >34 weeks
35–37	8.0	1,900–2,400	
38–40	8.5	2,500–3,100	
41–43	9.0	3,200–4,200	3.5–4.0

Shaded table adapted from Kemgley ST, Moreira JM, Petrone FL. Endotracheal tube length for neonatal intubation. *Resuscitation*. 2008;77(3):369–373.

Medications Used During or Following Resuscitation of the Newborn

Medication	Dosage/Route*	Wt (kg)	Total Volume (mL)	Precautions
Epinephrine 1:10,000 (0.1 mg/mL)	0.1 to 0.3 mL/kg Intravenous (preferred route)	1 2 3 4	0.1–0.3 0.2–0.6 0.3–0.9 0.4–1.2	Give rapidly; follow IV dose with 0.5–1 mL normal saline flush. Repeat every 3 to 5 minutes if HR <60 with chest compressions.
	0.5 to 1 mL/kg Endotracheal (acceptable until IV established)	1 2 3 4	0.5–1 1–2 1.5–3 2–4	After ET dose, may give IV epinephrine as soon as IV route is established.
Volume expanders Normal saline O-negative PRBC	10 mL/kg IV	1 2 3 4	10 20 30 40	Not responding to steps of resuscitation and has signs of shock or history of acute blood loss. Give over 5 to 10 minutes.

*Note: Endotracheal dose may not result in effective plasma concentration of drug, so vascular access should be established as soon as possible. Drugs given endotracheally require higher dosing than when given intravenously.

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NRP325

The recommendations in this publication do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

ANNEXURE III – MASTER CHART

Name	IP Number	Age of Mother	Antenatal Risk Factors	Mode of delivery	LSCS indication	AVD Indication	Liquor	Gestational Age (weeks)	Birth weight (Kg)	Sex	Cried at Birth	PPV Duration ;	CPAP/ FFO	LR CPAP Outcome	LR FFO Outcome	LR CPAP pressure	LR CPAP duration (min)	Flow rate (L/min)	LR FFO Duration (min)	Respiratory support at the point of admission to NICU	Modified Downes score at admission to NICU	Problems in NICU	Respiratory support in NICU	Duration of respiratory support in NICU	NICU stay	Final Outcome	Final diagnosis
Jyoti	1049582	19	-	NVD			Clear	36	2.7	Female	Yes		CPAP	Improved		5	15										
Swati	-	21	-	NVD			Clear	38	3.3	Male	Yes		FFO		Improved			2	10								
Ashwini	1041662	19	Other	LSCS	CPD		Clear	39	3.7	Female	Yes		CPAP	Improved		5	15										
balavva	1041783	31	Hypertension	LSCS	MSL Fetal distress		MSL	39	2.1	Female	Yes		CPAP	Improved		5	20										
Pooja patil	1046945	22	-	NVD			MSL	37	2.2	Female	Yes		CPAP	Shifted to NICU		5	20			Yes	2	Respiratory distress	O2 by nasal	2 days	4 Days	Discharged -	MSAF Birth
Bibi Ayesha	1050069	38	None	NVD			MSL	41	2.6	Female	Yes		CPAP	Shifted to NICU		5	10			Yes	3	Respiratory distress	Nasal CPAP , O2	4 Days	9 Days	Discharged -	MSAF Birth
Sujata	1050370	22	None	NVD			Clear	38	2.8	Male	Yes		FFO		Shifted to			3	10	Yes	1	Respiratory distress	O2 by nasal	2 Days	4 Days	Discharged -	Transient Tachypnea of
Mangal	1054265	32	None	LSCS	MSL Fetal distress		MSL	40	3	Female	Yes		FFO		Shifted to			3	15	Yes	2	Respiratory distress	O2 by nasal	2 Days	12 Days	Discharged	MSAF Birth
Heena	1054119	28	Other	LSCS	Prev LSCS		Clear	38	3	Female	Yes		FFO		Improved			2	5								
Shakuntala	1054625	22	None	AVD		Poor maternal	Clear	39	2.8	Female	Yes		FFO		Improved			5	5								
Shreedevi	1054631	19	None	NVD			Clear	39	2.6	Female	Yes		FFO		Improved			3	5								
Priya	-	23	None	LSCS	MSL fetal distres		MSL	37	2.2	Female	Yes		FFO		Improved			5	5								
Veena	1054930	-	Other	LSCS	Failed induction		Clear	39	3.4	Male	Yes		FFO		Improved			5	5								
Akshata	1055256	25	None	LSCS	Breech/MSL		MSL	37	2.2	Male	Yes		FFO		Shifted to			30	5	Yes	2	Respiratory Distress	O2 by nasal	3 Days	7 Days	Discharge 7	MSAF birth
Shweta	1055400	23	Other	LSCS	MSL Fetal distress		MSL	39	2.5	Female	Yes		CPAP	Improved		5	20										
Laxmi	1055478	24	None	LSCS	Failure of induction		MSL	39	2.2	Female	Yes		CPAP	Improved		5	20										
Ajamin twin 1	1055821	21	None	LSCS	Twin pregnancy		Clear	37	2.6	Male	Yes		CPAP	Improved		5	10										
Malashree	1055978	23	PROM	LSCS	MSL Fetal distress		MSL	37	2.6	Male	Yes		CPAP	Shifted to NICU		5	20			Yes	2	Respiratory Distress	O2 by nasal	2 Days	5 Days	Discharge 5	MSAF birth
Maheshwari	1056134	-	None	NVD			Clear	38	2.4	Male	Yes		CPAP	Improved		5	15										
Nagavva	1056271	-	None	NVD			Clear	38	2.7	Male	No	<60 sec	FFO		Improved			5	15								
Sumitra	1056299	-	None	LSCS	MSL Fetal Distress		MSL	40	2.3	Female	Yes		FFO		Improved			5	15								
Sanjana	1056438	20	None	NVD			Clear	38	2.5	Male	Yes		CPAP	Improved		5	15										
Akshata	1056731	21	Other	LSCS	Oligohydramnios		Clear	41	3.3	Male	Yes		CPAP	Improved		5	15										
Gautami	1056798	27	None	NVD			MSL	37	2.3	Male	Yes		CPAP	Improved		5	15										
Shilpa	1061185	33	Other	LSCS	Failed induction		Clear	38	2.9	Male	Yes		FFO		Improved			2	10								
Priyanka	1061153	25	None	LSCS	Prev LSCS		Clear	39	3.2	Male	Yes		CPAP	Improved		2	10										
Ashwini	1062996	23	None	NVD			MSL	39	2.9	Male	Yes		CPAP	Improved		2	10										
Aashadevi	1062648	28	None	LSCS	MSL Fetal Distress		MSL	39	4.5	Male	Yes		FFO		Improved			2	20								
Archana twin 1	1062685	29	PV Bleed	LSCS	Prev LSCS		Clear	37	2.5	Male	Yes		FFO		Improved			2	10								
Mandira	6171879	21	Other	NVD			Clear	38	2.6	Male	Yes		FFO		Improved			2	10								
Archana Twin 2	1062688	29	PV Bleed	LSCS	Prev LSCS		Clear	37	2.2	Male	No	<60 sec	FFO		Shifted to			3	45	Yes	1	Perinatal	O2 by nasal	1 Day	10 Days	Discharged-	Perinatal asphyxia with
Manjula	-	32	Hypertension	LSCS	Severe PE		Clear	36	2.1	Male	Yes		CPAP	Improved		5	10										
Malashree	1063069	30	Hypertension	LSCS	Prev LSCS		Clear	37	2.8	Male	Yes		FFO		Improved			2	10								
Rekha Twin 2	1063677	42	Hypertension	LSCS	Twin Pregnancy		Clear	36	2.3	Male	Yes		CPAP	Improved		5	20										
Rekha Twin 1	1063676	42	Hypertension	LSCS	Twin Pregnancy		Clear	36	1.6	Female	Yes		FFO		Shifted to			3	30	No	0	Preterm/LBW	None	-	12 Days	Discharged-	Preterm/LBW
Siddavva	1063836	20	None	AVD		Poor Maternal	Clear	36	2.4	Male	No	<60 sec	CPAP	Shifted to NICU		5	30			Yes	3	Respiratory	Nasal CPAP	3 Days	9 Days	Discharged-	Perinatal asphyxia wtih
Komal	1064281	23	None	LSCS	Prev LSCS		Clear	37	2.9	Female	Yes		FFO		Improved			3	10								
Gangamma	1064287	27	Other	LSCS	Prev LSCS/RHD		Clear	39	2.5	Female	Yes		FFO		Improved			3	5								
Krutika	1064573	23	PROM	LSCS	Anamnios		Clear	39	3	Female	Yes		FFO		Improved			2	15								
Afreen	1064468	28	Hypertension	LSCS	Prev LSCS/PE		Clear	38	2.8	Female	Yes		CPAP	Improved		5	5										
Ganga	1065355	32	Other	LSCS	Prev LSCS		Clear	40	3.6	Male	Yes		FFO		Improved			2	10								
Vijaya	1066199	22	Thyroid	LSCS	Failure of induction		MSL	40	2.6	Female	No	<60 sec	FFO		Shifted to			5	45	Yes	1	Perinatal	O2 by nasal	1 Day	7 Days	Discharged -	Perinatal asphyxia with
Arati	1066494	22	None	LSCS	MSL/Fetal distress		Clear	37	2.1	Male	Yes		FFO		Improved			2	10								
Tabassum	1067141	22	None	NVD			MSL	39	2.4	Female	Yes		CPAP	Improved		5	10										
Laxmi	-	21	Other	LSCS	CPD/Fetal distress		Clear	40	3.9	Male	No	<60 sec	CPAP	Shifted to NICU		5	15			Yes	2	Perinatal	O2 by nasal	2 Day	1 Month	Discharged -	Perintatal
Ashwini	1076751	19	None	NVD			Clear	40	2.6	Male	Yes		CPAP	Improved		5	10										
Vidya	1076175	25	None	LSCS	CPD/Fetal distress		MSL	40	3.5	Female	Yes		CPAP	Improved		5	15										
Savita	1072402	25	Other	LSCS	Fetal distress		Clear	35	1.8	Female	Yes		FFO		Shifted to			2	20	No	0	Late preterm/LBW	None	0	10 Days	Discharged -	Late preterm/LBW
Akshata	1072526	-	None	LSCS	Prev LSCS		Clear	37	2.4	Female	Yes		CPAP	Improved		5	10										
Roopa	1072545	-	None	LSCS	Oligohydramnios		Clear	40	3.2	Female	Yes		FFO		Improved			2	10								
Basavva	1072590	23	Diabetes mellitus	LSCS	Fetal distress/MSL		MSL	37	3.7		Yes		CPAP	Improved		5	5										
Priyanka	1072795	26	-	LSCS	Deep transverse		Clear	40	2.9	Male	Yes		CPAP	Improved		5	10										
Renuka	1075102	20	None	NVD			Clear	39	2.9	Male	Yes		FFO		Improved			2	10								
Rajashri	1075075	-	Diabetes mellitus	LSCS	Prev LSCS		Clear	37	2.2	Male	Yes		CPAP	Improved		5	15										
Kakersha	1075382	25	None	LSCS	CPD		Clear	40	3.7	Female	Yes		FFO		Improved			5	10								
Sunita	1075671	-	None	AVD		Poor bearing	Clear	37	3	Male	Yes		FFO		Improved			2	20								
Sarika	1095554	25	PROM	NVD			Clear	40	2.8	Male	Yes		FFO		Shifted to			2	10	Yes	1	Respiratory Distress	O2 by nasal	1	3 Days	Discharged -	TTN
Mehjabeen	-	23	None	AVD		Poor bearing	Clear	38	2	Male	Yes		FFO		Improved			2	10								
Laxmi	-	22	Thyroid	LSCS	Fetal distress/MSL		MSL	41	2.1	Female	Yes		FFO		Improved			2	10								
Asha	-	35	None	LSCS	Prev LSCS		Clear	39	2.8	Female	Yes		CPAP	Improved		5	10										
Yamuna	-	19	Diabetes mellitus	LSCS	Fetal distress/MSL		MSL	38	3.3	Male	Yes		FFO		Improved			2	20								

Mamata	-	22	None	LSCS	Fetal distress/MSL		MSL	39	3.4	Female	Yes		CPAP	Improved		5	15										
Misbah	1099536	23	None	LSCS	Fetal distress/MSL		MSL	39	3.2	Male	Yes		CPAP	Improved		5	5										
Laxmi	1089082	-	Thyroid, Other	LSCS	MSL		MSL	41	2.6	Female	Yes		FFO		Improved			2	15								
Kajol	1087730	25	PROM	NVD			Clear	37	3	Male	Yes		FFO		Improved			3	15								
Asha	108213	35	None	LSCS	Prev LSCS		Clear	39	2.8	Female	Yes		CPAP	Improved		5	10										
Bharati	1088378	21	None	NVD			Clear	38	3.2	Female	Yes		CPAP	Improved		5	5										
Akshata	1089073	24	PROM	LSCS	Fetal distress/MSL		Clear	38		Male	Yes		FFO		Improved			2	20								
Anjana	1089144	22	None	LSCS	Prev LSCS		Clear	38	2.6	Male	Yes		FFO		Improved			2	5								
Priyanka	1089611	35	None	LSCS	Prev LSCS		Clear	39	2.8	Female	Yes		CPAP	Improved		5	10										
Vidya	1089620	35	FGR	LSCS	Prev LSCS		Clear	37	2.5	Male	Yes		FFO		Improved			2	10								
Laxmi	10890426	-	Diabetes mellitus,	NVD			Clear	36	2.6	Male	Yes		CPAP	Improved		5	10										
Sunanda	1090625	22	None	LSCS	Prev LSCS		Clear	40	3.4	Male	Yes		FFO		Improved			2	20								
Pooja	1090894	25	Oligohydramnios	NVD			Clear	38	2.7	Female	Yes		CPAP	Improved			5	10									
Chaitralo	1091074	26	FGR	NVD			Clear	38	2.3	Female	Yes		CPAP	Improved			5	15									
Sakshi	1091232	32	Rh Negative	NVD			Clear	39	2.3	Female	Yes		FFO		Improved	Improved		3	10								
Vanita	1091351	31	PROM	NVD			Clear	37	2.5	Male	Yes		CPAP	Improved		5	10										
Ankita	1091414	23	None	NVD			Clear	37	2.3	Male	Yes		FFO		Improved			3	15								
Saba	1091846	21	None	NVD			Clear	40	3.1	Female	Yes		CPAP	Improved		5	5										
Geeta	1091841	-	Diabetes mellitus,	LSCS	Failure of induction		Clear	39	2.9	Female	Yes		FFO		Improved			2	15								
Sujata	1092198	23	Hypertension, Severe	LSCS	Pre-eclampsia		Clear	38	2.8	Male	Yes		CPAP	Improved		5	20										
Shalan	1092541	26	-	LSCS	Prev LSCS		Clear	38	2.7	Male	Yes		FFO		Improved			2	5								
Bibi Fatima	1092933	20	None	NVD			Clear	39	3.9	Male	Yes		FFO		Improved			3	10								
Ravikala	1097878	25	None	NVD			MSL	40	3	Male	Yes		CPAP	Shifted to NICU		5	10			No	0	Perinatal depression	None	0	2 Days	Discharged-	Perinatal depression
Megha	1095322	26	None	LSCS	Prev LSCS		Clear	40	3.1	Male	Yes		CPAP	Improved		5	15										
Sarika	1095594	25	PROM,	NVD			Clear	40	2.8	Male	Yes		FFO		Shifted to			3	20	No	0	Perinatal depression	None	0	3	Discharged	Perinatal depression
Ashwini	1095919	27	HBsAg +	NVD			Clear	37	2.5	Female	Yes		FFO		Improved			5	20								
Arati	1095727	22	None	NVD			Clear	38	2.6	Female	Yes		CPAP	Improved		5	15										
Bhagyashri	1096249	26	Hypertension	LSCS	Prev LSCS		Clear	38	3.7	Female	Yes		CPAP	Improved		5	10										
Meenaz	1096295	24	Rh Neg	NVD			Clear	40	3	Male	Yes		CPAP	Improved		5	15										
Nikita	1096622	24	None	NVD			Clear	38	2.5	Male	Yes		FFO		Improved			2	10								
Shraddha	1096706	24	None	NVD			MSL	37	2.4	Female	Yes		FFO		Improved			3	30								
Jyoti	1096997	24	Hypertension,	LSCS	Pre-eclampsia		Clear	37	2.6	Female	Yes		CPAP	Improved		5	10										
Sheetal	1097773	23	None	LSCS	Prev LSCS		Clear	36	2.8	Male	Yes		FFO		Improved			5	10								
Akshata	1097823	20	None	NVD			Clear	40	3	Male	Yes		FFO		Improved			3	20								
Lagmavva	1097853	25	None	LSCS	Prev LSCS		Clear	39	3	Female	Yes		FFO		Improved			3	5								
Pritam	-	24	Hypertension	LSCS	Failure of induction		Clear	39	2.8	Female	Yes		FFO		Improved			5	5								
Veena	1054930	-	Short stature	LSCS	Failed Induction		Clear	39	3.4	Male	Yes		FFO		Improved			5	5								
Sana	-	24	None	LSCS	Prev LSCS		Clear	38	2.8	Female	Yes		CPAP	Improved		5	10										
Ankita	1099344	21	None	NVD			Clear	38	3.4	Male	Yes		CPAP	Improved		5	15										
Pooja	1099849	24	Thyroid, Short	NVD			Clear	37	2.5	Male	Yes		FFO		Improved			3	10								
Ashwini	1099698	29	None	LSCS	Prev LSCS		Clear	38	3.1	Male	Yes		FFO		Improved	p		3	15								
Shubhangi	1099708	26	None	NVD			Clear	38	3.2	Male	Yes		CPAP	Improved		5	10										
-	-	-	-	-	-		-	-	-	-	-	-	-	-	-	-	-	-	-								
Shobha	1101126	25	-	LSCS	MSL, Fetal distress		MSL	42	2.6	Male	Yes		CPAP	Improved		5	20										
Shilpa	1101343	24	Hypertension	LSCS	CPD		Clear	39	3.1	Male	Yes		CPAP	Improved		5	10										
Zakiya	1101970	-	None	NVD			Clear	37	2.6	Male	Yes		CPAP	Improved		5	5										
Shruti	1102162	25	Anaemia	NVD			Clear	39	2.6	Female	Yes		CPAP	Improved		5	5										
Poonam	1102173	25	None	NVD			Clear	41	3.5	Female	Yes		CPAP	Improved		5	10										
Pooja	1102230	23	None	LSCS	MSL, Fetal distress		MSL	39	3.1	Female	Yes		FFO		Improved			5	20								
Asawari	1102241	-	Diabetes mellitus,	NVD			Clear	37	2.45	Male	Yes		FFO		Improved			3	10								
Snehal	1102246	22	Hypertension	LSCS	Prev LSCS		Clear	38	2.8	Female	Yes		FFO		Improved			3	10								
Suchita	1102766	23	Acute GE	NVD			Clear	38	2.8	Male	Yes		CPAP	Improved		5	10										
Zeba	1102772	26	PROM, FGR	NVD			Clear	37	2.2	Female	Yes		FFO		Improved			3	5								
Sushama	1102905	31	Fetal macrosomia	LSCS	Prev LSCS		Clear	38	4	Male	Yes		CPAP	Improved		5	15										
Pooja	1098951	22	None	NVD			Clear	36	2.4	Male	Yes		FFO		Shifted to			5	25	Yes	3		Nasal CPAP	1	3	Improved,	Transient tachypnea of
Snehal	1103076	21	Hypertension,	LSCS	Prev LSCS		Clear	39	2.9	Male	Yes		FFO		Shifted to			3	30	Yes	1		O2 by nasal	1	4	Improved,	Transient tachypnea of
Nikita	1103639	22	Hypertension,	NVD			Clear	40	3.2	Male	Yes		CPAP	Shifted to NICU		5	15			Yes	1		O2 by nasal	1	3	Improved,	Perinatal asphyxia with
Priyanka	1105154	23	Oligohydramnios	LSCS	MSL, Fetal distress		MSL	35	2.4	Male	Yes		FFO		Improved			3	15								
Neelamma	1105202	18	IUGR	NVD			Clear	39	2.4	Female	Yes		CPAP	Improved		5	10										
Sushmita	1105345	21	PROM	LSCS	Oligohydramnios		Clear	39	3.1	Male	Yes		FFO		Improved			3	10								
Shivakka	1105385	27	Thyroid	LSCS	Prev LSCS		Clear	39	3.1	Male	Yes		FFO		Improved			5	10								
Brunda	1106015	22	PROM, FGR	LSCS	MSL, Fetal distress		MSL	39	2	Female	Yes		CPAP	Improved		5	10										
Jyothi	1106104	-	PROM	LSCS	Prev LSCS		Clear	38	2.8	Male	Yes		FFO		Improved			3	15								
Bharathi	1106615	26	Pre-eclampsia + Rh	LSCS	MSL, Fetal distress,		MSL	39	3	Male	Yes		FFO		Improved			5	15								
Reshma	1107020	30	None	LSCS	Prev LSCS		Clear	40	3.7	Male	Yes		CPAP	Improved		5	10										
Sukanya	1107039	21	Rh Neg	NVD			Clear	40	3.2	Female	Yes		FFO		Improved			3	10								
Mayavva	1107117	19	PROM	LSCS	Oligohydramnios		Clear	38	2.3	Female	Yes		CPAP	Improved		5	10										
Sumayya	1128381	26	Diabetes mellitus	NVD			Clear	38	2.5	Male	Yes		CPAP	Improved		5	15										
Shashikala	1128545	20	None	NVD			Clear	39	2.3	Female	Yes		CPAP	Improved		5	15										
Malavva	1128408	26	PROM	LSCS	Anamnios		Clear	36	2	Female	Yes		FFO		Improved			3	15								