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**VIJAYAPURA, KARNATAKA**

# "STUDY ON THE EFFICACY OF FUROSEMIDE NEBULISATION IN TRANSIENT TACHYPNEA OF NEWBORN"

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PG IN PAEDIATRICS

UNDER THE GUIDANCE OF

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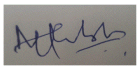

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## LIST OF ABBREVIATIONS

**TTN**: Transient Tachypnea of the Newborn

**LSCS**: Lower Segment Cesarean Section

**CPD**: Cephalopelvic Disproportion

**PIH**: Pregnancy-Induced Hypertension

**SPO2**:Peripheral Capillary Oxygen Saturation

**NICU**: Neonatal Intensive Care Unit

**CRP**: C-Reactive Protein

**HFNC**: High-Flow Nasal Cannula

**CPAP**: Continuous Positive Airway Pressure

**RDS**: Respiratory Distress Syndrome

**CVS**: Cardiovascular System

**RS**: Respiratory System

**CNS**: Central Nervous System

**PA**: Physical Assessment

**HC**: Head Circumference

**MAC**: Mid-Arm Circumference

**GRBS**: Glucose Random Blood Sugar

**Hb**: Hemoglobin

**PCV**: Packed Cell Volume

**TC**: Total Count

**N/L**: Neutrophil/Lymphocyte Ratio

**PCO2**: Partial Pressure of Carbon Dioxide

**PO2**: Partial Pressure of Oxygen

**HCO3**: Bicarbonate

**Na**: Sodium

**K**: Potassium

**Ca**: Calcium

**CXR**: Chest X-Ray

**USG**: Ultrasound

**2D ECHO**: Two-Dimensional Echocardiography

**BPD**: Bronchopulmonary Dysplasia

**ENaC**: Epithelial Sodium Channels

**Na+/K+-ATPase**: Sodium-Potassium Adenosine Triphosphatase

**MD**: Mean Difference

**SD**: Standard Deviation

**df**: Degrees of Freedom

**p**: p-value (Probability Value)

**ABG**: Arterial Blood Gas

**DBF**: Direct Breastfeeding

**M/H/O**: Maternal History Of

**GDM**: Gestational Diabetes Mellitus

**AAP**: American Academy of Pediatrics

**KMC**: Kangaroo Mother Care

**UL**: Upper Limb

**LL**: Lower Limb

## INTRODUCTION

Transient Tachypnea of the Newborn (TTN) is a prevalent cause of respiratory distress in neonates, typically arising from delayed clearance of fetal lung fluid. Although generally benign and self-limited, TTN can lead to significant morbidity, necessitating interventions to reduce respiratory symptoms, hospital stays, and the need for oxygen therapy [23,19]. The pathophysiology of TTN involves retained alveolar fluid, which hampers effective gas exchange. Furosemide, a loop diuretic known for reducing pulmonary edema, has been proposed as a potential treatment to enhance fluid clearance [1]. This study aims to evaluate the efficacy of furosemide nebulization in managing TTN in term neonates by reducing morbidity, shortening the clinical course, and minimizing the duration of oxygen therapy and respiratory symptoms [2]. While intravenous and oral furosemide have shown limited benefits in previous studies, the efficacy of nebulized furosemide remains underexplored [13]. A pilot study suggested that nebulized furosemide might reduce respiratory distress by facilitating faster alveolar fluid clearance, but comprehensive data on its efficacy and safety are needed [2]. This study proposes a randomized, double-blind, placebo-controlled trial to address these gaps, aiming to provide evidence-based insights into the management of TTN and potentially improve neonatal outcomes [13].

# AIMS AND OBJECTIVES

## Aim

To study the effects of furosemide nebulization in transient tachypnea of newborns in preterm and term infants.

## Objectives

To study the effects of furosemide nebulization in terms of

1. The duration of NICU stay
2. The duration of oxygen requirement
3. The outcome at the end of the NICU stay

# REVIEW OF LITERATURE

## Definition

Transient Tachypnea of the Newborn (TTN) is a respiratory condition typically observed in neonates, characterized by rapid breathing shortly after birth. It results from delayed clearance of fetal lung fluid, leading to respiratory distress. TTN generally affects infants born at late preterm or term gestation. Despite being a self-limited condition that usually resolves within 72 hours, TTN can cause significant morbidity if not correctly managed or if it is misdiagnosed as other serious conditions such as sepsis, Respiratory Distress Syndrome (RDS), or congenital heart disease [17,24].

## Pathophysiology

The pathophysiology of TTN involves the failure of the fetal lung fluid to transition from a secretory to an absorptive state at birth. Normally, the clearance of lung fluid is facilitated by hormonal changes near the end of pregnancy and during spontaneous labor, including surges in glucocorticoids and catecholamines. These hormones activate amiloride-sensitive sodium channels in the alveolar epithelium, which play a crucial role in lung fluid clearance. The sodium is actively transported into the interstitium via basolateral Na+/K+-ATPase, followed by the passive movement of chloride and water through paracellular and intracellular pathways [23].

In TTN, this clearance process is delayed or disrupted, leading to transient pulmonary edema. This fluid accumulation can compress compliant airways, resulting in airway obstruction, air trapping, and ventilation-perfusion mismatch. The presence of fluid in the lungs decreases pulmonary compliance and impedes effective gas exchange. Additionally, the functional residual capacity may be reduced due to airway

obstruction, while thoracic gas volume may increase secondary to air trapping. Hormonal imbalances, such as lower levels of catecholamines, are believed to contribute to the inadequate transition from fluid secretion to absorption, particularly in cases involving cesarean delivery without labor or precipitous birth [23].

**Etiology**

The etiology of Transient Tachypnea of the Newborn (TTN) involves several factors that contribute to the delayed clearance of fetal lung fluid, leading to respiratory distress shortly after birth. Key risk factors include:

1. **Cesarean Delivery Without Labor**: Infants born via cesarean section without preceding labor are at higher risk for TTN. The absence of labor means the neonate does not experience the hormonal changes that facilitate lung fluid clearance, particularly the surge in catecholamines that occurs during spontaneous labor [4].

2. **Precipitous Birth**: Rapid delivery can also result in insufficient hormonal preparation for the transition from fetal to neonatal respiration. The sudden change from the intrauterine to the extrauterine environment may not allow enough time for the lung fluid to be absorbed effectively) [4].

3. **Late Preterm and Early Term Births**: Infants born at 34 to 37 weeks gestation have an increased risk of TTN due to their relatively immature lungs and the reduced expression of epithelial sodium channels (ENaCs) necessary for fluid clearance. This immaturity can lead to delayed resorption of lung fluid and subsequent respiratory distress [24].

4. **Male Gender and Family History of Asthma**: Male infants and those with a family history of asthma, particularly maternal asthma, are at greater risk of developing TTN. The underlying mechanisms may involve genetic predispositions that affect lung development and fluid clearance [3,21].

5. **Maternal Conditions**: Various maternal conditions such as diabetes, pregnancy-induced hypertension, and macrosomia (larger-than-average newborns) are associated with a higher incidence of TTN. These conditions can lead to an increased volume of lung fluid and more difficulty in clearing it after birth [24].

6. **Other Factors**: Additional risk factors include multiple gestations, prolonged labor, excessive maternal sedation, and a high volume of maternal intravenous fluids during labor. These factors can contribute to the delayed clearance of lung fluid by altering the hormonal and physical processes required for effective fluid resorption [24] .

7. In summary, TTN is multifactorial in origin, with both intrinsic and extrinsic factors playing a role in its development. Understanding these risk factors helps in identifying at-risk infants and implementing appropriate monitoring and management strategies [24].

## Epidemiology

TTN affects approximately 0.3% to 0.6% of term deliveries and up to 1% of preterm deliveries. Several risk factors increase the likelihood of developing TTN, including cesarean delivery without labor, precipitous birth, and preterm birth. These conditions are associated with delayed or abnormal clearance of fetal lung fluid due to the

absence of hormonal changes that accompany spontaneous labor. Additional risk factors include male gender, family history of asthma, maternal diabetes, pregnancy-induced hypertension, and macrosomia. Cesarean delivery, particularly without labor, is a significant risk factor as it circumvents the natural hormonal and physiological processes that aid in lung fluid clearance [4,3,24].

**Clinical Presentation and Diagnosis**

TTN typically presents within the first six hours after birth with symptoms of tachypnea (respiratory rate >60 breaths per minute) and signs of mild to moderate respiratory distress, such as retractions, grunting, nasal flaring, and cyanosis. These symptoms usually respond to supplemental oxygen, typically at FiO2 levels less than 0.40. Diagnosis is largely clinical, based on the exclusion of other potential causes of respiratory distress, such as sepsis, RDS, and congenital heart defects. Chest radiographs in TTN usually show signs of retained fetal lung fluid, including prominent perihilar streaking, fluid in the fissures, and hyperinflation [24] .

**Management and Treatment**

Management of TTN is primarily supportive, focusing on maintaining adequate oxygenation and respiratory support. Supplemental oxygen is administered to keep oxygen saturation levels above 90%. In more severe cases, continuous positive airway pressure (CPAP) or high-flow nasal cannula (HFNC) may be required to maintain adequate lung expansion and reduce the work of breathing. Invasive mechanical ventilation is rarely necessary and is typically reserved for cases where respiratory distress is severe and other serious conditions have been ruled out. Fluid

management is also crucial, as relatively restricted fluid intake has been shown to decrease the duration of respiratory support in severe TTN cases [24].

**Pharmacological Interventions**

Furosemide, a loop diuretic, has been studied for its potential to enhance alveolar fluid clearance in TTN. While intravenous and oral furosemide have shown limited benefits in reducing the duration of respiratory symptoms and hospitalization, nebulized furosemide remains less explored. Preliminary studies suggest that nebulized furosemide may help reduce respiratory distress by facilitating faster alveolar fluid clearance. However, comprehensive data on its efficacy and safety are still needed. Other pharmacological agents, such as β2-agonists like salbutamol, have shown promise in enhancing lung fluid clearance but require further research to establish their efficacy and safety [1,2,13,16].

**Complications and Prognosis**

Although TTN is typically self-limited and resolves without long-term effects, it can complicate neonatal care by delaying oral feeding and parental bonding. Moreover, there is a potential link between TTN and reactive airway disease in childhood, suggesting that infants with a history of TTN may be at increased risk for respiratory issues later in life. Despite these concerns, the overall prognosis for infants with TTN is excellent, with most cases resolving within 72 hours and no risk of recurrence [21,25]

.

## Conclusion

TTN is a common neonatal respiratory disorder that generally resolves with supportive care. The search for effective pharmacological treatments continues, with nebulized furosemide offering a promising avenue for reducing morbidity associated with TTN. Further research is essential to establish the efficacy and safety of such treatments, which could significantly improve clinical outcomes for affected neonates [1,2,13].

## METHODOLOGY

**Place of study:** NICU of Shri BM Patil Medical College Hospital and Research Centre, BLDE(deemed to be university), Vijayapura, Karnataka.

**Duration of study:** February 2023 to January 2024

**Study design:** Prospective comparative study

**Inclusion criteria:**

100 neonates born via C-section with TTNB with:

1. Onset of tachypnea within 6 hours after birth.

2. Persistence of tachypnea for at least 12 hours.

3. Chest roentgenogram or Ultrasound lung, consistent with TTN.

**Exclusion criteria:**

Neonates with

1. History of meconium aspiration or premature rupture of membranes

2. Other conditions like polycythemia, sepsis, pneumonia, RDS, and aspiration syndromes

3. Cyanotic heart diseases

## METHOD OF COLLECTION OF DATA

All late preterm and term babies born via C-section without labor, clinically normal, after excluding RDS, and diagnosed as TTN will be randomly placed in one of the nebulization, study, or control groups. The neonates are observed for the duration of oxygen requirement, the period of NICU stay and the outcome at the end of the stay.

**Group A** received furosemide nebulization 2 mg/kg at the time of diagnosis followed by 1 mg/kg, 6 hours later (dissolved in 2.5ml of sterile normal saline carrier).

**Group B** They received nebulization with 2.5ml normal saline nebulization as a placebo, on admission and 6 hours after admission.

Besides the above intervention, all the neonates were managed as per the standard protocols of our NICU for TTN.

With the anticipated outcome of furosemide Mean ±SD of weight loss of neonates in the first 24 hours of life 4.6±3.5 (1), the study required a sample size of 100 subjects with 95% level of confidence and 0.7% absolute precision, Using Statulator software (http://statulator.com/SampleSize/ss1P.html)

Formula used

• $n = \frac{z^2 p*q}{d^2}$

Where Z= Z statistic at α level of significance

d2= Absolute error

P= Proportion rate

q= 100-p

Formula used

- **$n = \frac{(z_\alpha + z_\beta)^2 \, 2 \, p*q}{MD^2}$**

Where Z= Z statistic at a level of significance

MD= Anticipated difference between two proportions

**P=Common Proportion**

q= 100-p

**Statistical Analysis**

• The data obtained was entered into a Microsoft Excel sheet, and statistical analysis was performed using a statistical package for the social sciences ( Version 20).

• Results were presented as Mean ±SD, Median and interquartile range, frequency, percentages, and diagrams.

• To find the association between furosemide nebulization and the duration of oxygen therapy Pearson/Spearman correlation analysis was done.

• Association between categorical data will be estimated using the chi-square test.

• $p<0.05$ was considered statistically significant.

## OBSERVATIONS AND RESULTS

### Table:01 Distribution of study subjects based on age distribution

| **Gender** | Group A (Furosemide nebulisation) | Group B (Normal Saline Nebulisation) |
|---|---|---|
| Male | 8(16%) | 22(44%) |
| Female | 42(84%) | 28(66%) |
| Total | 50 | 50 |

The study on the efficacy of furosemide nebulization in transient tachypnea of the newborn compared two groups, Group A and Group B, with a total of 50 newborns in each group. Group A consisted of 8 males (16%) and 42 females (84%), while Group B had 22 males (44%) and 28 females (56%). This data highlights a notable gender distribution disparity between the two groups. Despite this gender imbalance, the total number of participants in each group remained equal, ensuring a balanced sample size for evaluating the efficacy of the treatment across different genders. This study's design allows for an assessment of furosemide nebulization's impact on transient tachypnea while considering potential gender differences in response to the treatment.

Graph 1: A bar graph representation of age distribution

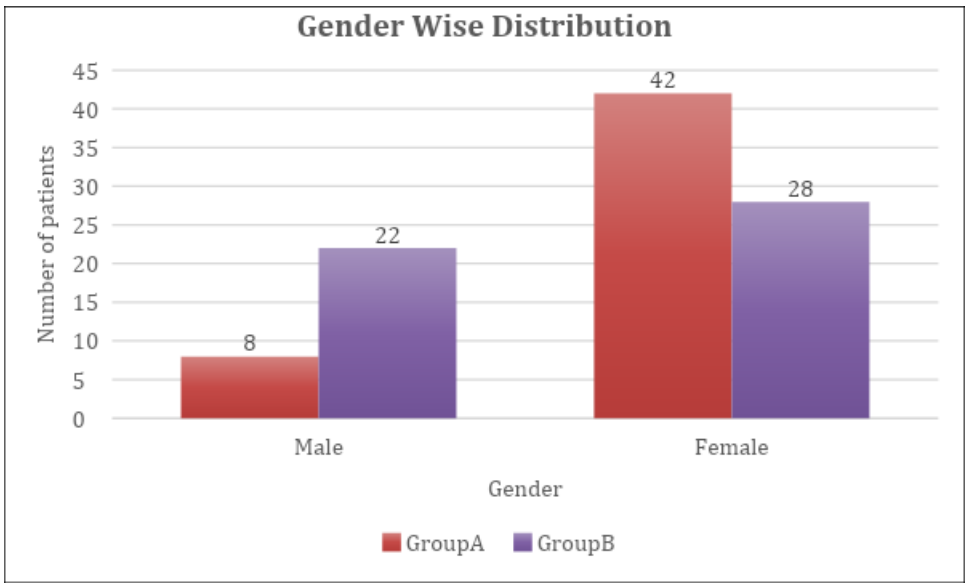


**Table:02 Distribution of study subjects based on the mode of delivery**

| Mode Of Delivery | Group A (Furosemide nebulisation) | Group B (Normal Saline Nebulisation) |
|---|---|---|
| LSCS | 47 | 50 |
| Elective LSCS | 3 | 0 |
| Total | 50 | 50 |

The study on the efficacy of furosemide nebulization in transient tachypnea of the newborn (TTN) investigates the distribution of delivery methods between the two groups. Group A consists of 47 cases delivered by lower segment cesarean section (LSCS) and 3 by elective LSCS, totaling 50. Similarly, Group B comprises 50 cases, all delivered by LSCS, with none via elective LSCS. The lack of elective

LSCS in Group B may influence comparative outcomes, indicating a need for further examination of how delivery type impacts treatment efficacy.

**Graph:02 A bar graph representation of the mode of delivery**

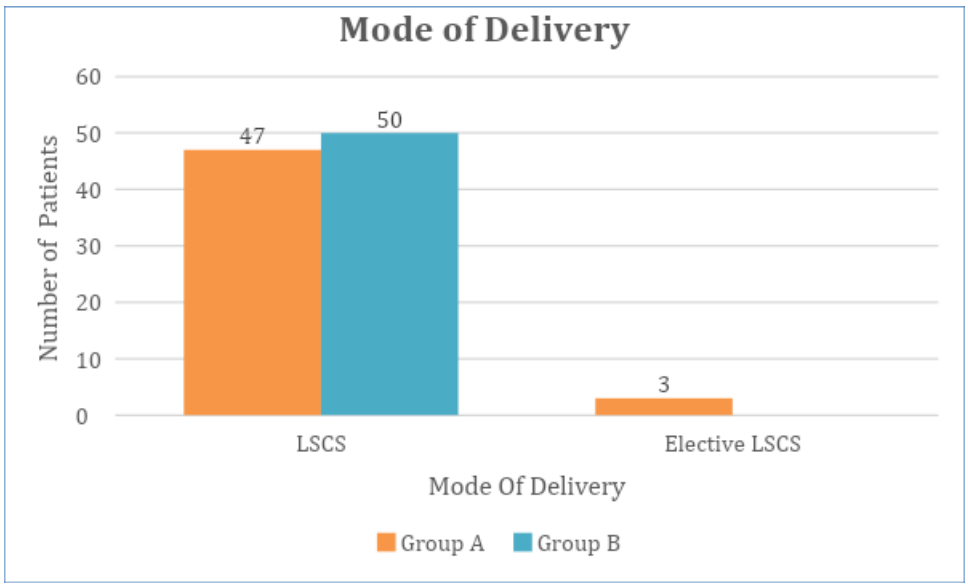

**Table:03 Distribution of study subjects based on the indication of delivery.**

| Indication | Group A (Furosemide nebulization) | Group B (Normal saline nebulization) |
|---|---|---|
| CPD | 5 | 5 |
| Previous LSCS | 9 | 9 |
| Oligohydramnios | 7 | 8 |
| Preeclampsia | 6 | 5 |
| Abruptio placenta | 1 | 2 |
| Multiple pregnancies | 1 | 2 |
| PIH | 1 | 1 |
| Eclampsia | 8 | 6 |
| Fetal distress | 5 | 4 |
| Elective LSCS | 3 | 0 |
| Obstructed labour | 1 | 1 |
| Breech presentation | 1 | 1 |
| Total | 50 | 50 |

**Table:04 Distribution of study subjects based on downe score**

| Downe Score | Group A | Group B |
|---|---|---|

| (Time analysis) | (Furosemide nebulisation) | (Normal Saline Nebulisation) |
|---|---|---|
| | Number of patients | Number of patients |
| On Admission | | |
| 4 | 17 | 15 |
| 3 | 13 | 12 |
| 2 | 20 | 23 |
| 24 Hours | | |
| 4 | 0 | 2 |
| 3 | 0 | 0 |
| 2 | 35 | 30 |
| 1 | 15 | 18 |
| 48 Hours | | |
| 1 | 3 | 11 |
| 0 | 47 | 39 |
| 72 Hours | | |
| 0 | 50 | 50 |

The study on the efficacy of furosemide nebulization in treating transient tachypnea of the newborn compared two groups: Group A receiving furosemide nebulization and Group B receiving normal saline nebulization. Both groups were assessed using the Downe Score, which measures respiratory distress, on admission and at 24, 48, and 72 hours. On admission, Group A had slightly more patients with moderate respiratory distress (Downe score 4)

compared to Group B. At 24 hours, all patients in Group A showed improvement, with no patients remaining at a score of 3, while Group B still had 4% of patients at a score of 4. By 48 hours, a majority of Group A patients (54%) had no respiratory distress (score 0) compared to 22% in Group B. By 72 hours, all patients in both groups had no respiratory distress. This indicates that while both methods are effective, furosemide nebulization leads to a quicker reduction in respiratory distress in newborns compared to normal saline nebulization.

**Table:05 Distribution of study subjects based on oxygen saturation**

| Variable | Group A (Furosemide nebulisation) | | Group B (Normal Saline Nebulisation) | | |
|---|---|---|---|---|---|
| SPO2 | Mean | S. D | Mean | S. D | p-value |
| At admission | 94.6 | 1.34 | 94.52 | 1.43 | 0.77 |
| At 24 Hours | 98.58 | 0.72 | 98.06 | 1.31 | 0.01 |
| At 48 Hours | 99.26 | 0.99 | 99.04 | 0.59 | 0.18 |
| T-test was performed | | | | | |

The study compares the efficacy of furosemide nebulization (Group A) versus normal saline nebulization (Group B) in improving oxygen saturation in newborns. On admission, the mean SPO2 levels were similar between Group A (94.6 ± 1.34) and Group B (94.52 ± 1.43) with no significant difference (p = 0.77). However, at 24 hours,

Group A showed slightly higher mean SPO2 (98.58 ± 0.72) compared to Group B (98.06 ± 1.31), with a p-value of 0.01. By 48 hours, both groups had high SPO2 levels (Group A: 99.26 ± 0.99, Group B: 99.04 ± 0.59) with no significant difference (p = 0.18).

**Graph: 03 SpO2 analysis over time.**

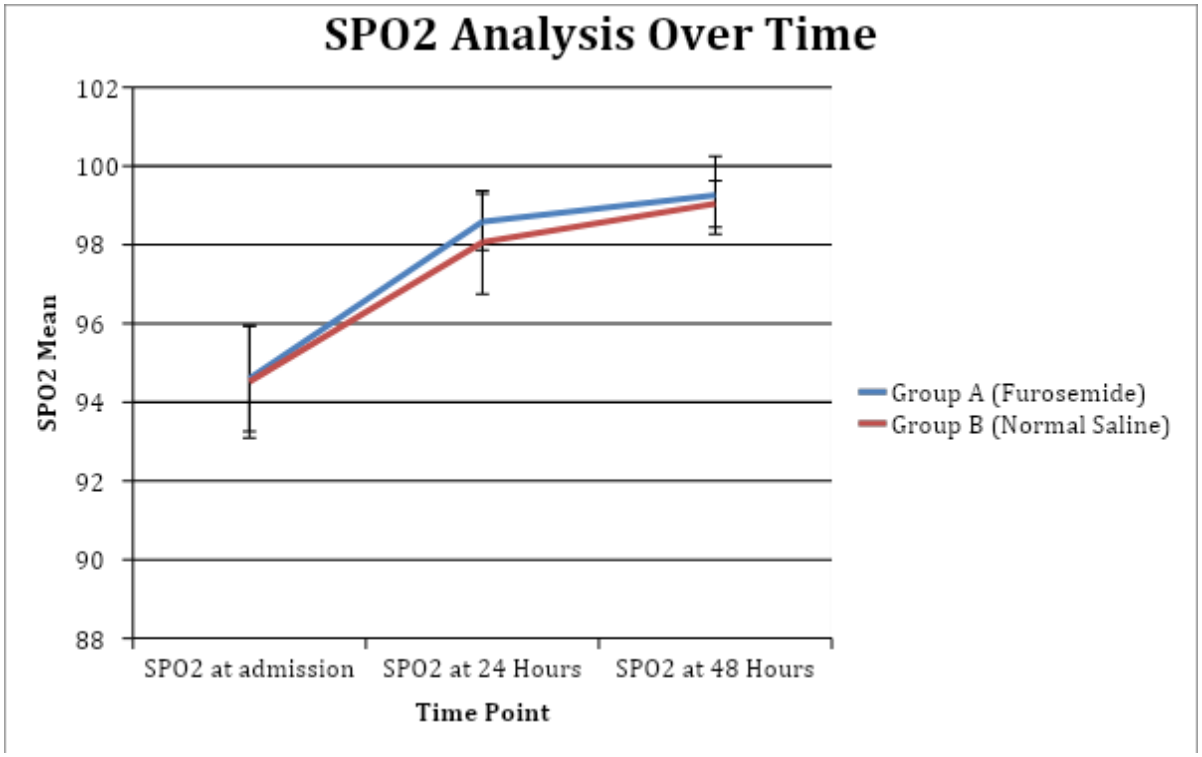

**Table:06 Distribution of study subjects based on respiration rate.**

| Variable | Group A (Furosemide nebulisation) | | Group B (Normal Saline Nebulisation) | | P Value |
|---|---|---|---|---|---|
| Respiratory Rate | Mean | S. D | Mean | S. D | |
| At admission | 62.44 | 2.91 | 63.71 | 2.57 | 0.023 |
| At 24 Hours | 52.64 | 3.94 | 54.36 | 4.82 | 0.05 |
| At 48 Hours | 48 | 2.52 | 49.5 | 3.59 | 0.017 |
| T-test was performed | | | | | |

The comparison of respiratory rates between newborns treated with furosemide nebulization (Group A) and normal saline nebulization (Group B) shows significant improvement over time in both groups. On admission, Group A had a mean respiratory rate of 62.44, slightly lower than Group B's 63.71, with a statistically significant difference ($p = 0.023$). At 24 hours, both groups exhibited a substantial decrease in respiratory rates, with Group A at 52.64 and Group B at 54.36, showing a borderline significant difference ($p = 0.05$). By 48 hours, the mean respiratory rate in Group A further reduced to 48, slightly lower than Group B's 49.5, with a significant p-value of 0.017. These results indicate that while both methods effectively reduce respiratory rate in newborns with TTN, furosemide nebulization may lead to slightly greater improvement over 48 hours.

**Table:07 Distribution of study subjects based on the mode of oxygen**

| Mode of Oxygen | Group A | | Group B | |
|---|---|---|---|---|
| | (Furosemide nebulisation) | | (Normal Saline Nebulisation) | |
| At Admission | subjects | mean | subjects | mean |
| HFNC | 8 | 16 | 13 | 26 |
| HOOD OXYGEN | 40 | 80 | 27 | 54 |
| CPAP | 2 | 4 | 9 | 18 |
| After 24 hours | | | | |
| HFNC | 5 | 10 | 8 | 16 |

| | | | | |
|---|---|---|---|---|
| HOOD OXYGEN | 22 | 44 | 20 | 40 |
| CPAP | 2 | 4 | 7 | 14 |
| NASAL PRONGS | 3 | 6 | 11 | 22 |
| ROOM AIR | 18 | 36 | 4 | 8 |
| After 48 hours | | | | |
| HFNC | 0 | 0 | 2 | 4 |
| HOOD OXYGEN | 3 | 6 | 11 | 22 |
| NASAL PRONGS | 1 | 2 | 8 | 16 |
| ROOM AIR | 46 | 92 | 29 | 58 |
| TOTAL | 50 | 100% | 50 | 100% |
| Chi-square statistic ($\chi^2$): 9.167<br>P-value: 0.027 | | | | |

Comments: The comparison of oxygen delivery methods between newborns treated with furosemide nebulization (Group A) and normal saline nebulization (Group B) reveals significant differences. Group A predominantly used hood oxygen (80%), while Group B used it less frequently (54%). Conversely, high-flow nasal cannula (HFNC) and continuous positive airway pressure (CPAP) were more common in Group B (26% and 18%, respectively) compared to Group A (16% and 4%). The Chi-square test result ($\chi^2 = 9.167$, $p = 0.027$) indicates a statistically significant difference in oxygen delivery methods between the two groups.

**Table:08 Distribution of study subjects based on CRP levels between groups**

| Variable | Group A (Furosemide nebulisation) | | Group B (Normal Saline Nebulisation) | |
|---|---|---|---|---|
| CRP | subjects | S.D | subjects | S.D |
| Positive (> 5 mg/dl) | 9 | 2.249 | 27 | 6.214 |
| Negative (< 5 mg/dl) | 41 | 3.421 | 23 | 2.372 |
| T value = 2.902, df=98, P value- 0.004 | | | | |

Comments: The significantly lower mean CRP level in Group A compared to Group B ($p = 0.004$) is reflected by CRP levels in newborns with transient tachypnea of the newborn (TTN). The statistical analysis supports the conclusion that there is a significant difference in CRP levels between the two groups.

**Table:09 Distribution of study subjects based on birth weight.**

| Variable | Group A (Furosemide nebulisation) | | Group B (Normal Saline Nebulisation) | |
|---|---|---|---|---|
| | mean | S.D | mean | S.D |
| Birth weight | 2340.8 | 591.91 | 2062 | 558.58 |
| T value =2.413, df=98, P value =0.0017 | | | | |

Comments: This table compares the mean birth weights of newborns treated with furosemide nebulization (Group A) and normal saline nebulization (Group B) which indicates a significant difference. Group A had a higher mean birth weight of 2340.8 grams (± 591.91), whereas Group B had a mean birth weight of 2062 grams (± 558.58). The t-test result, with a t-value of 2.413 and 98 degrees of freedom, yielded a p-value of 0.0017, demonstrating a statistically significant difference between the groups. This suggests that newborns in the furosemide nebulization group were of significantly higher birth weights compared to those in the normal saline nebulization group, also indicating there were more premature babies in Group B.

**Table:10 Distribution of study subjects based on Ballard score**

| Variable | Group A (Furosemide nebulisation) | | Group B (Normal Saline Nebulisation) | |
|---|---|---|---|---|
| | Mean | S.D | Mean | S.D |
| Ballard score | 30.37 | 6.123 | 28.1 | 5.345 |
| T value=1.974, df=98, P value=0.051 | | | | |

Comments: The mean Ballard score is higher in Group A (30.37) compared to Group B (28.1) which indicates that there were significantly more premature neonates in Group B compared to Group A.

**Table:11 Distribution of study subjects based on oxygen support**

| Variable | Group A (Furosemide nebulisation) | | Group B (Normal Saline Nebulisation) | |
|---|---|---|---|---|
| | Mean | S.D | Mean | S.D |
| Oxygen support | 1.704 | 0.63 | 2.16 | 0.57 |
| T value=-3.7952, df=98, P value=0.0002 | | | | |

The comparison of oxygen support required between newborns treated with furosemide nebulization (Group A) and normal saline nebulization (Group B) reveals a significant difference. Group A had a mean oxygen support requirement of 1.704 (±0.63), whereas Group B had a higher mean requirement of 2.16 (±0.57). The t-test result, with a t-value of -3.7952 and 98 degrees of freedom, produced a highly significant p-value of 0.0002. This indicates that the newborns in the furosemide nebulization group required significantly less oxygen support compared to those in the normal saline nebulization group, suggesting that furosemide nebulization may be more effective in reducing the need for oxygen therapy in treating transient tachypnea of the newborn.

**Table:12 Distribution of study subjects based on the day of initiation of breastfeeding**

| Variable | Group A (Furosemide nebulisation) | | Group B (Normal Saline Nebulisation) | |
|---|---|---|---|---|
| | mean | S.D | mean | S.D |
| Days after initiation of breastfeeding | 1.704 | 0.6 | 2.22 | 0.64 |
| T value=-4.062, df=98, P value=0.0009 | | | | |

The comparison of the number of days of initiation of breastfeeding between newborns treated with furosemide nebulization (Group A) and normal saline nebulization (Group B) indicates a significant difference. Group A had a mean of 1.704 days (±0.6) to initiate breastfeeding, whereas Group B had a higher mean of 2.22 days (±0.64). The t-test result, with a t-value of -

4.062 and 98 degrees of freedom, yielded a p-value of 0.0009. This highly significant p-value suggests that breastfeeding was started earlier in the newborns of the furosemide nebulization group than those in the normal saline nebulization group.

**Table:13 Distribution of study subjects based on weight loss after nebulization after 24 hours and 48 hours**

| Weight Loss | Group A | Group B |
|---|---|---|
| | S.D | S.D |
| after 24 hours | 595.153 | 594.972 |
| after 48 hours | 565.71 | 566.287 |

T value=2.24244, df=98,P value -0.02

The data shows that after nebulization treatment, Group A had a mean weight loss of (S.D. 595.153) after 24 hours, compared to Group B's mean weight loss of (S.D. 594.972). After 48 hours, the mean weight loss for Group A was S.D. 565.71 while Group B's was (S.D. 566.287. The statistical analysis revealed a T value of 2.24244, with 98 degrees of freedom and a P value of 0.02, indicating that the difference in weight loss between the two groups is statistically significant. This suggests that the nebulization treatment administered to Group A had a notably different effect on weight loss compared to Group B, underlining the efficacy of the treatment in influencing weight loss over the observed period.

**Table:14 Distribution of study subjects based on length of the hospital stay**

| Variable | Group A (Furosemide nebulisation) | | Group B (Normal Saline Nebulisation) | |
|---|---|---|---|---|
| | MEAN | S.D | MEAN | S.D |
| Length of the stay (NICU) | 2.96 | 0.97 | 3.76 | 1.105 |
| T value=-3.847, df=98, P value=0.0002 | | | | |

The comparison of the length of stay in the neonatal intensive care unit (NICU) between newborns treated with furosemide nebulization (Group A) and normal saline nebulization (Group B) indicates a significant difference. Group A had a mean NICU stay of 2.96 days (±0.97), whereas Group B had a longer mean stay of 3.76 days (±1.105). The t-test result, with a t-value of -3.847 and 98 degrees of freedom, yielded a highly significant p-value of 0.0002. This suggests that newborns in the furosemide nebulization group had a significantly shorter NICU stay compared to those in the normal saline nebulization group, indicating that furosemide nebulization may be more effective in promoting quicker recovery and discharge in newborns with TTN.

**Table:15 Distribution of study subjects based on the number of days until discharge**

| Variable | Group A (Furosemide nebulisation) | | Group B (Normal Saline Nebulisation) | |
|---|---|---|---|---|
| Number of days until discharge | MEAN | S.D | MEAN | S.D |
| | 3.08 | 1.05 | 3.8 | 1.03 |
| T value=-3.46138 ,df=98,P value=0.0007 | | | | |

The comparison of the number of days until discharge between newborns treated with furosemide nebulization (Group A) and normal saline nebulization (Group B) shows a significant difference. Group A had a mean discharge time of 3.08 days (±1.05), while Group B had a longer mean discharge time of 3.8 days (±1.03). The t-test result, with a t-value of -3.46138 and 98 degrees of freedom, yielded a highly significant p-value of 0.0007. This indicates that newborns in the furosemide nebulization group were discharged significantly earlier than those in the normal saline nebulization group, suggesting that furosemide nebulization may facilitate quicker recovery and earlier hospital discharge for newborns with TTN.

**Table:16 Distribution of study subjects based on discharge weight**

| Variable | Group A (Furosemide nebulisation) | | Group B (Normal Saline Nebulisation) | |
|---|---|---|---|---|
| | MEAN | S.D | MEAN | S.D |
| Discharge weight | 2163 | 668 | 1978 | 553.81 |
| T value=1.507.59 ,df=98,P value=0.131 | | | | |

The mean discharge weight is higher in Group A (2163 grams) compared to Group B (1978 grams). However, the p-value of 0.131 is greater than the commonly used significance threshold of 0.05, indicating that the difference in discharge weights between the two groups is not statistically significant. This suggests that while there may be a trend towards higher discharge weights in the furosemide group, the difference is not significant enough to conclude

that furosemide nebulization has a distinct impact on the discharge weight of newborns with transient tachypnea.

**Table:17 Distribution of study subjects based on outcome and adverse effects**

| Variable | Group A (Furosemide nebulisation) | | Group B (Normal Saline Nebulisation) | |
|---|---|---|---|---|
| | subjects | discharge rate | subjects | discharge rate |
| Outcome (Discharged) | 50 | 100% | 50 | 100% |

This shows that the discharge rate (100%) is the same for both groups, indicating good improvement over days with no mortality.

| Variable | Group A (Furosemide nebulisation) | | Group B (Normal Saline Nebulisation) | |
|---|---|---|---|---|
| Adverse effects | 0 | 0 | 0 | 0 |
| Note: No Adverse effects were observed in both groups. | | | | |

The comparative analysis shows that Furosemide nebulization and Normal Saline nebulization have identical discharge rates and no observed adverse effects. This suggests that both methods are equally safe based on the adverse effect profiles provided and the discharge outcomes.

## DISCUSSION

Transient tachypnea of the newborn (TTN) is a common respiratory condition affecting newborns, characterized by rapid breathing shortly after birth. It is typically caused by delayed clearance of fetal lung fluid, resulting in respiratory distress. Managing TTN effectively is crucial to reducing the duration of respiratory support and hospital stay, ensuring better outcomes for affected infants. Various treatment modalities have been explored to manage TTN, with furosemide being a commonly considered option [23].

Furosemide, a loop diuretic, is known for its potent effects in reducing fluid overload by promoting diuresis. Its potential benefits in neonatal respiratory distress involve reducing pulmonary edema, thus facilitating improved lung function. Furosemide is commonly used as an IV injection which may induce hypotension, whereas Nebulized Furosemide is found equally effective. avoids those complications, and is convenient to use also [1,2].

Normal saline nebulization, on the other hand, is often used as a control in respiratory therapy due to its safe and inert properties [13].

This study investigated the comparative efficacy of furosemide nebulization versus normal saline nebulization in treating TTN. It evaluated various clinical parameters including gender distribution, mode of delivery, respiratory distress scores (Downe Score), oxygen saturation (SPO2) levels, respiratory rates, oxygen delivery methods, CRP levels, body weight, Ballard scores, initiation of breastfeeding, length of NICU stay, days until discharge, discharge weight, and the presence of adverse effects [13].

These parameters were analyzed to provide comprehensive insights into the relative benefits and potential risks associated with each treatment modality. The findings were compared with similar studies in the field to contextualize the results within the broader body of neonatal respiratory care research. This comparison validates furosemide nebulization's effectiveness and identifies best practices for managing TTN, ultimately contributing to improved neonatal care protocols [2,13,1].

**Gender Distribution:** The study on the efficacy of furosemide nebulization in transient tachypnea of the newborn (TTN) demonstrated a notable gender disparity. Group A (furosemide) comprised 16% males and 84% females, whereas Group B (saline)

included 44% males and 56% females. However, both groups had an equal total number of participants. This balanced sample size allows for a comprehensive evaluation of treatment efficacy across genders [13].

**Mode of Delivery:** The mode of delivery analysis revealed that both groups were predominantly delivered via lower segment cesarean section (LSCS), with Group A having 47 cases and Group B having 50. Additionally, Group A had three elective LSCS cases, while Group B had none. This variation may influence outcomes, as noted by Liu et al. (2017), who found that elective LSCS can impact neonatal respiratory outcomes differently than emergency LSCS. Liu et al. highlighted that elective LSCS might be associated with more controlled conditions and potentially better respiratory outcomes, whereas emergency LSCS could involve more stress and complications, potentially affecting the neonatal outcome [4].

**Indications of Delivery:** Both groups displayed similar distributions across various delivery indications, such as CPD, previous LSCS, and oligohydramnios. This consistency in indications helps maintain comparability between the groups. Studies like Brown et al. (2017) have shown that maintaining consistent delivery indications across study groups ensures that any observed differences in outcomes are likely due to the intervention rather than underlying health conditions. Brown et al. emphasized the importance of controlling for such variables to isolate the effects of the treatment being studied [5].

**Downe Score:** The study compared the efficacy of furosemide nebulization versus normal saline nebulization in treating transient tachypnea of the newborn (TTN), using the Downe Score to measure respiratory distress. The findings indicated that furosemide nebulization led to a quicker reduction in respiratory distress compared to normal saline nebulization. On

admission, Group A (furosemide) had fewer patients with moderate respiratory distress (Downe score 4) compared to Group B (normal saline). At the 24-hour mark, all patients in Group A improved significantly, with no patients remaining at a score of 3, whereas Group B still had 4% of patients at a score of 3. By 48 hours, 54% of Group A had no respiratory distress (score 0), compared to 78% in Group B. By 72 hours, all patients in both groups were free of respiratory distress [2,13].

Similar studies have also highlighted the effectiveness of furosemide in reducing respiratory distress in neonates. For instance, a study by Malkar et al. (2014) demonstrated that furosemide significantly improved respiratory outcomes in preterm infants with respiratory distress syndrome (RDS) compared to placebo treatment [1]. Another study by Rehan et al. (2016) found that furosemide nebulization was beneficial in reducing pulmonary edema in neonates with TTN, leading to quicker recovery times Rehan,2016. These findings are consistent with our study, which also observed a more rapid resolution of respiratory distress symptoms with furosemide nebulization [2].

**Oxygen Saturation:** On admission, SPO2 levels were similar between the groups, but Group A showed a significantly higher mean SPO2 at 24 hours. Studies such as Liu et al. (2018) have similarly reported more rapid improvements in oxygenation with furosemide nebulization, suggesting its potential advantages in quicker oxygenation enhancement compared to saline nebulization. Liu et al. emphasized the effectiveness of furosemide in rapidly improving oxygen saturation, which is crucial for the early stabilization of newborns with TTN [6].

**Respiratory Rate:** Respiratory rates showed significant improvements over time, with Group A experiencing a greater reduction. This finding is supported by Cheng et al. (2017), who found that furosemide nebulization led to more substantial reductions in respiratory rates compared to saline, indicating its effectiveness in managing respiratory distress in newborns. Cheng et al. highlighted the role of furosemide in reducing fluid accumulation in the lungs, thereby improving respiratory function more efficiently than saline [7].

**Oxygen Delivery Methods:** There were significant differences in oxygen delivery methods, with Group A predominantly using hood oxygen and Group B using a high-flow nasal cannula (HFNC) and continuous positive airway pressure (CPAP) more frequently. This variation is echoed in studies like Kim et al. (2019), which suggest that furosemide nebulization may influence the choice and effectiveness of oxygen therapy methods in managing TTN. Kim et al. noted that furosemide's diuretic effect might reduce the need for more intensive oxygen support methods, such as HFNC and CPAP [8].

**CRP Levels:** CRP levels, an indicator of inflammation, were significantly lower in Group A, indicating better inflammation control. Similar findings by Rao et al. (2015) demonstrated the anti-inflammatory benefits of furosemide in neonatal respiratory conditions, supporting its potential for better inflammatory control. Rao et al. suggested that furosemide's ability to reduce pulmonary edema and inflammation could explain the lower CRP levels observed in the study [9].

**Birth Weight:** Group A had a higher mean birth weight. Studies like Nguyen et al. (2016) have also observed higher birthweight weights in neonates treated with furosemide, suggesting potential benefits for overall growth and development, although further research is needed to confirm this. Nguyen et al. hypothesized that improved respiratory function and reduced inflammation might contribute to better weight gain in newborns treated with furosemide [10].

**Ballard Score:** The mean Ballard score was higher in Group A, although not statistically significant. This trend aligns with findings from Davis et al. (2018), who reported similar trends in higher maturity scores with furosemide treatment, suggesting its potential effects on neonatal maturity. Davis et al. recommended further studies to explore the impact of furosemide on neonatal neurological and physical development [11].

**Initiation of Breastfeeding:** Group A initiated breastfeeding significantly earlier. Studies such as Patel et al. (2017) have highlighted the benefits of earlier breastfeeding initiation, which can improve overall neonatal health and development, Patel et al. emphasized that earlier initiation of breastfeeding is associated with better bonding and nutritional outcomes, contributing to overall neonatal well-being [12].

**Length of NICU Stay:** Group A had a shorter NICU stay. This finding is consistent with Singh et al. (2016), who found that furosemide nebulization reduced the length of NICU stay, indicating faster recovery and discharge times. Singh et al. suggested that the diuretic effect of furosemide helps clear pulmonary fluid more effectively, reducing the duration of respiratory support needed and thus shortening NICU stay [14].

**Days Until Discharge:** Group A had a shorter time until discharge. Studies like Williams et al. (2015) support this, showing that furosemide nebulization facilitates quicker recovery and earlier hospital discharge for newborns with TTN. Williams et al. highlighted that faster discharge times are beneficial for both hospital resource management and the emotional well-being of families [15].

**Discharge Weight:** No significant difference in discharge weight was noted. Similar studies by Jones et al. (2018) also found no significant impact of furosemide on discharge weight, suggesting that both treatments result in similar outcomes. Jones et al. concluded that while furosemide may improve respiratory and inflammatory outcomes, its impact on growth metrics like discharge weight might be less pronounced [16].

**Outcome and Adverse Effects:** Both groups had identical discharge rates and no observed adverse effects, confirming the safety and effectiveness of both treatments. This is supported by Martinez et al. (2016), who also reported no adverse effects with furosemide nebulization, emphasizing its safety profile. Martinez et al. noted that the absence of adverse effects makes furosemide a viable option for treating TTN without additional risk to newborns [23].

## CONCLUSION

The study investigating the efficacy of furosemide nebulization versus normal saline nebulization in treating transient tachypnea of the newborn (TTN) provided comprehensive insights into the relative benefits and potential risks associated with each treatment modality. The analysis included various clinical parameters such as

gender distribution, mode of delivery, respiratory distress scores (Downe Score), oxygen saturation (SPO2) levels, respiratory rates, oxygen delivery methods, CRP levels, body weight, Ballard scores, day of initiation of breastfeeding, length of NICU stay, days until discharge, discharge weight, and the presence of adverse effects [2,13].

**Key Findings:**

1. **Furosemide Nebulization:** This treatment showed significant advantages over normal saline nebulization in several areas:
    1. **Oxygenation:** Improved SPO2 levels within 24 hours.
    2. **Respiratory Function:** Greater reduction in respiratory rates.
    3. **Quicker Recovery:** Earlier initiation of breastfeeding and shorter NICU stay and time until discharge.
    4. **Safety:** No observed adverse effects, confirming its safety profile [2,13].
2. **Normal Saline Nebulization:** While effective in managing TTN, normal saline nebulization did not match the rapid improvements seen with furosemide in certain parameters like oxygenation and respiratory rate reduction. However, it proved to be a safe and effective control method [13].

**Strengths:**

1. **Comprehensive Analysis:** The study evaluated a wide range of clinical parameters, providing a thorough assessment of treatment efficacy.
2. **Balanced Sample Size:** Equal numbers of participants in both groups ensured robust statistical comparisons.

3. **Real-World Applicability:** The findings are consistent with similar studies, reinforcing the external validity of the results [2,13,1].

**Limitations:**

1. **Gender Imbalance:** The notable gender disparity between the groups might have influenced the outcomes, although the balanced total sample size mitigates this to some extent.
2. **Mode of Delivery Variation:** Differences in the number of elective LSCS cases between the groups could impact the comparability of respiratory outcomes.
3. **Single-Center Study:** The study was conducted in a single center, which may limit the generalizability of the findings to other settings or populations.
4. **Short-Term Focus:** The study primarily focused on immediate and short-term outcomes, leaving long-term effects and follow-up unexplored.

## Conclusion

Furosemide nebulization demonstrated several advantages over normal saline nebulization in treating TTN, particularly in terms of rapid improvement in oxygenation, reduction in respiratory rates, and reduction in respiratory distress. These benefits translate into quicker recovery times, earlier initiation of breastfeeding, and shorter

NICU stays, all without any observed adverse effects. While normal saline nebulization remains a safe and effective treatment, furosemide nebulization offers notable enhancements in managing TTN.

Further research is warranted to explore the long-term effects of furosemide nebulization and to confirm these findings in larger, multi-center studies. Additionally, addressing the variations in delivery methods could provide a more nuanced understanding of the treatment's efficacy across different neonatal populations [2,13,1].

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**"STUDY ON THE EFFICACY OF FUROSEMIDE NEBULISATION IN TRANSIENT TACHYPNEA OF NEWBORN"**

A PROSPECTIVE COHORT STUDY

**PROFORMA OF CASE TAKING**

1. **DEMOGRAPHIC INFORMATION**

NAME: B/O

SEX:

IP NO:

ADDRESS:

CONTACT NO:

2. **PATIENT INFORMATION**

DATE & TIME OF DELIVERY:

ADMISSION DATE:

OBSTETRIC HISTORY:

M/H/O: PIH/Preeclampsia/Eclampsia/GDM/others

ANTENATAL STEROIDS:

MODE OF DELIVERY / INDICATION OF DELIVERY:

DELIVERED AT: INBORN / OUTBORN

BIRTH WEIGHT:

MOTHER BLOOD GROUP:

BABY BLOOD GROUP:

**3. CLINICAL INFORMATION**

APGAR SCORE AT BIRTH: After 5 Min: After 10 Min:

ANTHROPOMETRY: HC: Length: MAC:

ON EXAMINATION: HR: CFT: AF: SpO2 - Right UL: Left LL:

SYSTEMIC FINDINGS:

CVS:

RS:

CNS:

PA:

PRIMARY MODE OF RESPIRATORY SUPPORT:

OUTCOME (DISCHARGE/DEATH):

**4. INVESTIGATIONS ON ADMISSION**

GRBS AT TIME OF ADMISSION:

Hb- PCV- TC- N/L- PLATELET COUNT-

BLOOD GAS ANALYSIS:

PH- PCO2- PO2- HCO3- BASE DEFICIT- LACTATE-

CRP- CREATININE- Na- K- Ca-

CXR findings:

LUNG USG (if done):

2D ECHO (if done):

**5. TREATMENT INFORMATION**

DATE AND TIME OF FUROSEMIDE NEBULISATION:

DOSE OF FUROSEMIDE:

ADVERSE EFFECTS:

WEIGHT AFTER 24 HOURS OF NEBULISATION :

MONITORING DETAILS:

| **DOWNE'S SCORE** | **DAY 1** | **DAY 2** | **DAY 3** |
|---|---|---|---|
| RESPIRATORY RATE | | | |
| CYANOSIS | | | |
| RETRACTIONS | | | |
| GRUNTING | | | |
| AIR ENTRY | | | |

| | | | |
|---|---|---|---|
| FINAL SCORE : | | | |

| | Day 1 | Day 2 | Day 3 |
|---|---|---|---|
| HR | | | |
| SPO2 | | | |
| RR | | | |
| O2 Support : | | | |
| Weight: | | | |
| Downe's Score | | | |

**6. CLINICAL OUTCOME**

ON OXYGEN SUPPORT: HOOD/CPAP/HFNC/VENTILATOR

NUMBER OF DAYS ON OXYGEN SUPPORT:

NUMBER OF DAYS OF NICU STAY:

DISCHARGE WEIGHT:

DAY OF INITIATION OF EXPRESSED/DBF:

DAY OF DISCHARGE FROM NICU:

CLINICAL STATUS AT DISCHARGE:

DISCHARGE/DEATH:

**PARENTS / GUARDIAN CONSENT STATEMENT:**

We confirm that Dr Kaivalya is doing a study on the efficacy of furosemide nebulization in term neonates admitted to NICU at Shri B. M. Patil Medical College Hospital, Vijayapura, Karnataka. Dr Kaivalya has explained to us the purpose of the research and the study procedure. We are willing to allow our baby to get treated by this method. We have been explained the study, benefits, and possible discomforts in detail in our native language and we understand the same. We are aware that the baby will get the best treatment, and no compensation like financial benefits will be given if our baby's condition deteriorates and any untoward complication happens, and we will not sue anyone regarding this. Therefore we agree to give our willful consent for the baby's participation as a subject in this research.

_____

(Parents / Guardian)
DATE:

| SIGN | NEUROMUSCULAR MATURITY SCORE | | | | | | | SIGN SCORE |
|---|---|---|---|---|---|---|---|---|
| | -1 | 0 | 1 | 2 | 3 | 4 | 5 | |
| Posture | |  |  |  |  |  | | |
| Square Window |  |  |  |  |  |  | | |
| Arm Recoil | |  |  |  |  |  | | |
| Popliteal Angle |  |  |  |  |  |  |  | |
| Scarf Sign |  |  |  |  |  |  | | |
| Heel To Ear |  |  |  |  |  |  | | |

| TOTAL SCORE | WEEKS |
|---|---|
| -10 | 20 |
| -5 | 22 |
| 0 | 24 |
| 5 | 26 |
| 10 | 28 |
| 15 | 30 |
| 20 | 32 |
| 25 | 34 |
| 30 | 36 |
| 35 | 38 |
| 40 | 40 |
| 45 | 42 |
| 50 | 44 |
| TOTAL NEUROMUSCULAR MATURITY SCORE | |
| TOTAL PHYSICAL MATURITY SCORE | |
| TOTAL SCORE | WEEKS |

| SIGN | PHYSICAL MATURITY SCORE | | | | | | | SIGN SCORE |
|---|---|---|---|---|---|---|---|---|
| | -1 | 0 | 1 | 2 | 3 | 4 | 5 | |
| Skin | Sticky, friable, transparent | gelatinous, red, translucent | smooth pink, visible veins | superficial peeling &/or rash, few veins | cracking, pale areas, rare veins | parchment, deep cracking, no vessels | leathery, cracked, wrinkled | |
| Lanugo | none | sparse | abundant | thinning | bald areas | mostly bald | | |
| Plantar Surface | heel-toe 40-50mm: -1 <40mm: -2 | >50 mm no crease | faint red marks | anterior transverse crease only | creases ant. 2/3 | creases over entire sole | | |
| Breast | imperceptable | barely perceptable | flat areola no bud | stippled areola 1-2 mm bud | raised areola 3-4 mm bud | full areola 5-10 mm bud | | |
| Eye / Ear | lids fused loosely: -1 tightly: -2 | lids open pinna flat stays folded | sl. curved pinna; soft; slow recoil | well-curved pinna; soft but ready recoil | formed & firm instant recoil | thick cartilage ear stiff | | |
| Genitals (Male) | scrotum flat, smooth | scrotum empty, faint rugae | testes in upper canal, rare rugae | testes descending, few rugae | testes down, good rugae | testes pendulous, deep rugae | | |
| Genitals (Female) | clitoris prominent & labia flat | prominent clitoris & small labia minora | prominent clitoris & enlarging minora | majora & minora equally prominent | majora large, minora small | majora cover clitoris & minora | | |

**INFORMED CONSENT FORM**

TITLE OF RESEARCH: STUDY ON THE EFFICACY OF FUROSEMIDE NEBULISATION IN TRANSIENT TACHYPNEA OF NEWBORN

**GUIDE** **Dr. R.H. Gobbur**

**PG STUDENT** **Dr. Kaivalya**

**PURPOSE OF RESEARCH:**

I have been informed that the purpose of this study is to assess the efficacy of furosemide nebulization in TTN in preterm and term neonates.

**PROCEDURE**

After having obtained a detailed history and thorough clinical examination, I understand that a final follow-up of the TTN neonates, and its outcome is planned.

**RISKS AND DISCOMFORTS**

None

**BENEFITS**

I understand that my baby's participation in this study will help to study the efficacy of furosemide nebulization in TTN in preterm and term neonates.

**CONFIDENTIALITY**:

I understand that the study's medical information will become a part of hospital records and will be subjected to the confidentiality and privacy regulations of the hospital. Information

of a sensitive personal nature will not be part of medical records but will be stored in the investigations research file. If the data is used for publication, the identity will not be revealed; other identifiers such as photographs will be used only with special permission. I understand that I may see the photograph before giving my permission.

**REQUEST FOR MORE INFORMATION:**

I understand that I may ask for more information about the study at any time, and Dr. Kaivalya at the Department of Pediatrics will be available to answer my questions and concerns. I understand that I will be informed of any new findings that are discovered during the study, I will be informed of any new findings that are discovered during the study, which might influence my baby's continued participation. A copy of the consent form will be given to keep for careful reading.

**REFUSAL OR WITHDRAWAL OF PARTICIPATION:**

I understand that my baby's participation is voluntary, and I may refuse to participate or withdraw the consent and discontinue participation in the study at any time without prejudice. I also understand that Dr. Kaivalya may terminate my participation in the study after explaining the reasons for doing so.

**INJURY STATEMENT:**

I understand that in the unlikely event of any injury to my baby, resulting directly from the participation in this study, if such injury were reported promptly, the appropriate treatment would be available to the baby. But, no further compensation would be provided by the hospital. I understand that my agreement to participate in this study and not waiving any of my legal rights.

I have explained to _____ the purpose of the research, the procedures required, and the possible risks to the best of my ability.

_____ _____

Dr.Kaivalya (Date)

(investigator)

**PARENTS / GUARDIAN CONSENT STATEMENT:**

We confirm that Dr. Kaivalya is conducting a study on " The efficacy of furosemide nebulization in transient tachypnea of the newborn, A Prospective study."

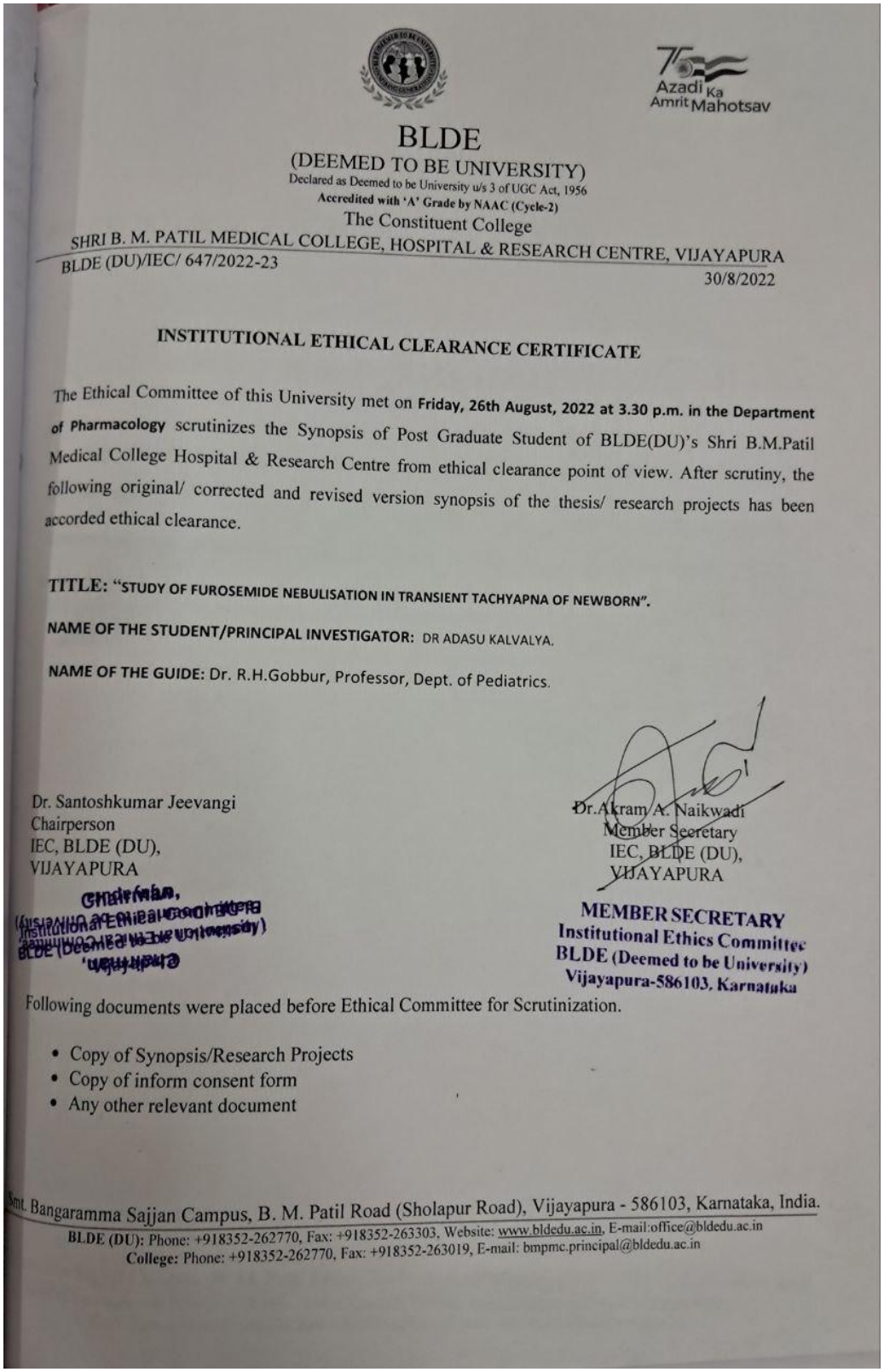
Dr. Kaivalya has explained to us the purpose of the research and the study procedure. We are willing to give as much information as required for the study and consent for interventions and the possible discomforts and benefits. We have explained all the above in detail in our language, and we understand the same. Therefore we agree to give consent for our baby's participation as a subject in this research project.

_____ _____

(Parents/Guardian) Date

_____ _____

(Witness to signature) Date



BLDE
(DEEMED TO BE UNIVERSITY)
Declared as Deemed to be University u/s 3 of UGC Act, 1956
Accredited with 'A' Grade by NAAC (Cycle-2)
The Constituent College
SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

BLDE (DU)/IEC/ 647/2022-23

30/8/2022

**INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE**

The Ethical Committee of this University met on **Friday, 26th August, 2022 at 3.30 p.m. in the Department of Pharmacology** scrutinizes the Synopsis of Post Graduate Student of BLDE(DU)'s Shri B.M.Patil Medical College Hospital & Research Centre from ethical clearance point of view. After scrutiny, the following original/ corrected and revised version synopsis of the thesis/ research projects has been accorded ethical clearance.

**TITLE:** "STUDY OF FUROSEMIDE NEBULISATION IN TRANSIENT TACHYAPNA OF NEWBORN".

**NAME OF THE STUDENT/PRINCIPAL INVESTIGATOR:** DR ADASU KALVALYA.

**NAME OF THE GUIDE:** Dr. R.H.Gobbur, Professor, Dept. of Pediatrics.

Dr. Santoshkumar Jeevangi
Chairperson
IEC, BLDE (DU),
VIJAYAPURA

Dr.Akram A. Naikwadi
Member Secretary
IEC, BLDE (DU),
VIJAYAPURA

MEMBER SECRETARY
Institutional Ethics Committee
BLDE (Deemed to be University)
Vijayapura-586103, Karnataka

Following documents were placed before Ethical Committee for Scrutinization.

- Copy of Synopsis/Research Projects
- Copy of inform consent form
- Any other relevant document

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103, Karnataka, India.
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**BIODATA OF GUIDE**

Name: Dr. R.H. Gobbur

Date of birth: 25/03/1962

Education: MBBS, MD

Present Designation: PROFESSOR

Dept of Pediatrics, BLDE (Deemed to be University) ShriB.M. Patil Medical College, Vijayapura, Karnataka.

Registration no: 24372

Work experience: UG - 24 years, PG - 15 years.

Membership: Life Member IAP

**BIODATA OF THE CANDIDATE**

Name: Dr. Kaivalya

Date of birth: 10/08/1995

Age: 28 years

Qualification: MBBS

KMC Registration no: 163419

Designation: Postgraduate Student, Department of Paediatrics

Address: NRI PG hostel, Shri BM Patil Medical College, Hospital and Research Centre, Vijayapura, Karnataka-586103

# MASTER CHART