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Effect of Inhaled Salbutamol on outcome of Transient Tachypnea of Newborn (TTN) in Neonatal Care Unit at AIMS Muzaffarabad

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ABSTRACT

Objective: To compare the outcome of inhaled salbutamol versus placebo, in addition to standard treatment, among neonates with TTN.

Study Design and Setting: A cross-sectional study was conducted in the Neonatal Unit, Department of Pediatrics Medicine, Abbas Institute of Medical Sciences, Muzaffarabad, over six months (14-Feb-2025 to 13-August-2025).

Methodology: The study included a total of 80 neonates who fulfilled the inclusion criteria. Neonates were divided into two groups in accordance with the treatment given to them as part of standard clinical treatment: inhaled salbutamol or nebulized normal saline. Descriptive analysis was performed using SPSS version 25. Quantitative variables were given as mean ± standard deviation, while qualitative variables were reported as frequencies and percentages. An independent sample t-test was conducted to compare outcomes between the two groups. Statistical significance was defined as p=0.05.

Results: The duration of oxygen therapy was significantly shorter in the salbutamol group (32.75 ± 2.12 hours) compared to the control group (78.20 ± 2.77 hours; p = 0.001). Similarly, the mean length of hospital stay was significantly reduced in the salbutamol group (3.05 ± 1.15 days) compared to the control group (5.78 ± 1.00 days; p = 0.001).

Conclusion: Inhaled salbutamol, in addition to standard treatment significantly reduced the length of oxygen withdrawal and length of hospital stay in neonates with TTN. It might therefore represent effective adjuvant therapy to enhance the outcome and lessen the burden on hospitals of infants with the condition.

Keywords: *B2-Agonist, Neonatal Respiratory Distress, Salbutamol, Transient Tachypnea of the Newborn*

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INTRODUCTION

Transient tachypnea of the newborn (TTN) is an important pulmonary illness with a unique set of clinical manifestations that stem from the inefficient and/or delayed removal of fluid from the foetal lungs that cause a range of pulmonary complications. This pulmonary condition is commonly found in neonates delivered at term, or at the late end of preterm gestation as well, given that its incidence is seen to be 5.7 incidences per every 1000 live births, thus representing a relative frequency in the neonatal population.[1]

The pathophysiological mechanisms that are implicated in TTN are related to an abnormal shift from foetal pulmonary mechanics to those of a fully mature neonate, which ultimately causes respiratory distress in those infants who suffer from this ailment. This transition, if perturbed, can have great clinical consequences and requires an in-depth understanding of the mechanisms responsible for the development of TTN to enable the development of efficient management strategies in these protocols-prone patients.[2]

The appearance of clinical signs like rapid respiration, presence of grunting sounds in respiration and the appearance of retractions within the chest cavity are generally apparent within the first 6 hours after the moment of birth. The

release of the lungs of fluids at the time of delivery is so much promoted by the presence of certain hormones that are released during this very delicate period. These hormones play an essential role in facilitating the clearance of fluid from the lungs by triggering a process that leads to the activation of certain ions channels linked to this physiological process.[3]

Infants diagnosed with Transient Tachypnea of the Newborn (TTN) may be found with sub-optimal levels of these vital hormones and as a result, may benefit considerably from administration of a focused pharmacological intervention that is specifically designed to promote removal of excess fluid from the lungs. Furthermore, there are a number of identifiable risk factors surrounding the development of TTN which include various things that happen to the child at birth, maternal health issues that may affect the baby, exposure to smoking while in the womb as well as cases of oxygen deprivation which can occur around the time of birth. In light of these multifaceted factors it is imperative that a comprehensive understanding of both the physiological mechanisms at play, as well as the external influences that could potentially make the condition worse in newborns, is followed when it comes to the management of TTN. Remember, premature breathing requires care of both clinical signs and fundamental reasons to maintain perfect respiratory health and general well being in affected babies.[4]

Numerous therapeutic interventions trying to offer some support have been proposed in the management of Transient Tachypnea of the Newborn (TTN) including but not limited to the use of: limiting fluid intake, empirical antibiotic administration, the use of furosemide and the considerations for the use of epinephrine.[5-6] These proposed treatment modalities play a crucial role in addressing the symptoms and complications associated with TTN, ultimately contributing to improved outcomes and patient's care.[7-8]

Kim et al. undertook a research investigation and discovered that the period of tachypnea following intervention was significantly reduced in the treatment group compared to the control group (31.3±23.7 h vs. 53.5±56.8 h, respectively). Additionally, the duration of oxygen therapy was markedly shorter in the treatment group (34.2±32.2 h) than in the control group (77.3±64.7 h), whereas the length of hospital stay remained comparable between the two groups (8.5±3.9 days vs. 8.8±3.2 days in treatment and control groups, respectively; $p>0.05$).[9] Armangil et al. observed that the length of hospitalization was significantly diminished in infants receiving treatment [4(2-5) days vs. 6(4-7) days].[10]

While the effectiveness of inhaled salbutamol in the treatment of transient tachypnea of the newborn (TTN) has been discussed in several international and national studies, there are lacunae in the use of inhaled salbutamol in the specific clinical contexts of Pakistan. Variations in neonatal care protocols, patient demographics and healthcare infrastructure may affect the treatment outcomes.

However, there is some locally generated data that looks at the efficacy of inhaled salbutamol at reducing the duration of TTN with its effect on hospitalisation rates in Pakistani neonatal units. This study is intended to provide region-specific evidence on the benefit and safety of inhaled salbutamol in the management of TTN in order to guide standardisation of treatment protocols that are specific to the local healthcare context. By filling this gap, the research could help in optimising neonatal care strategies, which could possibly reduce the length of hospital stays and the risk of nosocomial infections of affected neonates.

METHODOLOGY

The study was conducted in the Neonatal Unit of the Department of Paediatric Medicine, Abbas Institute of Medical Sciences, Muzaffarabad. The research period of the study was six months (14-Feb-2025 to 13-August-2025) after the research proposal was accepted. The study design used was a cross-sectional study. The ethical approval was obtained from Ethical Review Committee (ERC) of Abbas Institute of Medical Sciences, approval number: PED-2022-107-7159 dated: 12-10-2024.

A non-probability consecutive sampling method was used. The sample size was calculated using the OpenEpi calculator which showed that 80 cases (40 in each group). This was calculated using a 5% significance level, 80% power of test, and the anticipated mean duration of oxygen requirement as being 34.2+ 32.2 hours and 77.3+ 64.7 hours in the salbutamol group and placebo group of neonates diagnosed as transient tachypnea of the newborn.[9]

Inclusion Criteria: Infants of gestation >=37 weeks, irrespective of sex, who were less than 3 days old with transient tachypnea of the newborn were included in the study.. Exclusion criteria encompassed those displaying congenital anomalies or syndromes, meconium aspiration, iatrogenic pulmonary injury, multi-organ dysfunction, or alternative etiologies of tachypnea, including neonatal respiratory distress syndrome, persistent pulmonary hypertension of the newborn, congenital pneumonia, early onset sepsis, hypoglycemia, polycythemia, congenital heart malformations, or perinatal asphyxia.

Neonates that were treated with inhaled salbutamol were compared to those who received nebulized normal saline. No intervention from the researchers was given, and all treatments were done according to normal hospital practice.

The data was obtained by using a pre-designed proforma from the patient's medical records. The variables recorded included gestational age, birthweight, gender, respiratory rate, oxygen saturation level, duration of O_2 therapy, and length of hospital stay. Oxygen via nasal cannula at 5 L/min was applied to keep oxygen saturation between 90–95%. Chest X-rays were done to aid diagnosis.

The data entry and analysis were done by using SPSS version 25 software. Qualitative data, such as gender, were presented in terms of frequencies and percentages. Quantitative variables, including gestational age, weight, length of hospital stay, and oxygen requirements, were summarized as means and standard deviations. The independent sample t-test was used to examine differences between the two groups with regard to outcome variables. Data were stratified according to gestational age, gender, and birth weight to control for any potential effect modifiers. Following stratification, the independent sample t-test was re-applied, and p = 0.05 was considered statistically significant.

RESULTS

Within the population that received salbutamol, the demographic results showed the total of 27 males, representing a significant proportion of 67.5% of the total group, with 13 female, representing 32.5% of the total population, the groups were: in the placebo, we have 26 males with 65.0% of the total population and 14 females 35.0% of the total population, the group of 5 participants, showing an extraordinary gender distribution of the results obtained in both groups. In considering the gestational age, the average was carefully recorded as being 36.23 weeks with standard deviation 1.48 weeks in the salbutamol group, however the placebo group had a slightly higher gestational age with the average recorded as 36.73 weeks with standard deviation of 1.11 weeks, and interestingly, a majority of the neonates in both groups were born after reaching 36 weeks of gestation and the percentage has been recorded as 55.0% achieving the 36 weeks gestational age in salbutamol group in comparison to 52.5% Furthermore, mean birth weight of neonates in the salbutamol group was found to be 3028.78 gram with standard deviation of 303.53 gram whereas the placebo group showed a higher mean birth weight of 3155.63 gram with standard deviation of 262.53 gram; this finding was accompanied by higher number of neonates >3000 g in both groups, i.e. 60.0% in the salbutamol group as compared to 65.0% in the placebo group. Overall, these results showed that the underlying characteristics of both groups were exceptionally similar evaluated in terms of gender and gestational age distribution and birth weight.

In terms of average oxygen dependency time, it was carefully noted and the value discovered to be 32.75 hours with standard deviation values of 2.12 hours in the salbutamol group, which was a vast difference from the placebo group with an average of 78.20 hours and standard deviation values of 2.77 hours, with statistical significance denoted as p-value of 0.001. Similarly, the mean duration of hospitalization for neonates in salbutamol group was significantly decreased and recorded as 3.05 days with standard deviation of 1.15 days when compared with placebo group, which recorded average hospitalization duration of 5.78 days with standard deviation of 1.00 day, which was also found to be statistically significant as p-value in this case was 0.001. These compelling results strongly suggest that the administration of salbutamol has a profound impact in a significant reduction of both duration of oxygen dependency as well a reduction of hospital stay when compared to the placebo treatment group.

In addition, other analyses, presented in Tables 3 and 4, gave a more detailed stratification of outcomes according to the parameters of gender, gestational age and birth weight. Across all the subgroups based on these characteristics the administration of salbutamol consistently showed a lower oxygen requirement and a decreased duration of hospital stay compared with the placebo group with the differences in oxygen use and duration of stay proving statistically significant (p 0.001). Specifically, both male and female neonates regardless of if they were born with gestational ages of 36 weeks or less and greater than 36 weeks as well as neonates whose birth weights also fell below or greater than 3000 gram all displayed a uniform trend; that is, that the use of salbutamol was associated with a significantly shorter time of oxygen dependence as well as an earlier hospital discharge.

DISCUSSION

Transient tachypnea of the newborn (TTN) represents one of the most prevalent etiological factors contributing to the phenomenon of respiratory distress observed in neonates, as it is responsible for a significant proportion, specifically ranging from 40% to 50%, of the overall incidence of this condition among infants who are either born at full term or those classified as late preterm.[11-12] The medical condition in question is typically characterized by its self-limiting nature, meaning that it often resolves on its own without the need for extensive medical intervention; however, it frequently necessitates an extended period of oxygen therapy,

Table-1: Comparison of distribution of different variables between groups

Variables		Exposure Group (Salbutamol)	Non-Exposure Group (Placebo)
Gender	Male	27(67.5%)	26(65.0%)
	Female	13(32.5%)	14(35.0%)
Gestational age	<36 weeks	18(45.0%)	19(47.5%)
	>36 weeks	22(55.0%)	21(52.5%)
	Mean±S.D	36.23±1.48	36.73±1.11
Birth weight	<3000 grams	16(40.0%)	14(35.0%)
	>3000 grams	24(60.0%)	26(65.0%)
	Mean±S.D	3028.78±303.532	3155.63±262.53

Table-2: Comparison of outcomes between groups

OUTCOMES	Exposure Group (Salbutamol)	Non-Exposure Group (Placebo)	p-value
Mean duration of oxygen (hours)	32.75±2.12	78.20±2.77	0.001
Mean hospital stay (days)	3.05±1.15	5.78±1.000	0.001

Table-3: Stratification of duration of oxygen between groups with respect to different variables

Variables	Exposure Group (Salbutamol)	Non-Exposure Group (Placebo)	p-value
Gender			
• Male	32.48±2.21	78.46±2.06	0.001
• Female	33.31±1.88	77.71±3.81	0.001
Gestational age			
• <36 weeks	33.56±1.72	77.95±3.01	0.001
• >36 weeks	32.09±2.22	78.43±2.59	0.001
Birth weight			
• <3000 grams	32.25±2.17	79.00±2.41	0.001
• >3000 grams	33.08±2.06	77.77±2.90	0.001

Table-4: Stratification of duration of hospital stay between groups with respect to different variables

Variables	Exposure Group (Salbutamol)	Non-Exposure Group (Placebo)	p-value
Gender			
• Male	2.81±1.01	5.92±0.84	0.001
• Female	3.54±1.33	5.50±1.22	0.001
Gestational age			
• <36 weeks	2.56±0.85	5.47±1.02	0.001
• >36 weeks	3.45±1.22	6.05±0.92	0.001
Birth weight			
• <3000 grams	2.88±1.31	6.14±1.02	0.001
• >3000 grams	3.17±1.04	5.58±0.94	0.001

which can be quite intensive, along with hospitalization, both of which significantly contribute to escalating healthcare costs and simultaneously heighten levels of anxiety experienced by parents who are understandably concerned about the well-being of their child during this challenging time.[13]

The fundamental pathophysiological mechanism that underpins this condition is characterized by a significant delay in the clearance of pulmonary fluid in the fetus, which occurs as a direct consequence of both impaired transport of epithelial sodium and an inadequate surge of catecholamines at the moment of birth, thereby leading to complications associated with respiratory function and overall neonatal health.[14-15]

The underlying justification for the application of β2-agonists is deeply rooted in both empirical research and clinical observations, which collectively indicate that the activation of β2-adrenergic receptors plays a crucial role in facilitating the enhanced reabsorption of sodium and water through the alveolar epithelial cell membranes, consequently leading to a significant acceleration in the process of lung fluid clearance, which is essential for maintaining optimal respiratory function and overall pulmonary health.[16-17]

Extensive research conducted utilizing various animal models has unequivocally demonstrated that â2-agonists have a significant impact on enhancing the activity of alveolar epithelial sodium channels, which in turn facilitates the accelerated resolution of pulmonary edema, a condition characterized by the accumulation of fluid in the alveolar spaces of the lungs. This mechanistic insight is a strong starting point that serves as an argument for clinical use of salbutamol, a well-known beta 2 agonist, in the management of transient tachypnea of the newborn (TTN), a disease that may cause respiratory distress in neonates. Therefore, the results obtained from these studies not only highlight the pharmacological efficacy of beta 2 agonists in the management of pulmonary complications but also serve as a sign of their potential in therapeutic interventions in clinical situations such as TTN, in which an early intervention is extremely important in obtaining favourable results in the patient.[18]

In the current study, the effects of inhaled salbutamol on the incidence of transient tachypnoea of the newborn (TTN) was carefully evaluated by performing a detailed comparison analysis of both the oxygen treatment and the length of stay of the neonates in the salbutamol group with those in the placebo group. The mean duration of oxygen therapy in newborns who received salbutamol was significantly shorter than the duration of oxygen therapy in newborns receiving a placebo, and it was 32.75±2.12 hours versus 78.20±2.77 hours, respectively, with a p-value of 0.001, implying the validity of the study results.

Similarly, the salbutamol group had a shorter hospital stay compared to the placebo group, with the duration of hospital stay among the neonates of the salbutamol group being 3.05±1.15 days, while the placebo group had a longer hospital stay of 5.78±1.00 days, with a notable p-value of 0.001. Taken profferentively, these interesting findings add further evidence that the use of salbutamol, as an adjunctive agent along with standard therapeutic regimens, can be a remarkable acceleration of the process in the recovery course of babies with transient tachypnea.

Furthermore, our results closely correlate with earlier clinical trials that addressed such type of therapeutic intervention. Specifically, Yurdakok et al. performed an observational study that found that the oxygen requirement was significantly reduced in salbutamol-treated neonates (mean oxygen time of therapy was 34.2±32.2 hours compared to a much higher 77.3±64.7 hours in the placebo group, p-value <0.05 showing statistical significance).[19]

The research conducted by Mohammadizadeh and his colleagues explained that the duration of the administrated oxygen therapy to patients in the salbutamol group was much shorter and it is recorded at an average duration of 41.6-15.7 hours in contrast to the duration experienced by

the control group with a much longer duration recorded at 66.9-27.4 hours with statistically significant (p-value = 0.001) to the reliability of the conduct of research. Furthermore, the study also showed a very interesting finding in the reduction of the hospital stay, in patients of the salbutamol group with an average of 3.8±1.4 days, compared to the control group with a considerably longer duration of hospital stay at 5.3±2.1 days and a p-value of 0.003 further corroborating the significance of this difference. These findings collectively highlight the efficacy of salbutamol therapy not only in terms of outcome of reducing the duration of oxygen therapy but also in enabling a shorter recovery time, and so potentially improved overall patient outcomes and use of healthcare resources.[20]

In another randomised clinical trial, which the researchers Dani and colleagues performed, the researchers found a trend, though not statistically significant, for a shorter duration of oxygen therapy among the participants who received salbutamol, a widely used bronchodilator. However, it is important to note that the study may have been underpowered, which could have led to an inability to identify or find significant differences in outcomes between the treatment groups. Consequently, the implications of these results need to be interpreted with caution, as the fact that the results were not statistically significant raises questions about the robustness and reliability of the conclusions resulting from this particular investigation.[21]

A thorough meta-analysis undertaken by Sadeghnia et al. has presented strong evidence that the attainment of salbutamol administration contributes significantly less to the amount of days of oxygen therapy needed by patients and the overall length of their hospitalization in case of Transient Tachypnea of the Newborn (TTN) thus strengthening the concept that its inclusion in clinical routine as an adjunctive therapeutic option is in fact justified and benefits the patient. This study not only brings into the limelight the efficacy of salbutamol in improving the clinical course of TTN but also the importance of incorporating such pharmacological interventions in standard treatment protocols in order to improve the results of patient treatments. The results therefore recommend a change in thinking behind management of TTN and propose that salbutamol should routinely be considered as a viable adjunctive therapy that can be used in the clinical setting to optimise both the duration of dependence on oxygen and the overall utilisation of healthcare resources associated with-hospitalisation.[22]

In a more modern setting, Malakian and Bashar have published a randomised clinical trial with a mean duration of oxygen therapy of 28.4±14.2 hours in infants treated with salbutamol versus 56.3±21.7 hours in controls, requiring much longer duration of therapy ($p < 0.001$), strengthening the huge benefits of salbutamol in such an infant population.[23]

Further, a detailed review by the reputed authors Jain and Eaton has clearly highlighted the great potential that pharmacological stimulation for improving fluid uptake within lung parenchyma offers, and may well become a very promising therapeutic target in neonatal lung diseases such as TTN.[24]

The present study adds to this evidence by showing not only statistically but also clinically significant morbidity reduction. Interestingly, subgroup analysis indicated that the benefit of salbutamol was present among gender, gestational age, and birth weight subgroups, which argues for a wide applicability of the intervention.

However, there is some variation in the reported outcome. Whilst most studies show significant benefit, there are some studies that have found modest or no differences in oxygen requirement, which may be related to differences in the regimens of the doses, timing of administration, patient selection, and sample size. Nonetheless, the trend across multiple trials and systematic reviews is consistent with ours to support the use of inhaled salbutamol in TTN.

Limitations of the Study: This study was limited by its single-centre design and relatively small sample size, which may have a chance to affect the external validity. Only short-term outcomes such as oxygen therapy duration and length of hospital stay were assessed; long-term respiratory outcomes, readmissions, and possible adverse effects of salbutamol were not assessed. Future research should be conducted in the form of large, multicenter randomised controlled trials to confirm the efficacy and safety of salbutamol in TTN. The use of standardized dosing, as well as follow-up over the long term, should be considered to determine the long-term effects, whether beneficial or detrimental. Either with epinephrine, diuretics, or hypertonic saline, comparative data is available to sample comparisons to utilize optimum therapy. In addition, cost-effectiveness analyses would be of use in terms of policy-level decisions concerning widespread implementation of salbutamol therapy in neonatal care units. Lack of randomization may introduce selection bias and confounding, which can affect causal inference.

CONCLUSION

In addition to standard treatment, inhaled salbutamol is significantly associated with a decrease in the duration of oxygen therapy and the length of hospital stay of neonates with TTN. It could therefore be an effective adjunct therapy to improve outcomes and reduce the burden of hospitalization in affected infants.

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Authors Contribution:
Nuzhat Rasheed: Intro, Literature Review, data collection, Data analysis
Manzoor Ali Khan: Review the article, Result and Data analysis
Safia Akhtar: Literature Review, data collection, result
Maryam Latif: Literature Review, data collection, Data analysis
Sughra Latif: Literature Review, Data Collection

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