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Difference between Role of Nebulized Salbutamol and Nebulized Normal Saline in Treatment of Transient Tachypnea of New Born

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ABSTRACT

Background: Transient Tachypnea of the Newborn (TTN) is a common respiratory condition in neonates, characterized by rapid breathing due to delayed lung fluid clearance. Nebulized Salbutamol, a beta-agonist, is a potential treatment for improving respiratory outcomes. **Objective:** To compare the mean respiratory rate with inhaled salbutamol and normal saline in transient tachypnea of new born. **Study Design:** Randomized controlled trial. **Duration and Place of Study:** The study was conducted at the Department of Pediatrics, POF Hospital Wah Cantt, from June 2023 to December 2023. **Methodology:** A total of 60 neonates with TTN were randomly assigned to two groups: Group A (Salbutamol) and Group B (Normal Saline). Patients were assessed for respiratory rate before treatment and at intervals of 30 minutes, 60 minutes, and 4 hours after nebulization. The main outcome measure was the change in respiratory rate at 4 hours' post-treatment. **Results:** At baseline, the respiratory rates were similar in both groups: 77.00 ± 2.03 BPM in Group A and 76.90 ± 1.84 BPM in Group B ($p = 0.843$). At 30 minutes post-treatment, respiratory rates remained similar: Group A (72.17 ± 1.68 BPM) vs. Group B (72.37 ± 1.51 BPM, $p = 0.631$). At 60 minutes, no significant difference was observed: Group A (69.80 ± 1.76 BPM) vs. Group B (70.10 ± 1.70 BPM, $p = 0.507$). However, at 4 hours, Group A showed a significant improvement with a respiratory rate of 60.83 ± 1.62 BPM, while Group B had 76.27 ± 1.08 BPM ($p < 0.001$). **Conclusion:** Our study has demonstrated that nebulized Salbutamol is an effective treatment for reducing respiratory rates in neonates with TTN, with significant improvement observed at 4 hours post-treatment compared to normal saline.

INTRODUCTION

Transient Tachypnea of the Newborn (TTN) is a relatively common condition in neonates, especially those born through a cesarean section or preterm.[1] The condition is a direct etiology resulting from a failure in clearance of fetal lung fluid at birth resulting in increased effort at respiration as well as increased rate (tachypnea).[2] The signs are normally seen in early hours following birth and are marked by nasal flaring, retractions over the chest as well as increased rate.[3] Despite generally being a condition that is self-limiting with improvement in 24 to 72 hours, it is a cause of respiratory distress in both infant as well as parents in between.[4] A prompt identification as well as management are necessary in order to keep neonate comfortable as well as avert some serious complications in terms of either hypoxia or respiratory failure.

Management in TTN is supportive with a goal towards stabilizing neonatal respiration with a waiting period for spontaneous remission.[5] Monitoring in a neonatal intensive care unit (NICU), administration of supplemental oxygen in a way that keeps saturation at a level that is adequate, and measures that allow intake of food as well as fluid are involved. In some, non-invasive ventilation in terms of a continuous positive airway pressure (CPAP) can be implemented in order to ease respiration. Pharmacologic measures in terms of treatments that are nebulized have also been implemented in order to ease symptoms.[6] The treatment is implemented on a basis that is severity-based as well as in terms of neonatal reaction.[7] In overall terms, a preference is made towards avoiding distressing measures as much as is feasible with a secure course towards healing.

Nebulized salbutamol, a beta-2 adrenergic agonist, is a proposed therapeutic agent in TTN as a fluid clearance-accelerating agent with a bronchodilating activity.[8] Stimulation of beta-adrenergic receptors in the lung with salbutamol accelerates ion transport across

alveolar epithelial cells with resulting excess fluid reabsorption in lung. Reduction in both course of tachypnea as also in requirement for oxygen is seen in neonates with TTN treated with nebulized salbutamol with a possibility of shorter hospital stay.[9] Use is not universally acceptable, though, as its administration is followed by undesirable adverse effects in some form.[10] Proper titration in suitable subjects is essential in planning its modality of administration with more research before standardized application in TTN is made.

Nebulized normal saline is another adjuvant in the management of TTN, primarily as a vehicle on which drugs are delivered in addition or as a symptomatic relief agent by loosening and humidifying airway mucus.[11] Normal saline nebulization is not pharmacologically active, although it can facilitate enhanced mechanics in respiration by reducing resistance in the airway and enhancing mucociliary clearance. Some practitioners give it as a matter of routine in routine neonatal care in addition to therapies that involve CPAP or oxygen.[12] The lack of adverse reaction makes it a preferred agent; as adverse reaction is not common in relation to pharmacologic agents.

A study conducted by Salama AA and colleagues demonstrated that the average respiratory rate was 60.68 ± 3.86 BPM in newborns treated with inhaled salbutamol, compared to 76.28 ± 4.60 BPM in those receiving normal saline, in cases of transient tachypnea of the newborn.[13]

Comparison between the efficacy of nebulized salbutamol and that of nebulized normal saline in the treatment of transient tachypnea of the newborn (TTN) is crucial because TTN is a common neonatal respiratory condition. The available treatment methods lack a consensus on which is the most effective form of treatment. In a comparison between these two treatments, this study will provide evidence-based data that can simplify treatment protocols, hence improving neonatal outcomes as well as reducing both the severity as well as duration of neonatal distress in neonates with TTN.

METHODOLOGY

This study was conducted as a randomized controlled trial at the Department of Pediatrics, POF Hospital Wah Cantt, from June 2023 to December 2023. The sample size was calculated using the WHO sample size calculator, based on a 5% significance level, 80% power, and previously reported mean respiratory rates of 60.68 ± 3.86 BPM with salbutamol and 76.28 ± 4.60 BPM with normal saline.[13]

A total of 60 patients who met the inclusion criteria were recruited using non-probability consecutive sampling. The inclusion criteria were a gestational age of more than 35 weeks, both genders, and a diagnosis of transient tachypnea. Transient tachypnea was defined as the onset of respiratory distress within 6 hours of birth, accompanied by chest radiographic findings such as fluid in the minor fissures, hyperaeration, and bilateral perihilar vascular markings. Exclusion criteria included a history of meconium aspiration, congenital pneumonia, polycythemia, hypoglycemia, cardiac disorders, tachycardia, or arrhythmia.

Patients were randomly assigned into two groups through blind balloting. Group A received a single nebulized dose of salbutamol (0.15 mg/kg in 0.9% saline), while Group B received nebulized normal saline (0.9%) along with oxygen and IV fluids.

Respiratory rate, measured in breaths per minute (BPM), was recorded at baseline, 30 minutes, 60 minutes, and 4 hours after nebulization. The final respiratory rate was recorded after 4 hours, and all data were documented on a specifically designed proforma.

Statistical analysis was performed using SPSS version 25. Descriptive statistics, including mean ± SD for continuous variables and frequency distributions for categorical variables, were calculated. Independent t-tests were used to compare the mean respiratory rates between the two groups. Stratification by age, gender, and birth weight was performed to assess their potential influence on the respiratory rate, with post-stratification analyses conducted using independent t-tests. A p-value of ≤ 0.05 was considered statistically significant.

RESULTS

In terms of demographic characteristics, both groups (Group A: Salbutamol, Group B: Normal Saline) had similar mean gestational age (37.73 ± 1.01 weeks vs. 37.93 ± 1.22 weeks) and birth weight (3115.00 ± 134.00 g vs. 3131.67 ± 128.98 g), with gender distribution also being comparable (56.7% male in Group A and 53.3% male in Group B, respectively), as shown in Table-I.

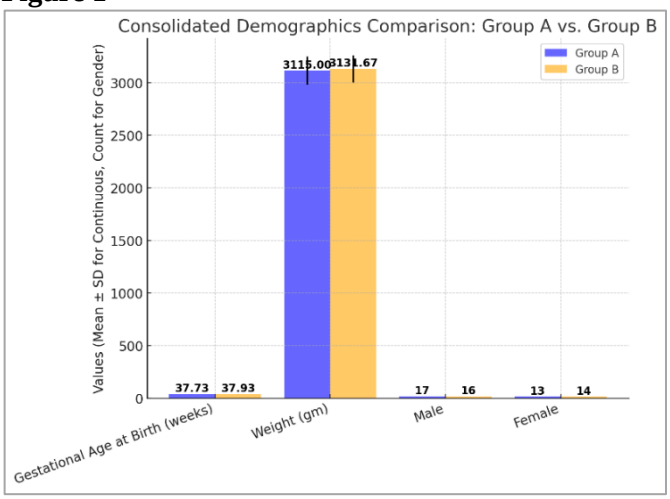
Table I

Demographics in both groups.

Demographics	Group A n=30 Mean±SD	Group B n=30 Mean±SD
Gestational Age at Birth (weeks)	37.733±1.01	37.933±1.22
Weight (gm)	3115.000±134.00	3131.666±128.98
Gender		
Male	17 (56.7%)	16 (53.3%)
Female	13 (43.3%)	14 (46.7%)

n=60

Figure 1



Regarding respiratory rates, before treatment, both groups had similar values: Group A had a mean of 77.00 ± 2.03 BPM, and Group B had 76.90 ± 1.84 BPM (p = 0.843, Table-II). At 30 minutes post-treatment, respiratory rates remained similar in both groups (Group A: 72.17 ± 1.68 BPM, Group B: 72.37 ± 1.51 BPM, p = 0.631). At 60 minutes, there was no significant difference either (Group A: 69.80 ± 1.76 BPM, Group B: 70.10 ± 1.70 BPM, p = 0.507). However, at 4 hours, a significant difference was observed: Group A showed a mean respiratory rate of 60.83 ± 1.62 BPM, while Group B had 76.27 ± 1.08 BPM (p < 0.001), indicating a strong improvement in Group A (Table-II).

Table II

Comparison of mean Respiratory Rate in both groups.

	Group A n=30	Group B n=30	t	P value
Respiratory Rate Before Treatment (BPM)	77.000±2.03	76.900±1.84	0.199	0.843
Respiratory Rate at 30 Min (BPM)	72.166±1.68	72.366±1.51	-0.483	0.631
Respiratory Rate at 60 Min(BPM)	69.800±1.76	70.100±1.70	-0.668	0.507
Respiratory Rate at 4 Hours(BPM)	60.833±1.62	76.266±1.08	-43.397	<0.001

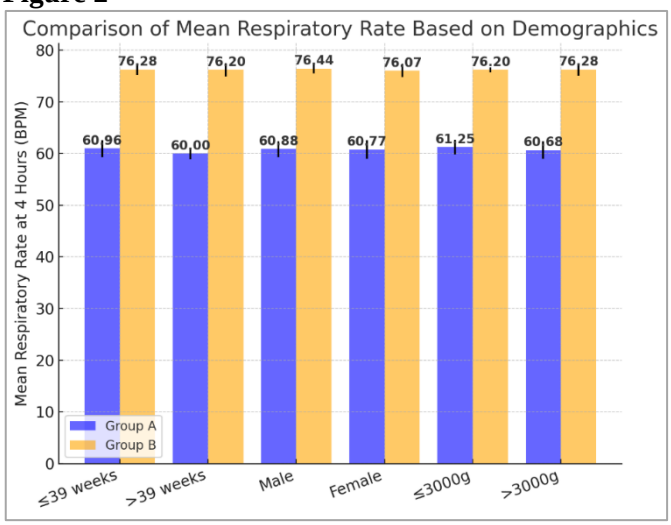
Further stratified analyses of the mean respiratory rate at 4 hours showed that significant differences persisted across demographic factors. For gestational age ≤39 weeks, Group A had a mean of 60.96 ± 1.66 BPM, while Group B had 76.28 ± 1.06 BPM (p = 0.000). For gestational age >39 weeks, Group A's mean was 60.00 ± 1.15 BPM, and Group B's mean was 76.20 ± 1.30 BPM (p = 0.000). A similar pattern was observed in gender, where males in Group A had 60.88 ± 1.54 BPM and Group B had 76.44 ± 0.89 BPM (p = 0.000), and females in Group A had 60.77 ± 1.79 BPM, while females in Group B had 76.07 ± 1.27 BPM (p = 0.000), as shown in Table-III. For birth weight ≤3000 g, Group A had 61.25 ± 1.39 BPM, and Group B had 76.20 ± 0.45 BPM (p = 0.000). For birth weight >3000 g, Group A's respiratory rate was 60.68 ± 1.70 BPM, and Group B's was 76.28 ± 1.17 BPM (p = 0.000).

Table III

Stratification of mean Respiratory Rate at 4 hours with respect to demographic factors in both groups

Demographic factors	Group		Mean Respiratory Rate at 4 hours (BPM) Mean	SD	p Value
Gestational Age at Birth (weeks)	≤39	A (n=26)	60.961	1.66	0.000
		B (n=25)	76.280	1.06	
	>39	A (n=4)	60.000	1.15	0.000
		B (n=5)	76.200	1.30	
Gender	Male	A (n=17)	60.882	1.54	0.000
		B (n=16)	76.437	0.89	
	Female	A (n=13)	60.769	1.79	0.000
		B (n=14)	76.071	1.27	
Birth weight (gm)	≤3000	A (n=8)	61.250	1.39	0.000
		B (n=5)	76.200	0.45	
	>3000	A (n=22)	60.681	1.70	0.000
		B (n=25)	76.280	1.17	

Figure 2



In the correlation analysis, the relationships between gestational age at birth, birth weight, respiratory rate before treatment, and respiratory rate at 4 hours were examined (Table-IV). The correlation between gestational age at birth and birth weight was weak but statistically significant (r = 0.212, p = 0.104), suggesting a slight positive association. However, the correlations between gestational age and both respiratory rate before treatment (r = -0.184, p = 0.159) and respiratory rate at 4 hours (r = 0.066, p = 0.617) were very weak and not statistically significant, indicating that gestational age did not have a meaningful effect on these respiratory measures.

Similarly, the correlation between birth weight and respiratory rate before treatment was minimal (r = -

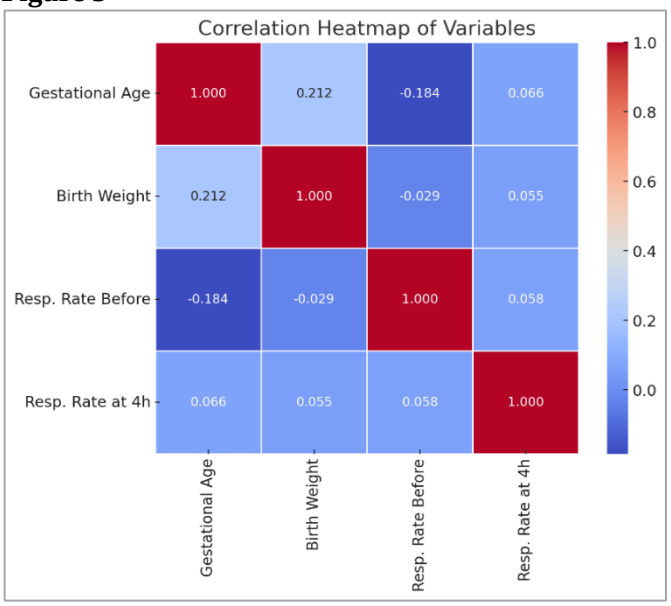
0.029, p = 0.826), and the correlation with respiratory rate at 4 hours was also weak (r = 0.055, p = 0.678), both of which were not statistically significant. Additionally, the respiratory rate before treatment showed a very weak positive correlation with the respiratory rate at 4 hours (r = 0.058, p = 0.662), which was not statistically significant either. This further supports the notion that the changes in respiratory rate at 4 hours were not strongly influenced by birth weight, gestational age, or initial respiratory rate.

Table IV

Correlation of Demographic Factors and Respiratory Rates Before and After Treatment

VARIABLES		Gestational Age at Birth	Birth Weight	Respiratory Rate Before Treatment	Respiratory Rate at 4 hours
Gestational Age at Birth	Pearson Correlation	1	0.212	-0.184	0.066
	Sig. (2-tailed)		0.104	0.159	0.617
Birth Weight	Pearson Correlation	0.212	1	-0.029	0.055
	Sig. (2-tailed)	0.104		0.826	0.678
Respiratory Rate Before Treatment	Pearson Correlation	-0.184	-0.029	1	0.058
	Sig. (2-tailed)	0.159	0.826		0.662
Respiratory Rate at 4 hours	Pearson Correlation	0.066	0.055	0.058	1
	Sig. (2-tailed)	0.617	0.678	0.662	

Figure 3



DISCUSSION

This study's results indicate that both treatments shared similar respiratory rates at baseline, but at 4 hours' post-treatment, nebulized Salbutamol (Group A) improved respiratory rate more in comparison with Normal Saline (Group B). This is a demonstration that beta-agonist Salbutamol can play a more effective role in reducing respiratory distress by improving both bronchodilation as well as respiratory mechanics.

This failure to have a significant difference in rate of respiration between groups at earlier time points (before treatment, 30 minutes, 60 minutes) can be attributed to progressive development in activity of Salbutamol, which may take longer time in exerting its effect on the respiratory tract. In contrast, significant improvement at 4th hour is a demonstration that Salbutamol is a sustained therapeutic agent with a likely activity in decreasing resistance in the airways as well as in improving ventilation, which is a central in the treatment of TTN.

Our research findings were consistent with a series of studies that evaluated the role of Salbutamol in the management of Transient Tachypnea of the Newborn (TTN). The study evaluated the effect of nebulized Salbutamol versus nebulized Normal Saline in management of TTN. In demographic profile, both study groups (Group A: Salbutamol, Group B: Normal Saline) had a comparable mean gestational age (37.73 ± 1.01 weeks versus 37.93 ± 1.22 weeks), as well as birth weight (3115.00 ± 134.00 g versus 3131.67 ± 128.98 g), with gender distribution also comparable (56.7% male in Group A versus 53.3% male in Group B, respectively). The same demographic equivalence is seen in studies by Babaei et al. [14] wherein no difference between treatment and placebo regarding gestational age, birth weight, as well as gender distribution, was seen.

With regards to respiratory rates, both cohorts prior to treatment were equal in terms of values: Group A having a mean rate of 77.00 ± 2.03 BPM, whereas in Group B 76.90 ± 1.84 BPM (p = 0.843). After 30 minutes after treatment, both cohorts' respiratory rates did not differ (Group A: 72.17 ± 1.68 BPM, Group B: 72.37 ± 1.51 BPM, p = 0.631). After 60 minutes, no difference (Group A: 69.80 ± 1.76 BPM, Group B: 70.10 ± 1.70 BPM, p = 0.507) did exist. But at 4 hours, a difference did occur: a mean rate in Group A of 60.83 ± 1.62 BPM, whereas in Group B 76.27 ± 1.08 BPM (p < 0.001), a significant improvement in Group A. The above is in agreement with that reported by Ahmed et al. [15] in which a more significant drop in respiratory rate in the Salbutamol group in comparison with that in the placebo (8.30 ± 1.37 vs. 2.67 ± 0.76, p < 0.001) was observed. Similarly, Babaei et al. [14] also reported significant improvement in terms of respiratory rate in the Salbutamol group in comparison with that in the placebo.

Stratified mean 4-hour rate of respiration also exhibited persistent difference in demographic variables. In gestational age ≤39 weeks, mean 60.96 ± 1.66 BPM was recorded in Group A, whereas 76.28 ± 1.06 BPM in

Group B (p = 0.000). In gestational age >39 weeks, mean in Group A recorded 60.00 ± 1.15 BPM, whereas mean in Group B recorded 76.20 ± 1.30 BPM (p = 0.000). The same trend in gender also followed, with males in Group A having 60.88 ± 1.54 BPM, whereas males in Group B having 76.44 ± 0.89 BPM (p = 0.000), whereas females in Group A having 60.77 ± 1.79 BPM, whereas females in Group B having 76.07 ± 1.27 BPM (p = 0.000). In birth weight ≤3000 g, mean in Group A recorded 61.25 ± 1.39 BPM, whereas mean in Group B recorded 76.20 ± 0.45 BPM (p = 0.000). In birth weight >3000 g, mean in Group A recorded 60.68 ± 1.70 BPM, whereas mean in Group B recorded 76.28 ± 1.17 BPM (p = 0.000). The trend in persistent improvement in rate of respiration with administration of Salbutamol in all these varying subgroups is similar as in that reported in study by Ahmed et al. [15] which also reported similar improvement in rate of respiration in terms of gestational age, birth weight, gender.

Lastly, correlation analysis did not establish statistical correlation between birth gestational age, birth weight, pre-treatment rate of respiration, and 4th hour rate of respiration with all having a p-value above 0.05. The implication is that demographic variables did not impact observed 4th hour rate of respiration difference. The study conducted by Malakian et al. [16] also failed to establish a statistical correlation between demographic variables and neonatal outcomes from treatment with Salbutamol.

Overall trends in our research are in line with those in comparable research, with a demonstration that nebulized Salbutamol is effective in reducing the rate of respiration in neonates with TTN with a noted improvement at 4 hours from treatment. The demographic homogeneity in these researches makes these observations more valid in that it is probable that nebulized Salbutamol can be a viable treatment in a range of neonatal populations. That these researches do not necessarily translate into a universal application in clinical care is noted, though, in that a Cochrane review conducted by Moresco et al. [17] noted a lack of sufficient studies with a request for additional research in order to conclusively determine the usefulness of Salbutamol in the treatment of TTN.

While informative, our study does have some limitations. A critical limitation is that it is a single-center study that could limit its applicability in more extensive, more varied populations. The sample size is also relatively small, which can limit its statistical power in detecting smaller between-groups' differences. Replication studies with more extensive sample sizes as well as multicenter participation will be necessary in order to confirm these observations. The 4-hour duration of follow-up also may not be sufficient in order to determine its long-term impact on respiratory outcomes, which will have to be evaluated in a study with a longer duration.

CONCLUSION

Our study has demonstrated that nebulized Salbutamol is a viable treatment in neonates with Transient Tachypnea of the Newborn (TTN), with a significant improvement in respiratory rates over that with normal saline. The conclusion is that Salbutamol is likely to be effective in alleviating respiratory distress as well as improving clinical outcomes in affected neonates. The study indicates that Salbutamol can be an efficacious treatment in the management of TTN, although more multicenter as well as larger sample studies are required in order to establish its long-term efficacy as well as safety.

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Author Contributions

Dr. Hajra Iqbal Alvi formulated the study, drafted the manuscript, and collected hospital data.
Dr. Sohail Ashraf contributed to study design, data analysis, and interpretation.
All authors read and approved the manuscript.

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