Research Paper

Nebulized Salbutamol for Treatment of Transient Tachypnea of the Newborn: A Randomized Placebo-controlled Clinical Trial in Iran

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ABSTRACT

Background: Transient tachypnea of the newborn (TTN) is caused by insufficient or delayed fetal lung fluid clearance, leading to ineffective gas exchange, respiratory distress, and tachypnea.

Objectives: This study aimed to investigate the effect of nebulized salbutamol on different severities of TTN in newborns.

Methods: This is a randomized double-blind, placebo-controlled, clinical trial on 64 neonates with TTN admitted to the neonatal intensive care units of Bouali and Imam Khomeini tertiary hospitals in Sari, north of Iran. They were divided into two groups (32 per group): The salbutamol group, which received 0.1 mL of nebulized salbutamol (ventolin, salbutamol sulfate 5 mg/mL) in 3 mL of normal saline 0.9%; and the placebo group, which received 2 mL of 0.9% nebulized saline as a placebo. The severity of TTN was determined based on the Silverman-Andersen respiratory severity (RSS) score. Data were analyzed in SPSS software, version 23, and P<0.05 was considered statistically significant.

Results: Among 64 neonates, 49(76.56%) were male. The mean weight was 3071±689 and 3139±539 grams in the placebo and salbutamol groups, respectively. There was no significant difference in the total RSS before treatment (6.25±1.685 vs 5.75±1.741; P=0.248) between groups, but it declined significantly after treatment (1.09±0.995 vs 1.94±1.5; P=0.010). The length of hospital stay and duration of respiratory support were significantly shorter in the salbutamol group compared to the placebo group (P<0.001), but there was no significant difference in the age at initiation of feeding.

Conclusions: The use of nebulized salbutamol can improve the condition of transient dyspnea in neonates with lower (RSS ≤6) or higher (RSS >6) TTN severity.

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Introduction

Transient tachypnea of the newborn (TTN) is a common, self-limited respiratory disorder resulting from delayed clearance of fetal lung fluid after birth [1, 2]. This condition is frequently observed in full-term or late-preterm infants, with an incidence rate of 5.7 per 1000 newborns [3, 4]. Symptoms of TTN usually appear within the first few minutes to hours after birth, and include tachypnea, nasal flaring, grunting, intercostal, subcostal, and suprasternal retraction [5, 6]. Respiratory distress is often resolved within 3-5 days, provided there are no complications [7, 8]. TTN is generally benign and self-limited, but in some newborns, it can cause pneumothorax, pulmonary hypertension, and some secondary problems such as increased monitoring, maternal-infant separation, unnecessary antibiotic therapy, prolonged hospital stay, and respiratory failure. There is no definitive treatment for TTN. The standard management of TTN involves supportive respiratory measures, which may include supplemental oxygen, nasal continuous positive airway pressure (CPAP), or, in severe refractory cases, mechanical ventilation [9, 10]. The use of prophylactic antibiotics is rational until a blood culture is reported [11, 4]. Drugs such as diuretics, inhaled racemic epinephrine, and inhaled beta-2 agonists may be effective in treating TTN, but none are definitive cures [12-14]. Salbutamol, a short-acting selective β2-adrenergic receptor agonist, enhances the clearance of lung fluid by stimulating epithelial sodium channel activity and improving tachypnea in newborns with TTN [15, 16].

Recent studies have reported that salbutamol can significantly improve the TTN score, reduce the duration of hospitalization and the need for supportive oxygen therapy, and facilitate earlier feeding in newborns [3, 15, 17-20]. Several studies have assessed the efficacy of salbutamol in patients with varying severities of TTN; however, no study has been performed in northern Iran. Therefore, this study aimed to evaluate the efficacy of inhaled salbutamol in treating TTN in newborns and assess the outcome based on the different severities of TTN. The novelty of this study lay in determining the TTN severity based on the Silverman-Andersen respiratory severity score (RSS), a measure that had not been applied previously.

Materials and Methods

Study design and participants

In this double-blind randomized clinical trial, newborns with TTN admitted to the neonatal intensive care unit (NICU) of Bouali and Imam Khomeini tertiary hospitals in Sari, Mazandaran Province, northern Iran, were evaluated from March 2022 to April 2023. Newborns with a gestational age of >34 weeks who met the TTN diagnostic criteria, including tachypnea (a respiratory rate >60 breaths per minute) with or without cyanosis, respiratory distress, and chest x-ray findings in favor of TTN [21], were enrolled in this study. TTN diagnosis based on chest x-ray findings was done by a neonatologist. In case of meconium aspiration, pneumonia, complex congenital heart disease, tachycardia (heart rate >180 beats per minute), an RSS <4, a need for respiratory support with a ventilator after birth, sepsis, respiratory distress syndrome (RDS) diagnosis during hospitalization and administration of surfactants, the samples were excluded. Empirical antibiotic therapy, supplemental oxygen therapy, and supportive care were applied for all patients. Based on previous studies, the sample size was calculated as 60, with 30 allocated to each group [12] at a 95% confidence interval (CI) level and considering a test power of 85%.

Patients were randomly selected using the permuted block randomization method with blocks of 4 and randomly divided into two parallel groups of salbutamol (n=32) and placebo (n=32) on the sealed envelope website. Patients were stratified into two groups based on the severity of TTN (RSS score >6 and RSS score 4-6). The patients were blinded to the drug administered and group allocation. Placebo and drug had the same color and shape in appearance and were coded by the researcher, and each patient had a drug code. The drug administration was done by an experienced nurse who was blind to the group allocation. Figure 1 presents the flowchart of sampling and allocation processes.

Assessments

Data, including gender, mode of delivery, birth weight, Apgar score, history of prelabor rupture of membranes (PROM), history of diabetes and asthma in mothers, type of respiratory support (CPAP, oxygen therapy alone), partial pressure of oxygen (PO_2) and carbon dioxide (PCO_2), and arterial blood gas (ABG), were first recorded. Empirical antibiotic therapy was initiated after culture sampling in cases that were unresponsive to oxygen supplementation and supportive management.

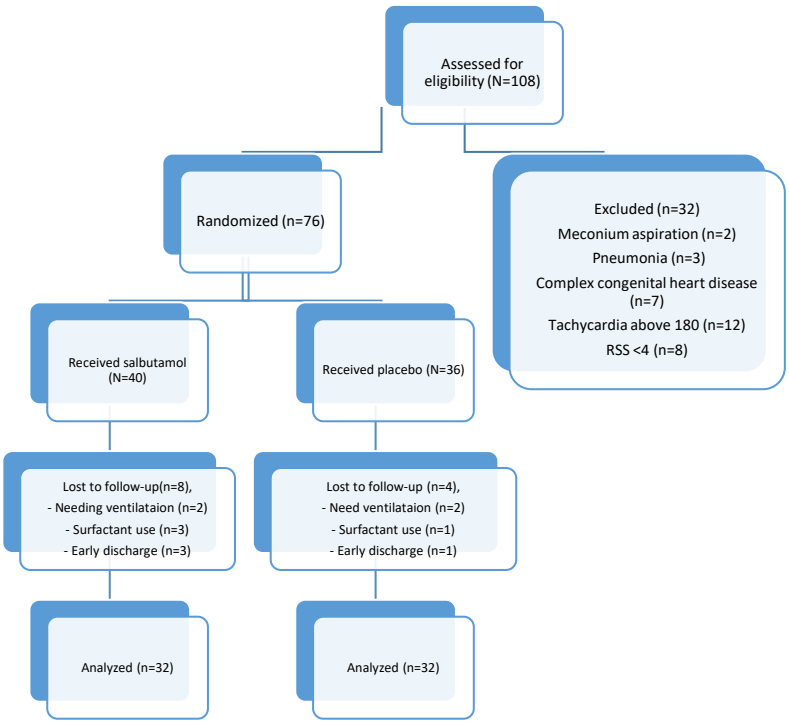

Figure 1. The flowchart of sampling and allocation processes

The severity of TTN was assigned based on the RSS (a score of 4-6 and >6) [22]. The RSS assesses five parameters of respiratory effort, yielding a total score ranging from 0 (representing comfortable breathing) to 10 (representing severe respiratory distress). If the RSS was ≥6, the nasal CPAP or supplemental oxygen was initiated. When the respiratory rate reached <60 and abdominal distention was not present, feeding was initiated.

The primary outcomes included the duration of initial nasal CPAP and supplemental oxygen therapy, post-treatment PO_2 and PCO_2 levels, length of hospitalization, and age at initiation of feeding, determined by achieving an RSS score <4 along with stabilization of heart rate, respiratory rate, and oxygen saturation (SpO_2). ABG was analyzed 4 hours after the administration of 4 doses of salbutamol. Supplementary oxygen or CPAP was used to reach an oxygen saturation of 90-95%. The RDS score was checked after hospital admission and before administration of drugs.

Intervention

In the salbutamol group, 0.1 mL of salbutamol (Ventolin, salbutamol sulfate 5 mg/mL) was nebulized in 3 mL of 0.9% normal saline. Salbutamol was then administered at a standard dose of 0.15 mg/kg via daily nebulization using a jet nebulizer with a continuous oxygen flow of 5 liters per minute for 10 minutes and every 6 hours for one day. The placebo group was given 2 mL of 0.9% saline as a placebo, administered via nebulizer at the same intervals and duration as those for the salbutamol group. The complications of salbutamol treatment (agitation, irritability, tachycardia, arrhythmia, blood pressure variability, vomiting, hypokalemia, and muscle cramps) were assessed at all times of drug administration and for 24 hours thereafter. If any complications happened, therapeutic or supportive care was done, or salbutamol was discontinued.

Data analysis

After recording demographic characteristics and clinical findings, analyses were performed in SPSS software, version 23. Qualitative variables were presented as frequencies (percentages), while quantitative variables were expressed as Mean±SD for normally distributed data and as median with 25^{th} and 75^{th} percentiles for abnormally distributed data. Comparisons between groups were conducted using the independent t-test for normally distributed quantitative variables and the Mann-Whitney U test for abnormally distributed quantitative variables. The chi-square test was applied for qualitative variables. P<0.05 was considered statistically significant.

Results

The baseline demographic and clinical characteristics of newborns are presented in Table 1. No significant differences were observed between the groups regarding gender, mode of delivery, birth weight, or type of respiratory support (P>0.05). The mean birth weight was 3071±689 g in the placebo group and 3139±539 g in the salbutamol group (P=0.207). No significant difference was observed in TTN severity (P=0.248) at baseline based on the total RSS; however, a significant difference was found after treatment (P=0.01) (Table 2). Regarding the disease outcomes, the intervention group had significantly shorter length of hospital stay and duration of respiratory support (P<0.05), whereas the age at initiation of feeding did not differ significantly between groups (Table 3). While upper chest movement, lower chest retraction, and xiphoid retraction did not differ significantly between groups, nares dilatation and expiratory grunt showed significant improvement in the salbutamol group (P<0.05).

Patients were categorized based on their pre-treatment RSS into two subgroups: A group with a score of 4-5 and a group with a score of 6 or higher. The disease outcomes in these two subgroups are presented in Table 4. The length of hospital stay and duration of respiratory support were significantly lower in both RSS subgroups of the salbutamol group compared to those in the placebo group (P<0.05). The age at initiation of feeding was similar between the salbutamol and placebo groups in two RSS subgroups (P>0.05). No adverse effect of salbutamol was reported in this study.

Table 1. Baseline demographic and clinical characteristics of participants in two groups

Characteristics		No./No. (%)/Mean±SD		P
		Salbutamol Group	Placebo Group	
Gender	Male	27	22	0.237
	Female	5	10	
Nasal CPAP		20(62.5)	19(59.4)	0.798
Age at admission (d)		1.25±0.44	1.13±0.336	0.206
Birth weight (g)		3139±521	3071± 689	0.660
Gestational age (w)		37.5±0.984	36.81±1.84	0.067
Delivery	CS	25	28	0.509
	NVD	7	4	
APGAR score (1st min)		4.69±1.148	5.88±1.008	0.321
APGAR score (5th min)		34.56±25.854	67.5±36.976	0.321
Heart rate/min		138±7	139±0.880	0.522
Respiratory rate/min		73±9	72±8	0.540
PH		7.34±0.07	7.35±0.05	0.651
HCO_3		24±5	23±3	0.344
PCO_2		43±1	42±8	0.548
PO_2		81±43	85±53	0.754
Oxygen saturation		89±4	89±4	0.577

CS: Cesarean section, NVD: Normal vaginal delivery.

Table 2. Severity of respiratory involvement based on RSS before and after treatment in two groups

RSS Items	Phase	Mean±SD		P
		Salbutamol Group	Placebo Group	
Upper chest movement	Pre-treatment	1.63±0.492	1.44±0.504	0.137
	Post-treatment	0.28±0.457	0.5±0.508	0.075
Lower chest retraction	Pre-treatment	1.34±0.483	1.31±0.471	0.794
	Post-treatment	0.25±0.44	0.5±0.508	0.039
Xiphoid retraction	Pre-treatment	1.5±0.508	1.44±0.504	0.623
	Post-treatment	0.56±0.504	0.75±0.44	0.118
Nares dilatation	Pre-treatment	0.5±0.508	0.31±0.471	0.131
	Post-treatment	0±0	0±0	0.010
Expiratory grunt	Pre-treatment	1.28±0.634	1.25±0.568	0.836
	Post-treatment	0±0	0.19±0.397	0.012
Total	Pre-treatment	6.25±1.685	5.75±1.741	0.248
	Post-treatment	1.09±0.995	1.94±1.501	0.010

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Discussion

This study aimed to investigate the efficacy of nebulized salbutamol in newborns with transient tachypnea. Our findings indicate that after treatment, the total RSS improved significantly in the salbutamol group compared to the placebo group. Also, nares dilatation and expiratory grunt domains of RSS showed significant improvement in the salbutamol group. Additionally, the salbutamol group experienced significantly shorter length of hospital stay and respiratory support duration compared to the placebo group.

Salama et al. conducted a study on 150 neonates with gestational age of 35-39 weeks in three groups (50 received a single dose of salbutamol, 50 received a double dose of salbutamol, and 50 served as controls). They concluded that inhaled salbutamol reduced the duration of supplemental oxygen therapy, hospitalization, and time of initiation of feeding, without any reported adverse effects [20]. In a study by Kim et al. on 40 hospitalized neonates with TTN (28 receiving inhaled salbutamol and 12 receiving placebo), the duration of supplemental oxygen therapy and empirical antibiotic treatment was significantly shorter in the salbutamol group. However, the duration of tachypnea, time of initiation of enteral feeding, and length of hospital stay were similar between groups. No adverse effects were reported in any groups [10]. In the triple-blind clinical trial by Malakian et al., TTN score and severity were compared between the groups that received inhaled salbutamol or normal saline. The salbutamol group demonstrated shorter durations of hospitalization and oxygen therapy, as well as earlier initiation of oral feeding [9]. These findings are consistent with our results. In our study, the total TTN score reduced significantly in

Table 3. Disease outcomes in two groups

Outcome	Mean±SD		P
	Salbutamol Group	Placebo Group	
Length of hospital stay (d)	4.69±1.148	5.88±1.008	0.000
Duration of respiratory support (h)	34.56±25.854	67.5±36.976	0.000
Age at initiation of feeding (d)	2.75±0.88	2.63±0.609	0.511

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Table 4. Disease outcomes categorized by pretreatment RSS subgroups (TTN severity)

Severity Category	Outcome	Mean±SD		P
		Salbutamol Group	Placebo Group	
Pretreatment RSS (4-5)	Length of hospital stay (d)	4.31±1.01	5.67±1.19	0.001
	Duration of respiratory support (h)	26.63±21.69	63.78±44.99	0.005
	Age at initiation of 1st feeding (d)	2.75±0.683	2.56±0.511	0.351
Pretreatment RSS (≥6)	Length of hospital stay (d)	5.06±1.18	6.14±0.66	0.005
	Duration of respiratory support (h)	42.5±27.87	72.29±24.86	0.004
	Age at initiation of 1st feeding (d)	2.75±1.065	2.71±0.726	0.917

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the salbutamol group similar to the mentioned studies. It seems that the acute respiratory benefit of salbutamol is acceptable. However, long-term results and the safety of the drug should also be considered.

Basiri et al. in a study on 52 newborns in two groups of nebulized sodium chloride (control) and salbutamol reported significantly lower TTN scores and shorter duration of respiratory support in the salbutamol group but there was no significant difference in length of hospital stay, duration of antibiotic therapy, time to start oral feeding and maximum oral feeding time between two groups [11]. El-Badawy et al. prospectively compared 100 full-term neonates with TTN in four equal groups receiving nebulized budesonide, epinephrine, salbutamol, and normal saline. After 48 hours, there was a significant decrease in the respiratory rate in the salbutamol group. The 48-hour TTN clinical score was significantly lower in the salbutamol group compared to the normal saline control group [15]. Khushdil et al. evaluated 100 newborns with TTN in four groups of nebulized salbutamol, furosemide, furosemide + nebulized salbutamol, and only supportive care (control). The mean duration of oxygen dependency and the need for mechanical ventilation were significantly lower in the salbutamol + furosemide group compared to the control group. The mean duration of oxygen dependency was not significantly different in the salbutamol group compared to the control group [17]. Mussavi et al. studied neonates with TTN who received either nebulized albuterol or a placebo. In treatment group, duration of CPAP and respiratory distress score decreased significantly and the PO_2 increased significantly. No adverse effects were observed in any groups [13]. In the randomized controlled clinical trial by Al Lahony et al., after 4 hours of inhaled therapy, the placebo group exhibited higher respiratory rates, oxygen requirements, TTN scores, need for respiratory support, and longer hospitalization, whereas the salbutamol group showed significantly higher arterial pH and PO_2. No significant differences were observed between groups in heart rate or serum potassium levels [12]. Babaei et al. included 80 neonates with TTN who received either nebulized salbutamol or a placebo. The salbutamol group experienced significantly shorter durations of tachypnea, hospitalization, oxygen therapy, and time to initiate enteral feeding. However, no significant differences were observed between groups in the duration of mechanical ventilation, need for or duration of CPAP, or incidence of pneumothorax [16]. Talaat et al. studied 100 neonates with TTN in two groups of inhaled salbutamol and normal saline. The salbutamol group demonstrated significantly shorter durations of respiratory support and hospitalization, as well as lower respiratory rates, fraction of inspired oxygen, and TTN score [18]. Mohammadzadeh et al. evaluated the effects of inhaled salbutamol versus placebo in 70 neonates with TTN. They concluded that inhaled salbutamol facilitated earlier initiation of enteral feeding, reduced the duration of respiratory support, and shortened hospitalization in neonates with moderate to severe TTN [7]. In our study, the salbutamol group demonstrated significantly shorter durations of hospitalization and respiratory support compared to the placebo group, whereas the time to initiate feeding was similar between groups. Discrepancies among different studies may be attributed to differences in study settings and sample sizes. It remains unclear whether salbutamol had a long-term effect on the duration of hospitalization, respiratory support, or initiation of feeding.

Conclusion

In conclusion, nebulized salbutamol seems to improve acute respiratory distress in neonates with TTN. This im-

provement is evident in neonates with both lower (RSS ≤6) and higher (RSS >6) disease severity. Further studies with larger sample sizes are recommended to evaluate the long-term effects of nebulized salbutamol.

Ethical Considerations

Compliance with ethical guidelines

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Written informed consent was obtained from the parents or legal guardians of all neonates prior to enrollment. The study was approved by the Ethics Committee of Mazandaran University of Medical Sciences, Sari, Iran (Code: IR.MAZUMS.REC.1402.166) and was registered by the Iranian Registry of Clinical Trials (IRCT) (Code: IRCT20091201002801N6).

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Authors contributions

Conceptualization: Abbas Dabbaghzadeh; Methodology: Roya Farhadi, Javad Ghaffari and Abbas Dabbaghzadeh; Data curation and writing: Maedeh Gooran and Marziyeh Taji; Supervision: Javad Ghaffari and Abbas Dabbaghzadeh; Investigation and final approval: All authors.

Conflicts of interest

The authors declared no conflict of interest.

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