ORIGINAL RESEARCH

Use of aerosolized Ambroxol in the management of respiratory distress syndrome in children

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ABSTRACT
Background: Premature newborns are the main victims of respiratory distress syndrome (RDS), commonly referred to as hyaline membrane illness. It happens when premature babies' lungs don't contain enough surfactant. The present study was conducted to assess use of aerosolized Ambroxol in the management of respiratory distress syndrome. **Materials & Methods:** 70 preterm infants of both genderswere divided into 2 groups of 35 each. Group I patients received an intravenous infusion of 30 mg/kg of Ambroxol for two days after receiving an injection of 15 mg/kg in the umbilical vein as soon as they were born. Group II received an aerosolized Ambroxol treatment, which involved inhaling 30 mg/kg of Ambroxol for two days right after birth. At the initial assessment, parameters such the enrolled newborns' temperature, heart rate, respiration rate, and SaO2 and mortality ratewere measured. **Results:** The mean respiratory rate in group I was 63.4 cycles/min and in group II was 66.8 cycles/min. The mean heart rate in group I was 146.3 beats/ min and in group II was 144.6 beats/min. The mean temperature in group I was 36.8 degrees C and in group II was 36.2 degrees C. The mean SaO2 in group I was 95.3% and in group II was 95.8%. The incidence of RDs was seen in 18 in group I and 13 in group II patients. 21 patients in group I and 14 in group II required mechanical ventilation. Mortality was 5 in group I and 11 in group II. **Conclusion:** Ambroxol can be atomized or given intravenously to premature babies, however atomizing or breathing is more effective than intravenous Ambroxol at preventing respiratory distress syndrome.
Keywords: Ambroxol, Respiratory distress syndrome, temperature

INTRODUCTION

Premature newborns are the main victims of respiratory distress syndrome (RDS), commonly referred to as hyaline membrane illness. It happens when premature babies' lungs don't contain enough surfactant. A chemical called surfactant aids in maintaining the alveoli, the lungs' tiny air sacs, open.[1] Babies with respiratory distress syndrome (RDS) frequently have fast breathing, grunting sounds, respiratory distress, and bluish skin from low oxygen levels. Some neonates may have an influx of inflammatory cells as a result of oxygen toxicity from their anatomically immature lungs, barotrauma, and volutrauma. This reaction could exacerbate the vascular damage and lead to bronchopulmonary dysplasia, or BPD.[2]

Bromhexine hydrochloride's main N-desmethyl metabolite is ambroxol hydrochloride ($C_{13}H_{18}Br_2N_2O$).[3] In addition to the muco-kinetic and muco-ciliary effects of the parent compound, Ambroxol has gained several new but important pharmacological properties, such as surfactant stimulatory, anti-inflammatory, antioxidant, and local anesthetic effects, thanks to the removal of a methyl group and the addition of a hydroxyl group in the para-trans position of the cyclohexyl ring.[4] There are various formulations of it available. Ambroxol is a more recent inducer of fetal lung maturity than corticosteroids, and less research has been done on its efficacy. However, a growing body of data indicates that it can successfully prevent RDS when administered prenatally without harming the infant.[5]The present study was conducted to assess use of aerosolized Ambroxol in the management of respiratory distress syndrome.

MATERIALS & METHODS

The present study was conducted on 70 preterm infants of both genders. All parents were informed regarding the study and their written consent was obtained.

Data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 35 each. Group I patients received an intravenous infusion of 30 mg/kg of Ambroxol for two days after receiving an injection of 15 mg/kg in the umbilical vein as soon as they were born. Group II received an aerosolized Ambroxol treatment, which involved inhaling 30 mg/kg of Ambroxol for two days right after birth. At the initial assessment, parameters such the enrolled newborns' temperature, heart rate, respiration rate, and SaO2 were measured. After 24 hours of delivery, the blood gas values, complications, and incidence of RDS were compared. Measurements were made of the following: pH, SaO2 percentage, PCO2 mmHg, PaO2 mmHg, OI during M.V., MAP during M.V., length of M.V. (hours), and mortality rate. Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I Assessment of parameters

Parameters	Group I	Group II	P value
Respiratory rate	63.4	66.8	0.52
Heart rate	146.3	144.6	0.75
Temperature	36.8	36.2	0.81
SaO2 (%)	95.3	95.8	0.78
RDS at 24 hours	18	13	0.05
mechanical ventilation	21	14	0.05

Table I, graph I shows that mean respiratory rate in group I was 63.4 cycles/min and in group II was 66.8 cycles/min. The mean heart rate in group I was 146.3 beats/ min and in group II was 144.6 beats/min. The mean temperature in group I was 36.8 degrees C and in group II was 36.2 degrees C. The mean SaO2 in group I was 95.3% and in group II was 95.8%. The incidence of RDs was seen in 18 in group I and 13 in group II patients. 21 patients in group I and 14 in group II required mechanical ventilation. The difference was significant (P< 0.05).

Graph I Assessment of parameters

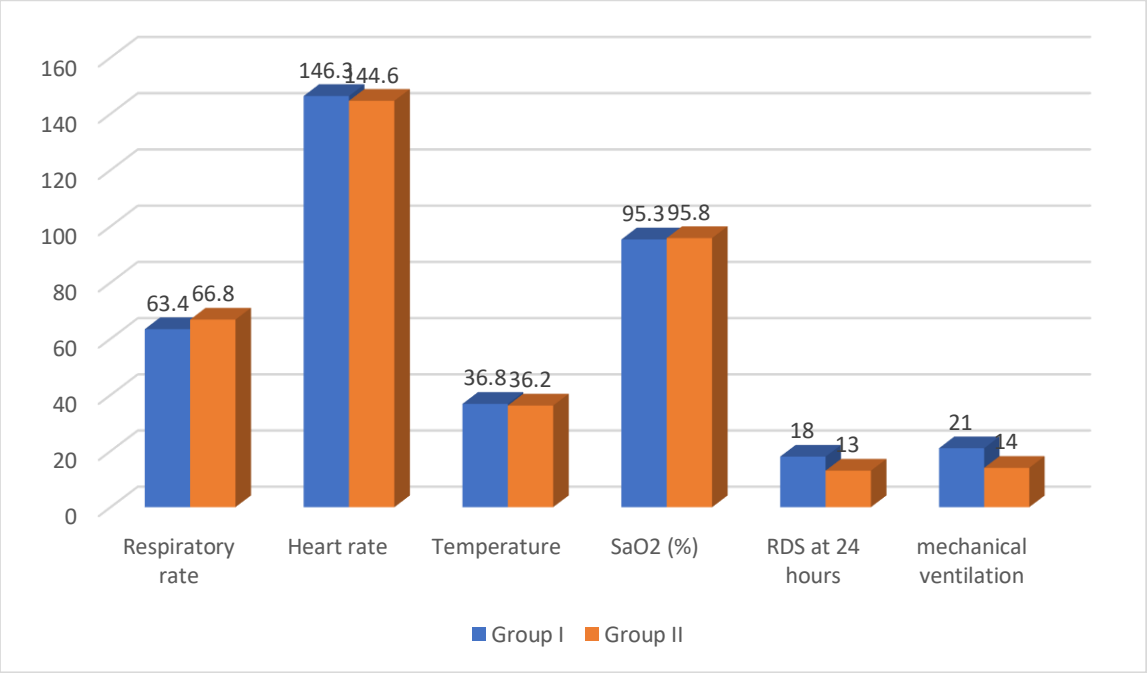
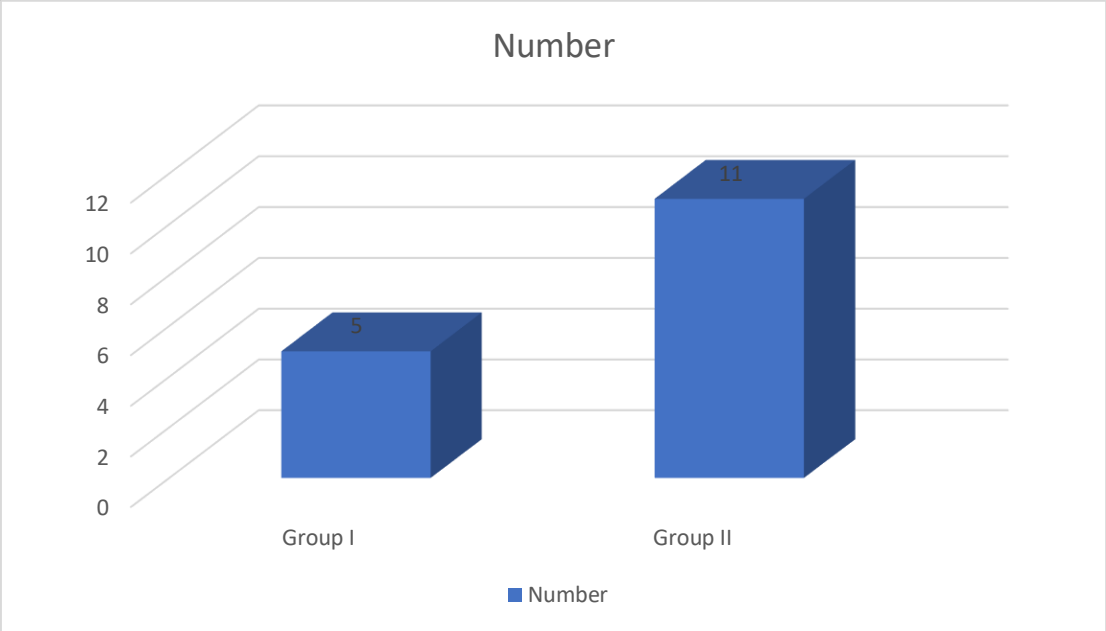


Table II Mortality rate in both groups

Mortality	Number	P value
Group I	5	0.01
Group II	11	

Table II, graph II shows that mortality was 5 in group I and 11 in group II. The difference was significant (P< 0.05).

Graph II Mortality rate in both groups



DISCUSSION

About 11% of all babies are born prematurely, and the percentage is growing in many countries across the globe.[6] Optimal early therapy for these infants is expected to improve their health for the rest of their lives as the number of patients in this cohort increases and overall survival improves.[7] The European Consensus Group summarized the extensive research on RDS management into best-practice principles.[8] Among other tactics for the optimal management of RDS, these included prenatal practices, early delivery room management, mechanical and non-invasive breathing aid, surfactant therapy, and supportive care.[9]The present study was conducted to assess use of aerosolized Ambroxol in the management of RDS.

We found that mean respiratory rate in group I was 63.4 cycles/min and in group II was 66.8 cycles/min. The mean heart rate in group I was 146.3 beats/ min and in group II was 144.6 beats/min. The mean temperature in group I was 36.8 degrees C and in group II was 36.2 degrees C. The mean SaO2 in group I was 95.3% and in group II was 95.8%. The incidence of RDs was seen in 18 in group I and 13 in group II patients. 21 patients in group I and 14 in group II required mechanical ventilation. According to Leurti et al[10], women between the ages of 27 and 34 who were either threatened with or had scheduled an early delivery were admitted. The prevalence of RDS was evaluated in 169 healthy newborns born before to week 37. Of them, 86 were born to 76 moms who had betamethasone treatment, and 83 to 76 mothers who received Ambroxol treatment. The total incidence of RDS was substantially higher in the betamethasone group (31%) than the Ambroxol group (13%). When it came to twin births, babies born before the 31st week, ROM to delivery times more than 48 hours, treatment to delivery times between 2 and 7 days, and female babies, Ambroxol was noticeably more successful than betamethasone. Compared to the group of newborns treated with Ambroxol (9% with one fatality), the neonatal infection rate was significantly greater in the betamethasone-treated infant group (18% with four fatalities). According to these findings, Ambroxol might be a good substitute for steroids in the fight against RDS.

We observed that mortality was 5 in group I and 11 in group II. Li et al[11]assessed the effectiveness of high-dose Ambroxol (990 mg/day) in the improvement of oxygenation and prevention of postoperative respiratory complications in the patients with acute cervical spinal cord injury (CSCI).A total of 61 acute CSCI patients admitted to the Intensive Care Unit (ICU) were included in the study. They were graded as ASIA A and ASIA B according to the classification of the American Spinal Injury Association (ASIA) and were randomly divided into two groups: one group received intravenous Ambroxol at 990 mg/day for 5 consecutive days after operation; the other group treated without Ambroxol served as control. The results of arterial blood gas analysis on postoperative day 3 and 5 and occurrence of pulmonary complications within 5 days after operation were evaluated.The group treated with high-dose Ambroxol showed a lower rate of postoperative pneumonia and hypoxemia within 5 days after operation. On the 3rd and 5th days, the oxygenation index in the high-dose Ambroxol group (291.02 ± 34.96 and 301.28 ± 37.69) was significantly higher than in the control group (230.08 ± 26.25 and 253.82 ± 26.26), with significant differences between the two groups (P = 0.045 and 0.041).

The shortcoming of the study is small sample size.

CONCLUSION

Authors found that Ambroxol can be atomized or given intravenously to premature babies, however atomizing or breathing is more effective than intravenous Ambroxol at preventing RDS.

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