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ORIGINAL ARTICLE

Assessment of outcome of aerosolized Ambroxolin the management of RDS

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ABSTRACT:
Background: Respiratory distress syndrome (RDS), also known as hyaline membrane disease, is a breathing disorder that primarily affects premature infants. The present study was conducted to assess outcome of aerosolized Ambroxolin the management of RDS. **Materials & Methods: Results:** The mean respiratory rate in group I was 65.1 cycles/min and in group II was 67.7 cycles/min. The mean heart rate in group I was 148.3 beats/ min and in group II was 142.9 beats/min. The mean temperature in group I was 36.2 degrees C and in group II was 36.5 degrees C. The mean SaO2 in group A was 94.1% and in group II was 94.5%. The incidence of RDs was seen in 18 in group I and 14 in group II patients. 18 patients in group I and 14 in group II required mechanical ventilation. The difference was significant (P< 0.05). Death occurred in 6 in group I and 10 in group II. The difference was significant (P< 0.05). **Conclusion:** When given early to preterm newborns, Ambroxol can be administered intravenously or by atomizing; however, atomizing or inhaling works better than intravenous Ambroxolfor preventing RDS.
Keywords: Ambroxol, Respiratory distress syndrome, ventilation

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INTRODUCTION

Respiratory distress syndrome (RDS), also known as hyaline membrane disease, is a breathing disorder that primarily affects premature infants. It occurs due to insufficient surfactant in the lungs of premature infants.[1] Surfactant is a substance that helps keep the small air sacs in the lungs (alveoli) open. Babies with RDS often have difficulty breathing (respiratory distress), rapid breathing, grunting sounds, and a bluish tint to their skin due to lack of oxygen.[2]

Due to a combination of barotrauma, volutrauma, and oxygen toxicity from their structurally immature lungs, certain newborns may experience an influx of inflammatory cells. This response may worsen the vascular damage and result in BPD (bronchopulmonary dysplasia).Ambroxolhydrochloride (C13H18Br2N2O) is the principal N-desmethyl metabolite of bromhexine hydrochloride.[3] The removal of a methyl group and the addition of a hydroxyl group in the para-trans position of the cyclohexyl ring have enhanced Ambroxolto acquire several new but significant pharmacological properties, including surfactant stimulatory, anti-inflammatory, anti-oxidant, and local anesthetic effects, in addition to the muco-kinetic and muco-ciliary effects of the parent compound.[4]It is available in multiple formulations. Compared to corticosteroids, Ambroxolis a more recent inducer of fetal lung maturity, and its effectiveness has been studied less. But more and more research has shown that when given antenatally, it can effectively prevent RDS without having a negative impact on the fetus. More research is required since the use of postnatal intravenous Ambroxolin the treatment and prevention of RDS is still debatable.[5]The present study was conducted to assess outcome of aerosolized Ambroxolin the management of RDS.

MATERIALS & METHODS

The present study was conducted on 56preterm 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 28 each. Group I patients were injected with 15mg/kg Ambroxolin umbilical vein immediately after birth followed by intravenous infusion of Ambroxol30mg/kg for 2 days. Group II was aerosolized Ambroxoltreatment administered by Ambroxol30mg/kg for 2 days by inhalation immediately after birth. Parameters such as vital signs of the enrolled neonates at the initial assessment respiratory rate, heart rate, temperature and SaO_2 were assessed. The incidence of RDS and complication and blood gas results were compared after 24 hours of the birth. PaO2 mmHg, PCO2 mmHg, SaO2 %, pH, need for mechanical ventilation, OI during M.V, MAP during M.V, duration of M.V(hrs) and mortality rate were recorded.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	65.1	67.7	0.91
Heart rate	148.3	142.9	0.15
Temperature	36.2	36.5	0.26
SaO2 (%)	94.1	94.5	0.38
RDS at 24hours	18	14	0.05
mechanical ventilation	20	15	0.05

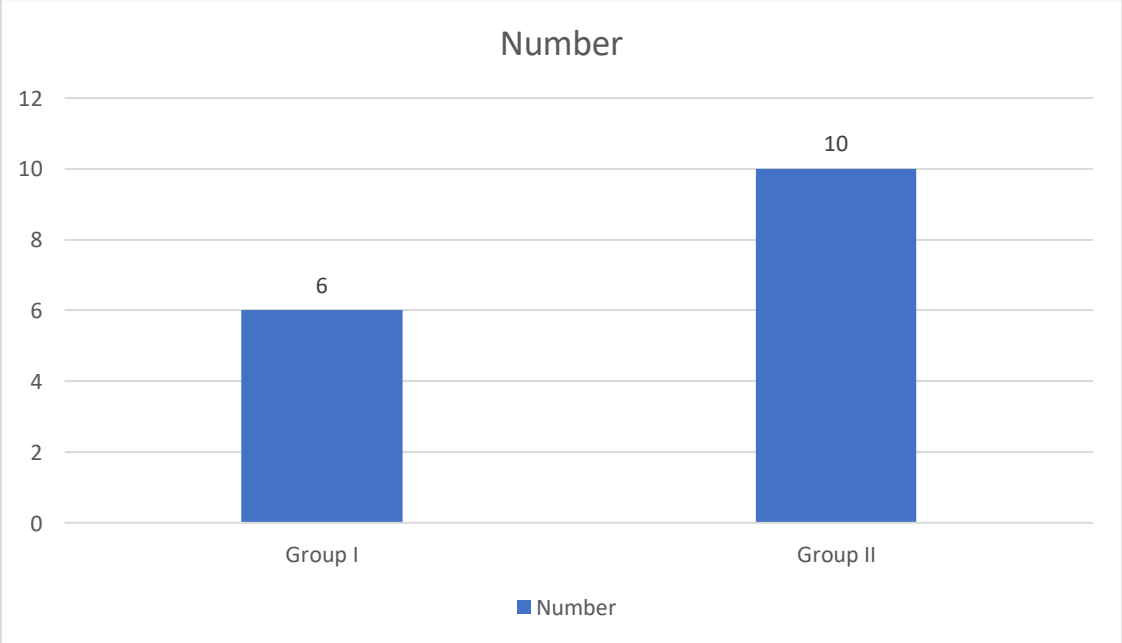
Table I shows that mean respiratory rate in group I was 65.1 cycles/min and in group II was 67.7 cycles/min. The mean heart rate in group I was 148.3 beats/ min and in group II was 142.9beats/min. The mean temperature in group I was 36.2degreesC and in group II was 36.5 degrees C. The mean SaO2 in group A was 94.1% and in group II was 94.5%. The incidence of RDs was seen in 18 in group I and 14 in group II patients. 18 patients in group I and 14 in group II required mechanical ventilation. The difference was significant (P< 0.05).

Table II Assessment of mortality

Mortality	Number	P value
Group I	6	0.03
Group II	10	

Table II, graph I shows that death occurred in 6 in group I and 10 in group II. The difference was significant (P< 0.05).

Graph I Assessment of mortality



DISCUSSION

Preterm birth affects about 11% of all infants, and the number is rising in many nations throughout the world.[6] As the number of patients in this cohort expands and overall survival improves, optimal early therapy of these infants is likely to enhance their health for the rest of their lives. The European consensus group compiled a lot of research on the management of RDS and summarised it as best-practice guidelines.[7] This included antenatal techniques, early delivery room management, mechanical and non-invasive respiratory assistance, surfactant therapy, and supportive care, among other strategies for the best management of RDS.[8]The present study was conducted to assess outcome of aerosolized Ambroxolin the management of RDS.

We found that the mean respiratory rate in group I was 65.1 cycles/min and in group II was 67.7 cycles/min. Baranwal et al[9]evaluated efficacy of high-dose oral Ambroxolin acute respiratory distress syndrome (ARDS) with respect to ventilator-free days (VFD).Sixty-six mechanically ventilated patients (1 month to 12 years) with ARDS who were hand-ventilated for <24 hr before pediatric intensive care unit admission.Majority (91%) had pneumonia and bronchiolitis. Two study groups were similar in baseline characteristics. Mean partial pressure of arterial oxygen/fraction of inspired oxygen and

oxygenation index were >175 and <10, respectively, with no difference in the two study groups. VFD were similar in the two study groups. Overall mortality was 26%. No adverse events were noted with ambroxol.Among ventilated pulmonary ARDS patients with oxygenation index of <10, mortality was 26%. Ambroxoldid not improve VFD. Study with higher and more frequently administered doses of Ambroxolin larger sample is suggested after having generated relevant pharmacokinetic data among critically ill children.

We found that the mean heart rate in group I was 148.3 beats/ min and in group II was 142.9 beats/min. The mean temperature in group I was 36.2 degrees C and in group II was 36.5 degrees C. The mean SaO2 in group A was 94.1% and in group II was 94.5%. The incidence of RDs was seen in 18 in group I and 14 in group II patients. 18 patients in group I and 14 in group II required mechanical ventilation. Leurti et al[10] found that women of 27 to 34 weeks gestation with threatened premature delivery or planned premature delivery were admitted. The incidence of RDS was assessed in 169 viable neonates born before the 37th week. Of these 86 were born of 76 mothers treated with beta-methasone and 83 of 76 mothers treated with ambroxol. The overall incidence of RDS was significantly (P less than 0.05) higher in the betamethasone group (31%) than the Ambroxolgroup (13%). Ambroxolwas significantly more effective than betamethasone in twin births, in infants born before the 31st week, when ROM to delivery time was more than 48 hours, when treatment to delivery time was between 2 and 7 days and in female infants. The neonatal infection rate was significantly higher (P less than 0.05) in the group of betamethasone treated infants (18% with four fatalities) than in the group of Ambroxoltreated infants (9% with one fatality). These results suggest that Ambroxolmay be a valid alternative to steroids for prevention of RDS.

The shortcoming of the study is small sample size.

CONCLUSION

Authors found that when given early to preterm newborns, Ambroxolcan be administered intravenously or by atomizing; however, atomizing or inhaling works better than intravenous Ambroxolfor preventing RDS.

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