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TO COMPARE THE EFFECTIVENESS OF NEBULISATION WITH ADRENALINE, 3% HYPERTONIC SALINE AND NORMAL SALINE IN BRONCHIOLITIS IN CHILDREN OF 2 TO 24 MONTHS OF AGE BASED ON CLINICAL SEVERITY SCORE AND NEBULISATION FREQUENCY.

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Abstract

Background & Method: We conducted a double blinded study at Index Medical College Hospital & Research Centre, Indore. The sample size was determined to be minimum of 120 cases as based upon previous years admission due to acute bronchiolitis. Initially, 146 cases were included in the study out of which 23 cases dropped out of the study after giving consent by guardian for participation in the study as they left against medical advice from the hospital.

Result: The mean difference of CSS between 0 minutes to 60 minutes of nebulisation between groups in all cases was 0.4 ± 0.6, between 60 minutes and 4 hours was 0.8 ± 0.6, between 4 to 8 hours was 0.7 ± 0.6, between 8-12 hours was 0.6 ± 0.4, between 12-24 hours was 1.6 ± 0.9 and between 24-48 hours was 1.9 ± 0.9.The mean values and resultant p-value of ANOVA of various nebulising agents used for improvement in CSS shows significant association between various nebulising agents used along with improvement in CSS at the end of assessment at 48 hours of treatment.

Conclusion: This study was conducted to establish the efficacy of each nebulisation agent (i.e. adrenaline, 3% hypertonic saline and normal saline) currently used and compare the outcomes as there is not enough evidence amongst Indian population on level of efficacy of each drug in causing improvement in symptoms and signs in various severities of bronchiolitis in early childhood. Comparison of significant improvement in mean difference in CSS at various intervals in all cases compared between groups by post hoc test revealed non-significant difference (p-value 0.700) between 3% hypertonic saline and normal saline.

Keywords: nebulisation, adrenaline, bronchiolitis & clinical.

Introduction

Bronchiolitis is one of the acute lower respiratory infections (ALRI). There is no uniform definition of bronchiolitis, and no definite age limitation[1]. According to a subcommittee of the American Academy of Pediatrics (AAP) together with the European Respiratory Society (ERS), in 2006, it is a clinical diagnosis, recognized as "a constellation of clinical symptoms and signs including a viral upper respiratory prodrome followed by increased respiratory effort and wheezing in children less than 2 years of age"[2]. Another useful definition, which has been used in many clinical studies, is: the first episode of wheezing in a child younger than 12 to 24 months who has physical findings of a viral respiratory infection and has no other explanation for the wheezing [3].

Various studies have been done to determine most effective drug useful in relieving symptoms in acute bronchiolitis. But still treatment with a particular drug for nebulisation remains controversial[4].

A prospective, double blinded, randomized clinical trial was done by Flores-González et al in Spain published in April 2016 which aimed at comparing the length of stay in hospitalized patients treated with 3% hypertonic saline with placebo and 3% hypertonic saline with epinephrine[5]. Secondary outcome aimed at assessing the effectiveness and safety of treatment. Both groups received standard life support and were randomly treated with nebulised 3% hypertonic saline (7 ml) with either placebo or epinephrine (3 ml). Nebulisations were initially administered every four hours and frequency was then modified according to patient's need.

Material & Method

We conducted a double blinded study at Index Medical College Hospital & Research Centre, Indore over duration of January 2019 to December 2020.

The sample size was determined to be minimum of 120 cases as based upon previous years admission due to acute bronchiolitis and as per study by Khanal A et al[6] and Sreenivasa et al[7]. Initially, 146 cases were included in the study out of which 23 cases dropped out of the study after giving consent by guardian for participation in the study as they left against medical advice from the hospital.

Inclusion criteria

Children aged 2 to 24 months with acute moderate or severe bronchiolitis, which were assessed on the basis of Clinical

Severity Scoring system (CSS) at the time of admission, were included in the study after valid written informed consent.

Exclusion criteria

- Children below 2 months and above 24 months
- Children between 2 to 24 months with any underlying cardiac disease
- Children between 2 to 24 months with any underlying congenital respiratory malformations or acquired respiratory disorders with wheezing due to other conditions
- Those children who received prior nebulisations or steroids within last one week before admission from other hospital.

Results

Table 1: Comparison of mean CSS in all cases, cases with moderate bronchiolitis and severe bronchiolitis in each group

Category	Mean CSS ± SD			
	Adrenaline	3% Hypertonic Saline	Normal Saline	Total
Moderate Bronchiolitis	5.3 ± 2.18 (N=39)	5.3 ± 1.06 (N=39)	5.9 ± 0.8 (N=38)	5.5 ± 1.27 (N=116)
Severe Bronchiolitis	5.8 ± 1.52 (N=4)	5.1 ± 1.41 (N=1)	7.6 ± 1.09 (N=2)	6.1 ± 1.09 (N=7)
All Cases	5.4 ± 1.58 (N=43)	5.3 ± 1.05 (N=40)	6 ± 0.8 (N=40)	5.6 ± 1.27 (N=123)

Mean CSS of all cases in the study was 5.6 ± 1.27 with mean CSS of 5.4 ± 1.58 in adrenaline group, 5.3 ± 1.05 in 3% hypertonic saline group and 6 ± 0.8 in normal saline. Total cases with moderate bronchiolitis were 116 (94.3%) with mean CSS of 5.5 ± 1.27. Cases with moderate bronchiolitis were 39 (90.6%) in adrenaline group, 39 (97.5%) in 3% hypertonic saline group and 38 (95%) in normal saline group with mean CSS of 5.3 ± 2.18, 5.3 ± 1.06 and 5.9 ± 0.8 respectively. Seven (5.7%) out of 123 cases had severe bronchiolitis with mean CSS of 6.1 ± 1.09. Cases with severe bronchiolitis were 4 (9.3%), 1 (2.5%) and 2 (5%) in adrenaline group, 3% hypertonic saline group and normal saline group respectively with mean CSS of 5.8 ± 1.52, 5.1 ± 1.41 and 7.6 ± 1.09 respectively.

Table 2: Comparison of significant improvement in "mean difference of CSS" between various time intervals in all cases compared between groups

Time interval	Mean difference in CSS±SD	p-value between the three groups using ANOVA
0' - 60'	0.4±0.6	0.001
60' - 4 hrs	0.8±0.6	
4 hrs - 8 hrs	0.7±0.6	
8 hrs - 12 hrs	0.6±0.4	
12 hrs - 24 hrs	1.6±0.9	
24 hrs - 48 hrs	1.9±0.9	

The mean difference of CSS between 0 minutes to 60 minutes of nebulisation between groups in all cases was 0.4 ± 0.6, between 60 minutes and 4 hours was 0.8 ± 0.6, between 4 to 8 hours was 0.7 ± 0.6, between 8-12 hours was 0.6 ± 0.4, between 12-24 hours was 1.6 ± 0.9 and between 24-48 hours was 1.9 ± 0.9.The mean values and resultant p-value of ANOVA of various nebulising agents used for improvement in CSS shows significant association between various nebulising agents used along with improvement in CSS at the end of assessment at 48 hours of treatment.

Table 3: Comparison of mean frequency of nebulisation in the groups

Category	Mean ± SD Frequency of Nebulisation (hrs)		
	Normal Saline	Adrenaline	3% Hypertonic Saline
Moderate bronchiolitis	4.3 ± 2.2	3.6 ± 1.5	4.3 ± 2.2
Severe bronchiolitis	5 ± 1.5	2.8 ± 1.2	5 ± 1.5
All cases	5 ± 1.5	4.3 ± 1.5	5 ± 1.5

Based on mean value of frequency of nebulisation required, nebulisation with adrenaline is least effective followed by equal efficacy of 3% hypertonic saline and normal saline.

Discussion

In our investigation, mean CSS of all cases in the examination was 5.6 ± 1.27 and mean CSS in adrenaline bunch was 5.4 ± 1.58, while mean CSS in 3% hypertonic saline gathering was 5.3 ± 1.05 and 6 ± 0.8 in typical saline gathering. Cases with moderate bronchiolitis were 39 (90.6%) in adrenaline gathering, 39 (97.5%) in 3% hypertonic saline gathering and 38 (95%) in typical saline gathering with mean CSS of 5.3 ± 1.61, 5.3 ± 1.06 and 5.9 ± 0.8 separately. Seven (5.7%) out of 123 cases had serious bronchiolitis with mean CSS of 6.1 ± 1.09. Cases with serious bronchiolitis were 4 (9.3%), 1 (2.5%) and 2 (5%) in adrenaline gathering, 3% hypertonic saline gathering and typical saline gathering individually with mean CSS of 5.8 ± 1.52, 5.1 ± 1.41 and 7.6 ± 1.09 separately. Toward the finish of 48 hours of treatment, mean CSS was improved most with adrenaline followed by 3% hypertonic saline followed by typical saline in generally cases and cases with moderate bronchiolitis[8]. Additionally, there was improvement in CSS with critical relationship between different nebulising specialists utilized alongside progress in CSS toward the finish of evaluation at 48 hours of treatment which implies that each of the three medications are powerful for nebulisation in intense bronchiolitis[4]. Yet, on exposing information to post hoc test it was seen that there was non-critical relationship between 3% hypertonic saline and ordinary saline demonstrating that both have equivalent viability.

In cases with moderate bronchiolitis, on exposing information to post hoc test it was seen that toward the finish of 48 hours of treatment there was non critical relationship among adrenaline and 3% hypertonic saline demonstrating equivalent viability of the two medications when utilized for treatment in moderate bronchiolitis and there was huge distinction seen among adrenaline and typical saline gathering and 3% hypertonic saline and ordinary saline group[9].

Conclusion

This study was conducted to establish the efficacy of each nebulisation agent (i.e. adrenaline, 3% hypertonic saline and normal saline) currently used and compare the outcomes as there is not enough evidence amongst Indian population on level of efficacy of each drug in causing improvement in symptoms and signs in various severities of bronchiolitis in early childhood. Comparison of significant improvement in mean difference in CSS at various intervals in all cases compared between groups by post hoc test revealed non-significant difference (p-value 0.700) between 3% hypertonic saline and normal saline.

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