Original Research Article

A study of efficacy of nasal continuous positive airway pressure in bronchiolitis

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Abstract

Objective: To evaluate the efficacy of nasal continuous positiveairway pressure (n CPAP) in decreasing respiratory distress inbronchiolitis. **Design:** Randomized controlled trial. Participants: 72 infants (age <1y) hospitalized with a clinical diagnosis of bronchiolitis were randomized to receive standard care, or n CPAP in addition to standard care, in the first hour after admission. 23 parents refused to give consent for participation. 2 infants did not tolerate n CPAP. **Intervention:** The outcome was assessed after 60 minutes. IfnCPAP was not tolerated or the distress increased, the infant was switched to standard care. Analysis was done on intention-to-treat basis. **Main outcome measures:** Change in respiratory rate, Silverman-Anderson score and a Modified Pediatric Society of New Zealand Severity Score. **Results:** 14 out of 32 in n CPAP group and 5 out of 35 in standard care group had change in respiratory rate ≥10 (P=0.008). The mean (SD) change in respiratory rate [8.0 (5.8) vs5.1 (4.0), P=0.02] in Silverman-Anderson score [0.78 (0.87) vs0.39 (0.73), P=0.029] and in Modified Pediatric Society of New Zealand Severity Score [2.5 (3.01) vs. 1.08 (1.3), P=0.012] were significantly different in the n CPAP and standard care groups, respectively. **Conclusion:** n CPAP helped reduce respiratory distress significantly compared to standard care.

Key Word: n CPAP Ventilation, Respiratory distress, Respiratory Syncytial Virus, Wheezing infant.

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INTRODUCTION

Bronchiolitis is characterized by edema, mucus secretions and damage of airway epithelium with necrosis, causing air flow obstruction and distal air trapping, atelectasis and a ventilation perfusion mismatch that leads to hypoxemia and increased work of breathing. Clinical improvement with significant falls in respiratory rate, pulse rate and pressure of carbon dioxide (pCO_2) has been reported with the use of Continuous positive airway pressure (CPAP) in Bronchiolitis. In this study, we evaluated whether CPAP is clinically beneficial in infants with moderate-to severebronchiolitis during the first hour of treatment.

MATERIAL AND METHODS

This randomized control trial was conducted at Department of Pediatrics, Darbhanga Medical College and Hospital, Laheriasarai, Bihar from April 2016 to March 2017. All patients who werehospitalized with a clinical diagnosis of acutebronchiolitis were eligible for inclusion in the study. Bronchiolitis was defined as respiratory distress(respiratory rate ≥50/min) in an infant aged 1 month to 1year, along with wheezing on auscultation and hyper inflatedlung. Infants who were in imminent need of ventilator support were excluded. Approval for the trial was obtained from thehospital's research ethics committee. Informed consent of the parents of eligible children was obtained. Patients were then randomized to receive CPAP or standard care. Randomization into the two groups was done in blocks of8 using computer software and allocation to the groups was done using sequentially-numbered opaque sealedenvelopes. All patients received standard care, which included maintenance of adequate hydration and oxygenation, while the intervention group received bubble CPAP in addition to the standard care. Bubble CPAP was delivered in the pediatric ward with a Gregorycircuit. Oxygen saturation was noted before

starting treatment and oxygen was supplemented if the saturationwas <92%. Those in the intervention group received oxygen through the bubble CPAP system while the standard care group received oxygen through mask or hood. All children were monitored continuously during the study period. The protocol mandated that CPAP would be stopped if the distress of the patients increased (defined as increase in RR of more than 10), or if the infant was very restless and not tolerating CPAP. If the saturation fell below 90% in either group and persisted to be so for more than >15 minutes despite oxygen supplementation, the child was considered for mechanical ventilation. Treatment decisions were based on the judgment of the treating physician but the changes made were documented. The respiratory rate (RR), Silverman-Anderson score, and a Modified Pediatric Society of New Zealand severity score (MPSNZ-SS) were assessed before starting treatment and at 1 hour following the start of treatment. Respiratory rate was assessed by the staff nurse on duty. The respiratory rate was counted for 60 seconds continuously or in 2 blocks of 30 seconds. The Silverman-Anderson score was assessed by the doctor on duty. The MPSNZ-SS was also assessed by the doctor on duty based on the history and the clinical parameters. It was evaluated by modifying the Pediatric Society of New Zealand (PSNZ) severity scoring system that is based on six parameters (respiratory rate, chest wall indrawing, nasal flaring or grunting, feeding, history of behaviour, cyanosis). The original PSNZ guidelines used cyanosis as a criteria but we substituted it with oxygen saturation. Each of these parameters was assigned a score of 1 to 3 with increasing severity and a final score was calculated. The primary outcome was to compare the change in respiratory rate after the first hour of treatment among the two groups. A decrease in respiratory rate of 10 or more was considered clinically significant difference. The secondary outcomes were the change in Silverman-Anderson score and the MPSNZ-SS. A previous study reported a 24% change in respiratory rate (RR) in the study group compared to negligible change in the standard care group[4]. For a type I error of 0.05 and a type II error of 0.2, we calculated that a sample size of 72 was needed for a 1:1 ratio of standard care to CPAP.

Statistical analysis: Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected, non parametric tests were used. Respiratory rate (RR) at admission, change in respiratory rate after 1 hour of treatment (RR), and modi fied Pediatric Society of New Zealand Severity Score (MPSNZ-SS) at admission were normally distributed and were compared using independent T test and non-parametric data as age in months, RR at the end of 1 hour, Silverman-Anderson (SA) score, MPSNZ-SS at the end of 1 hour, and the change in MPSNZ-SS (MPSNZ-SS) were compared using Mann-Whitney test between two groups. Change in (RR<10 and ≥10) was compared using chi square test between the two groups. Wilcoxon ranked sum test was used to compare RR, SA Score and MPSNZ-SS within groups across follow-up.

RESULTS

The study was continued till 72 patients were recruited. A total of 117 children were hospitalized with a provisional diagnosis of bronchiolitis during this period. Fig.1 depicts the flow of participants in the study. The baseline characteristics of the two groups are described in Table I. There was no significant difference between the two groups. Table II shows the mean change in respiratory rate, Silverman-Anderson score and MPSNZ-SS in the two groups after 1 hour of treatment. There was statistically significant improvement in RR, SA score and MPSNZ-SS in the bubble CPAP group when compared to standard care group. In the bubble CPAP group, 14 out of 32 patients showed clinically significant improvement (RR≥10), whereas 5 out of 35 patients had clinically significant improvement in the standard care group (P=0.008). Three patients needed mechanical ventilation within 1 hour of starting treatment as the distress progressively worsened. Of these, two were from the CPAP group and one was from standard treatment group. CPAP had to be stopped in two children before 1 hour, as they were very restless and became more agitated following start of CPAP. TableII compares the outcomes between two groups.

Table 1: Baseline characteristics In The study groups

Characteristics	Bubble CPAP group (n= 36)	Standard care group (n=36)	P value
Age (mo)	4.0 (2.6)	4.7 (3.1)	0.36
Male gender, No. (%)	26 (72.2)	28 (77.8)	0.59
Respiratory rate	70 (11)	67 (7)	0.17
SA score	4.2 (2.1)	3.8 (1.7)	0.74
MPSNZ-SS	12.4 (2.7)	11.7 (2.4)	0.21

SA: Silverman Anderson; MPSNZ-SS: Modified Pediatric Society of New Zealand Severity Score; All values in mean (SD)

Table2: comparison of change inrespiratory distress in

The two groups after 1 hour

Parameter	*Bubble cpap*	*Standard care*	*P value*
Respiratory rate	8 (6)	5 (4)	0.02
Sa score	0.78 (0.87)	0.39 (0.73)	0.03
Mpsnz-ss	2.5 (3.0)	1.1 (1.3)	0.01

SA:Silverman-Anderson; MPSNZ-SS: Modified Pediatric Society of New Zealand Severity Score; All values in mean (SD).

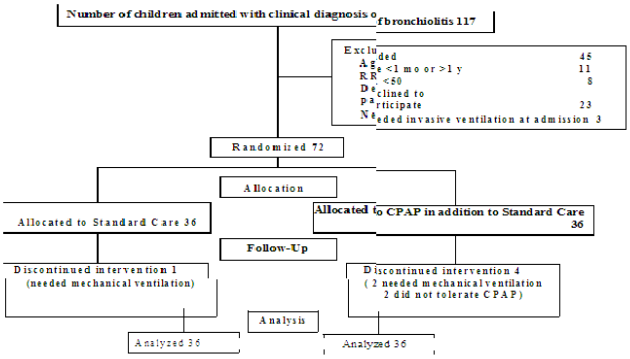

Figure 1: Study flow chart

DISCUSSION

In this randomized controlled trial, we documented that CPAP significantly reduced the respiratory rate in comparison to standard care in infants with bronchiolitis. The Silverman-Anderson score and MPSNZ-SS also showed significant improvement with CPAP during the first hour of treatment. Bronchiolitis is a clinical diagnosis with limited role of laboratory and radiological evaluation. We included all infants during the bronchiolitis season with respiratory distress and a respiratory rate ≥50, at the time of admission. As pneumonia is also common in this age group and it also presents with similar symptoms initially, it is possible that few patients included in the study were cases of pneumonia. Ours was an open label study and could have been influenced by observer bias. Patient parameters were assessed by the doctors and nurses on duty who were aware of the intervention, and that may have resulted in assessment bias. Though our study was continued for an hour, in children who benefited from CPAP, this was continued beyond 1 hour, till the clinician decided that CPAP was no longer necessary. Exact data on duration of CPAP was not collected as it was not part of the protocol. We evaluated the respiratory rate only for the first hour; functional outcome such as need for invasive ventilation and duration of hospital stay were not evaluated. The magnitude of change in the mean RR in our study was much less than that seen in a study from Ghana, where children (age 3 months to 5 years) with respiratory distress (including asthma and pneumonia) were treated with CPAP. Among studies that evaluated at the role of CPAP in bronchiolitis, Milesi, *et al.* found that the use of CPAP decreased inspiratory work in young infants with bronchiolitis. Thia, *et al.* studied the effect of CPAP on change in partial pressure of CO_2 (pCO_2) in children with bronchiolitis, and observed a significant reduction in pCO_2 with use of CPAP when compared to standard care. Machen, *et al.* also studied the role of CPAP in infants and children with respiratory distress, and documented that CPAP was most beneficial for infants with bronchiolitis. However, a Cochrane review suggests that effect of CPAP in children with bronchiolitis is uncertain and larger trials with adequate power are required to further evaluate it. The mechanism by which CPAP works in bronchiolitis is likely to be multifactorial. CPAP works by keeping the airways open, increasing clearance of secretion and improving gas exchange. Although CPAP has been associated with adverse effects such as nasal mucosal damage, mucosal excoriation, scarring, pressure necrosis, pneumothorax and a decrease in cardiac output, none of the patients included in our study had any significant adverse effect. Our study suggests that CPAP significantly decreases the respiratory rate in patients of acute bronchiolitis in the first hour of treatment. Trials are needed to further investigate if CPAP could be of value in decreasing need of invasive

mechanical ventilation and the total duration of hospital stay in children with bronchiolitis.

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