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3% Hypertonic saline vs normal saline nebulization in children with acute bronchiolitis. Critical appraisal of an article “Hypertonic (3%) saline vs 0.9% saline nebulization for acute viral bronchiolitis: A randomized controlled trial. Sharma BS, Gupta MK, Rafik SP, *Indian Pediatr.* 2013 Aug;50(8):743–47”

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ABSTRACT

Question: Nebulization with hypertonic saline have been shown to be effective in management of acute bronchiolitis in different studies. In the present study duration of hospital stay and clinical severity scores of children admitted with acute bronchiolitis were compared between two groups. One group received nebulization with 3% hypertonic saline while other group received nebulization with 0.9% normal saline.

Methods: This study was a double blinded randomized controlled trial conducted in a tertiary care teaching hospital in Jaipur, India from September 2009 to December 2010. Study population included 250 hospitalized children aged 1–24 months with clinical diagnosis of acute bronchiolitis of moderate severity as assessed by clinical severity score proposed by Wang et al. The study population was randomized into two groups to receive either nebulization of 4 ml of 3% hypertonic saline or 4 ml of 0.9% saline, along with 2.5 mg salbutamol in both groups, at 4 hourly intervals till the patients were fit for discharge. Fitness for discharge was defined by authors as “feeding well, no need of IV fluids and oxygen therapy, clinical severity scores ≤ 3 , absence of accessory muscle use or tachypnoea (respiratory rate < 31 breaths/min) and oxygen saturation $> 92\%$ on air”.

Main results: The results of the study were in three forms viz baseline characteristics, duration of hospital stay and improvement in clinical severity scores between above two groups. Baseline characteristics were similar in both groups. The clinical severity scores were recorded at the time of recruitment and twelve hourly thereafter till discharge. The median clinical severity scores of the two groups were similar at the time of recruitment and thereafter in two groups. The duration of hospital stay was 63.93 ± 22.43 h in 3% saline group which was similar to 63.51 ± 21.27 h in 0.9% saline group ($P = 0.878$). None of parents, caregivers or treating physicians were reported any adverse events in both groups.

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Conclusion: Nebulization with 0.9% normal saline or 3% hypertonic saline has got similar efficacy in terms of duration of hospital stay and improvement in clinical severity scores among the children admitted with acute bronchiolitis.

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1. Commentary

Present study¹ was conducted in the patients of acute bronchiolitis, a common health problem of infants. The authors compared the clinical efficacy of nebulization of 3% hypertonic saline to 0.9% saline. Their hypothesis was that nebulization with 3% hypertonic saline would achieve better clinical improvement. Therefore the authors have tested a relevant and clinically useful hypothesis.

This study was well conducted with low drops out and appropriate sample size, adequate randomization and double blinded study.

In this study patients were enrolled over a period of 24 h after admission however after admission and before enrolment what kind of treatment (for example systemic steroid and or nebulization with racemic adrenaline) was given is not mentioned in the manuscript. If the co-interventions were not equally distributed in both groups and among patients with similar severity scores, this might affect the outcome, hence is a potential confounder. Participant flow diagram of the study has been given but reason for two drop outs in normal saline arm is not given. Though the authors have lucidly mentioned the method of randomization but who generated the number and who allocated and implemented or executed the intervention has not been mentioned. Tests used for statistical analysis has been described but the name of software used for analysis has not been mentioned.

In the study median clinical severity scores with inter-quartile range has been reported in abstract but in results section it was given in the form of line diagram. Since these scores followed a non parametric distribution, hence if the result of median severity scores were shown as Box Whisker plot instead of line diagram it would have been better.

In the clinical severity scores proposed by Wang et al² and used in the current study, there are four parameters i.e. respiratory rate, wheezing, retractions, and general condition. Generalizability of Wang et al clinical score for a study population of wide range of age (children aged 1–24 months) is not clear. For example if a patient is of age 2 months with RR 46/min according to WHO is normal but as per Wang et al clinical score is 2. This can lead misclassification and adversely affect generalizability.

Since drop outs was very low (2/250) in the study hence intention to treat analysis or per protocol analysis would not

affect the result. However no mention has been done about type of analysis reported. Authors have not mentioned about the seasonal variability of admissions of patients with acute bronchiolitis and site characteristics including numbers of beds and admission rates. This would have increased generalizability of the study. On assessing the study according to the modified CONSORT³ checklist the study fails to full fill the addition criteria not mentioned earlier. Firstly for each primary and secondary outcome, result for each group and the estimated effect size and it's precision (17a) has not been reported. Secondly registration number and name of trial registry (23) is not given, therefore the full clinical trial protocol (24) cannot be accessed.

2. Conclusion

The nebulization with 3% hypertonic saline was not superior to 0.9% saline in terms of duration of hospital stay and improvement in clinical severity scores among the children admitted with acute bronchiolitis. On the basis of critical appraisal further larger trials are needed to refute or accept 3% nebulization as a routine practice in acute bronchiolitis.

Conflicts of interest

The author has none to declare.

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