

A Comparison Study: Treat Acute Bronchiolitis Infants with Hypertonic Saline by Small Volume Jet Nebulizer and Portable Vibrating-Mesh Nebulizer

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Abstract

By convention, treatment for acute bronchiolitis infants has been predominantly confined to aerosol therapy delivered by small-volume jet nebulizer (SVN). However, such therapy suffers from concomitant inconsistencies such as, but not limited to, varying drug concentration, drug temperature variation and excess noise. Whether a vibrating-mesh nebulizer could circumvent traditional limitations yet alleviate symptoms was unclear. Herein, our randomized clinical trial revealed that a portable vibrating-mesh nebulizer (Pocket Air) had achieved comparable end-points when administering hypertonic saline and could potentially serve as an improved therapeutic approach for future treatments.

Methods

According to inclusion/exclusion criteria, 64 infants with acute bronchiolitis are collected and randomly separated into two groups (Figure 1). Two groups are treated by the same clinical pathway except two kinds of nebulizer, Pocket Air (MicroBase Technology Corporation, Taiwan) and SVN (GaleMed Corporation, Taiwan), are used respectively. Patients' information including, basic information, severity score (respiratory effort, oxygen saturation, and respiratory rate), hospital stay duration, intravascular-line day, are collected and analyzed.

Aerosol particles of Pocket Air and SVN are characterized by Spraytec (Malvern instruments, UK). Several parameters, including Dv10, Dv50, Dv90, Span Factor, and percentage of particle size under 5 μm, are used to compare differences between Pocket Air and SVN.

A questionnaire (contained 5 items, weight, aerosol flow, noise in operation, ease of cleaning and performance) is used for evaluating quality of Pocket Air. This clinical trial is approved by institutional review board of Chang Gung Memorial Hospital, Taiwan.

Conclusions

In current trial, we showed that Pocket Air was equally effective in treating acute bronchiolitis infants using hypertonic saline when compared with the SVN. Users had also praised the experience of utilizing Pocket Air when delivering aerosol to infants. Therefore, Pocket Air may serve as an alternative approach to deliver treatments for bronchiolitis and possible follow-up maintenance at home.

Results

Basic information (age, male/female proportion, body height, body weight) and severity score of two randomly assigned treatment groups (Pocket Air and SVN) were similar (Table 1). More importantly, after treatment, severity score; hospital stay duration; and intravascular-line day for both Pocket Air and SVN group were statistically equivalent (Table 1). Thus, the recovery outcome was analogous across different delivery methodologies.

Aerosol generated by Pocket Air and SVN exhibited an overlapping distribution. More specifically, the aerosol spectrum was tighter and more concentrated in Pocket Air (Figure 2).

Finally, according to data collected from the questionnaire, users showed a clear preference for Pocket Air due to superior operation properties such as portability, reduced-noise, easy to cleaning and consistency (data not shown).

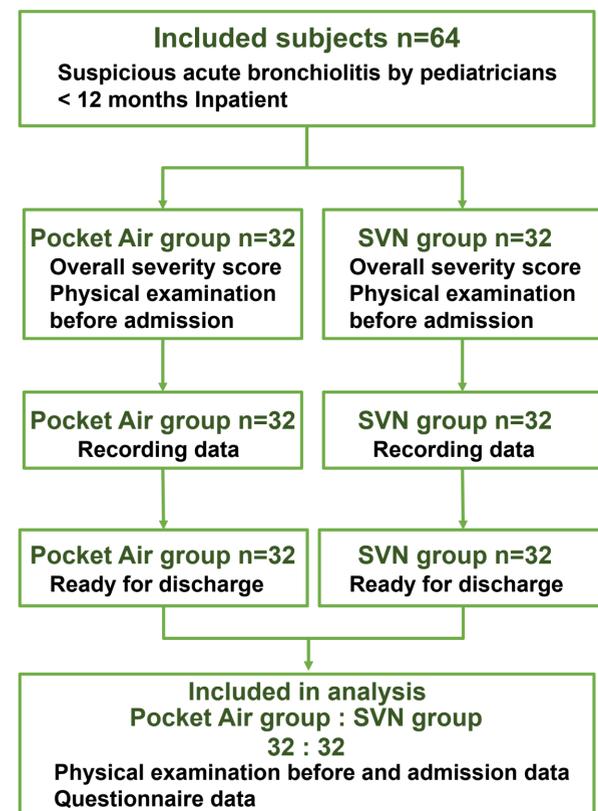


Figure 1: Flow chart of enrollment.

Table 1: Comparison of portable vibrating-mesh nebulizer (Pocket Air) group and small volume jet nebulizer (SVN) group

| | Pocket Air group (n=32) | SVN group (n=32) | p-value |
|-------------------------|-------------------------|------------------|---------|
| Before treatment | | | |
| Severity score | 4.92 ± 1.31 | 4.30 ± 1.44 | 0.652 |
| Age (month) | 6.66 ± 2.85 | 5.69 ± 3.03 | 0.944 |
| Male: Female | 21:11 | 20:12 | 0.798 |
| Body height (cm) | 68.11 ± 6.93 | 67.39 ± 10.7 | 0.460 |
| Body weight (kg) | 8.13 ± 1.67 | 9.42 ± 9.64 | 0.751 |
| After treatment | | | |
| Severity score | 2.59 ± 1.07 | 2.55 ± 1.16 | 0.654 |
| Hospital stay duration | 3.94 ± 1.66 | 3.97 ± 1.88 | 0.944 |
| Intravascular-line day | 2.16 ± 1.46 | 2.31 ± 1.47 | 0.671 |

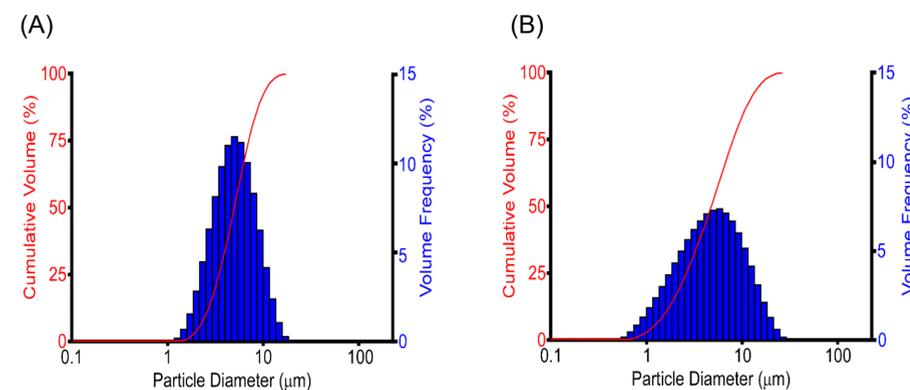


Figure 2: Particle characteristics of Pocket Air and SVN. (A) Drop size distribution of Pocket Air. (B) Drop size distribution of SVN. (C) Particle characteristics comparison of Pocket Air and SVN.

| | Pocket Air | SVN | p-value |
|-------------|--------------|--------------|-------------------------|
| Dv10 (μm) | 2.67 ± 0.11 | 1.60 ± 0.14 | 2.6 × 10 ^{-5*} |
| Dv50 (μm) | 5.09 ± 0.13 | 4.80 ± 0.53 | 3.5 × 10 ⁻¹ |
| Dv90 (μm) | 10.13 ± 0.64 | 11.55 ± 1.44 | 1.4 × 10 ⁻¹ |
| Span Factor | 1.46 ± 0.10 | 2.07 ± 0.12 | 3.5 × 10 ^{-4*} |
| <5 μm (%) | 48.70 ± 1.91 | 52.56 ± 5.4 | 2.5 × 10 ⁻¹ |

n=4, * Statistical significance p < 0.05