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Medication Delivery Of CF Drugs Via A Breath Actuated Nebulizer (BAN): Review Of Delivery Performance Versus A Breath Enhanced Nebulizer (BEN) Commonly Used With Such Medications

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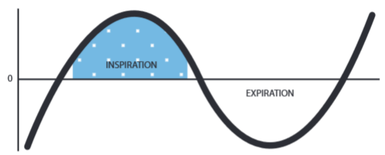
Introduction

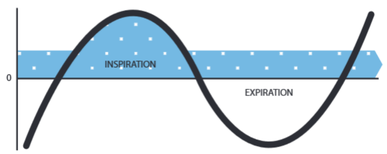
- Medications to manage care of cystic fibrosis (CF) patients are often delivered via a nebulizer, as such treatment is generally easy to use and enables delivery of the typical doses needed.
- A breath actuated device will reduce fugitive emissions and provide dose assurance (because dosing is not dependent on breathing pattern), however there are sometimes questions around the dose delivered to the patient when changing between continuous and breath actuated delivery modes.
- This study compares the two delivery modes for a number of commonly used CF medications in the home.

BREATH ACTUATED DELIVERY



Breath actuated delivery only produces aerosol during the inspiratory cycle. No medication is lost between breaths or during breaks in treatment.

BREATH ENHANCED DELIVERY



An increase in medication is delivered through the inspiratory cycle, and reduced during exhalation, although still generated.

Methods

- Four different medications were evaluated:
  a) 7% Hypertonic Saline
  b) Tobramycin
  c) Dornase Alpha
  d) Colistimethate Sodium
- Delivery was compared for each with a breath actuated device (***AeroEclipse® XL BAN™*** Nebulizer paired with ***Ombra®*** Table Top Compressor, Monaghan Medical) and a continuous breath enhanced nebulizer (LC PLUS† BEN paired with PARI BOY† SX Compressor, PARI).
- The medication delivery was compared using data from existing laboratory studies, in terms of the performance measures reported in each study.

AeroEclipse® XL BAN™ **Nebulizer with *Ombra®* Table Top Compressor**

LC PLUS† BEN with PARI BOY† SX Compressor

Results

- 7% Hypertonic Saline: The ***BAN™*** Nebulizer exhibited an 81.6% fine droplet fraction compared to 71.2% with the BEN device, indicative of slightly smaller droplets, more likely to be delivered to the lungs.
- Tobramycin: The ***BAN™*** Nebulizer again exhibited a slightly higher fine particle fraction than the BEN device (72% vs 64%) and delivered a total mass of 141 mg compared to 83 mg for the BEN device.
- Dornase Alpha: The ***BAN™*** Nebulizer exhibited a fine droplet mass of 428 µg compared to 349 µg with the BEN device.
- Colistimethate Sodium: The fine droplet mass for the ***BAN™*** Nebulizer was similar to the BEN device for the first 12 minutes of delivery, with the breath actuated device continuing to deliver medication for an additional 7 minutes.

Medication	Metric	***AeroEclipse® XL BAN™*** **Nebulizer / *Ombra®* Table Top Compressor**	**LC PLUS† BEN / PARI BOY† SX Compressor**
7% Hypertonic Saline	Fine Droplet Fraction	81.6%	71.2%
Tobramycin	Fine Particle Fraction Total Mass	72% 141mg	64% 83mg
Dornase Alpha	Fine Droplet Mass	428µg	349µg
Colistimethate Sodium	Fine Droplet Mass	Approx. 26mg at 12 minutes increasing to a little over 40mg at sputter	Approx. 25mg at 12 minutes (sputter)

Conclusion

- Although the medication delivery in the various lab studies was reported using differing metrics, a common trend was that the ***BAN™*** Nebulizer delivered at least as much or more medication than the BEN device in each case.
- Reviewing the safety data for the drugs themselves shows that the higher delivery with the ***BAN™*** Nebulizer was within acceptable dosing ranges.
- On the basis of these studies, clinicians could select the ***BAN™*** Nebulizer for delivery of CF medications, with the added value of a breath actuated system offering low fugitive emissions and improved dosing consistency.

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