Effect of Inhalation Patterns on the Delivered Dose of Symbicort† from a Dry Powder Inhaler Compared to a Metered Dose Inhaler plus Valved Holding Chamber

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Rationale:

- The latest guidelines from the Global Initiative for Asthma (GINA) no longer recommends SABA-only treatment for Step 1 therapy. This is based on evidence that a SABA-only treatment increases the risk of severe exacerbations, and that adding any Inhaled Corticosteroid (ICS) significantly reduces that risk.

- Options for ICS delivery can be via Dry Powder Inhaler (DPI) or Metered Dose Inhaler (MDI), however, if delivering an ICS via MDI, a spacer should also be prescribed.

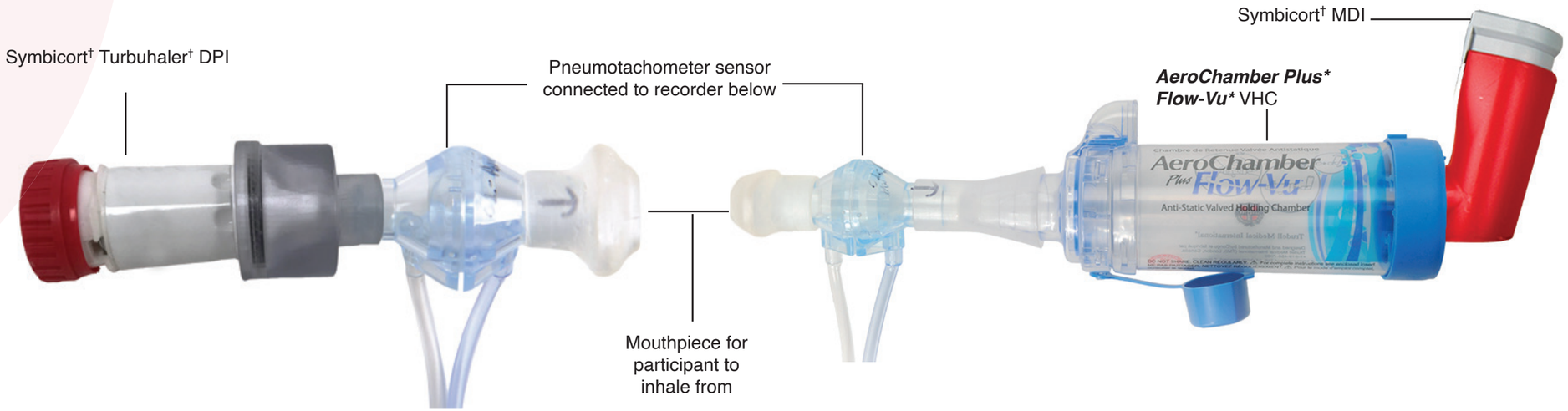
- This study evaluated the impact of inhalation maneuvers on medication delivery from either DPI or MDI Symbicort† 80/4.5 (80 µg budesonide /4.5 µg formoterol furoate) with a spacer (***AeroChamber Plus* Flow Vu*** VHC).

Methods:

- Inhalation waveforms were recorded from 5 DPI and MDI+VHC subjects and replayed via a breathing simulator attached to the adult Aerosol Delivery to an Anatomic Model (ADAM) oropharyngeal airway which was used to provide a clinically relevant laboratory determination of medication delivery of Symbicort†.

- DPI subjects inhaled as per their usual treatment regimen whereas VHC subjects were instructed to inhale via either i) slow deep inhalation or ii) following 2-3 inhalations as per VHC instructions.

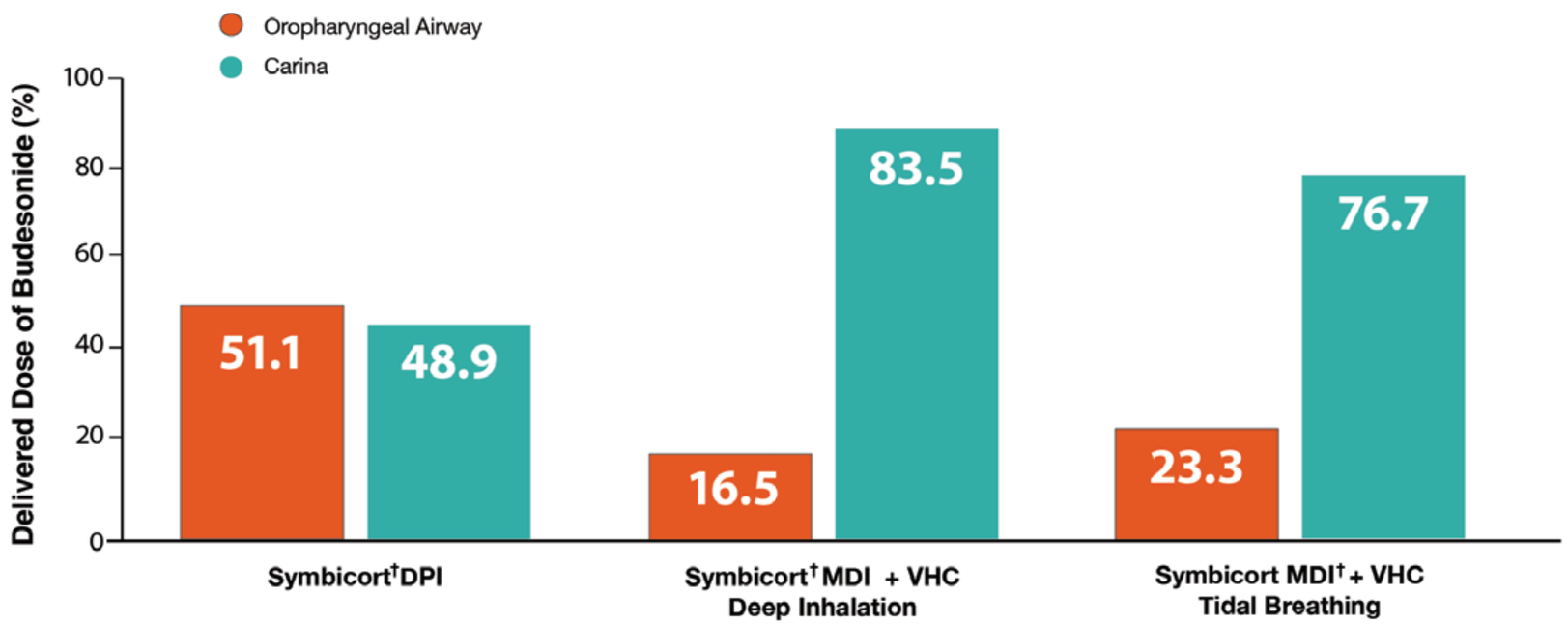
- Following delivery of medication, all components of the apparatus were assayed for Active Pharmaceutical Ingredients (API) via HPLC-spectrophotometry.



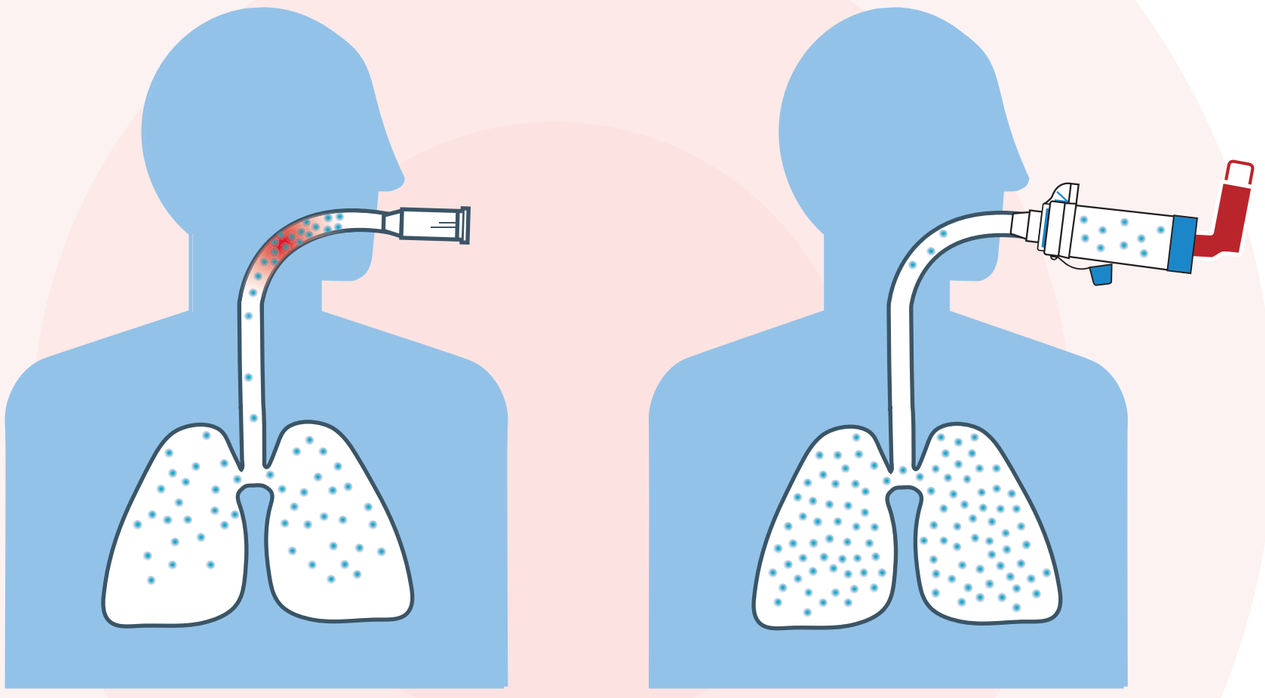
Results:

Product	API	Delivered Dose (µg/actuation)	
		Oropharyngeal Airway	Carina
Symbicort DPI	Budesonide	21.1±8.1	20.2±7.9
	FF	1.0±0.4	1.0±0.4
Symbicort MDI + VHC Deep Inhalation	Budesonide	7.1±3.9	35.9±4.0
	FF	0.3±0.2	2.1±0.2
Symbicort MDI + VHC Tidal Breathing	Budesonide	9.7±9.6	32.0 ±6.8
	FF	0.4±0.4	1.9±0.4

Percentage of Delivered Dose of Budesonide via each Delivery Method



Conclusion



DPI

MDI + *AeroChamber Plus* Flow-Vu VHC**

- The widely differing inspiratory flow profiles from Turbuhaler† DPI contributed to greater variability in delivered dose to the carina.

- MDI delivery via the ***AeroChamber Plus* Flow-Vu**** VHC resulted in significantly increased mass to the carinal region irrespective of inhalation maneuver as well as reduced oropharyngeal deposited mass which *in vivo* is likely to result in reduced throat irritation or thrush in the mouth and throat.

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