

Real-world retrospective study demonstrates device choice impacts asthma control

6 February 2018. A real-world study in more than 18,000 patients has demonstrated superior asthma control with the **AeroChamber Plus* Flow-Vu*** Anti-Static Valved Holding Chamber (VHC) compared with other chambers.¹ According to this new retrospective study, published in *Pulmonary Therapy*, the **AeroChamber Plus* Flow-Vu*** Anti-Static VHC was associated with a significant delay in time to first exacerbation ($p=0.0005$) and a significant 13% reduction in Emergency Room/Accident and Emergency (ER/A&E) visits ($p=0.0167$) compared with control, non-anti-static chambers. There was also a strong trend towards a reduction in hospitalisations ($p=0.0702$). The **AeroChamber Plus* Flow-Vu*** Anti-Static VHC was made available on prescription in the UK in November 2017.

The study results for the 8,586 patients who could be followed-up for at least 12 months show:

Healthcare Utilisation	AeroChamber Plus* Flow-Vu* Anti-Static VHC n = 4,293	Control, Other VHC n = 4,293	% Difference	p Value
Patients with at least 1 Hospitalisation (n, %)	127 (3%)	157 (3.7%)	19%	$p=0.0702$
Patients with at least 1 ER/A&E visit (n, %)	462 (10.8%)	533 (12.4%)	13%	$p=0.0167$

In this real-world study, the **AeroChamber Plus* Flow-Vu*** Anti-Static VHC was associated with:



A significant reduction in ER/A&E visits
 $P=0.0167$



A strong trend towards reduction in hospitalisations
 $P=0.0702$

The **AeroChamber Plus* Flow-Vu*** Anti-Static VHC is designed with user-friendly features to improve patients' inhaler technique² and to ensure delivery of the intended dose of medication, leading to real clinical benefits for patients. The chamber is made from an antistatic polymer which prevents electrostatic charge-related loss of medication to the walls of the chamber and allows it to be used straight out of the packet without pre-treatment or priming.^{3,4} This device has a dedicated inhalation indicator (branded as



the **Flow-Vu*** Inhalation Indicator). This feedback tool gives caregivers the ability to confirm that there is a proper facemask seal, which helps the caregiver to coordinate actuation of the pressurised metered-dose inhaler (pMDI) with inhalation and to count breaths, thus ensuring the patient gets the intended dose of their prescribed medications.

“At Trudell Medical UK Limited we aim to bring innovative solutions to real-life problems, unlocking improved outcomes for respiratory patients. The current NHS crisis is exacerbated by patients presenting to A&E with respiratory problems that often get worse in winter. Our new **AeroChamber Plus* Flow-Vu*** Anti-Static VHC may reduce some of the 121,000 A&E attendances made by asthma patients every year in the UK,” said Dr Alan Clark, Regional Head, Europe, Trudell Medical UK Limited. “A 13% reduction may mean 15,730 fewer visits to A&E by asthma patients each year. Furthermore, if all people with asthma currently using a pMDI plus VHC in the UK were switched to the **AeroChamber Plus* Flow-Vu*** Anti-Static VHC, our budget impact model shows that in one year the UK health system could reallocate £7.2m of healthcare resources to other areas of need due to reduced demand by patients with asthma.⁵”

Innovation in respiratory drug delivery is needed in the UK. The National Review of Asthma Deaths in the UK reported that misunderstanding and misuse of inhalers may have contributed to a significant number of the 195 asthma deaths reported during 2012.⁶ Despite effective medication being available, 82% of asthma patients report being poorly controlled.⁷

“It’s great to see a company take a very good product and make it even better by putting the patient at the centre of the development process and using their feedback to make it easier to use. The data strongly suggest that by improving delivery of medication to the lungs the **AeroChamber Plus* Flow-Vu*** Anti-Static VHC can demonstrably reduce use of hospital resources,” said Dr Dermot Ryan, President of the Respiratory Effectiveness Group and former primary care physician.

For those with asthma, particularly children, the choice of VHC - sometimes referred to as spacer/holding chamber devices^{8,9,10,11} - to help deliver medication is an important consideration. It is also evident that performance differences exist between VHCs. Thus, chamber shape, volume and length, the use of conventional statically charged versus anti-static materials, inhalation valve function, and facemask design have all been variously implicated in performance differences between different spacers/VHCs.^{3,12,13} Therefore, it is important to note that not all spacers/VHCs perform equally well.¹⁴

Currently there are a small number of VHC brands available that are made of clear antistatic polymers. A new *in vitro* evaluation of VHC equivalence published this month in *Pulmonary Pharmacology and Therapeutics*¹² provides evidence that the **AeroChamber Plus* Flow-Vu*** Anti-Static VHC delivers aerosolised drug more effectively than a number of other antistatic VHCs. Four similarly sized antistatic VHCs were compared ‘out of the box’ with a pre-treated reference chamber (**AeroChamber Plus*** VHC)

with respect to retention of drug particles within the device and respirable dose fraction delivered. Only the **AeroChamber Plus* Flow-Vu*** Anti-Static VHC demonstrated a similar profile of dose retention and delivery versus the reference chamber. The following antistatic VHCs: Compact Space Chamber Plus® (Medical Developments); the OptiChamber Diamond™ (Philips Respironics, Inc); and InspiraChamber™ (Lupin Pharmaceuticals, Inc; not available in the UK); all retained approximately twice as much drug, delivering around half the dose compared with the **AeroChamber Plus* Flow-Vu*** Anti-Static VHC and reference chamber.

'This *in vitro* equivalence study shows that even superficially similar antistatic chambers deliver different amounts of medication, and reinforces the view that chambers, including newer antistatic chambers, should not automatically be considered interchangeable,' said Dr Sanjeeva Dissanayake, lead author of equivalence study.

Asthma is a common respiratory condition which affects 5.4 million people in the UK.⁷ Asthma is estimated to cost the UK ≥£1.1 billion each year.¹⁵ Inhalation is the recommended route of administration for asthma medications; it provides direct targeting of drug to the lungs, and side effects are reduced compared with systemic medications. Inhaled corticosteroids (ICS) and bronchodilators administered by pMDIs are the mainstay of long-term asthma treatment, the goals of which are to improve symptoms and prevent the occurrence of exacerbations.¹⁶ Unfortunately, poor inhaler technique is common, resulting in less of the delivered drug reaching the lungs, with much of it being deposited on the back of the throat and then swallowed.¹⁷ Inhaler technique has not improved over the past 40 years, with the most frequent pMDI errors being in coordination, speed and/or depth of inspiration and no post-inhalation breath-hold.¹⁸

The Global Initiative for Asthma's report recommends the use of spacers to improve pMDI drug delivery.¹⁶ In the UK, a joint Scottish Intercollegiate Guidelines Network (SIGN) / British Thoracic Society (BTS) guideline on the management of asthma recommends a pMDI and a spacer as the preferred method of delivery for children.¹⁹ They advise a facemask for young children then a mouthpiece when the child is old enough.¹⁹ In addition, the National Institute for Health and Care Excellence (NICE) guidance on inhaler devices for routine treatment of chronic asthma in older children recommends a pMDI with an appropriate spacer as first choice for those aged 5-15.²⁰ The SIGN/BTS guideline also recommends a spacer for adults receiving high doses of inhaled corticosteroid.¹⁹

Studies indicate that patients who use a VHC with their pMDI have better asthma control.²¹ Chambers were designed to hold the aerosol in the chamber until the patient is ready to inhale, which reduces the need for good coordination between inhalation and inhaler actuation, and to reduce the oropharyngeal deposition²² meaning the drug gets into the patient's lungs. Effectiveness of these devices can be adversely affected by the design, including the chamber electrostatic charge, a commonly reported cause of inconsistent medication delivery.²³

Real-world study co-author, Dr Jason Suggett (Group Director of Global Science and Technology, Trudell Medical International) said that the study also further supports the fact that chambers are not interchangeable. “The European Medicines Agency recommended in 2009 that development of a pMDI should include the testing of at least one specific named chamber, and that any substitution must be supported by appropriate *in vitro* or clinical data demonstrating equivalence”, he commented. “We presented laboratory data at the recent *Respiratory Drug Delivery Europe* meeting¹⁴ that confirmed that not all chambers perform equally well with the same pMDI, which underlines the importance of recognising the impact and potential risks of substituting one device for another.”

About Trudell Medical UK Limited (TM-UK)

TM-UK is committed to enhancing the quality of life for people of all ages with respiratory conditions. We and our affiliate, Trudell Medical International (“TMI”), are family-owned healthcare companies. TMI designs, develops and manufactures a wide range of high quality, innovative medical devices and is home to a global Aerosol Lab and Research Centre. Several of the TMI medical devices that TM-UK sells are available to patients in over 110 countries worldwide.

The **AeroChamber*** brand of Valved Holding Chambers is made available in the UK by TM-UK. Their efficacy has been validated in numerous peer-reviewed publications.

About AeroChamber* brand Valved Holding Chambers (VHC), including the AeroChamber Plus* Flow-Vu* Anti-Static VHC

Developed in 1983 to address the needs of asthma and COPD patients having difficulty in taking their pMDI medications correctly, the **AeroChamber*** brand of VHCs has innovated continuously to improve patient ease of use and quality of life as well as clinical outcomes and provide healthcare system savings.

- **AeroChamber Plus*** is the global leading VHC brand, with safety and efficacy validated in numerous third party clinical evaluations amongst various patient populations. The **AeroChamber Plus*** brand of VHCs is the most widely prescribed VHCs in the UK.²⁴
- **AeroChamber Plus* Flow-Vu*** is an anti-static VHC designed to deliver the intended prescribed dose via the pMDI, similar to using a pMDI alone with perfect technique. An additional feature is the incorporation of the **Flow-Vu*** Inhalation Indicator for the caregiver to observe effective inhalation. A recent study showed that caregiver quality of life improved almost four-fold when using the **AeroChamber Plus*** VHC with the **Flow-Vu*** Inhalation Indicator versus the same VHC without the indicator.²⁵ The **Flow-Vu*** Inhalation Indicator provides real time feedback confirming effective inhalation and minimising the incidence of ambient air leakages into the space between facemask and face that could impair medication delivery.

- The range of **AeroChamber Plus* Flow-Vu*** Anti-Static VHCs were launched in the UK in November 2017. www.aerochamber.co.uk

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