



WHITE PAPER

Performance of Thayer Valved Holding Chambers with an albuterol sulfate MDI Product Marketed in the USA

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SUMMARY

INTRODUCTION

Valved holding chambers (VHCs) are used to: (1) reduce the non-respirable portion of drug administered to a patient from a metered dose inhaler (MDI), and (2) allow for un-coordinated timing between actuation of the MDI and patient inhalation/exhalation. Non-respirable particles are larger in diameter and known to deposit in the mouth and throat which can cause undesirable side effects.

METHODS

An albuterol sulfate MDI drug product marketed in the US was used to demonstrate the difference in drug delivery between using the MDI alone and dosing the MDI through a VHC. MDI canisters were purchased and tested for particle size distribution using an 8-stage Andersen Cascade Impactor (ACI) with a USP induction port and an airflow rate of 28.3 L/min. The same test was then repeated twice for the same MDI canisters, first with the addition of LiteAire VHCs and second with PrimeAire VHCs. In all cases, drug deposition on the ACI stages was measured using a validated HPLC assay with UV detection. Respirable doses and non-respirable doses were determined based on known stage cut-off sizes.

RESULTS

Figure 1 displays the results of the present study. Without a VHC ("MDI Alone" in the figure), the respirable dose (green bar) was found to be $36 \pm 15 \mu\text{g}$, while the respirable doses (greens bars) with the PrimeAire and LiteAire were found to be $28 \pm 10 \mu\text{g}$ and $33 \pm 15 \mu\text{g}$, respectively. The non-respirable dose (red bars) was reduced from $58 \pm 12 \mu\text{g}$ with the MDI alone to $3 \pm 1 \mu\text{g}$ and $5 \pm 3 \mu\text{g}$ with the PrimeAire and LiteAire, respectively. Note the error bars represent 1 standard deviation about the mean.

CONCLUSION

Without reducing the respirable dose ($p > 0.2$), the LiteAire and PrimeAire both substantially reduce the non-respirable dose delivered ($p < 0.0001$) to the patient as compared to the MDI alone.



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Efficacy of Thayer VHCs with an albuterol sulfate MDI Marketed in the USA

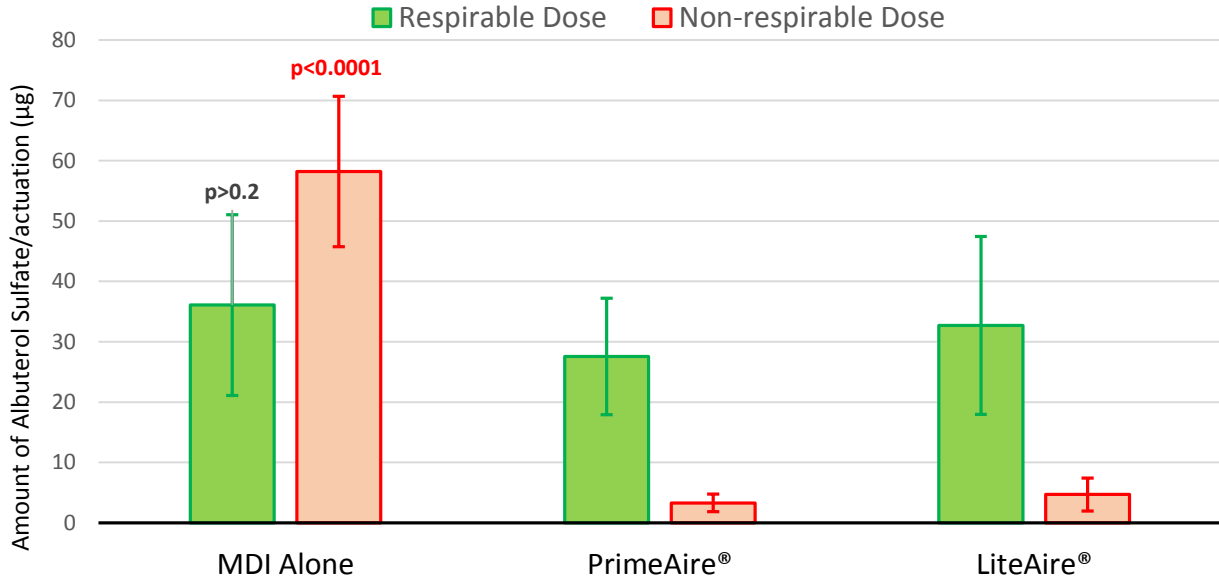


Figure 1. Differences in non-respirable doses (red bars) of albuterol sulfate delivered to the patient via MDI when the PrimeAire and LiteAire VHCs are used. The error bars represent 1 standard deviation about the mean. The reduction in non-respirable doses (red bars) delivered to the patient are substantial and significant ($p < 0.0001$) when the PrimeAire or LiteAire are used, while the respirable doses (green bars) remain unchanged ($p > 0.2$).