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# The misconception of using floating patterns as an accurate means of measuring the contents of metered-dose inhaler devices

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**Background:** Patients and physicians have searched for a reproducible method of determining the amount of medication that a metered-dose inhaler (MDI) contains as well as a reliable method of determining when their MDI is empty. Previously, patients have been instructed to float their canister in water, and depending upon the position attained, have been able to estimate the amount of medication within the canister.

**Objective:** To investigate whether the floating patterns of MDIs are a reliable method of determining the contents contained within an inhaler canister, including that of the newer devices containing the non-chlorofluorocarbon (CFC) propellant.

**Methods:** Fifteen albuterol sulfate MDIs (Proventil HFA; Schering, Kenilworth, NJ), 15 triamcinolone acetonide MDIs (Azmecort; Rhône-Poulenc Rorer, Collegeville, PA), and 15 fluticasone propionate MDIs (Flovent; GlaxoSmith Kline, Research Triangle Park, NC) were obtained from their respective companies. Each device was floated in a clear container full of water before any actuations. The devices were then actuated into the air at 2-minute intervals and each subsequently floated following 25%, 50%, 75%, and 100% of the prescribed number of actuations and its position within the container observed. The canisters were then actuated until no visual spray was produced from the nozzle and again their floating positions within the container observed.

**Results:** Each of the three MDIs tested had unique floating patterns both before any actuation as well as throughout the various actuations.

**Conclusions:** This study demonstrates that the floating method is not an accurate means by which patients can identify the amount of medication contained within an inhaler device. This includes both conventional MDIs containing CFC propellant, as well as the newer non-CFC MDIs.

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## INTRODUCTION

Patients and physicians need a reproducible method of determining the amount of medication that a metered-dose inhaler (MDI) contains, as well as a reliable method of determining when an inhaler is empty. The continuity of anti-inflammatory therapy will be compromised if canisters are falsely assumed to deliver active medication when, in fact, they are not.<sup>1</sup> Ultimately,

there can be life-threatening consequences if an individual's MDI does not contain medication during an acute asthma attack.

One method is to keep an accurate count of the number of actuations used from an individual inhaler. This, however, is an impractical method of keeping track. Other methods involve shaking the canister or test spraying the inhaler before use.<sup>2</sup> Neither is reliable, as inhalers on the market today are made to actuate many more times than stated on the label, ultimately discharging solely propellant without medication. Another method to determine the amount of medication an inhaler contains is the flotation method.

In this method, the canister is placed in a container of water and the position observed to determine the amount of medicine. This can be visualized in Figure 1. Ideally, position V would represent the canister before any actuations. This would then progress through positions IV to I at the various increments of actuations, ie, 75% full, 50% full, 25% full, and empty. As new propellants with differing buoyancies have been developed and used in MDIs, these floating characteristics may be affected. Thus, we examined these new non-chlorofluorocarbon (CFC) MDIs as well as conventional MDIs with regard to their floating patterns.

## METHODS

Fifteen albuterol sulfate (Proventil HFA, 150 dose; Schering, Kenilworth, NJ), 15 triamcinolone acetonide (Azmecort, 240 dose; Rhône-Poulenc Rorer, Collegeville, PA), and 15 fluticasone propionate (Flovent, 44 µg, 120 dose; GlaxoSmith Kline, Research Triangle Park, NC) devices were obtained. Each canister and actuator was numbered to ensure that each canister would use the same actuator. The canisters were then placed into a glass container filled with tap water before actuation of the devices to establish where the device came to rest while completely full. The devices were then actuated following the correct method of "firing" an inhaler into the free air. Each device was actuated at intervals of no less than 2 minutes apart so as to allow the full dose to be delivered with each actuation.<sup>3</sup> The devices were subsequently placed in the container to observe their floating patterns after the canisters were actuated to 75% full, 50% full, 25% full, and empty as per the number of doses the canister reportedly con-

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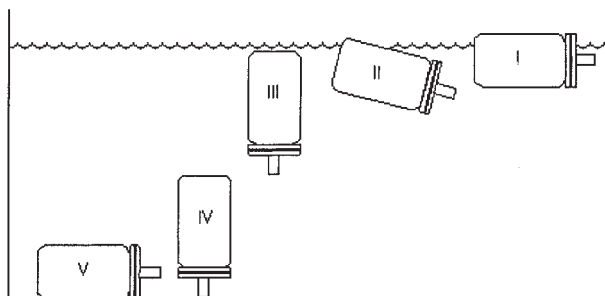


Figure 1. Canister positions attained in container of water.

tained. The canisters were then emptied until an absolute zero amount of material or propellant was contained within the canister. This was determined when an actuation produced no visual spray from the nozzle. The devices were again floated in the container to determine their positions. The total number of actual actuations was documented, as was the position that the canister attained at each of the above stated actuation totals.

## RESULTS

Each of the three MDIs tested had unique floating patterns both before any actuation as well as throughout the various points of data collection. As can be seen in Table 1 there was considerable variability. All albuterol sulfate (Proventil HFA) canisters initially obtained the vertical floating position III. All 15 devices maintained this vertical position up to 75% of the prescribed doses (Table 1 and Fig 1). Three of the 15 canisters continued to maintain this same vertical position at 100% of the prescribed actuations as the remaining 12 attained a horizontal floating position

as demonstrated by position II. The canisters were then emptied with the total number of actuations ranging from 283 to 320 (mean of 302), at which time all attained the horizontal floating position (position II).

The triamcinolone acetonide (Azmecort) devices all attained a horizontal position as demonstrated by position V before actuation (Table 1 and Fig 1). After 25% of the prescribed actuations were completed, the canisters obtained a vertical position shown as in position IV. At 50% of the prescribed doses the canisters remained vertical but obtained position III. After 75% of the prescribed actuations, the canisters remained in position III. After the canister had been actuated the 100% of the prescribed doses, the canisters rotated onto their sides and obtained position II. The devices were then emptied with the total number of actuations for the triamcinolone acetonide devices ranging from 313 to 338 (mean of 327), at which time all attained position II.

All fluticasone propionate (Flovent, 44  $\mu$ g) canisters attained position V

before any actuation (Table 1 and Fig 1). At 25% of the prescribed actuations, the canisters attained the vertical position IV. At 50% of the prescribed actuations, the canisters obtained position III. At 75% and 100% of the actuations, the canisters maintained position III. Each device was then emptied with range of 156 to 169 (mean of 163) actuations until absolutely no contents remained within the device and, at this point, the canisters attained position II. The qualitative nature of these results does not allow statistical analysis to be used.

## DISCUSSION

Inhalation devices are an extremely complex dosage form. A number of factors including the type of propellant, physical and chemical interactions among the active drug, propellants, and inactive ingredients, valve performance, ambient temperature and humidity, adequacy of shaking, time interval between actuations, influence the performance of these devices.<sup>4</sup>

One possibility for the variation in floating patterns is the propellant as well as other contents used by the various manufactures. The Azmecort unit contains a microcrystalline suspension of triamcinolone acetonide in the propellant dichlorodifluoromethane and dehydrated alcohol USP 1% wt/wt.<sup>5</sup> Proventil HFA is a pressurized unit containing a microcrystalline suspension of albuterol sulfate in propellant HFA-134a (1,1,1,2-tetrafluoroethane), ethanol, and oleic acid. HFA-134a is an alternative propellant which contains no chlorine and, therefore, has no ozone-depleting potential and is chemically and biologically inert.<sup>6,7</sup> The Flovent 44  $\mu$ g unit contains a microcrystalline suspension of fluticasone propionate in a mixture of two chlorofluorocarbon propellants (trichlorofluoromethane and dichlorofluoromethane) with lecithin.<sup>8</sup> The items within each canister may affect the nozzle performance of each of the different devices over time as well as affect the floating pattern itself. In view of the fact that the Proventil HFA canister initially floated, and the other

Table 1. Mean Canister Positions Attained by Three Metered-Dose Inhaler Devices

	100%	75%	50%	25%	0%	Total <sup>5</sup>
Exp position <sup>1</sup>	V	VI	III	II	I	
Proventil HFA <sup>2</sup>	III	III	III	III	II	302
Azmecort <sup>3</sup>	V	IV	III	III	II	327
Flovent <sup>4</sup>	V	IV	III	III	III	163

<sup>1</sup> Expected position at the various medication intervals (See Fig 1)

<sup>2</sup> Proventil HFA Canister (150 recommended actuations)

<sup>3</sup> Azmecort Canister (240 recommended actuations)

<sup>4</sup> Flovent 44  $\mu$ g Canister (120 recommended actuations)

<sup>5</sup> Total number of actuations until an absolute zero amount of material or propellant was contained within the canister

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devices tested did not, it is possible that the new non-CFC propellant affects the buoyancy of the canister.

In their 1993 study, Williams et al<sup>2</sup> state that insufficient information concerning the amount of drug remaining in an MDI is given by the manufacturer, therefore making them "unsafe." This problem has been corrected with the production of the Diskus (Glaxo-Smith Kline) apparatus, which has a mechanism directly on the device that counts the doses remaining. Similarly, the Pulmicort Turbuhaler (budesonide; AstraZeneca, Wilmington, DE) has an indicator contained on the device that has a red mark that appears when only 20 doses remain.

This study demonstrates an important qualitative outcome that challenges existing methods of determining the amount of medication held within an inhaler canister. The three different canisters represent a wide spectrum of the basic medications available to patients in a MDI formulation, including the newer non-CFC based formulation.

## CONCLUSION

The results of this study concur with previous studies highlighting the difficulty that patients have in determining

the actual amount of medication that their inhaler device contains.<sup>2-4,6</sup> As demonstrated, the floating method is not an accurate method to identify the amount of medication contained within an inhaler device. This includes the newer non-CFC inhaler devices, such as Proventil HFA. This is the first study to evaluate whether or not this type of device would have similar floating patterns as those of previously studied devices. As shown, this new propellant demonstrates different floating characteristics. This will, without doubt, add further to the confusion patients have regarding the contents of their inhaler devices. Manufacturers must develop more reliable means to allow patients to evaluate the contents contained within their inhaler device and the number of actuations that remain before the device begins to deliver unreliable dosages. This would greatly benefit patients in their attempts to control their asthma.

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