TECHNICAL NOTE

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Evaluation of the Effect of Asthma Inhalers and Nasal Decongestant Sprays on a Breath Alcohol Test

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ABSTRACT: The effects of eight prescription and non-prescription asthma inhalers and four over-the-counter nasal decongestants on the DataMaster, an evidential breath alcohol instrument, were evaluated. Subjects self administered the medication, and breath alcohol tests were administered immediately after use and following a 15 min waiting period. The only preparation which produced any effect on the instrument was Primatene Mist which contains 34% ethyl alcohol. The alcohol was, however, eliminated from the breath in the usual pattern of mouth alcohol elimination, and after 5 min there was no longer any effect. The inclusion of a 15 min deprivation period prior to an evidential breath test, during which time nothing is introduced into the mouth, is an adequate safeguard against interference with the test caused by alcohol containing inhalers.

KEYWORDS: forensic science, forensic toxicology, breath alcohol, inhalers, asthma

Concerns are frequently raised over the potential for false positive or mouth alcohol "results from an evidential breath alcohol" test following use of nasal decongestant sprays, or bronchodilatory inhalers used in the treatment of asthma. Since some of these products contain ethanol, there is a legitimate reason to evaluate the possibility that their use might effect the results of a breath test. Furthermore, most inhalers also contain volatile halocarbon propellants, whose effects have not been investigated on infrared breath test instruments.

The use of a 15 or 20 min observation/alcohol deprivation period to allow dissipation of any exogenous alcohol in the mouth prior to the administration of a breath alcohol test is a standard component of all responsible evidential breath alcohol programs, and should be retained even with instruments that have mouth alcohol detection capabilities. The principle of mouth alcohol detection in the DataMaster relies on identification of an abnormal (negative) slope, inconsistent with equilibrium expired air. The latter should have a positive slope throughout the exhalation. At low levels of mouth alcohol, (less than about 0.03), the slope of the curve may not be negative throughout the exhalation and therefore may not be detected as invalid.

We recently evaluated the effects of a number of inhalers and decongestant nasal sprays on an evidential breath test conducted on an infrared breath test instrument (DataMaster, National Patent Analytical Systems, Mansfield, OH). The tests were performed under extreme conditions, such that the smallest ethanol effect whatsoever could be observed if it existed. Breath samples were provided immediately (within 10 s) after use of the product, and again 15 min later. No foreign objects or substances were introduced into the mouth or nose during this deprivation period, as would be required in a real evidential test under most administrative procedures.

Methods

Eight asthma medications were evaluated Azmacort (Rorer, PA) (200 μg triamcinolone acetonide per actuation (oral)); Vanceril (Schering, NJ) (beclomethasone dipropionate, 42 μg per dose (oral)); Vancenase (Schering, NJ) (beclomethasone dipropionate, 42 μg per dose (nasal)); Ventolin (Allen and Hanbury's, NC) (albuterol, 90 μg per dose (oral)); Beclovent (Allen and Hanbury's, NC) (beclomethasone dipropionate, 42 μg per dose (oral)); Beconase (Allen and Hanbury's, NC) (beclomethasone dipropionate, 42 μg per dose (oral)); Rhinocort (Astra MA) (budesonide, 32 μg per dose (nasal)), and Primatene Mist (Whitehall, NJ) (epinephrine, 0.2 mg epinephrine per dose (oral)). All these medications are dispensed from a pressurized aerosol dispenser. Beconase, Beclovent, Vancenase, Vanceril, and Ventolin use trichloromonofluoromethane and dichlorodifluoromethane as a propellant, and contain oleic acid. Rhinocort uses trichloromonofluoromethane, dichlorotetrafluoromethane, and dichlorofluoromethane, as propellants. Azmacort uses dichlorodifluoromethane and contains 1% w/w dehydrated ethanol, and Primatene Mist uses unspecified fluorocarbons as propellant, and contains 34% ethanol (1,2). Primatene Mist is the only non-prescription product in this group.

Four non-prescription decongestant nasal spray preparations were evaluated; 4-way Nasal Spray (Bristol Meyers, NY) (Oxymetazoline hydrochloride, 0.05%); Duration 12 Hour nasal spray (Schering Plough, NJ) (Oxymetazoline hydrochloride, 0.05%); Afrin Nasal Spray (Schering Plough, NJ) (Oxymetazoline hydrochloride, 0.05%); and Vicks Inhaler (Richardson-Vicks, OH) (1-desoxyephedrine, camphor, lavender oil, menthol). None of these products contains any ethyl alcohol.

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To test the asthma medications, an asthmatic female (SD) who takes or has taken the medications described above under directions from her doctor, volunteered to take each drug, on separate occasions, and blow into a DataMaster. In addition, two healthy male subjects tested the Primatene Mist, which is available without prescription and also contains the highest amount of ethanol. Institutional review for this and related projects was granted by the Human Subjects Committee at the University of Washington, and all subjects gave informed consent. The asthmatic subject did not have an asthmatic attack at any the time during the testing, and at no time was unable provide samples sufficient for analysis by the DataMaster.

All subjects were given a preliminary breath test on the DataMaster to ensure that they were alcohol-free. Each of these products was used in the manner described by its manufacturer and the subject was tested immediately on a DataMaster instrument to determine the result. Subjects were also re-tested after 15 min. Each product was tested by at least two subjects.

The administration of each product was performed according to the directions of its manufacturer, which typically involved one or two applications delivered into the mouth or nose during inspiration, followed by a 10 s breath hold. The subject then exhaled directly into the DataMaster. Following an air blank, an external standard simulator test, and second air blank, a second breath sample was supplied by the volunteer approximately 2 min after the first. To replicate an actual evidential breath test, the subject was then observed for 15 min and instructed not to eat, drink, smoke, or place anything in their mouth during that interval. A second duplicate test was then conducted, without any further administration of inhaler or spray. The instrument test protocol includes an optical filter test to check calibration, optics and software, four blank tests, and two subject samples. The accuracy of the instrument was determined prior to the evaluation of any medications, by the use of a 0.10g/210L quality control simulator standard.

Results and Discussion

The results of the initial and 15 min breath tests for each medication are shown in Table 1. None of the nasal decongestant sprays produced any reading on the DataMaster.

Of the asthma medications tested, Vanceril, Beclovent, and Azmacort are used by patients who require chronic treatment with corticosteroids for control of their bronchospasm (3). These drugs do not reverse acute bronchospasm, rather, they help avoid bronchospasm and must be used for several days before any symptomatic relief is seen. Vancenase, Rhinocort and Beconase are used in the relief of symptoms of seasonal or perennial rhinitis, and must be used in the same way. Ventolin is used to bring acute relief from bronchospasm in patients with reversible obstructive airway disease and in the prevention of exercise induced bronchospasm. None produced any effect on the breath test.

Primatene Mist which contains 34% ethanol, is also used for the treatment of acute bronchospasm, and was the only product which affected the breath test. It's use immediately prior to providing a breath sample, caused the instrument to register an invalid sample on the first exhalation on all three subjects, as a result of the detection of an apparent "mouth alcohol" exhalation curve (4,5). Had the sample not been rejected as invalid, the alcohol equivalent result would have been around 0.12g/210L. The rate of disappearance of alcohol from the breath was monitored in the two male subjects, by having them provide a continuous series of breath samples, after using the Primatene inhaler. An example of the alcohol elimination curve is shown in Fig. 1. There was no measurable alcohol on the breath of this subject after 265 s ($4^1/_2$ min). There was no effect in any of the three subjects after the 15 min deprivation period was observed. An asthmatic subject, having an attack such that Primatene or other acute therapies must be administered during that period, would not be a suitable subject for a breath test, and should be offered a blood alcohol test where local regulations permit.

Azmacort, which contains 1% ethanol, produced no apparent alcohol result on the DataMaster. It should be noted that each actuation of the dispenser produces only about 20 μL of liquid, that is to say 0.2 μL of ethanol, which is apparently dissipated rapidly. Azmacort is not used for acute treatment of asthma attacks, and there is, therefore, no need for it to be used during that deprivation period.

Other workers have previously evaluated this issue with other instruments and inhaler products. Gomm et al. (6) tested 20 different aerosol inhalers, and 5 nasal sprays available in the United Kingdom, on both screening and evidential, infrared and fuel cell, breath test instruments. Their methods did not, however, involve the use of a human subject, rather introducing the inhalers into a moisturized air stream from a compressed air tank. Unfortunately,

TABLE 1—*Breath test results following use of the inhalers. Data shows the results of duplicate breath readings, immediately following use of the inhaler (Time 1) and after 15 min (Time 2). All readings are in g/210L.*

Product	Active Ingredient	Ethanol Content	Time 1	Time 2
Asthma Medications				
Azmacort	triamcinolone acetonide	1%	0.000, 0.000	0.000, 0.000
Primatene	epinephrine	34%	Invalid sample	0.000, 0.000
Vancenase	beclomethasone dipropionate	none	0.000, 0.000	0.000, 0.000
Vanceril	beclomethasone dipropionate	none	0.000, 0.000	0.000, 0.000
Beclovent	beclomethasone dipropionate	none	0.000, 0.000	0.000, 0.000
Beconase	beclomethasone dipropionate	none	0.000, 0.000	0.000, 0.000
Rhinocort	budesonide	none	0.000, 0.000	0.000, 0.000
Ventolin	albuterol	none	0.000, 0.000	0.000, 0.000
Decongestant sprays				
4 Way	oxymetazoline hydrochloride	none	0.000, 0.000	0.000, 0.000
Duration	oxymetazoline hydrochloride	none	0.000, 0.000	0.000, 0.000
Afrin	oxymetazoline hydrochloride	none	0.000, 0.000	0.000, 0.000
Vicks	1-desoxyephedrine	none	0.000, 0.000	0.000, 0.000

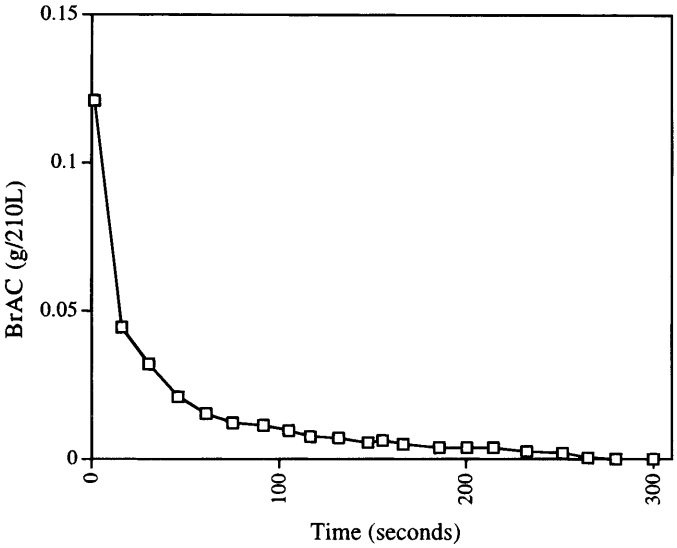

FIG. 1—*Sequential breath samples from one male subject after administration of Primatene Mist, showing peak breath alcohol concentration (BrAC) on each exhalation. After 265 seconds, there was no measurable alcohol in the breath sample provided.*

they do not indicate whether any of the products they tested contained alcohol. They did not find an apparent ethanol reading from any of the inhalers with either breath test technology.

In a more extensive study, Westenbrink and Sauve (7) evaluated, using human subjects, the effects of asthma inhalers on fuel cell, wet chemistry, and gas chromatography (GC) based instruments. They did not evaluate infrared instruments. They noted that in non-ethanol containing inhalers, no apparent ethanol was observed on any instrument employing fuel cell or wet chemistry techniques. They did, however, find that the presence of freon 114, used as a propellant in some of the products, did cause interference with the GC instrument when a 15 min deprivation period was not observed immediately before the test. When observed, however, the deprivation period allowed the dissipation of all freon. They also found that in ethanol-containing inhalers, with an ethanol content of 33%, any effect from ethanol had dissipated within 2–8 min (mean 3.6 min) following use, meaning that no effect would be observed providing that the inhaler was not used during the 15 min deprivation immediately preceding the test.

Importantly, the three technologies evaluated by Westenbrink and Sauve (7) (wet chemistry, fuel cell, and gas chromatography) do not have any slope detector technology which monitors the exhalation profile in real time, and can therefore distinguish between true breath alcohol and alcohol coming from the mouth or upper respiratory tract. This makes the documentation of the 15 min deprivation period all the more critical when using these methods.

On a related topic, Gomm et al. (8) evaluated the blood/breath ratio of alcohol in human subjects, before and after the use of a salbutamol (albuterol) bronchodilator. They found no significant difference in this ratio between asthmatic subject and controls, or in asthmatic subjects before and after inhaler use, suggesting that breath test on asthmatic subjects able to fulfill the sampling requirements are likely to be valid.

In view of the results obtained by us, and those noted by other workers, several points are evident. Firstly, the only constituent of inhaler medications which might exert an effect on the DataMaster is ethanol, which is present in only a few such products. Secondly, even when alcohol is present, a relatively high concentration is required (33%) to have any effect, which in any event may be detected by the instrument as mouth alcohol. Thirdly, we confirm that the observation of a 15 min deprivation period prior to the test will eliminate any possibility of interference from alcohol present in an inhaler medication.

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