New formulation metered dose inhaler increases breath alcohol levels

P. W. BARRY AND C. O'CALLAGHAN

Department of Child Health, University of Leicester, Leicester, U.K.

A new, chlorofluorocarbon-free metered dose inhaler containing salbutamol, with small amounts of ethanol as a co-solvent, has recently been released. We evaluated the effect on breath alcohol levels of two inhalations from this metered dose inhaler. In 10 volunteers, breath alcohol levels rose to 17.9 µg 100 ml⁻¹ breath after an inhalation with a good technique, and to 35 µg 100 ml⁻¹ breath (the current legal limit for driving in the UK) after a poor inhalation. Breath alcohol levels were reduced by the use of a spacer device, and in all cases fell to near zero after 2 min. In patients who have just used this type of metered dose inhaler, breath alcohol measurements should be deferred for at least 2 min.

Introduction

Chlorofluorocarbons (CFCs) are currently used as propellants in metered dose inhalers. The ozone-depleting potential of these chemicals has led to proposals to end their production (1). Metered dose inhalers (MDIs), which do not contain ozone-depleting chemicals, are being developed and an MDI containing salbutamol using the less ozone-depleting hydrofluoroalkane HFA 134a has recently been launched in the U.K. (Airomir, 3M Pharmaceuticals, Loughborough, U.K.). This formulation contains a small amount of ethanol as a co-solvent, each actuation delivering 4 µl of ethanol. We wished to determine whether use of the Airomir MDI affected measurements of breath alcohol levels.

Methods

Ten healthy adult volunteers, aged 24–36 years, took part in the study in which two breaths of salbutamol (100 µg per actuation from the Airomir MDI) were inhaled on each of three different days. None of the subjects were taking medication, and none had taken alcohol in the 12 h before the test. Prior to starting, breath alcohol levels were measured using a Lion Alcolmeter (Lion Laboratories, Barry, Wales, U.K.). On 3 separate days, in random order, subjects used the metered dose inhaler with good inhaler technique; with poor inhaler technique; or with a spacer device.

To simulate good inhaler technique, subjects were instructed to shake the MDI, place the MDI between their lips and inhale, actuating the MDI at the beginning of inhalation. They then held their breath for 10 s, before repeating the manoeuvre with a second actuation of the MDI.

To simulate poor inhaler technique, subjects repeated the manoeuvre on a separate day, but actuated the MDI when inhalation was completed. They then held their breath for 10 s, before repeating the manoeuvre.

To determine the effect of spacer use, Airomir was inhaled via an Aeroborm spacer device (Trudell Medical, Hamilton, Canada). Subjects were instructed to shake the MDI, attach the MDI to the spacer, place the spacer mouthpiece between their lips and inhale, actuating the MDI at the beginning of inhalation. They then held their breath for 10 s, before repeating the manoeuvre with a second actuation of the MDI.

In all cases, breath alcohol levels were measured after the second inhalation, and again after 2 and 5 min. The study was approved by the Leicestershire Ethical Review Committee and informed consent was obtained from the subjects.

Results

The results are shown in Table 1. Breath alcohol levels were increased immediately after using the inhaler, from 0 to a mean of 17.9 µg 100 ml⁻¹ breath. This was more marked where poor inhaler technique was imitated, breath alcohol rising to a mean of 35 µg 100 ml⁻¹ breath, the current legal limit for driving in the U.K. In most subjects, breath alcohol levels returned to 0 by 2 min.
Table 1. Breath alcohol levels (μg 100 ml⁻¹ breath) after using Airomir metered dose inhaler, mean and range. A level of 35 μg 100 ml⁻¹ breath is above the current legal limit for driving in the U.K.

<table>
<thead>
<tr>
<th>Time of estimate</th>
<th>'Trained inhaler technique'</th>
<th>'Untrained inhaler technique'</th>
<th>Inhaler + spacer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediately before MDI use</td>
<td>0.1 (0–1)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Immediately after MDI use</td>
<td>17.9 (7–26)</td>
<td>35 (23–49)</td>
<td>11.4 (5–19)</td>
</tr>
<tr>
<td>2 min after MDI use</td>
<td>1.5 (0–4)</td>
<td>1.4 (0–4)</td>
<td>1 (0–4)</td>
</tr>
<tr>
<td>5 min after MDI use</td>
<td>0.1 (0–1)</td>
<td>0.5 (0–2)</td>
<td>0</td>
</tr>
</tbody>
</table>

Discussion

Use of the Airomir formulation of salbutamol metered dose inhaler is not likely to lead to systemic effects of alcohol intoxication, as such small volumes of ethanol are delivered. However, we have found that use of the Airomir inhaler transiently increases breath alcohol levels. We assessed the effect of inhalation of two actuations from the MDI. Current guidelines for the management of acute severe asthma (2) suggest that up to 20 repeated actuations may be given, and in this case breath alcohol levels are likely to be even higher. The increase in breath alcohol is probably due to aerosol impacting in the mouth, as the level was greatest when poor inhaler technique was used, and was reduced by the use of a spacer device that minimized oropharyngeal deposition of aerosol (3). Similar transient rises in breath alcohol measurements have been found after swilling the mouth with alcohol-containing mouthwashes (4). Conventional CFC containing MDIs do not affect breath alcohol measurements (5).

The current legal limit for breath alcohol levels in the U.K. is 35 μg 100 ml⁻¹ of breath, a level that was exceeded by four subjects in this study. Our findings suggest that breath alcohol measurements are unreliable as estimates of intoxication in patients who have just used their Airomir metered dose inhaler. As the effect is transient, it is unlikely that use of Airomir could lead to a false prosecution for drunken driving or be used in the defence of a drunken driver. In patients who have just used their Airomir inhaler, breath alcohol measurements should be deferred for at least 2 min, and others suggest a 15-min period prior to an evidential breath test (6).

Acknowledgement

We thank Lion Laboratories, Barry, Wales for the loan of the alcolmeter.

References