A study to investigate the ability of subjects with chronic lung diseases to provide evidential breath samples using the Lion Intoxilyzer® 6000 UK breath alcohol testing device

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The Lion Intoximeter® 3000 has been used for evidential breath testing in the U.K. for some years. Some individuals with lung diseases have difficulty in providing evidential breath samples using the device. This study describes an investigation that we have carried out on a newer instrument — the Lion Intoxilyzer® 6000UK — which is now in use in the U.K. The study was designed to investigate the ability of subjects with a variety of lung diseases to provide evidential breath samples using this device. The 40 adult subjects investigated comprised 10 normal controls, 10 with asthma, 10 with chronic obstructive pulmonary disease (COPD) and 10 with restrictive lung disease. After baseline spirometry, subjects were given alcohol to drink, the quantity based upon body weight. After a gap of at least 20 min, subjects were asked to provide evidential breath samples in accordance with the test procedure built into the Lion Intoxilyzer 6000UK. The results showed that two asthmatic subjects, four with COPD and three with restrictive lung disease failed to provide evidential breath samples even after four attempts. Despite the device requiring a minimum sample volume of 1·2 l, eight of the nine subjects who failed had a forced vital capacity (FVC) of more than 1·5 l. Seven of these nine subjects had a forced expiratory volume in 1 sec (FEV1) of less than 1·0 l. In conclusion, this study has shown that some subjects with lung diseases may have difficulty in providing evidential breath samples using the Lion Intoxilyzer 6000 UK.

Key words: breath alcohol; lung function; Intoxilyzer; chronic lung disease.

Introduction

Police in the U.K. currently use a screening device for roadside breath alcohol testing. If a roadside screening test proves positive or if the subject is unable to activate the device, he or she is arrested and taken to the Police Station to provide an evidential breath sample. The Lion Intoximeter® 3000 has been in use in police stations for evidential breath testing for many years. Some individuals with lung diseases have difficulty in providing evidential breath samples using the device (1). We have looked at a newer instrument, the Lion Intoxilyzer® 6000UK, in order to assess whether subjects with a respiratory disease have difficulty in providing evidential breath samples using the device. Chest Physicians are frequently asked to give an opinion as to whether a subject with lung disease may have been unable to provide evidential breath samples because of impaired lung function. The aim of this study was to investigate whether one or more spirometric parameters could indicate which subjects would be unable to provide evidential breath samples using the Lion Intoxilyzer 6000 UK. A previous study looking at the Lion Alcolmeter® SL2 (a roadside testing device) found that subjects with a forced expiratory volume in 1 sec (FEV1) of less than 1·5 l or a FEV1 of less than 50% of predicted value were unlikely to be able to activate the device (2). A later study looking at the Lion Alcolmeter SL-400 (a newer roadside testing device) found that subjects who had a FEV1 of less than 1·1 l were unlikely to be able to activate the device (3).

Methods

SUBJECTS

The subjects studied consisted of 10 adult controls who had no evidence of underlying lung disease, 10 subjects with chronic obstructive pulmonary disease (COPD), 10 with asthma and 10 with restrictive lung disease. The subjects with lung disease were recruited from patients at the City Hospital.
Hospital, Dudley Road, Birmingham, U.K. All subjects gave written informed consent and the study received approval from the Hospital Ethics Committee.

For the purposes of the study, subjects with COPD were those who had a FEV₁ less than 50% of predicted value and the criteria for diagnosis were as recommended by the British Thoracic Society (4). Subjects with asthma were those who had a forced expiratory ratio (FER or FEV₁/FVC) less than 60% and at least 15% reversibility in FEV₁ after a bronchodilator. Those with restrictive lung disease had a forced vital capacity (FVC) less than 2.5 l and FER ≥ 70%. All of the subjects with lung disease also had a clinical diagnosis and history consistent with the respective disease category.

RESPIRATORY FUNCTION TESTING

Subjects were invited to attend in the early afternoons. Spirometry was performed strictly in accordance with British Thoracic Society/Association of Respiratory Technicians and Physiologists (BTS/ARTP) guidelines (5) shortly after arrival. All subjects were asked to avoid consuming alcohol on the day of the visit, to eat a light breakfast and then to refrain from eating until after the investigations were completed. The subjects with lung disease were asked to avoid using any inhaled medication for at least 4 h before they attended. The instrument used for spirometry was a Spirobank Multifunction spirometer (MIR Medical International Research, Albano Laziale, Rome, Italy) connected to a laptop computer. Control of the Spirobank spirometer, data capture and results presentation were via Océan WinSpiro operating software provided by the manufacturer. The spirometer calibration was checked prior to each test run. Spirometry results were recorded as the best of at least three valid and technically acceptable procedures, where the results for each parameter were within 5% tolerance for each individual subject. Reference values were calculated for each subject from age, height and sex data using the European Respiratory Society (ERS) algorithms in accordance with the published ERS 1993 update algorithm set.

BREATH TESTING DEVICE

A Lion Intoxilyzer 6000UK machine was used for breath alcohol analysis. The device is a micro-processor controlled, multi-filtering infrared spectrometer. The effect of other alcohols (e.g. methanol, propyl alcohol, isopropyl alcohol) and ketones (e.g. acetone) in the breath on the analysis is low and predictable. The device has an enhanced specificity for ethanol via primary and secondary infrared wavelengths. If interfering substances are present in the sample, the test procedure aborts and the message ‘Interfering Substance—Unsatisfactory Specimen 1’ is displayed and printed. The measurement range for the Lion Intoxilyzer 6000UK is 0–220 μg alcohol 100 ml⁻¹ of breath. The minimum sample volume required by the device is 1.2 l, delivered in a continuous manner at a flow greater than 12 l min⁻¹. The mouth pressure required to generate the minimum continuous flow of 12 l min⁻¹ through the breath sampling pathway with non-return valve mouthpiece attached is 18 mBar.

BREATH TESTING PROCEDURE

The breath testing procedure is preprogrammed into the Lion Intoxilyzer 6000UK by the manufacturer and cannot be altered by the operator. The procedure sequence is identical to that of the previous device—the Lion Intoximeter 3000. Immediately prior to commencement of the test procedure, the operator is instructed to attach a new mouthpiece to the device. Single use mouthpieces are prepacked by the manufacturer. The operator then proceeds to enter the subject’s surname, forenames, gender and date of birth via the device’s alpha-numeric operating keypad. Having verified the details entered, the operator is then asked to confirm commencement of the breath test procedure. The device then moves into the analytical test phase. The remainder of the test cycle runs fully automatically: there is nothing which the subject or operator can do to influence the course of the analysis. During the test phase, the instrument progresses through a number of steps, as detailed below.

Step 1—air blank 1

The instrument purges itself with room air to ensure it is alcohol-free. Only an air blank reading of 0 μg 100 ml⁻¹ will allow the test to proceed to the next step. During the purging and air blank process, air is drawn into the instrument through the breath tube. By attaching the mouthpiece prior to this procedure, therefore, this item is itself checked to ensure and prove that it is contaminant free and that it is not blocked. If this test does fail, for any reason, the instrument will abort the procedure and display an alert message.

Step 2—simulator check 1

A sample of alcohol vapour from a certified gas simulator cylinder provided by an independent Home Office supplier is analysed as a calibration check—again, fully automatically. Only a reading in the range 32–37 μg 100 ml⁻¹ inclusive is acceptable otherwise the instrument will abort the procedure.

Step 3—air blank 2

The instrument again purges itself with room air, then tests itself to ensure it is free of alcohol from the gas standard. Only a reading of 0 μg 100 ml⁻¹ will allow the test to proceed to the next stage.
Step 4—subject’s breath specimen 1

The subject has 3 min in which to supply this first specimen. The manufacturers claim that this 3-min period should allow up to five attempts. The operator gives the subject the instructions to take a deep breath, to place the mouthpiece in his or her mouth and then to exhale continuously through the mouthpiece to make an audible ‘beeper’ device sound and to bring up vertical and horizontal bars on the instrument display. The vertical bar indicator displays flow rate of breath through the instrument and this must be maintained above a level of 12 l min⁻¹ throughout the breath. The larger horizontal bar indicator shows the volume of breath (minimum 1-2 l required) exhaled into the device and the volume still to be provided. If the subject has alcohol in his or her breath, then this horizontal bar indicator will reflect the approach to alveolar air. As this point approaches, the analyser monitors the rate of change of breath alcohol and identifies when a plateau (consistent with alveolar air) occurs. If the subject has no alcohol in their breath, then the horizontal display will simply represent the provision of the 1-2 l breath requirement as made in such circumstances. The subject must continue to exhale at a rate above 12 l min⁻¹ until the criteria above have been satisfied, the machine has sounded a double ‘beep’ tone and the message ‘Breath Specimen Accepted’ has appeared on the instrument display. At this point the breath sample has been analysed but no reading is shown at this stage. This is intended to stop giving perhaps borderline positive subjects a motive for indulging in some respiratory technique (e.g. hyperventilation prior to blowing) in an attempt to reduce the breath alcohol level in respect of their second specimen. If the subject does not blow continuously, or blows and then stops too early, then the attempt is aborted and the system purges before inviting the subject to repeat his or her attempt. If the message ‘Breath Specimen Accepted’ is not displayed during this step of the procedure, then the subject has failed the evidential breath test by failing to provide a specimen of breath.

Step 5—air blank 3

The instrument again purges itself with room air then tests itself to ensure it is free of alcohol from the first breath specimen. As in the previous air blank steps, a reading of 0 μg 100 ml⁻¹ is required to allow the test to proceed.

Step 6—subject’s breath specimen 2

The subject has a further 3 min to supply this second specimen. This second 3-min period is independent of the first. The same instructions are given to the subject as for the first specimen. Again, no result is shown until the end of the procedure, after the final calibration check. If the message ‘Breath Specimen Accepted’ is not displayed during this step of the procedure, then, as in Step 4, the subject has failed the evidential breath test by failing to provide a specimen of breath.

Step 7—air blank 4

The instrument again purges itself with room air, then tests itself to ensure it is free of alcohol from the second breath specimen. Only a reading of 0 μg 100 ml⁻¹ will allow the test to proceed to the next stage.

Step 8—simulator check 2 and final purge

A further sample of alcohol vapour from the gas simulator is now analysed as a final calibration check. Only if this reading is in the range 32–37 μg 100 ml⁻¹ inclusive can the breath test readings already obtained (but yet to be displayed) be used in evidence. The instrument now purges the alcohol from its system, so that it is clear until next required for use.

Step 9—results and printout

The readings are now displayed followed by a printout of the breath alcohol readings and the two calibration check results. The printout is generated in a format which allows it to be signed by the operator and submitted as an evidential document.

PRE-ALCOHOL BREATH TESTING

Subjects were requested to provide two evidential breath samples in accordance with the procedure and instructions described above.

ADMINISTRATION OF ALCOHOL

Those subjects who were able to provide two evidential breath samples in the pre-alcohol phase were then given a quantity of vodka (40% vol), depending on body weight, diluted with an equal volume of fruit juice. The amount of alcohol required to achieve a breath alcohol level of around 35–45 μg 100 ml⁻¹ breath was calculated according to body weight using the following formula, provided by Lion Laboratories Ltd:

\[
\text{Volume of alcohol (40\% vol) required (ml)} = \text{Subject’s weight (kg)} \times 2.162
\]

The physiological reason for diluting the alcohol with an equal volume of fruit juice is that the rate of absorption of alcohol in the stomach is greatest at 20% by volume. For the purposes of the study, this also made the ingestion of alcohol more palatable. The subjects were asked to consume the entire quantity of alcohol within 15 min.

POST-ALCOHOL BREATH TESTING

Twenty minutes after completing the ingestion of the alcohol/fruit juice mixture, the subjects were requested to provide two further evidential breath samples in accordance with the procedure and instructions previously described.
Results

Consumption of alcohol was not a factor in determining success or failure as all subjects who failed to provide evidential breath samples failed in the pre-alcohol phase of the study. The manufacturers state that the 3-min subject breath specimen periods should allow up to five attempts. Our study showed that only four attempts were feasible during each of the two specimen periods, taking into account the need to instruct subjects properly, to allow reasonable time for recovery between attempts, and the fact that patients with COPD in particular may take considerably longer to exhale than others. The details of the subjects investigated are shown in Table 1. The mean (+SD) results for spirometry are shown in Table 2. Figure 1 shows the FEV1 results according to whether or not the subjects were able to succeed in activating the device. The groups who succeeded and who did not succeed were compared for each of the four sub-groups (control, asthma, COPD and restrictive disease) for the following spirometric parameters: peak expiratory flow (PEFR); forced expiratory volume in 1 sec (FEV1); forced vital capacity (FVC); forced expiratory ratio (FER or FEV1/FVC).

In addition, these parameters were also expressed as percent predicted reference value and potential differences analysed between the successful and unsuccessful groups. Table 3 shows the mean breath alcohol measurements recorded by the Lion Intoxilyzer 6000UK.

Two asthma subjects, four COPD subjects and three restricted subjects failed to provide two evidential breath samples in accordance with the test procedure prescribed by the manufacturer. Of these subjects, seven out of the nine had a FEV1 of less than 1 l. Of the nine failures, eight had a FVC greater than 1·5 l (range 1·64–3·03 l).

Table 1. Mean age (±SD) and sex of subjects investigated

<table>
<thead>
<tr>
<th>Subject group</th>
<th>Mean age (years)</th>
<th>Male (n)</th>
<th>Female (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control (n=10)</td>
<td>32·7 (±6·4)</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Asthma (n=10)</td>
<td>58·3 (±12·8)</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>COPD (n=10)</td>
<td>68·4 (±8·5)</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Restricted (n=10)</td>
<td>52·5 (±11·9)</td>
<td>3</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 2. Mean spirometric values (±SD) of subjects investigated

<table>
<thead>
<tr>
<th>Subject group</th>
<th>Mean FEV1 (l)</th>
<th>Mean FER (%)</th>
<th>Mean FVC (l)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control (n=10)</td>
<td>4·5 (±0·9)</td>
<td>80·9 (±7·8)</td>
<td>5·6 (±0·9)</td>
</tr>
<tr>
<td>Asthma (n=10)</td>
<td>1·5 (±0·7)</td>
<td>44·0 (±9·0)</td>
<td>3·3 (±1·1)</td>
</tr>
<tr>
<td>COPD (n=10)</td>
<td>1·0 (±0·3)</td>
<td>37·0 (±8·8)</td>
<td>2·8 (±0·6)</td>
</tr>
<tr>
<td>Restricted (n=10)</td>
<td>1·7 (±0·5)</td>
<td>82·1 (±10·5)</td>
<td>2·0 (±0·5)</td>
</tr>
</tbody>
</table>

Discussion and conclusions

The manufacturers state that a minimum breath sample volume (i.e. the amount required to be expired regardless of alcohol content) using the Lion Intoxilyzer 6000UK is 1·2 l, and a minimum continuous expiratory breath flow rate of 121 min⁻¹ is required. In patients with lung disease, maintaining such a minimum flow rate for a period of time may be problematical given the intrinsic resistance of the breath sampling pathway (18 mBar at 121 min⁻¹). Twenty-nine of the 30 subjects with lung disease that we investigated had a FVC of greater than 1·5 l but, nevertheless, eight of them failed to provide evidential breath samples despite having four attempts during each of the two sampling periods. The expiratory breath flow rate fell below the 121 min⁻¹ continuous threshold required during the breath sampling period for these subjects. Figure 1 shows that there was some overlap between the successful and unsuccessful groups regarding...
this respiratory function measurement. Of the various lung function measurements, FEV₁ (as indicated in Fig. 1) was of some predictive value in that subjects who were unable to provide evidential breath samples were unlikely to have a FEV₁ greater than 1 l. There was, however, still some overlap even with this parameter in that two subjects with an FEV₁ of less than 1·0 l were able to provide evidential breath samples. These two subjects both had restrictive lung disease. Otherwise there appeared to be no obvious difference between the ability to succeed or not to succeed and the type of underlying lung disease. All of the other spirometric parameters analysed such as FVC, FER, PEFR, FEV₁% predicted, FVC% predicted, etc. showed considerably more overlap between the successful and unsuccessful subjects compared to the FEV₁ measurement.

In conclusion, this study has shown that subjects with lung diseases may have difficulty in providing evidential breath samples using the Lion Intoxilyzer 6000UK as has been the case with previous evidential devices (1). Most of the subjects who were unable to activate the device had a FEV₁ of less than 1 l.

Acknowledgements

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References