Evaluation of inhaler technique mastery and handling errors with Spiromax®, Easyhaler®, and Turbuhaler® devices (FINHALER)

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BACKGROUND

- Asthma is a chronic inflammatory respiratory disease affecting an estimated 300 million people worldwide.¹
- The annual direct treatment costs for asthma in Finland have reached over 200 million Euros and the indirect costs were estimated to be 470–550 million Euros.²
- The therapeutic efficacy of an inhalation therapy requires the drug(s) to reach the targeted areas of lower lung³ and there is an increasing body of evidence to suggest that correct use of the inhalation device is critical for optimal drug delivery.⁴
- Studies have shown that inhaler use is often highly suboptimal. Research indicates that between 20–82% of patients (depending on the type of inhaler and method of assessment) do not master their dry powder inhalers.² ³

OBJECTIVE

To evaluate device mastery with dry powder inhalers, Spiromax®, Respisclick®, Easyhaler®, and Turbuhaler® in inhaler-naïve participants.

METHODS

- This was a single-site, single-visit, crossover study at the Åbo Akademi University, Turku, Finland.
- Healthy inhaler-naïve participants aged ≥18 years (N=120) were randomly assigned to one of the six assessment groups (Figure 1).
- Participants were observed using each of the three empty devices without active substance (Spiromax®, Easyhaler®, and Turbuhaler®; Figure 2) in a counter-balanced order.
- To evaluate the proportion of participants achieving device mastery (defined as an absence of healthcare professional [HCP] observed errors), a three step approach was used: (a) Intuitive use (with no instructions) ² ³, (b) after reading the Patient Information Leaflet (PIL), (c) after HCPs provided instructions.
- Trained HCPs monitored use and recorded errors based on the Device-Specific Handling Error Checklist (DSHEC), based on the approved PIL for each of the devices.
- Descriptive and exploratory analyses were performed to assess the endpoint variables – the proportion of participants achieving device mastery at each of the three steps. The number, type, and characteristic of device handling errors were also assessed.

RESULTS

- The majority of study participants (n=79; 66%) were aged 20–29 years old, 25% were male, and almost all participants (99%) were educated to a university level.
- During Step 2 (after reading the PIL), the percentages of participants who used the device without error were higher with Spiromax® (93.3%) compared with Easyhaler® (58.3%), or Turbuhaler® (70.7%) (Table 1). This difference was significant for all comparator groups (p<0.001 [Spiromax vs Easyhaler®] and Spiromax vs Turbuhaler®; Table 1).
- Similarly, in Step 1, Spiromax® was associated with a greater level of device mastery compared with Easyhaler® or Turbuhaler®, 37.5% of patients were able to use Spiromax® with no errors in Step 1 (intuitive use) compared with 0% with Easyhaler® (p<0.001) and 9.2% with Turbuhaler® (p<0.001) (Table 1).

Table 1. Proportion (%) of participants who were able to use Spiromax®, Easyhaler® or Turbuhaler® without observed errors in Steps 1–3

<table>
<thead>
<tr>
<th>Group</th>
<th>Device</th>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>Spiromax</td>
<td>37.5</td>
<td>92.2</td>
<td>99.2</td>
</tr>
<tr>
<td>Group 2</td>
<td>Easyhaler</td>
<td>92.3</td>
<td>76.7</td>
<td>99.8</td>
</tr>
<tr>
<td>Group 3</td>
<td>Turbuhaler</td>
<td>92.2</td>
<td>74.7</td>
<td>99.8</td>
</tr>
</tbody>
</table>

One observation was added to the Easyhaler® group to perform the statistical analysis.

- The device mastery level was high (>95%) with all three devices during Step 3 (after receiving instructions from the HCP).
- The number of participants observed making errors at each step varied between the three devices. The mean proportion of observed errors during Steps 1 and 2 was lower with Spiromax® (12.4% and 0.8%) compared with Easyhaler® (16.8% and 5.0%); both p<0.001 or Turbuhaler® (17.6% [p<0.002] and 2.8% [p<0.001]). The mean proportion of observed errors during Steps 1 and 2 was similar between the devices in Step 3 (0.1%, 0.5%, and 0.1%, for Spiromax®, Easyhaler®, and Turbuhaler®, respectively).
- Since the types of device handling manoeuvres differ between Spiromax®, Easyhaler®, and Turbuhaler®, the percentages of handling errors were evaluated during preparation, inhalation and after inhalation in Steps 1–3 for each device and for each of the device-specific handling manoeuvres (Figure 3).
- The most common errors in Step 1 were related to orientation for Spiromax® (51.3%), shaking for Easyhaler® (95.8%), and priming for Turbuhaler® (55.8%).
- In general, age, educational level and gender were not significantly associated with the occurrence of handling errors. ns: not significant.

CONCLUSIONS

- Spiromax® was associated with higher levels of device mastery evidenced by intuitive use (no instructions) or after written instructions (PIL), and fewer errors compared with Easyhaler® and Turbuhaler®, irrespective of patient age, gender, or education level.
- The higher levels of device mastery achieved with Spiromax could potentially improve adherence and may lead to improved asthma control and a reduction in overall treatment costs.

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References