

# PA4258 Real-life inhaler technique in asthma patients using the electronic ProAir Digihaler

Henry Chrystyn,<sup>1</sup> Guilherme Safioli,<sup>2</sup> Dan Buck,<sup>3</sup> Lena Granovsky,<sup>4</sup> Enric Calderon,<sup>3</sup> Thomas Li,<sup>5</sup> Michael Reich,<sup>4</sup> Tanisha Hill,<sup>5</sup> Michael DePietro,<sup>5</sup> and Roy Pleasants<sup>6</sup>

<sup>1</sup>Inhalation Consultancy, Leeds, UK; <sup>2</sup>Teva Pharmaceuticals Europe BV, Amsterdam, The Netherlands; <sup>3</sup>Teva Pharmaceuticals, Waterford, Ireland; <sup>4</sup>Teva Pharmaceuticals, Petah Tikva, Israel; <sup>5</sup>Teva Branded Pharmaceuticals R&D Inc., Frazer, PA, USA; <sup>6</sup>University of North Carolina at Chapel Hill, School of Medicine, Chapel Hill, NC, USA

## BACKGROUND AND AIMS

- Inhalation therapy is the cornerstone of asthma management, delivering medication to the site of action. However, treatment is reliant upon correct inhaler technique to allow for optimal deposition of medication.
- Despite correct inhaler technique demonstrations in clinical practice or during study visits, patients typically do not maintain correct technique at home, and errors are common.
- A lack of reliable information about inhaler technique is a challenge when managing patients with asthma.<sup>1,2</sup>

Figure 1. ProAir Digihaler



- The ProAir Digihaler (salbutamol 90µg/dose; **Figure 1**) is an electronic multi-dose dry powder inhaler (eMDPI) with an integrated module that can accurately record inhalation parameters (peak inhalation flow [PIF], inhalation volume, inhalation duration, and time to PIF) with a time stamp, providing objective information on use and technique.<sup>3,4</sup>
- This analysis aimed to describe issues related to inhaler technique by using data from the integrated Digihaler in asthma patients prone to exacerbations.

## METHODS

### Patients

- Patients (≥18 years old) were eligible if they:
  - Had ≥1 severe asthma exacerbation 12 months prior to screening.
  - Had poorly controlled asthma, defined by an Asthma Control Questionnaire-5 score of ≥1.5.<sup>5</sup>
  - Received stable, at least moderate doses of inhaled corticosteroids (equivalent to ≥440µg daily of fluticasone propionate) for ≥3 months, with or without other asthma controller medications, and showed competency in the use of the Digihaler.
- Patients were required to discontinue treatment with their short-acting bronchodilators, and replace them with ProAir Digihaler.

### Study design

- Data were gathered from a 12 week, multi-centre, open-label study (NCT02969408) conducted between February 2017 and February 2018, where patients with exacerbation-prone asthma used Digihaler (1–2 inhalations every 4 hours) as required.
- Digihaler recorded each use, and inhalation parameters: PIF, inhalation volume, inhalation duration, and time to PIF.
- Data were downloaded directly from Digihaler for analysis (the companion smart device application was not used in this study).
- Inhaler event definitions are shown in **Table 1**.

Table 1. Inhaler event definitions

Event status
PIF 30–59L/min
PIF 60–119L/min
PIF 120–199L/min
Very low inhalation flow (PIF <18L/min) or no inhalation
Low inhalation flow (PIF 18–29L/min)
Unexpected multiple inhalations recorded as one event*
Air vent block (PIF ≥200L/min)

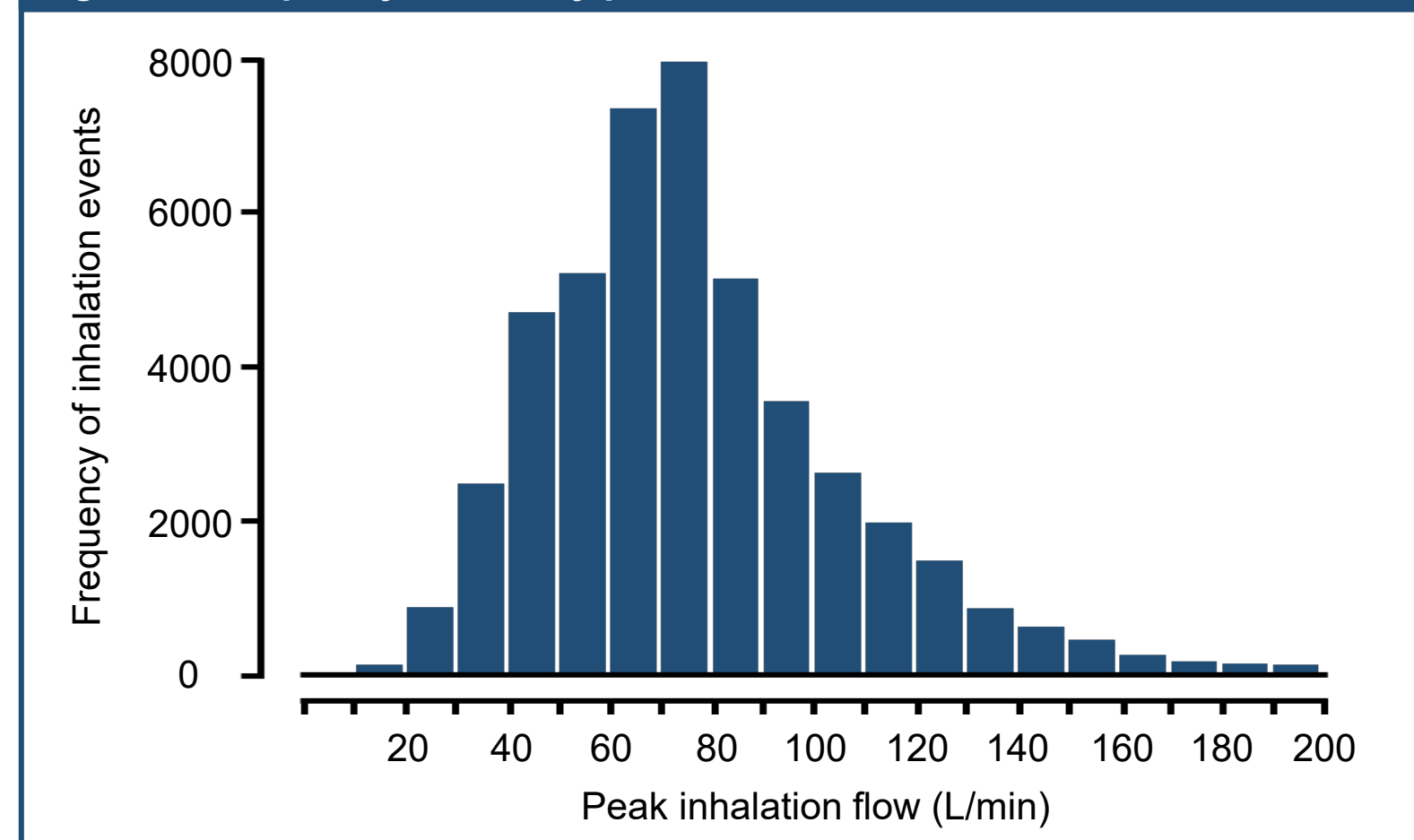
\*i.e. >1 inhalation prior to cap closure. PIF, peak inhalation flow.

## RESULTS

### Inhalation parameters

- Of 376 patients who used Digihaler at least once, 363 (96.5%) patients made ≥1 valid inhalation.
- A total of 53374 inhalation events were downloaded from 773 inhalers.
- The following mean (SD) inhalation variables were recorded:
  - PIF: 76.8 (29.3) L/min (range: 18–199L/min),
  - Inhalation volume: 1.44 (0.92) L
  - Time to PIF: 0.52 (0.45) seconds
  - Inhalation duration: 1.53 (0.88) seconds.
- **Figure 2** shows the frequency (count of events) across the PIF range of 18–199L/min.
- PIFs of 60–119L/min and 30–59L/min were generated during 51.5% and 21.5% of recordings, respectively.

Figure 2. Frequency counts by peak inhalation flow rate



- **Table 2** shows the frequency of inhalation events, and the average PIF, inhalation volume, inhalation duration, and time to PIF by inhalation status.

Table 2. Frequency of inhalation events and inhalation variable averages by inhalation status\*

Inhalation status	Count events (%)	PIF, mean (SD), L/min	Inhalation volume, mean (SD), L	Inhalation duration, mean (SD), S	Time to PIF, mean (SD), S
PIF 30–59, L/min	11463 (21.5)	47.7 (7.8)	1.03 (0.64)	1.68 (1.08)	0.61 (0.6)
PIF 60–119, L/min	27466 (51.5)	82.1 (15.3)	1.51 (0.78)	1.49 (0.76)	0.5 (0.37)
PIF 120–199, L/min	3710 (7.0)	140.8 (18.3)	2.63 (1.31)	1.62 (0.8)	0.53 (0.36)
Very low inhalation flow (PIF <18L/min**) or no inhalation	6774 (12.7)	N/A	N/A	N/A	N/A
Low inhalation flow (PIF 18–29L/min)	735 (1.4)	24.5 (3.1)	0.38 (0.46)	1.13 (1.27)	0.39 (0.67)
Unexpected multiple inhalations recorded as one event	2442 (4.6)	78 (47.8)	1.21 (1.22)	1.19 (0.9)	0.43 (0.39)
Air vent block (PIF ≥200L/min)	277 (0.5)	245 (47.2)	5.02 (2.81)	1.89 (0.82)	0.74 (0.54)

\*Technical errors (507 events, 0.9%), such as timeout, and unexpected exhalation and inhaler parameter errors, were not included.  
\*\*The lowest recorded PIF was 18.9L/min. L, litres; PIF, peak inhalation flow; S, seconds; SD, standard deviation.

## CONCLUSIONS

- Digihaler offers opportunities to identify real-life problems with inhaler technique, increasing the chances of improving treatment outcomes.
- In this study, 80% of the inhalation events were recorded with a PIF above 30 L/min, indicating good or at least acceptable technique, even without feedback from the companion smart device app.
- The 12.7% of inhalations recording a very low PIF (<18 L/min) or no inhalation suggest instances where patients prepared a dose by opening the cap but did not inhale.
- Further studies evaluating Digihaler with a companion app would be useful to determine whether information obtained could help improve patient–device interaction by addressing specific inhalation errors, and provide objective, actionable information to healthcare providers.

### References

1. Blakey JD, et al. Eur Respir J 2018;52:1801147.
2. Lycett HJ, et al. J Med Internet Res 2018;20(12):e293.
3. ProAir Digihaler. Available at: <https://www.proairdigihaler.com>.
4. Chrystyn H, et al. Eur Respir J 2018, 52: Suppl 62, PA681.
5. Korn S, et al. Ann Allergy Asthma Immunol.2011;107:474–479.

### Disclosures

RP has received grants from Boehringer Ingelheim and personal fees from Grifols, Sunovion, and Teva Pharmaceuticals. GS, DB, LG, EC, TL, MR, TH and MDeP are employees of Teva Pharmaceuticals. Some authors may own stock from the respective companies they work for. HC declares no conflict of interest.

### Acknowledgements

This analysis was sponsored by Teva Pharmaceuticals. Medical writing support for this poster presentation was provided by Melanie Francis and Ian C. Grieve, PhD, of Ashfield Healthcare Communications, part of UDG Healthcare plc, and was funded by Teva Pharmaceuticals.

