Impact of Digital Breath-Guiding on Inhalation Technique and Drug Deposition

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Background

- Inhalation technique is a critical factor in effective inhalation therapy.
- Optimal inhalation is characterized by slow and deep inhalation maneuvers – and high lung deposition, short nebulization times.
- Short nebulization times are crucial for patient acceptance and good therapy adherence.
- Digital breath-guiding has the potential to improve inhalation technique by supporting patients in adopting a more efficient breathing pattern.

Aim and Objective

- To evaluate the usability and impact of digital breath-guiding on inhalation parameters of the eFlow Integrated.

Figure 1: A) eFlow Integrated and Breath-Guide app with lung animation during inhalation. B) Breath-Guide app warning screen when inhalation exceeds 30 L/min

Method

- We conducted a non-interventional usability evaluation with 64 participants: healthy individuals and patients with both obstructive and restrictive lung disease (Table 1).
- They performed dry inhalation maneuvers with three device configurations:

eFlow® Open System (OS)
No breath-guiding
- Commercially validated reference device
- Bolus effect for high lung dose and short nebulization time

eFlow® Integrated
Breath-guiding via device
– flow resistance and
– haptic and visual feedback when exceeding flow limit of 30 L/min

eFlow® Integrated & App
Breath-guiding via
– device (same as B), plus
– direct app feedback and guiding towards slow and deep inhalation (see Fig. 1)

- Flow rate was recorded with Sensirion® SFM3300 flow sensor positioned between device and participant
- Anonymized inhalation parameters were analyzed and compared:
  – peak inspiratory flow (PIF),
  – inspiratory/expiratory (I/E) ratio,
  – breath duration and
  – tidal volume
- Statistical analysis was conducted using ANOVA
- Pulmonary deposition rate in the clinically relevant lung regions was estimated using in silico based alveolar and thoracic deposition per unit time (deposition rate, DR)

Table 1: baseline characteristics of the participants

Variable	Healthy	Obstructive	Restrictive	Total
Indication e.g.	-	Asthma, COPD, CF, Bronchiectasis	Pulmonary fibrosis, Sarcoidosis	-
N	25	24	15	64
Mean Age	41.12 ± 11.31	50.67 ± 17.64	60.73 ± 11.46	49.30 ± 15.81
Mean Height (cm)	175.4 ± 7.17	171.88 ± 8.66	168 ± 7.96	172.34 ± 8.33
Mean Weight (kg)	72.68 ± 12.04	69.46 ± 16.82	72.4 ± 12.59	71.41 ± 14.00

Results

- Compared with the reference configuration, breath-guiding shifted participants' breathing patterns towards a slower and deeper inhalation.
- PIF was significantly lower with the eFlow Integrated (with or without app) than with the proven eFlow OS (28.5 vs. 35.5 L/min; $p<0.05$).
- Breath-guided inhalation (with or without app) improved the I/E ratio (0.94 vs. 0.81; $p<0.05$). App use prolonged breath duration (8.2 s vs. 6.0 s without app), both expected to improve aerosol delivery efficiency and nebulization time.
- App use was associated with higher tidal volumes (1.4 L vs. 1.0 L; $p<0.05$), contributing to higher simulated deposition rates.
- Simulated deposition rate increased from the already efficient eFlow OS to the eFlow Integrated (+3.7%) and was highest with app-based breath-guiding (+15.5%).

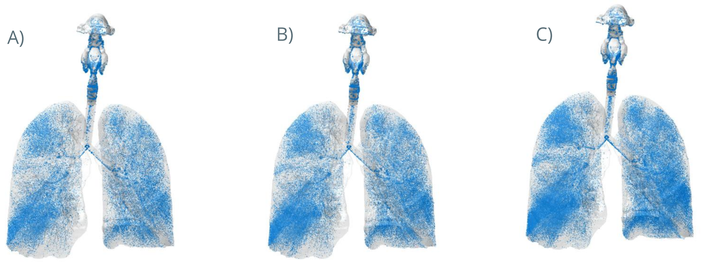

Figure 2: in silico simulated lung deposition of A) eFlow OS B) eFlow Integrated with breath-guiding C) eFlow Integrated with Breath-Guide app.
All in silico simulations were conducted with a standardized obstructive breathing pattern by Ebenbuild

Conclusion

- Use of digital breath-guiding can improve inhalation technique
- Optimized breathing patterns were associated with higher simulated pulmonary deposition rates
- These findings suggest potential benefits for inhalation efficiency, hence reduced nebulization time and warrant further investigation of potential clinical benefits.