

Online Supplement

Original Research

Use of a Digital Inhaler to Assess COPD Disease Variability and Identify Impending Acute COPD Exacerbations: A Pilot Study

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Supplemental Table E1. Study inclusion and exclusion criteria

Inclusion Criteria
Adults over age 40
Established COPD defined as physician diagnosis along with spirometry confirmation (post-BD FEV1/FVC<0.70) within the last two years and an FEV1 ≤ 80% predicted
Regular albuterol use (defined as at least one inhalation weekly in each of the last four weeks)
History of cigarette smoking ≥ 10 pack-years
Currently outpatient (non-hospitalized)
Medical records confirmed history of two moderate AECOPD (defined as use of antibiotic or steroids to treat clinical event consistent with AECOPD) <i>or</i> One severe AECOPD (defined as emergency department/hospital visit) in prior 12 months
Access to smartphone/tablet/computer and internet
Willing to switch their current rescue inhaler to ProAir Digihaler
Exclusion Criteria
Allergy to or inability/contraindication to using albuterol sulfate
Condition that, in the opinion of the site investigator, would compromise the subject's ability to participate in the study

Supplemental Table E2. Correlation of Digihaler recorded SABA use compared with reported SABA use at month 1, 2 and 3

Self-reported SABA use	Actual Digihaler SABA use, mean (SD)		
	Month 1 (n=40)	Month 2 (n=39)	Month 3 (n=41)
3+ times per day	4.0 times/day (3.2)	3.4 times/day (2.8)	2.4 times/day (2.4)
1-2 times per day	2.1 times/day (2.8)	2.0 times/day (1.9)	2.3 times/day (2.3)
2 or 3 times per week	9.8 times/week (14.0)	4.2 times/week (7.7)	3.5 times/week (7.0)
Once per week or less	N/A	1.4 times/week (4.2)	0.7 times/week (2.8)

Note: Summary statistic of actual SABA use calculated based on number of valid inhalations per day reported in the 30 days prior to month x visit. $p < 0.001$ for correlation.

Supplemental Table E3: Summary of Digihaler App daily self-assessment responses

Variable ^a	Facial Icon Selected by Patient			<i>p</i> -value
	 n=686	 n=650	 n=129	
Peak inspiratory flow (L/min)	64.9 (16.1)	70.1 (23.0)	65.4 (20.8)	<0.001
Inhalation volume (L)	1.3 (0.4)	1.4 (0.6)	1.41 (0.7)	0.006
Inhalation duration (msec)	1738.3 (661)	1728.0 (698)	1776.0 (674)	0.8
Time to peak (msec)	509.9 (318)	492.2 (328) ^b	433.5 (221)	0.04
Number of inhalations per day	3.3 (2.6) ^c	3.4 (2.9) ^d	4.4 (3.5) ^e	<0.001

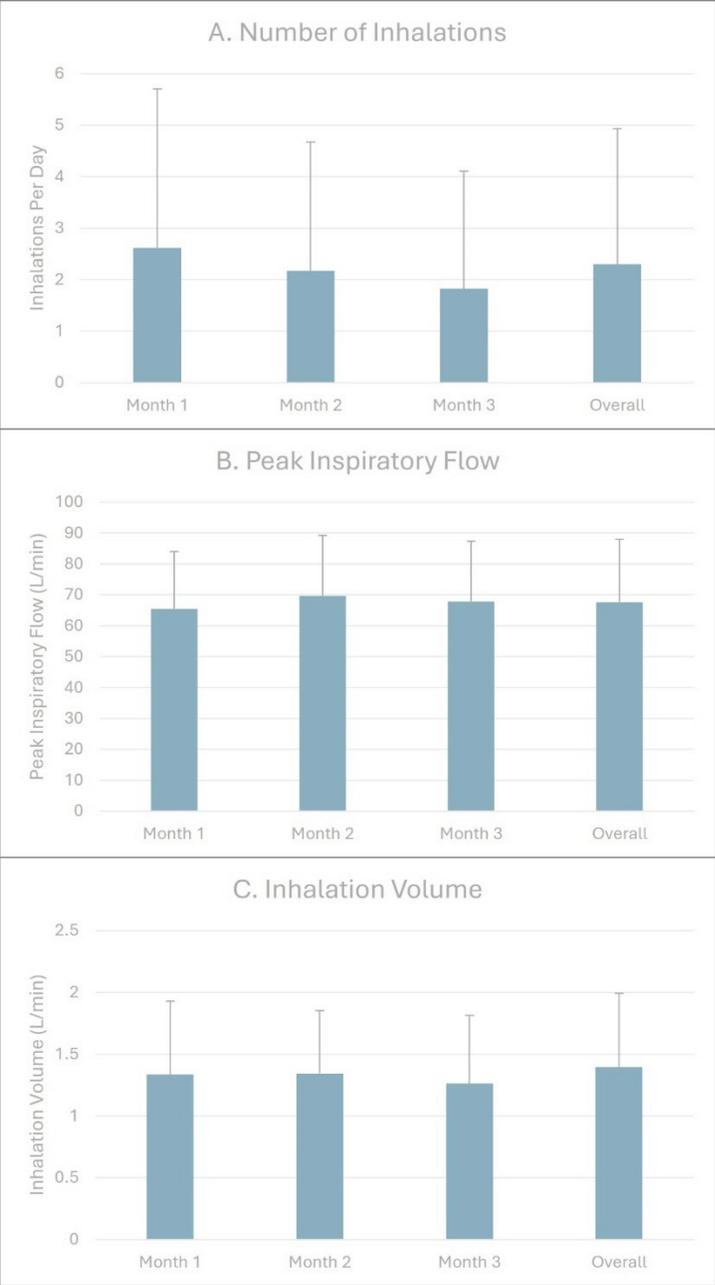
^amean (SD); ^bn=648 ^cn=814; ^dn=758; ^en=140
Note: Correlation is calculated based on records reported by patients with DSA assessment and the Digihaler record on the same assessment day.

Supplemental Table E4. Correlation of inhaler recorded metrics with CAT score at month 1, 2, and 3

Correlation Assessed	Correlation coefficient		
	Month 1 (n=3319)	Month 2 (n=2698)	Month 3 (n=2407)
CAT vs. Peak inspiratory flow	-0.1	-0.05	0.03
CAT vs. Inhalation volume	-0.06	-0.2	-0.1
CAT vs. Inhalation duration	0.1	-0.1	-0.1
CAT vs. Time to peak	0.1	-0.1	-0.3
CAT vs. Number of inhalations per day	-0.01	0.1	-0.1

Note: Correlation coefficient is calculated between monthly reported CAT and the average of the Digihaler records captured in the 30 days prior to CAT score reporting date.

Supplemental Figure E1. Variation in ProAir Digihaler Metrics. Error bars represent standard deviation



Supplemental Figure E2: Daily self assessment questionnaire in the Digihaler App



Daily Self-Assessment >

Select the face that best represents how you've been feeling today:



Save Your Self-Assessment



Home



Data



Digihalers
and Safety



Profile