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Assessing asthma control: comparison of electronic-recorded short-acting beta-agonist rescue use and self-reported use utilizing the asthma control test

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ABSTRACT

Background: Question 4 (Q4) of the Asthma Control Test (ACT) asks patients to report their SABA use over the prior 4 weeks, a criterion for evaluating the impairment domain of asthma control. Biases in recall may lead to a misclassification of asthma control and has implications for asthma control determination and management strategies.

Objective: To correlate objective electronic-recorded short-acting beta-agonist (SABA) use with self-reported use via Q4 of the ACT.

Methods: Patients ≥ 18 years of age with a self-reported diagnosis of asthma were enrolled in a digital health electronic medication monitoring (EMM) platform, which recorded the date and time of SABA actuations and prompted the completion of the ACT. The correlations between ACT Q4 responses and EMM-recorded SABA use were evaluated using Spearman's rank correlation coefficients.

Results: 1,062 patients (mean age: 35.4 years, mean ACT: 16.3) were included in analyses. Higher Q4 scores, indicating lower SABA use, were moderately and negatively correlated with EMM-recorded SABA use ($\rho = -0.59$ [95% CI: -0.63, -0.54]). Thirty-five percent of patients underreported SABA use when comparing Q4 to EMM-recorded SABA use.

Conclusions: While ACT Q4 and EMM-recorded use were moderately correlated, underreported SABA use on the ACT highlights the need for objective measures of SABA use in asthma control assessments. The use of EMM-recorded SABA data has the potential for clinicians to more accurately determine asthma control, guide changes to controller therapy, and estimate imminent exacerbation risk.

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Introduction

The National Heart, Lung, and Blood Institute National Asthma Education and Prevention Program Expert Panel 3 (EPR-3) and Global Initiative for Asthma (GINA) provide guidelines for assessing and establishing asthma control (1,2). Within these guidelines, asthma control has been divided into impairment and risk domains. The use of short-acting beta-agonists (SABA) is a key criterion when evaluating the impairment domain of asthma control. The increased use of SABA in adults and adolescents with not well controlled or very poorly controlled asthma is an independent predictor of exacerbations, a component of the risk domain (3).

The focus of asthma management has been to achieve control, with the goal of preventing exacerbations and limiting day-to-day impairment. EPR-3 defines not well-controlled asthma as SABA use on greater than 2 days per week and very poorly controlled asthma as SABA use several times per day (2). GINA defines uncontrolled asthma based on SABA use more than twice per week (1).

The Asthma Control Test (ACT) provides a validated assessment of control and was designed to correlate with physician assessment of control (4,5). Question 4 (Q4) of the ACT specifically addresses patient self-reported SABA use over the prior 4 weeks. Imprecise or biased recall of past SABA use may lead

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to a misclassification of asthma control, which could lead to inappropriate controller therapy choice. Inaccurate self-reporting has been observed with paper and electronic symptom diaries (6–8). Similar issues of self-reported adherence to inhaled medication have also been observed in many clinical settings and trials (9–15).

In the assessment of present risk for asthma deterioration, it is unclear at present whether all 5 questions of ACT are required or whether Q4 in isolation provides an adequate estimate. ACT Q4 focuses on one domain in the assessment of asthma control (4), but ACT Q4 responses alone may be as important as the total ACT in predicting severe exacerbations (16). More accurate assessment of SABA use with EMMs may also therefore improve prediction of exacerbations.

Digital health tools, including electronic medication monitors (EMMs), are increasingly being incorporated into asthma management, allowing real-time assessment of medication use through objective and passive data collection (17). EMMs have been employed to track SABA use and improved asthma control, measured by ACT, at a population level (18). This technology may reduce the limitation and bias of patient-reported SABA use that has been observed in prior studies of EMMs (19,20).

The objective of this observational study was to evaluate the correlation between objective, electronically recorded SABA use and self-reported use via ACT Q4 responses. The hypothesis was that electronically recorded SABA use is associated with self-reported SABA use.

Methods

From January 2016 to 2018, patients ≥ 18 years of age with a self-reported diagnosis of asthma were enrolled in a digital health platform (Propeller Health, Madison, WI) consisting of electronic medication monitors (EMMs) and a companion mobile application (“app”). Patients were enrolled through their healthcare system or self-enrolled through print and digital media campaigns. EMMs were provided at no charge due to programs with healthcare systems, pharmaceutical companies or Propeller Health. Patients attached the EMMs to their SABA inhalers which recorded the time and date of each actuation. EMM data were transmitted via Bluetooth to patients’ paired smartphone or data hub and was viewable on the mobile app or online. The digital health platform has been described in detail elsewhere (18,21).

At the time of enrollment, patients were asked their age and were prompted to complete the ACT through the app that day and monthly thereafter. Patients were included if they completed an ACT and had a minimum of 4 weeks of EMM use prior to the date of the ACT. The first ACT per patient meeting this criterion was included in analyses. As defined in the ACT, self-reported SABA use was categorized by patients as (1) ≥ 3 times per day; (2) 1–2 times per day; (3) 2–3 times per week; (4) once a week or less; or (5) not at all. EMM-recorded SABA use was quantified weekly and averaged over the 4 weeks prior to completion of the ACT. EMM-reported SABA use was grouped in bins comparable to ACT Q4 categorizations: (1) >14 puffs/week; (2) >3 to 14 puffs/week; (3) >1 to 3 puffs/week; (4) >0 to 1 puffs/week; or (5) 0 puffs/week.

The correlation between Q4 responses and EMM-recorded SABA use was evaluated using Spearman’s rank correlation coefficients (ρ) with 95% confidence intervals (CIs). The agreement of Q4 vs. EMM-recorded SABA use equivalents were estimated using the weighted Cohen’s kappa (22) with 95% CIs. Thresholds for agreement and correlation were: 0.00 = poor, 0.00–0.20 = slight, 0.21–0.40 = fair, 0.41–0.60 = moderate, 0.61–0.80 = substantial and 0.81–1.0 almost perfect (23). As a sensitivity analyses, agreement and correlation also was evaluated by age group: 18–29, 30–39, and 40 years of age and older.

This study met the criteria for an institutional review board exemption by Copernicus Group IRB (PRH1-18-132). Patients were required to agree with the Propeller Health terms of use.

Results

There were 1,062 patients included in this study (Table 1), with a mean (standard deviation) age of 35.4 (11.9) years, weekly SABA use of 7.7 (15.8) puffs/week, and ACT of 16.3 (4.9). Approximately 69% of patients’ asthma was not well controlled or poorly controlled (ACT < 20). ACT Q4 responses identified 39% of patients reported using their SABA inhaler once a week or less (response 4) or not at all (response 5) in the prior 4 weeks.

Higher Q4 scores, indicating lower SABA use, were moderately and negatively correlated with EMM-recorded SABA use ($\rho = -0.59$ [95% CI: -0.63 , -0.54]) overall and in all age groups (Table 2). Figure 1 demonstrates the agreement for the associations of Q4 with EMM-recorded SABA use. The percent agreement between Q4 and EMM-defined

SABA use was 41.8%, with a weighted kappa of 0.57 (95% CI: 0.52, 0.62). Thirty-five percent of patients underreported SABA use comparing Q4 to EMM-recorded SABA use. Agreement and correlations were mostly moderate in each age group, with highest measures among patients 30–39 years (Tables 2 and 3).

Table 1. Baseline characteristics of the study population ($n = 1,062$).

Characteristic	n (%) or mean (SD)
Age (years)	35.4 (11.9)
ACT score (range: 5–25)	16.3 (4.9)
ACT Question 4 ^a responses	
3 or more times per day	146 (13.7)
1 or 2 times per day	234 (22.0)
2 or 3 times per week	263 (24.8)
Once a week or less	298 (28.1)
Not at all	121 (11.4)
Asthma control (derived from ACT score)	
Poorly controlled (≤ 15)	443 (41.7)
Not well controlled (16 to 19)	287 (27.0)
well Controlled (≥ 20)	332 (31.3)
Rescue inhaler use (puffs/week over 4 weeks)	7.7 (15.8)

ACT, asthma control test; n , number; SD, standard deviation.

^aACT question 4: During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?

Table 2. Spearman rank correlation coefficients (ρ) of ACT vs. weekly SABA use over four weeks overall and by age group.

Analysis	ρ (95% CI)
ACT Q4 vs. SABA use	
All ages, $n = 1,062$	−0.59 (−0.63, −0.54)
18–29 years, $n = 371$	−0.57 (−0.65, −0.49)
30–39 years, $n = 362$	−0.63 (−0.71, −0.55)
40+ years, $n = 329$	−0.57 (−0.66, −0.48)

ACT Q4, asthma control test question 4; CI, confidence interval n , number; SABA, short-acting beta-agonists.

Discussion

In this study of patients with self-reported asthma, objectively captured EMM-recorded SABA use was compared to self-reported SABA use on ACT Q4. Results suggest that lower EMM-recorded SABA use was moderately correlated with higher ACT Q4 responses, which indicates lower SABA use. However, self-reported SABA use led to underreporting in 35% of patients, highlighting the need for objective measures.

The majority of patients in this study had asthma that was not well controlled at baseline as evident by the average ACT score of 16.3 and 69% of patients with an ACT < 20 . Comparatively, in the validation study of the ACT the mean age of the study population was similar to the present study, but 52% had not well-controlled or poorly controlled asthma (24).

This is the first study to our knowledge to utilize EMMs in a large population to compare objective SABA use with self-reported SABA use through ACT Q4. A similar study that utilized EMMs (Nexus6 Limited, Auckland, New Zealand) in 150 adults with asthma found a moderate agreement between electronically monitored vs. self-reported SABA use. They also observed that self-reported SABA use exceeded EMM-recorded use on average but underreported SABA use in high users (20). A longitudinal study of EMMs (Propeller Health, Madison, WI) found a modest correlation ($r = 0.36$) of daily diary self-report vs. EMM-measured SABA use within eleven patients with COPD over 16–84 days (19). Misreporting and underreporting of SABA use may be due to forgetfulness or for patients wanting to report to their health care

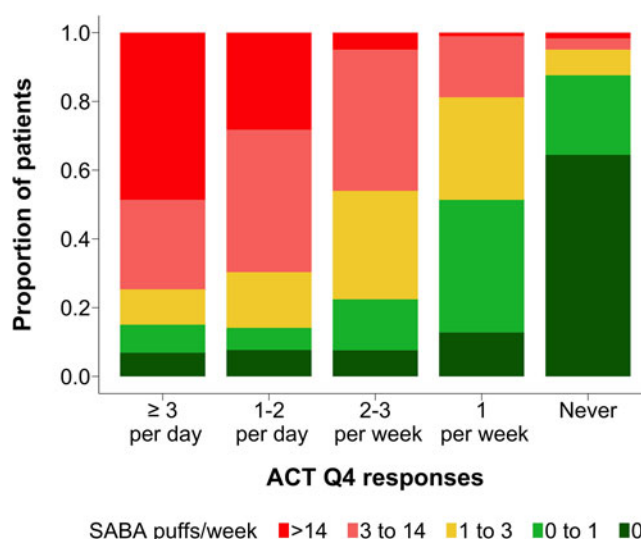


Figure 1. Association of objective EMM-recorded SABA use for each self-reported ACT Q4 response.

Table 3. Agreement statistics between ACT question 4 responses and weekly SABA use overall and by age group.

Statistic	ACT Q4 ^a vs. categories of weekly SABA use ^b
% agreement	
All ages, <i>n</i> = 1,062	41.8
18–29 years, <i>n</i> = 371	38.3
30–39 years, <i>n</i> = 362	44.2
40+ years, <i>n</i> = 329	43.2
Weighted kappa	
All ages, <i>n</i> = 1,062	0.57 (0.52, 0.61)
18–29 years, <i>n</i> = 371	0.54 (0.46, 0.63)
30–39 years, <i>n</i> = 362	0.61 (0.53, 0.68)
40+ years, <i>n</i> = 329	0.55 (0.46, 0.64)

ACT Q4, asthma control test question 4; CI, confidence interval *n*, number; SABA, short-acting beta-agonists.

^aSABA use (1) 3 or more times per day; (2) 1 or 2 times per day; (3) 2 or 3 times per week; (4) Once a week or less; (5) Not at all.

^bSABA use over prior 4 weeks: (1) > 14 times/week; (2) 3 to 14 times/week; (3) > 1 to 4 times/week; (4) > 0 to 1 times/week; (5) 0 times/week.

provider that their asthma is under control when it may not be.

The present study has limitations. The study population consisted of patients with self-reported asthma, however, self-reported diagnoses may not be as accurate as those using pulmonary function tests, claims data and/or provider-confirmed diagnoses. Some EMM-recorded SABA use may be due to accidental actuations, pretreatment prior to physical activity or exposure to a known trigger, or use as a part of the patients' daily routine. Also, SABA use recorded in this study may be underestimated if patients used a separate SABA inhaler without an attached EMM. Finally, social, demographic and clinical characteristics were not available in the study population. Future work should investigate how these factors that may explain discrepancies in objective vs. self-reported SABA use.

This large study population provides a real-world representation of SABA use patterns, which may provide more clinically valuable data and better reflect actual SABA use compared to self-report. Data from EMMs may be accurately evaluated in real-time—outside their providers' offices—to screen for patients with not well controlled asthma. By identifying patterns of SABA overuse, EMMs may provide objective information potentially important in determining asthma control and imminent exacerbation risk. SABA use may also be related to changes in controller adherence and thus be used as a teaching tool with the patient.

The ability of EMMs to provide passively collected objective data minimizes patient recall error and provides real-time actuation data. EMMs may be an advantageous tool to allow for objective collection of

data that can account for SABA use underreporting and be included in asthma control assessments that inform the selection of appropriate controller therapy. This study adds to our understanding of the relationship between self-reported and objective SABA use, which may be helpful when incorporated into clinical practice.

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Declaration of interest

W. Anderson has served as a consultant for Astra Zeneca. R. Gondalia, L. Kaye, M. Barrett, and D. Stempel report compensation from their employer, Propeller Health. H. Hoch has served as a consultant for Astra Zeneca; has received EMMS from Propeller Health for other research studies; received a loan repayment grant from the NIH; and study funding from the Colorado Department of Public Health and Environment, as well as Children's Hospital Colorado. S. Szefer has served as a consultant for Boehringer-Ingelheim, Genentech, GlaxoSmithKline, Aerocrine, Astra Zeneca, Daiichi Sankyo, Roche, Teva, Propeller Health, Sanofi, and Regeneron; and received grants from GlaxoSmithKline.

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