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PHARMACOTHERAPY



Electronic medication monitoring versus self-reported use of inhaled corticosteroids and short-acting beta₂-agonists in uncontrolled asthma

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ABSTRACT

Objective: Current standard of care, patient self-report and clinician estimation, overestimates true inhaled corticosteroids (ICS) adherence. We compare self-reported inhaled ICS and short-acting beta 2-agonists (SABA) use with objective data from electronic medication monitors (EMMs).

Methods: Adults with uncontrolled asthma and prescribed ICS and SABA were enrolled. At visit one, participants' ICS and SABA inhalers were fitted with EMMs to track real-time medication usage over 14 days. Participants were asked to complete paper diaries to self-report medication usage over the same period. Participant self-report of ICS adherence and SABA use versus objective ICS adherence and SABA use was compared using Wilcoxon signed-rank tests.

Results: One hundred participants (80% female, mean age 48.5 years, 60% completed college, 80% privately insured) had complete data. Participant self-report (median (IQR): 0.8 (0.0, 2.0)) was greater than objectively measured (median (IQR): 0.43 (0.1, 2.1)) SABA use, but the difference was not statistically significant ($P=0.64$). Participant self-report (median (IQR): 97 (67, 100)) was significantly greater than objectively measured (median (IQR): 75 (54, 93)) ICS adherence ($P=0.002$).

Conclusions: Significant discrepancies between self-report and objective ICS usage were observed. EMM can provide clinicians with accurate data on ICS medication taking behavior, thus reducing medication regimen complexity, side effects, and costs.

Abbreviations: ICS: inhaled corticosteroids; SABA: short-acting beta2-agonists; EMM: electronic medication monitor; EPR-3: expert panel report 3; ACT: asthma control test; IQR: interquartile range

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Introduction

Poor adherence to inhaled corticosteroids (ICS) is a major, and potentially modifiable, risk factor with a significant impact on asthma control. Large population-based studies of ICS prescription refill rates demonstrate poor ICS adherence is associated with increased rates of asthma-related deaths (1,2).

To effectively intervene to improve ICS adherence, clinicians need to accurately measure it at the individual level. Current standard of care, patient

self-report and clinician estimation, overestimates ICS medication utilization behavior (3). Patients commonly report what they believe clinicians want to hear, and clinicians in turn assume that their patients are following treatment plans as prescribed. ICS adherence counseling takes time and frequently may not be addressed during a busy clinic. This analysis aims to compare participant self-report to an FDA-cleared electronic medication monitor (EMM) objective measurement of ICS use.

Methods

Detailed methods and results of the trial have been previously published, and this report focuses on data collected during the 14-day run-in period (4). In short, eligible participants were 25–65 years of age, had uncontrolled asthma, were prescribed ICS-containing and short-acting beta 2-agonists (SABA) inhalers, and owned a smartphone. The NorthShore University HealthSystem Institutional Review Board approved the study protocol, and all study participants provided written informed consent. ClinicalTrials.gov (NCT03860519).

Adherence to ICS and SABA usage were measured during the 14-day run-in (i.e. between the enrollment and randomization visits) via self-report and passively with EMM (Propeller Health, WI, USA (5)). Self-report data were completed for daily ICS and SABA with paper diaries for the 14 prior days during the randomization visit. Over the same period, objective data was collected remotely using EMMs fitted to participants ICS and SABA inhalers. This analysis focuses on concordance rates between self-reported and EMM measures of ICS and SABA usage.

Self-reported and objective ICS adherence and SABA use were compared using Wilcoxon signed-rank tests. Daily adherence was defined as: (the number of recorded actuations per day divided by the prescribed dose) $\times$ 100. Adherence was capped at 100%. All analyses were run in R version 3.6.1.

Results

One hundred participants were enrolled and had a mean (SD) age of 48.5 (12.3) years. Participants were predominantly female (80%) and White (68%) (95% non-Hispanic), while a smaller proportion of participants were Black or African American (26%) or Asian (6%). All patients had uncontrolled asthma (defined as ≥ 1 of the following criteria: EPR3 asthma guidelines (81%), ACT score < 20 (67%), ≥ 2 oral corticosteroid bursts for an asthma exacerbation in the prior year (47%), and/or ≥ 1 asthma-related emergency department visit or hospitalization in the prior year (28%)). Participants were privately insured (80%), Medicare (9%), Medicaid (9%), or a combination (2%). A majority of participants had at least a baccalaureate, college, or postgraduate degree (60%). Of note, 18% were prescribed ICS monotherapy and 82% were prescribed ICS-containing combination therapies.

Participant self-report for SABA use was higher than objectively measured SABA use. The difference, though, was not statistically significant (respectively,

median (IQR): 0.8 (0.0, 2.0) versus 0.43 (0.1, 2.1) puffs/day; $P=0.64$) (Table 1). Participant self-report for controller medication use was also higher than objectively measured use. The difference for ICS adherence was statistically significant (respectively, median (IQR): 97 (67, 100) versus 75 (54, 93)%; $P=0.002$) (Table 1).

Discussion

This study demonstrated that, in a sample of adults with uncontrolled asthma and prescribed ICS and SABA, self-reported use of ICS and SABA exceeded objective EMM measured use, however this difference was only statistically significant for the over-reporting by participants of ICS containing controllers.

Discrepancies between self-report and objective EMM measurement of ICS use have important implications for clinical practice. For uncontrolled and severe asthmatics, who account for a disproportionate burden of asthma morbidity, mortality, and costs in the US (6), it is imperative to obtain objective ICS adherence. Without accurate data, clinicians continue to make recommendations to increase the dose of ICS and/or add other controller medications, oral corticosteroids, or biologics which may contribute to increased side effects and cost without improving asthma outcomes rather than address the issue of adherence (7). Increasing use of SABA may additionally be a trigger for altering treatment regimens and needs to be accurately assessed.

Despite the availability of these FDA-cleared EMM remote technologies, patients (e.g. privacy, autonomy), clinicians (e.g. liability, increased administrative burden and uncompensated work) and payers (e.g. cost) cite barriers to implementation (8). However, with the recent widespread adoption of telemedicine during the COVID-19 pandemic (9), the US health care system is being forced to overcome challenges to continue to provide care. Remote monitoring devices and wearable technologies that objectively measure medication usage, GPS location, indoor and outdoor air pollution levels, physical activity, and respiratory rate can work synergistically with telemedicine to optimize patient care (10).

This study has several limitations. First, self-report versus objectively measured ICS and SABA use was only compared over a 14-day period. However, 14-days may not allow enough time to account for variability in work and weekend schedules, as well as possible “dose dumping.” Second, the study population was largely White, female, privately insured and well-educated and the findings may not be

Table 1. Objective versus self-reported ICS adherence ($n=96^a$) and SABA use ($n=91^b$).

	Median (IQR)	Wilcoxon signed-rank test
Objectively measured SABA use, puffs/day	0.43 (0.1, 2.1)	$P = .64$
Self-reported SABA use, puffs/day	0.8 (0.0, 2.0)	
Objectively measured ICS adherence	75 (54, 93)	$P = .002$
Self-reported adherence	97 (67, 100)	

Abbreviations: IQR, interquartile range; SABA, short-acting beta₂-agonists.

^a n does not equal 100 due to: early withdrawal ($n=1$), lacking a final study visit ($n=2$), or first synced their inhaler sensor after baseline ($n=2$) or did not have a sensor for their SABA inhaler ($n=4$).

^b n does not equal 100 due to early withdrawal ($n=1$), lacking a final study visit ($n=2$), or first synced their inhaler sensor after baseline ($n=1$).

generalizable. Yet prior work by Mosnaim et al. demonstrated even larger discrepancies between self-report and objectively measured ICS adherence data in low-income, minority adolescents with uncontrolled asthma (11). Third, participants during the randomization visit were aware that their inhaled medication use was being tracked and this may have altered their report of utilization. Nevertheless, even though they knew that they were being objectively monitored, they continued to over-report ICS adherence. Fourth, this study measured medication actuation, but did not measure proper inhaler technique. Video recording of inhalation technique may address this limitation but requires additional technology and time for HCP review (12). Fifth, randomized controlled trials testing the impact of participant self-monitoring via EMM and Mobile App plus remote clinician feedback on ICS adherence and SABA use are needed. A recent study by Mosnaim et al. demonstrated that this intervention maintained high baseline ICS adherence and reduced SABA use (4).

In conclusion, the use of participant self-report of ICS adherence as part of the standard of care may be suboptimal and may lead to treatment decisions that contribute to increased side effects and costs. While the COVID-19 pandemic has challenged the health care system to adopt telemedicine and address barriers to the implementation of remote monitoring and wearable technologies, such digital tools are likely to continue being used beyond the pandemic to enhance telehealth.

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None.

Author contributions

Participated in study concept design: GM, DS, LK, RG, MS. Acquisition of data: CG, BA, NBO. Performed data analysis: RG. Data interpretation: GM, DS, LK, RG, SS. Wrote or contributed to the writing of the manuscript: All authors

Authors' consent for publication

All authors have reviewed the manuscript and consent to its publication.

Declaration of interest

Giselle Mosnaim receives research grant support from Teva and Sanofi-Regeneron; has received research grant support from Astra-Zeneca, Alk-Abello, Genentech, GlaxoSmithKline and Propeller Health; and has served as a consultant and/or member of an scientific advisory board for GlaxoSmithKline, Sanofi-Regeneron, Teva, Novartis, Astra-Zeneca, Boehringer Ingelheim and Propeller Health. She has also served as a speaker for HCPLive.

Confirmation of unpublished work

The submitted manuscript represents original work, has not been published elsewhere, is not currently being considered for publication at any other journal, and has not been posted as a preprint in any public or private domain.

Ethics approval and consent to participate

The NorthShore University HealthSystem Institutional Review Board approved the study protocol, and all study participants provided written informed consent. The study was also registered on ClinicalTrials.gov (NCT03860519).

Availability of data and materials

The medication use data that supported this study are not publicly available because are considered Protected Health Information (PHI) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in the US, and as such are only accessible under specific authorization of access following HIPAA guidelines.

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