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Determination of asthma control using administrative data regarding short-acting beta-agonist inhaler purchase

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ABSTRACT

Background: Symptom control is a primary goal in asthma. We hypothesized that administrative data regarding rescue inhaler purchases may correlate with asthma symptom control. **Methods:** We identified all patients who purchased short-acting beta-agonist (SABA) inhalers during the course of one year in the database of a Health Maintenance Organization (HMO). Primary physicians identified asthma patients and classified their asthma symptom control into three groups according to the Global Initiative for Asthma (GINA) guidelines. Asthma patients were asked to answer symptom questionnaires and grade their asthma control. SABA inhaler purchases were compared between asthma control groups as classified by the guidelines, the physicians and the patients. We also compared the agreement on asthma control between the three methods of classification. **Results:** Of 241 asthma patients, 83 completed the questionnaires. Using the GINA guidelines criteria, 26 were symptom controlled, 46 were partially controlled and 11 were uncontrolled. SABA inhaler purchases were not significantly lower in the controlled group. Using patients' overall impression of their asthma control, the mean numbers of SABA inhalers purchased were 1.5, 4.4 and 6.4 per year in the controlled, partially controlled and uncontrolled groups, respectively ($p = 0.03$). Patients' classification of asthma control had better agreement ($\kappa = 0.34$) with GINA guidelines than physician's agreement ($\kappa = 0.05$). **Conclusion:** When using administrative data for asthma patients, 2 or more SABA inhaler purchases in one year should alert the physician for the need for asthma control evaluation. Purchase of at least 4 SABA inhalers a year may be regarded as a marker for asthma that is not controlled.

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Introduction

Asthma is a chronic disease affecting about 300 million people worldwide and causing the death of 2,500,000 people each year [1]. Most persons with asthma in the USA (64.4%) reported taking quick-relief inhaler prescription medicine, while long-term controller (oral or inhaler) prescription medicine use was reported less frequently (33.5%) [2]. It is well recognized that patients' reports may underestimate the use of reliever medication, the perception of asthma severity and asthma control for different reasons [3]. The risk of severe asthma attacks and mortality from uncontrolled asthma is correlated to the number of reliever canisters used [4–7]. Increased risk for intensive care admissions and mechanical ventilation is related to use of more than four canisters of inhaled beta-agonists 3–12 months prior to hospitalization [8].

According to the 2014 Global Initiative for Asthma (GINA) guidelines [9], patients may be classified as

symptom controlled, partially controlled or uncontrolled according to the reliever medication use for symptoms as one of the criteria. Administrative data have been used in studies evaluating the relation between asthma prescriptions and disease outcomes. In a study published in 1996, it was found that higher prophylaxis to bronchodilator medication prescription ratio had on average lower hospital admission rates for asthma [10]. In another study in children with persistent asthma, the ratio of controller to reliever medication dispensed was inversely related to emergency department (ED) visits among children dispensed 4 relievers/person-year [11]. Several studies using administrative data showed that a higher controller to reliever medication ratio indicates lower likelihood of asthma exacerbation [12–15]. However, the ratio itself does not differentiate between persons who use high levels of controllers coupled with a high level of relievers, and persons who use low levels of both drugs. Further studies

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showed that the largest effect size for predicting asthma exacerbations was for the number of short-acting beta-agonist (SABA) canisters dispensed [16, 17].

Herein we present a cross-sectional study in which we explore the utility of electronic pharmacy data regarding the number of the SABA inhalers purchased to estimate the level of asthma control. Our goal is to find the minimal number of SABA canister purchases that will correlate with partially controlled and uncontrolled asthma according to the GINA guidelines classification and to compare it to the primary care physician's (PCP) and the patient's overall estimations of asthma control.

Methods

The study was conducted in community clinics in the Dan-Petah-Tiqwa district of Clalit Health Services (CHS), the biggest publically funded Health Maintenance Organization (HMO) in Israel. Patients in Israel have free access to their PCP and contribute a minimal co-payment for essential drugs. All of the drug purchases have computer records and could be traced by specific queries. The study was approved by the Institutional Review Board of Meir Medical Center, Kfar Saba, Israel.

Patients were enrolled from November 2012 to August 2014. We recruited PCPs in the area served by the main pulmonary clinic of CHS, Dan-Petah-Tiqwa district in the center of Israel. We provided participating PCPs with lists of all their patients who purchased SABA inhalers during the past 12 months. PCPs were asked to specify the reason for prescribing the inhaler for each patient and, if a patient had asthma, to answer the question: In the past 12 months what was the level of asthma control? Choose one – Controlled, partially controlled or uncontrolled. Patients who were identified as having asthma by their PCPs were asked to complete a multiple choice questionnaire regarding their asthma symptoms and to grade their overall asthma severity and control during the past 12 months. Questions regarding asthma control were: (1) During the past year, did you experience shortness of breath at day-time? (2) Did you wake up at night because of shortness of breath, chest discomfort or cough during the last year? (3) Did you take your rescue inhaler? For these questions, patients had to choose one option: no; less than once a month; every month but less than once a week; once a week; twice a week; more than twice a week but not every day; or every day. (4) During the past year, did you limit your activity because of your asthma? Choose one: Never; not frequently; most of the time and always. The question regarding their overall estimation of the asthma control was: How do you define your asthma disease in the past year? Choose one – Completely controlled; good control; partially controlled; not

enough controlled and completely uncontrolled. We considered answers 1 and 2 as controlled, answer 3 as partially controlled, and answers 4 and 5 as uncontrolled.

Asthma level of symptom control according to the GINA guidelines [9] was classified using patients' questionnaires by addressing their answers to the relevant questions in the GINA criteria. For each patient, we determined asthma control using the answers to the above four questions. Thus, we obtained three separate estimates of asthma control: (1) PCP estimates; (2) patient overall estimates and (3) estimates according to the GINA guidelines.

Statistical analysis

We used analysis of variance (ANOVA) for continuous parametric variables and the Kruskal–Wallis rank-sum test for non-parametric variables. For categorical variables, we used chi-squared or Fisher's exact test. Inter-rater agreements for categorical variables were calculated using Cohen's kappa test (unweighted). Statistical analysis was performed using R software, version 2.15.2 (R Project for Statistical Computing).

Results

Twenty-three of 39 (59%) PCPs serving approximately 30,000 patients from 11 clinics agreed to participate in the study. Using administrative data, we found a total of 475 patients (1.58%) who purchased SABA inhalers during the 12 months prior to our first contact with the PCP. The mean age ($\pm$ SD) of the patients was 37.3 ± 11.2 years, and 226 (47.5%) were males.

Of the 475 patients, 241 patients had asthma according to the PCPs' questionnaires, and the other 234 patients had other diagnoses as an indication for SABA inhaler use (Figure 1). Of the 241 asthma patients, only 83 (34%) completed patient questionnaires. Patient characteristics are summarized in Table 1. The average age of the patients was 36.7 years, and 52% were males. The characteristics of patients who did not complete the questionnaires were similar to those who completed the questionnaire, as were the average numbers of SABA inhaler purchases (3.5 ± 4.8 vs. 3.4 ± 6.3 , respectively). Therefore, we believe the subgroups that completed questionnaires are reasonably representative of the entire group.

Using GINA guidelines to classify patient symptom control, we found 26/83 (31.3%) to be controlled, 46/83 (55.4%) to be partially controlled and 11/83 (13.3%) to be uncontrolled patients.

SABA inhaler purchase

Our primary analysis was to evaluate the number of SABA inhalers purchased according to the level of

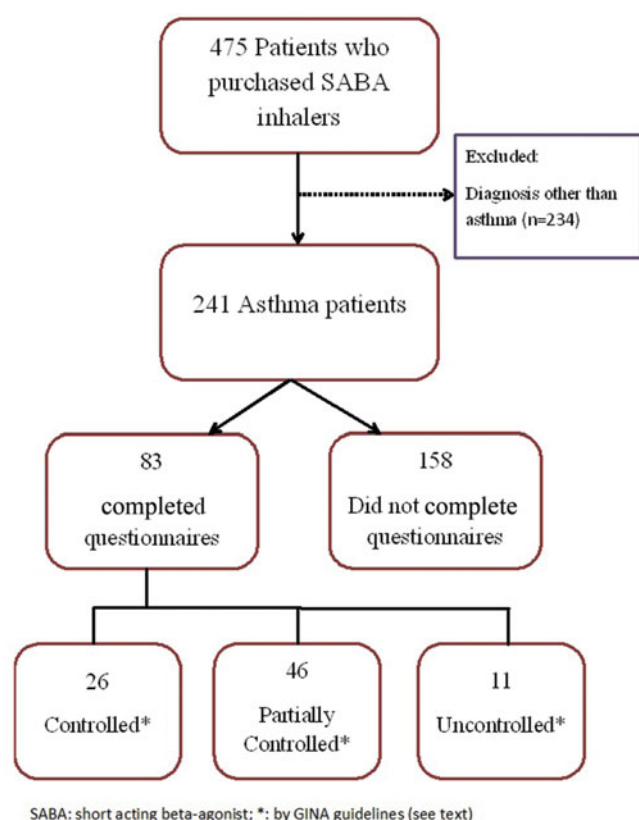


Figure 1. Flow chart of the study population.

asthma control in the year prior to physicians' and/or patients' questionnaire date (Table 2). Classified according to the GINA guidelines, the mean number of SABA inhaler purchases in the controlled group was 1.5 ± 2 inhalers/years, vs. 3.2 ± 5.4 and 7.6 ± 12 inhalers/years, respectively, in the partially controlled and uncontrolled groups ($p = 0.782$) (Figure 2A). Age was not statistically significantly different between the three groups of control

Table 1. Characteristics of asthma patients.

	Total	Asthma patients w/o questionnaires	Asthma patients with questionnaires
No. (%)	241	158 (65.6)	83 (34.4)
Age (years, mean (SD))	36.7 (10.1)	36.2 (9.5)	37.7 (11.1)
Male (%)	125 (52)	83 (53)	42 (51)
SABA inhaler purchase (per year, mean (SD))	3.44 (5.3)	3.5 (4.8)	3.4 (6.3)
Place of Birth (n (%))			
Israel	190 (78.9)	129 (81.7)	61 (73.5)
Former USSR, Eastern Europe and Iran*	25 (10.4)	17 (10.8)	8 (9.6)
Europe and USA	3 (1.2)	3 (1.9)	0
South America	3 (1.2)	1 (0.6)	2 (2.4)
Africa	20 (8.3)	8 (5)	12 (14.5)

Notes. *Two patients. SABA: short-acting beta-agonist; SD: standard deviation.

according to the GINA guidelines, but there were significantly fewer males (37%) in the partially controlled group than those in the controlled and uncontrolled groups (69 and 64%, respectively, $p = 0.02$).

SABA inhaler purchases were also compared according to physicians' and patients' estimation of asthma control (Table 2). Differences between the asthma control groups, as classified by the physicians, in the number of SABA inhaler purchases (Figure 2B) were not significant. The mean numbers of inhaler purchases were 3 ± 6.1 , 3.6 ± 6.8 and 5.3 ± 7.8 inhalers/years in the controlled, partially controlled and uncontrolled groups, respectively ($p = 0.31$). Numerically, the mean number of SABA inhalers purchased per year was the lowest in the controlled group, intermediate in the partially controlled group and the highest in the uncontrolled group irrespective of the method of classifying asthma control. However, the difference between the groups was statistically significant only when asthma control was classified by the patients (Table 2 and Figure 2C): 1.5 ± 2.3 inhalers/years in the controlled patients vs. 4.4 ± 8.4 and 6.4 ± 8.2 inhalers/years in the partially controlled and uncontrolled groups, respectively ($p = 0.03$).

Asthma control according to physicians' and patients' evaluations

Our second objective was to compare the level of agreement between the three methods regarding asthma control. We compared physicians' and patients' agreement with the GINA guidelines (Table 3) and physician's-patient's agreement (Table 4). Of the 26 controlled patients by the GINA guidelines, 21 and 23 were classified as controlled by physicians and patients, respectively. Partially controlled asthma, according to the GINA guidelines, was classified by the PCP as controlled asthma in 33 of 46 patients and by 17 partially controlled patients. Only 10 of the 46 partially controlled patients were classified as such by their PCPs. Among the 11 patients with uncontrolled asthma according to the GINA guidelines, only one patient was correctly classified by the PCP and 5 (45%) by the patients. Of the remaining uncontrolled asthma patients, 5 were classified as controlled by the PCP and 1 was classified as controlled by the patient.

Overall, physicians overestimated patient's asthma control, and agreement between physicians and the GINA guidelines classification of symptom control was poor (Cohen's kappa = 0.0511, non-significant). On the other hand, patients' overall assessment of their symptom control had significantly better agreement with the GINA guidelines' classification (Cohen's kappa = 0.34, $p = 0.000059$). Doctors' and patients' agreement regarding asthma control is summarized in Table 4. Overall,

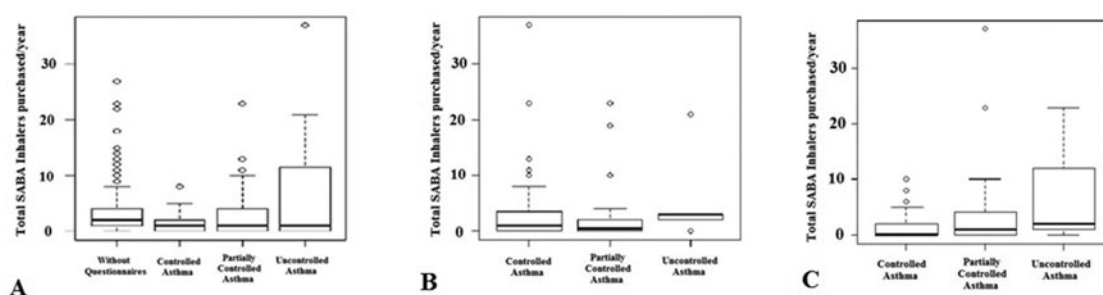


Figure 2. SABA inhalers purchased per year. A – according to the GINA guidelines classification of asthma control. B – according to physicians' classification of asthma control. C – according to patients' classification of asthma control. The box represents 25th and 75th percentile, the line in it represents the median, the whiskers represent $1.5 \times$ interquartile range and the dots represent external values.

Table 2. SABA inhaler purchases by asthma symptom control groups classified according to the GINA guidelines, and physicians' and patients' assessments.

	Asthma control				
	Total	Controlled	Partially controlled	Uncontrolled	<i>p</i> -Value
Asthma control by GINA guidelines criteria					
No. of patients (%)	83	26 (31.3)	46 (55.4)	11 (13.3)	
Age years (SD)	37.7 (11.1)	36.2 (11.3)	37.4 (11)	42.8 (10.6)	0.24
Male (%)	42 (51)	18 (69)	17 (37)	7 (64)	0.02
SABA inhaler purchase mean (SD)	3.4 (6.3)	1.5 (2)	3.2 (5.4)	7.6 (12)	0.782
Asthma control by physicians' assessment					
No. of patients (%)	83	59	18	6	
Age years (SD)		35.6 (11.2)	44.3 (8.8)	38.3 (10.7)	0.014
Male (%)		31 (53)	8 (44)	3 (50)	0.83
SABA inhaler purchase mean (SD)		3 (6.1)	3.6 (6.8)	5.3 (7.8)	0.31
Asthma control by patients' assessment					
No. of patients (%)	82*	41	25	16	
Age years (SD)		35.7 (10.7)	37.8 (11.5)	42.1 (11.2)	0.152
Male (%)		24 (59)	8 (32)	9 (56)	0.096
SABA inhaler purchase mean (SD)		1.5 (2.3)	4.4 (8.4)	6.4 (8.2)	0.03

Notes. SABA: short-acting beta-agonist; SD: standard deviation.

*1 patient did not classify his asthma level of control.

Table 3. Asthma control agreement between the GINA guidelines, physicians' and patients' assessments.

No.	Asthma control – by GINA guidelines				p-Value
	Total 83	Controlled 26	Partially controlled 46	Uncontrolled 11	
		Asthma control by physicians (%)			
Controlled	59 (71.1)	21 (25.3)	33 (39.8)	5 (6)	0.235
Partially controlled	18 (21.7)	3 (3.6)	10 (12)	5 (6)	
Uncontrolled	6 (7.2)	2 (2.4)	3 (3.6)	1 (1.2)	
		Asthma control by patients* (%)			
Controlled	41 (50)	23 (28)	17 (20.7)	1 (1.2)	0.000019
Partially controlled	25 (30.5)	2 (2.4)	19 (23.2)	4 (4.9)	
Uncontrolled	16 (19.5)	1 (1.2)	10 (12.2)	5 (6.1)	

Note. *1 patient did not classify his asthma level of control.

Table 4. Asthma control agreement between physicians' and patients' assessments.

No.	Asthma control by patients*				p-Value
	Total 82	Controlled 41	Partially controlled 25	Uncontrolled 16	
Asthma control by physicians (%)					
Controlled	59 (71.9)	28 (34.1)	19 (23.2)	12 (14.6)	0.752
Partially controlled	17 (20.7)	10 (12.2)	5 (6.1)	2 (2.4)	
Uncontrolled	6 (7.3)	3 (3.7)	1 (1.2)	2 (2.4)	

Note. *1 patient did not classify his asthma level of control.

there was no agreement between physicians and patients (Cohen's kappa = -0.0185 , $p = 0.752$).

Discussion

In this study, we chose SABA inhaler purchases as a simple marker for asthma control that could be easily used as an administrative marker in a large population. We found low levels of SABA inhaler purchases in partially controlled and uncontrolled patients as defined by the GINA guidelines [9], even if they do not seek medical intervention.

When we used GINA guidelines criteria to determine asthma symptom control, we did not find a statistically significant difference between the groups in the mean number of SABA inhalers purchased in the year previous to the questionnaire. However, 75% of the controlled patients purchased ≤ 2 inhalers, which is well below the mean number of inhalers purchased by the partially controlled and uncontrolled patients (3.2 and 7.6, respectively). Using physicians' impression for asthma control, we could not discriminate between groups by the number of SABA inhaler purchases. On the other hand, when we used the general impression of asthma control by the patients, we found statistically significant differences between asthma control groups. The mean number of SABA inhalers purchased was 1.5, 4.4 and 6.4 in the controlled, partially controlled and uncontrolled groups, respectively ($p = 0.03$). The median number of SABA inhalers purchased for the uncontrolled group was 2, equal to the purchases of 75% of the controlled patients as was assessed both by the guidelines and by patients' general assessment. Schatz and colleagues found that persistent asthma patients who purchased 3–6 canisters per year were shown to be at a significantly greater risk of subsequent exacerbations and poorer symptom control than the patients who received fewer canisters, and that the risk increased progressively for 7–12 and >12 canisters per year [7]. In another study, they found cutoffs of 11 and 12 SABA canisters dispensed in a year as predicting a high risk for emergency hospital care and for oral corticosteroid dispensation, respectively [16]. However, as mentioned previously, their studies were conducted in a selected group of persistent asthma patients selected from a database using electronic criteria.

Asthma control agreement between the GINA guidelines [9] criteria, physicians and patients was found to be low. In this study, physicians overestimated asthma control more than patients. However, patients' general estimation of asthma control had better agreement (Cohen's kappa = 0.34) with guidelines' category of symptom control than physicians. A low level of agreement for asthma control between physicians and patients has been

previously described. In a study by Boulet and colleagues of 856 patients with uncontrolled asthma, 66.2% of patients and 43.3% of physicians rated asthma symptom control as adequate to very good [20]. A very low level of agreement between asthma control and physicians' and patients' perceptions of asthma control was found in a study of 777 adults and children [21]. Both physicians and patients overestimated asthma control with substantial agreement of 0.7 (95% CI, 0.65–0.74). A patient–pulmonologist concordance of asthma's impact on daily life and the satisfaction of treatment was evaluated in a large study of 1160 patients and 300 pulmonologists in Spain [22]. A concordance of 57% was found between pulmonologists and patients regarding disease impact on patient's daily life. In 26% of cases, pulmonologists underestimated the impact of the disease on daily life compared to patients, mostly among uncontrolled patients.

There were several limitations in our study. First, our cohort is relatively small. Larger population may better differentiate between the groups. Second, asthma symptom control assessment by the GINA guidelines [9] refers to the past 4 weeks. In order to estimate the number of SABA inhalers purchased in one year, we asked the patients to estimate the average frequency of symptoms and rescue medication over a year. Since asthma severity and control often fluctuate over time (seasons, viral infections, allergies, etc.), patient recall of control over an entire year may be imprecise. Another limitation of our study is that SABA inhalers are not the only rescue medication that patients use. Since our goal was to find an easy and single method as a marker for asthma control, we did not include information about the use of soluble beta-agonists for nebulizers, other reliever medications such as anticholinergic medications, or rapid-onset long-acting beta-agonists such as formoterol as a monotherapy or in combination with inhaled corticosteroids. Furthermore, patients purchase more inhalers than they actual need for rescue use, such as for availability in several locations (home, car, work, etc.) or for sports activities which are not a component of the criteria for asthma control. It is likely that the more controlled patients practice sports, and this might partially explain the small differences between the groups.

Common practice suggests that patients should be evaluated for asthma control and the need for controller medication treatment if two or more canisters of reliever medications are used per year. However, to the best of our knowledge, this is the first study to support such practice using a unique methodology. In this study, asthma patients were identified by their SABA canister purchases and then the number of canisters was correlated to their level of asthma control using physicians' and patients' questionnaires. We suggest that when using

administrative data, 2 or more SABA inhaler purchases in one year should alert the physician to perform an asthma control evaluation. The purchase of ≥ 4 SABA inhalers a year (the mean number of SABA inhalers purchased by the partially controlled group according to patients' general assessment was 4.4) should be considered as a marker for asthma that is not controlled. Automatic alerts in electronic records that these thresholds have been exceeded may improve asthma management.

Abbreviations

CHS	Clalit Health Services
CI	confidence interval
ED	emergency department
GINA	Global Initiative for Asthma
HMO	Health Maintenance Organization
OR	odds ratio
PCP	primary care physician
SABA	short-acting beta-agonist
SD	standard deviation

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Disclosures/conflicts of interest

Dr. Shlomi has received lecture fees and/or consultancy fees from TEVA, GSK, Rafa Laboratories, AstraZeneca and Boehringer-Ingelheim. Dr. Segel has received lecture fees and/or consultancy fees from TEVA, Rafa Laboratories, SuperPharm and Boehringer-Ingelheim. All other authors have nothing to declare.

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