

# Budesonide inhaler device switch patterns in an asthma population in Swedish clinical practice (ASSURE)

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## SUMMARY

**Background:** Dry powder inhaler (DPI) device switch in asthma treatment could potentially increase with the entrance of new devices. We examined the switch patterns of budesonide (BUD) DPI analogues available in Sweden. **Methods:** This observational real-life study linked primary healthcare medical records data from the Västra Götaland region to national Swedish registries, and included asthma patients (ICD-10-CM J45) prescribed BUD in a multidose DPI. Index date: first dispense of BUD DPI. Switch date: prescription of another BUD DPI device. Study outcomes (switch vs. non-switch) were exacerbations and prescription of short-acting  $\beta_2$ -agonists. Study period was 1 July 2005 to 31 October 2013. **Results:** Overall, 15,169 asthma patients were on treatment with BUD DPI; 1178 (7.35%) switched to another BUD DPI during the study. Pair-wise 1:1 matching of switchers vs. non-switchers resulted in two groups of 463 patients each (mean age 36 years, 55% female patients). A 25% higher exacerbation rate was seen postswitch (0.40 vs. 0.32;  $p = 0.047$ ). Switchers were 4.5 year younger and had lower medication possession rate than non-switchers. Switch without primary healthcare visit did not differ between groups regarding consultations and exacerbations (no visit 4.96 and 0.90; visit 4.29 and 0.77, respectively). However, patients without primary healthcare visit at switch had significantly more outpatient hospital visits (2.01 vs. 0.81;  $p < 0.001$ ). **Conclusions:** Considering the low switch rate, asthma patients and physicians in Swedish general practice seem reluctant to switch to another BUD DPI device. Switch, especially without primary healthcare visit, was associated with decreased asthma control resulting in higher exacerbation rate and more outpatient hospital visits.

## Introduction

Asthma is a chronic respiratory disease requiring careful and individually tailored treatment (1), where mainly three aspects should be considered when prescribing: pharmacological treatment, dosing and delivery device (2). Despite intraclass similarities, asthma medications should not be considered as interchangeable, as suboptimal asthma control following device switch has been reported to be a potential concern (3–6). If the switch, medication and/or device is performed without consent and medical need, an increased demand for subsequent healthcare services have been reported (7,8). To reach optimal treatment effect, the choice of device should be made in consultation between the physician and the patient and be in accordance with patient's needs, situation and preference (9). Patient education on correct inhaler handling is a key factor,

ensuring good inhalation technique and compliance (10). Switching a patient from one type of inhaler device to another without education may result in confusion regarding handling of the new device, with potential increased frequency of critical handling errors that may result in decreased dose delivery (5,11–13).

However, asthma is associated with a considerable burden on healthcare budgets (14,15). Cost-containment measures are increasing as more devices become available, which may lead to prescriber pressure to switch patients to a less costly delivery device (15).

Budesonide (BUD) is indicated for treatment of asthma patients according to GINA Guidelines step 2 (1). In Sweden, where asthma patients are managed primarily in primary healthcare, three multidose DPIs containing the inhaled corticosteroid (ICS) BUD are available. The analogues, Giona Easyhaler

### What's known

Budesonide (BUD) dry powder device (DPI) switch, consented or not, may be an increasingly common option for strained healthcare budgets as analogue DPI devices become available. The patterns of switch in a Swedish regional asthma population, its impact on healthcare utilisation and the associated outcomes have previously not been investigated.

### What's new

The study showed that less than 10% of the asthma patients, although increasing by year examined, switched BUD DPI during the study period. Patients who switched were younger and had lower medication possession ratio than non-switchers. Device switch was generally associated with reduced disease control (exacerbations).

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### Disclosures

Ekberg Jansson, Svenningsson, Rågdell and Nilsson do not have any competing financial interests in relation to the present work described. Thuresson is a full-time employee at an independent statistical company, contracted by AstraZeneca for the statistical analyses in the present work. Stratelis and Telg are full-time employees of the study sponsor, AstraZeneca.

(Orion Pharma, Espoo, Finland) and Novopulmon Novolizer (Meda, Solna, Sweden), are priced somewhat lower than the first available BUD DPI, Pulmicort Turbuhaler (AstraZeneca AB, Södertälje, Sweden). Although pharmacokinetic studies show a bioequivalence for the steroid in the three available devices, the devices differ with respect to both delivery design and handling technique.

The extent of consented or non-consented BUD DPI switch, as well as patient characteristics associated with switch among asthma patients in Swedish healthcare is unknown. The aim of this retrospective observational matched cohort study in general practice in Sweden was to provide scientific insights on inhaler device switching of asthmatic patients treated with BUD DPI.

## Patients and methods

### Study design, methods and data sources

This observational cohort registry study linked primary healthcare records data to data from national mandatory Swedish registries (National Patient Register, Cause of Death register and Swedish Prescribed Drug Register). Electronic medical records data [e.g. date of birth, gender, diagnosis according to the International Classification of Diseases, 10th revision, Clinical Modification codes (ICD-10-CM) and primary healthcare contacts] were extracted (16). Data linkage was performed by the Swedish National Board of Health and Welfare; the database was managed by the Sahlgrenska Academy, University of Gothenburg. Patients' personal identification number was replaced by a study identification code before data processing.

The study included 46 primary healthcare centres (21 private; 25 public centres) from the Västra Götaland region. This region (a mix of rural and urban areas) covers approximately 20% of the Swedish population. No formal selection of primary healthcare centres was performed.

The study period covered 1 July 2005 to 31 October 2013, except for inpatient and outpatient visits and deaths which were available up until 2012. Index date was defined as the date of first dispensed BUD DPI prescription; switch date as date of a prescription of a BUD DPI different to the previously prescribed device. Reason for inhaler device switch was not captured.

The study protocol was reviewed and approved by the regional ethics committee in Gothenburg, Sweden (reference number 1018-12).

### Study population

Eligible patients were  $\geq 6$  years of age with an asthma diagnosis (ICD-10-CM J45) within 3 months

after first dispensed prescription of BUD in a multi-dose DPI [Anatomical Therapeutic Classification (ATC) System Class R03BA02]. Patients diagnosed with COPD (ICD-10-CM J44), prescription of ipratropium bromide (ATC R03BB01) or prescription of tiotropium bromide (ATC R03BB04) were excluded. Both new and prevalent BUD users were included.

*Switch population:* A patient with a recorded switch from index BUD DPI to another BUD DPI device.

*Non-switch population:* A patient without any recorded change in index BUD DPI device.

*Valid switch population:* Patients with data available both 12 months pre- and postswitch.

*Nested case-control population:* Patients with data available for 12 months prior to switch.

Subgroup analyses stratified on medication possession rate (MPR) were also performed.

### Study measures

*Medications:* Prescription claims were defined as long-acting  $\beta_2$ -agonists (LABAs), R03AC12, R03AC13, R03CC12; short-acting  $\beta_2$ -agonists (SABAs), R03AC02, R03AC03; ICSs, R03BA; oral corticosteroids (OCS), H02AB; and antibiotics, J01AA, J01CA.

*Comorbidities:* Rhinitis, ICD-10-CM J30-J31.

*Hospitalisations:* Asthma hospital admissions with ICD-10-CM J45 as main diagnosis and/or ICD-10-CM J45.0A, J45.0B, J45.0W, J45.1A, J45.1W or J46.9 as main or secondary diagnoses.

*Asthma status:* Classified as controlled, partly controlled or uncontrolled based on SABA and oral steroid use because of respiratory causes year prior switch. Controlled: no oral steroids and not more than one SABA prescription claim; partly controlled: one oral steroid and/or two SABA prescription claims; uncontrolled: more than one oral steroid and/or more than two SABA prescription claims the preceding year.

*Medication possession ratio:* An estimate of number of days covered by medication during a 1-year period; calculated as the number of dispensed doses divided by 2 (assuming two doses per day) during a time interval of interest divided by the number of days in the time interval and multiplied by 100. MPR year prior to switch was divided by:  $\text{MPR} \geq 80\%$ ,  $\text{MPR} \geq 40\%$  to  $< 80\%$ ,  $\text{MPR} \geq 1\%$  to  $< 40\%$ , or  $\text{MPR} 0$ .

### Study outcomes

*Consultations:* Composite measure of primary healthcare visits (nurse/physician), and outpatient hospital visits to specialist care.

*Exacerbations:* Defined as either an asthma-related hospitalisation or dispense of OCS (ATC code

H02AB) or antibiotics (ATC code J01.AA or J01.CA).

**SABA prescriptions:** Defined as prescriptions of either R03AC02, R03AC03.

**LABA prescriptions:** Defined as prescriptions of either R03AC12, R03AC13, R03AC18.

### Statistical methods

Total population is described at index date, and for patients switching inhaler device (switchers) also at switch date. Continuous variables are described as mean; standard deviation and categorical variables are described as absolute and relative frequencies.

**Analyses of switchers vs. non-switchers:** Compared valid switched population with matched non-switchers with respect to exacerbations and healthcare resource utilisation 1 year following switch (Wilcoxon rank sum test). A switch was matched with first dispense of a new prescription for a non-switched patient.

**Nested case-control analyses:** To evaluate factors associated with a switch, all switched patients (cases) with data available for at least 1 year prior to switch was matched with a non-switcher (controls) on: exact match for type of DPI device, and approximate match for dispense date, and overall duration of index DPI device prescription time. Data are presented for the year preceding the switch (Wilcoxon rank sum test).

Data management used SAS version 9.2 (SAS Institute Inc, Cary, NC); statistical analyses used R version 3.0.1. Matching used the 'Match' function in

'Matching' in R (17). A p-value below 0.05 is considered as significant, but as no adjustment for multiple comparisons has been performed, the p-values should be considered as exploratory.

## Results

### Patient characteristics

In total, 15,169 patients [mean age, 40 years; female patients, 8767 (58%)] were identified to be on treatment with a BUD DPI during the study period (Figure 1). Of these, 2544 patients were prescribed Giona Easyhaler, 741 Novopulmon Novolizer, and the remaining 11,884 patients were prescribed Pulmicort Turbuhaler (Figure 2). Among the identified asthma patients, 598 individuals switched to an ICS other than BUD, 2598 patients switched to a fixed ICS/LABA combination, and another 10,428 patients remained on the originally prescribed index DPI until the end of observation. In addition, 367 patients died during the study period (Figure 1). These 13,991 patients were all excluded from further analyses.

### Switched population

The remaining 1178 patients (7.35% of the BUD DPI population) were switched from their index BUD DPI to their switch BUD DPI during the study period (Figure 3). A marked increase in number of switched patients was seen from year 2011 and onwards. There was no difference in switch rate between private and public clinics (data not shown).

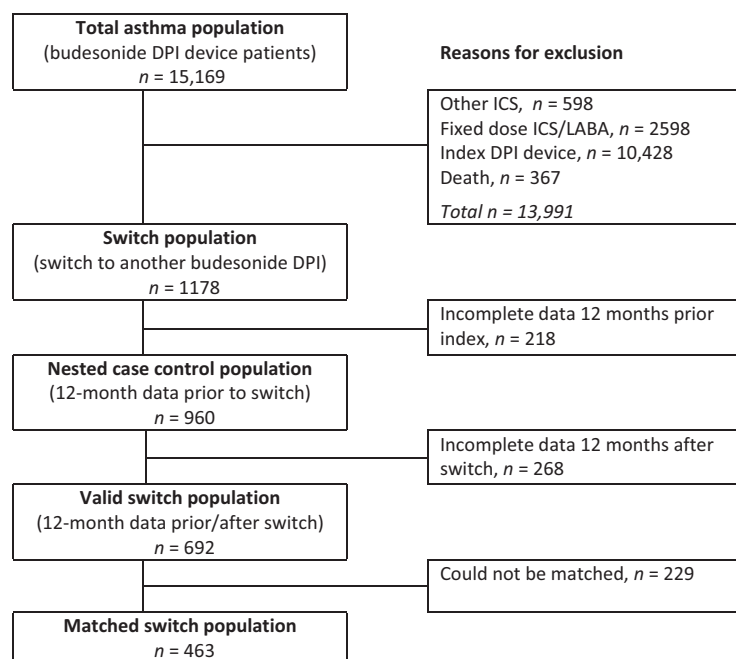


**Figure 1** Patient flow chart. *n*, number of patients

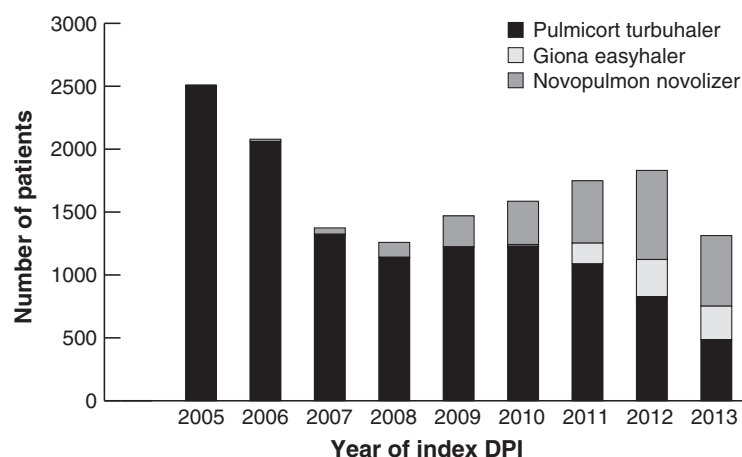


**Figure 2** Prescription of index budesonide DPI devices (number of patient) by study year

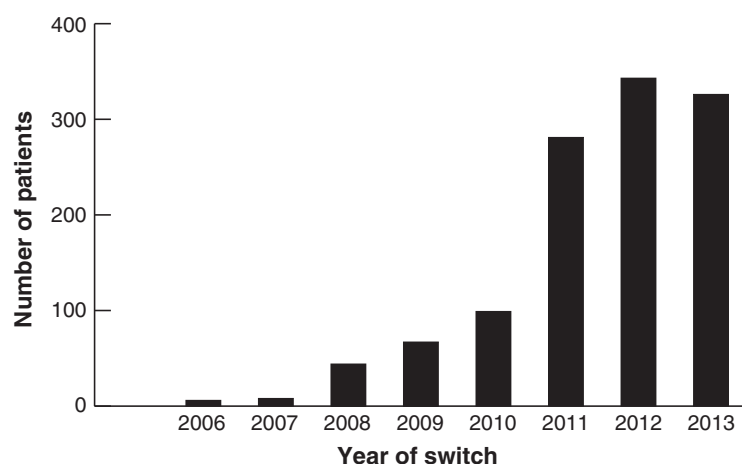


**Figure 3** Overall switch by study year from index budesonide DPI device to another budesonide DPI device,  $n = 1178$  patients

Of the patients who switched BUD DPI device, 960 patients had available data 12 months prior to switch DPI, and 692 patients had available 12-month data both pre- and post-index and were considered as valid switchers. Among the valid switchers, 337 patients (49%) had an MPR of 0 prior to switch, i.e. no BUD prescription claims during the pre-index year. When the patients were stratified according to asthma control, 437 patients (63%) were considered controlled and 117 (17%) of the patients were considered partly controlled.

The highest number of switchers could be identified from Pulmicort Turbuhaler to Giona Easyhaler (2nd available device;  $n = 531$ ) and from Turbuhaler to Novopulmon Novolizer ( $n = 111$ ). In addition, one patient was switched from Novolizer to Easyhaler, one patient from Novolizer to Turbuhaler, 15 patients from Easyhaler to Novolizer, and 33 asthma patients were switched from Easyhaler to Turbuhaler.

Pair-wise matching (1:1) of switchers vs. non-switchers resulted in two cohorts of 463 patients each (Figure 1), with similar characteristics (Table 1). Eighty-three per cent of the patients in the matched cohorts were well controlled and 12% were partly controlled. The proportion of patients with MPR = 0% was 53%; MPR = 1–40, 18%; MPR = 40–80, 13%; and MPR = 80–100, 17% (Table 1).

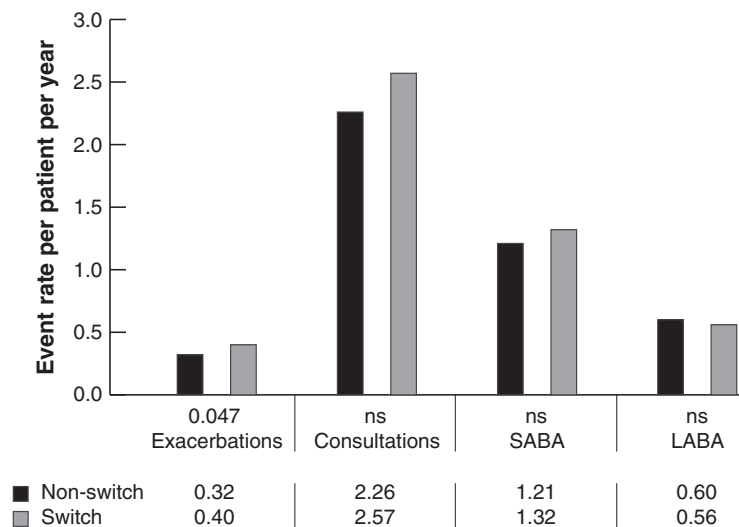
Switchers who could be matched were younger, had better asthma control and fewer exacerbations as compared with patients for whom a matching patient among non-switchers could not be found (data not shown).

Following matching, the postswitch exacerbation rates were 0.40 and 0.32 per patient per year in the switched and the non-switched groups, respectively ( $p = 0.047$ ). Number of consultations postswitch was 2.57 in the switched group and 2.26 in the non-switched group (Figure 4). The prescription of SABA

**Table 1** Patient characteristics of 1:1 matched population (switchers vs. non-switchers) prior to index budesonide device switch

|                                                     | Non-switchers<br><i>n</i> = 463 | Switchers<br><i>n</i> = 463 | p-value |
|-----------------------------------------------------|---------------------------------|-----------------------------|---------|
| Age, mean years (SD)                                | 36.0 (21.6)                     | 36.3 (21.8)                 | 0.870   |
| Female, <i>n</i> (%)                                | 254 (54.9)                      | 254 (54.9)                  | 1.000   |
| <b>MPR class, <i>n</i> (%)</b>                      |                                 |                             |         |
| 0                                                   | 245 (52.9)                      | 245 (52.9)                  | 1.000   |
| 1–40                                                | 82 (17.7)                       | 82 (17.7)                   |         |
| 40–80                                               | 59 (12.7)                       | 59 (12.7)                   |         |
| 80–100                                              | 77 (16.6)                       | 77 (16.6)                   |         |
| <b>Asthma control prior to switch, <i>n</i> (%)</b> |                                 |                             |         |
| Controlled                                          | 382 (82.5)                      | 382 (82.5)                  | 1.000   |
| Partly controlled                                   | 56 (12.1)                       | 56 (12.1)                   |         |
| Uncontrolled                                        | 25 (5.4)                        | 25 (5.4)                    |         |
| LABA dispenses, mean number (SD)                    | 0.37 (1.1)                      | 0.37 (1.1)                  | 0.694   |
| SABA dispenses, mean number (SD)                    | 0.56 (0.98)                     | 0.56 (0.98)                 | 1.000   |
| Exacerbations, mean number (SD)                     | 0.10 (0.36)                     | 0.10 (0.36)                 | 1.000   |
| Consultations, mean number (SD)                     | 1.23 (2.6)                      | 1.43 (2.7)                  | 0.110   |
| Rhinitis, <i>n</i> (%)                              | 27 (5.8)                        | 20 (4.3)                    | 0.369   |

SD, standard deviation; *n*, number; MPR, medication possession ratio; LABA, long-acting  $\beta_2$ -agonists; SABA, short-acting  $\beta_2$ -agonists. Patients were matched on the following criteria: exact match for type of DPI device, gender, MPR classification and asthma status; approximate match for age, number of consultations, number of exacerbations, number of SABA dispenses, dispense date and overall duration of index DPI device prescription time.

**Figure 4** Postswitch outcomes (exacerbations, consultations, SABA and LABA use) following 1:1 matching of switchers vs. non-switchers, *n* = 463 patients per group

was numerically higher in the switched group compared with the non-switched group (1.32 vs. 1.21) while prescription of LABA showed an opposite trend (0.56 vs. 0.60) (Figure 4).

In a subgroup analysis, when excluding patients with MPR equal to 0%, 218 patients remained in each group (MPR 1–100% during the pre-index year). Among these, 20% more consultations were

recorded in the switched group during the year following switch (ns). No difference was seen regarding exacerbations.

### Case-control analysis

To evaluate possible factors of predictive variables for a switch of BUD DPI, a nested case-control analysis was performed on all switchers with data

**Table 2** Case-control analysis of switchers with data available for at least 12 months prior to switch vs. non-switchers (baseline)

|                                                  | Non-switcher<br><i>n</i> = 960 | Switcher<br><i>n</i> = 960 | p-value |
|--------------------------------------------------|--------------------------------|----------------------------|---------|
| Age, mean years (SD)                             | 43.2 (21.7)                    | 38.8 (21.9)                | <0.001  |
| Female, <i>n</i> (%)                             | 596 (62.1)                     | 565 (58.8)                 | 0.161   |
| <b>MPR class, <i>n</i> (%)</b>                   |                                |                            |         |
| 0                                                | 307 (32.0)                     | 483 (50.3)                 | <0.001  |
| 1–40                                             | 206 (21.5)                     | 167 (17.4)                 |         |
| 40–80                                            | 174 (18.1)                     | 124 (12.9)                 |         |
| 80–100                                           | 273 (28.4)                     | 186 (19.4)                 |         |
| <b>Asthma control prior switch, <i>n</i> (%)</b> |                                |                            |         |
| Controlled                                       | 587 (61.6)                     | 619 (64.9)                 | 0.303   |
| Partly controlled                                | 175 (18.4)                     | 155 (16.2)                 |         |
| Uncontrolled                                     | 191 (20.0)                     | 180 (18.9)                 |         |
| LABA, mean number (SD)                           | 0.60 (1.5)                     | 0.37 (1.2)                 | <0.001  |
| SABA, mean number (SD)                           | 1.17 (1.8)                     | 1.02 (1.6)                 | 0.190   |
| Exacerbations prior switch, mean number (SD)     | 0.53 (1.2)                     | 0.47 (1.2)                 | 0.263   |
| Consultations prior switch, mean number (SD)     | 5.74 (5.9)                     | 5.95 (5.8)                 | 0.530   |
| Rhinitis, <i>n</i> (%)                           | 44 (4.6)                       | 53 (5.5)                   | 0.405   |

SD, standard deviation; *n*, number; MPR, medication possession ratio; LABA, long-acting  $\beta_2$ -agonists; SABA, short-acting  $\beta_2$ -agonists.

available for the 1 year prior index (*n* = 960). These patients were matched 1:1 with non-switchers using index DPI, year and time from index DPI to switch. The results showed that patients who were switched were 4.5 years younger and had lower MPR than the non-switched population (MPR = 0 was seen in 50% vs. 32% of the populations, respectively). The use of LABA was significantly less in the switched group (0.37 vs. 0.60; *p* < 0.001) (Table 2).

### Healthcare contacts at switch

Asthma patients with a visit to a nurse or a physician in primary healthcare the same day as the switch DPI was prescribed and having available data 1 year postswitch (*n* = 214) was compared with patients without any primary healthcare contact at switch (*n* = 116). The groups did not differ 1 year postswitch with respect to healthcare consultations and exacerbations (no visit 4.96 and 0.90; visit 4.29 and 0.77; respectively). However, patients without a primary healthcare visit at switch had significantly more outpatient hospital visits during the year following switch (2.01 vs. 0.81; *p* < 0.001).

### Switch-back

Postswitch, patients who were controlled prior to switch were more likely to continue with the new device (82%) compared with uncontrolled patients (74%). Uncontrolled patients were also more likely to switch-back within 1 year postswitch (17.8%) compared with controlled patients (12%). Addition

of LABA and fixed ICS/LABA combinations was more commonly seen in the uncontrolled group, 12% and 5% respectively.

## Discussion

The present observational matched cohort study covered a large (*n* = 15,169) population with mild asthma (GINA step II) (1), with low prescription claim of inhaled steroids and very few hospitalisations. In this mild asthma population, despite the availability of less costly devices, less than 10% of the patients were switched from their prescribed BUD index DPI medication. The switched patients were younger and had more commonly a medication possession ratio defined as zero (MPR = 0) when compared with patients who remained on their index DPI throughout the study period.

This suggests that physicians are selective when considering switch and that they may be reluctant to switch patients because of medication cost alone. Still, the healthcare sector today is put under financial pressure with an increased focus on reducing medication costs by enforcement to adhere to the regional drug recommendation list. This is likely reflected in the increased number of patients switched from 2011 and onwards. If this trend continues during the coming years, the effect on patient outcomes needs to be carefully monitored not to jeopardise patient health. There was no difference in switch rate between public vs. private primary

healthcare facilities, indicating that the financial pressure and adherence to regional drug recommendations is similar regardless of caregiver type.

The comparison of switchers to a matched non-switched population during the year following switch showed that switchers experienced reduced disease control reflected by significantly more exacerbations than non-switchers. In addition, switch was associated with numerically more consultations. Importantly, patients who were switched without a concomitant visit in primary healthcare, indicating switch by phone contact or at pharmacy without patient education, had significantly more outpatient visits.

In this matched population of mild asthma patients, the results indicate that the actual switching from the BUD index DPI, consented or not, has an effect on patients' disease control.

The reason for this finding can only be speculated, but it may reflect low adherence or incorrect use of the switched device leading to disease deterioration. For patients with less controlled asthma, it is important to identify the reason for poor control and based on that decide on appropriate treatment options (18). Still, it is important to recall that the patients who actually switched were younger, with lower MPR than the patients remaining on their index DPI. One reason may be that when under financial pressure, physicians may need to actively choose for which patients a switch from index medication may cause least negative effect. In this study, the high proportion of well-controlled patients, despite a low MPR, may indicate a non-persistent asthma diagnosis or a low treatment adherence to inhaled steroids because of very mild disease. However, this being an observational register study, the low MPR is based on prescription claims alone and actual use cannot be ensured. The outcome following switch of patients with more severe asthma still remains to be investigated.

Patent protection for many branded inhaled medications has expired, leading to the development and growing availability of analogues. Even though therapeutically equivalent to original branded options, inhalation devices vary markedly in their design, method of operation and drug delivery. This requires physician awareness of commonly available devices, ability to evaluate the patients' inhalation technique ensuring proper device use and assurance that the inhalation method is appropriate for the individual patient (13). Suboptimal inhaler technique (19) and inhaler mishandling (20) are still common in real life use.

In the present study, adherence to inhaled steroids is low. In uncontrolled asthma, incorrect inhaler usage and non-adherence to therapy are recognised as major factors, and lack of device continuity may

increase these problems (6). Decreased adherence with asthma medications, whether intentional or unintentional, is a common outcome of switching (7,21). In concordance with our findings, Thomas and co-workers have shown that real-world asthma outcomes vary depending on the device, suggesting that devices are not interchangeable (22). In a recently published work, it is recommended that patients with stable disease should remain on their current device (23). This has also been stated in ERS/ISAM taskforce report (13).

If nevertheless a device switch is implemented, the choice of device should be made in consultation between physician and patient; and to reach optimal treatment effect, the choice should also be according to the patient's needs, situation and preference (7,9). In addition, the importance of patient education should be in focus (4). A device switch without a face-to-face consultation has been shown to be associated with worsened asthma control (5). Prescribers should therefore not only consider the reduced acquisition cost inferred by the medication switch but also the cost of potential additional healthcare needs that the patients subsequently may have (8). In keeping with this, we report on increased healthcare recourse utilisation in hospital care following switch without consultation.

The present study is a retrospective observational registry study, a design that has its limitations. Reason for switch is not known and it could be argued that the low MPR in the majority of patients may indicate non-persistent asthma. Although the included patients were matched pair-wise, potential unknown confounders may still reside in the data. The low number of switchers did not reach enough statistical power for most of the comparisons between switchers and non-switchers. Following matching, the per cent well-controlled patients increased from 63% to 82%, which might not be representative for all valid switchers.

However, this study also comes with a number of important strengths, whereof one being the primary healthcare setting used to identify the asthma patients and the lack of restrictions with regard to, for example age, employment status and healthcare insurance. The non-biased data extraction from electronic primary healthcare records linked to mandatory national healthcare registers with high coverage and quality, together with the opportunity to follow individual patients through their treatment journey by use of personal identification numbers provide a robust data set. The study includes all patients with asthma from participating centres in a region representative for a Swedish population.

In summary, asthma patients and physicians in primary healthcare in Sweden seem reluctant to switch to

less costly devices because of cost alone. In this mild asthma population with very few switchers, a switch, especially without primary healthcare consultation, was associated with decreased asthma control. If a switch is considered, patient education and follow up after switch are likely important to ensure maintained disease control, also in a mild asthmatic population.

## Author contributions

All authors participated equally in the study conception, design and statistical analysis planning. MT was

responsible for statistical analyses, AEJ and FN for the manuscript draft and finalisation, and AEJ for handling of data and the study database. All authors analysed and interpreted the data, revised the manuscript, had access to complete study data, and had authority over manuscript preparation, approval of final version and the decision to submit for publication. AEJ is guarantor.

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