Lack of asthma and rhinitis control in general practitioner-managed patients prescribed fixed-dose combination therapy in Australia

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Lack of asthma and rhinitis control in general practitioner-managed patients prescribed fixed-dose combination therapy in Australia

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ABSTRACT
Objectives: The first aim of the study (i) assess the current asthma status of general-practitioner-managed patients receiving regular fixed-dose combination inhaled corticosteroid and long-acting beta, agonist (FDC ICS/LABA) therapy and (ii) explore patients’ perceptions of asthma control and attitudes/behaviors regarding preventer inhaler use. Methods: A cross-sectional observational study of Australian adults with a current physician diagnosis of asthma receiving ≥2 prescriptions of FDC ICS/LABA therapy in the previous year, who were recruited through general practice to receive a structured in-depth asthma review between May 2012 and January 2014. Descriptive statistics and Chi-Square tests for independence were used for associations across asthma control levels. Results: Only 11.5% of the patients had controlled asthma based on guideline-defined criteria. Contrarily, 66.5% of the patients considered their asthma to be well controlled. Incidence of acute asthma exacerbations in the previous year was 26.5% and 45.6% of the patients were without a diagnosis of rhinitis. Asthma medication use and inhaler technique were sub-optimal; only 41.0% of the preventer users reported everyday use. The side effects of medication were common and more frequently reported among uncontrolled and partially controlled patients. Conclusions: The study revealed the extent to which asthma management needs to be improved in this patient cohort and the numerous unmet needs regarding the current state of asthma care. Not only there is a need for continuous education of patients, but also education of health care practitioners to better understand the way in which patient’s perceptions impact on asthma management practices, incorporating these findings into clinical decision making.

Introduction
Asthma is a common episodic respiratory disease and remains a major human and economic burden globally [1]. In Australia, asthma affects 10% of the population and in 2015, the estimated direct costs from hospitalisations, treatment and health care utilisation were $1.2 billion and indirect costs from disability and premature death were $24.7 billion [2,3]. Despite the advances in our understanding of the disease, the availability of effective treatments and the development of international and national guidelines [4,5] to help optimise the management of asthma and improve patient outcomes, asthma remains poorly controlled.

Poorly controlled asthma creates a greater economic burden on individuals, communities and health care systems and controlled disease [6]. Poor asthma control is associated with an increased risk of exacerbations, diminished quality of life, debilitation, reduced productivity and increased health care utilisation [7–9]. Furthermore, poor asthma control and history of exacerbations are among the risk factors for future asthma exacerbations [4–6]. Other risk factors include poor inhaler technique and poor adherence [6]. Poor asthma control may be attributed to a broad range of inter-related factors many of which stem from patients having poor asthma knowledge, inadequate understanding of their
therapy or misconceived health beliefs due to insufficient asthma education [10,11]. This, in turn, may reflect poor knowledge and skills of the health care professional (HCP) [12].

Over the past decade, a number of multinational surveys have shown that asthma control, when measured by various instruments, remains sub-optimal [13–20]. Several international ‘real-life’ clinical studies conducted in general practice and hospital outpatient clinics have also shown that poor asthma control is prevalent, despite the availability of treatments [21–23]. More recently, the European Recognise Asthma and Link to Symptoms and Experience (REALISE) survey [24] and the REALISE Asia survey [25] have confirmed that asthma control continues to remain poor, with many patients perceiving their asthma to be trivial and well controlled despite the presence of symptoms and exacerbations. In part, this may be due to low patient expectations [26,27]. In Australia, apart from a recent population-based online survey reporting poor asthma control in 45.3% of the participants [20], little is known about the asthma control status of adults with a current diagnosis of asthma who are prescribed fixed-dose combination inhaled corticosteroid and long-acting beta2 agonist (FDC ICS/LABA) therapy in primary care. FDC ICS/LABA therapy is recommended for moderate–severe asthma (as represented by step 3 or above in international and national guidelines) [4,5], and is reported to have been prescribed in 49.5% of the GP encounters for asthma among Australian adults in 2011 [3]. We hypothesised that the asthma status of adults with a current physician diagnosis of asthma who are considered to have moderate–severe asthma and are treated appropriately, is poor, and that there are several patient-related factors that contribute to this.

The study aimed to measure the current asthma status of general practitioner (GP)-managed patients with moderate–severe asthma-prescribed regular FDC ICS/LABA therapy and to explore patient attitudes and behaviours regarding asthma medication use. This study was part of an international initiative conducted in seven European countries; implementing Helping Asthma in Real-life Patients (iHARP) among 5000 patients with moderate–severe asthma who are managed in a real-life setting to help optimise asthma management and improve patient outcomes. Here, we report the Australian data from the iHARP initiative. The specific objectives of the study were to:

i. assess asthma symptoms, indicators of acute exacerbations, levels of guideline-defined asthma control, inhaler device technique and rhinitis symptoms and treatment use;
ii. investigate patients’ perceptions of asthma control in relation to their guideline-defined level of control and history of asthma exacerbations;
iii. explore patient attitudes and behaviours regarding preventer inhaler use;
iv. examine associations between guideline-defined control and asthma symptoms, indicators of acute exacerbations, rhinitis symptoms, patterns of preventer inhaler use, and side effects from inhaled preventer medication.

Methods

Study design

This study took the form of a cross-sectional observational study conducted on a sample of general practice patients enrolled to receive a comprehensive structured review of their asthma between May 2012 and January 2014.

Participants and setting

A convenience sample of GP practices from the Sydney metropolitan area was approached to participate in the study. Their involvement in this study required GPs to identify asthma patients from the practice database who fulfilled the inclusion criteria based on their medical records. General practice managers then sent eligible patients a letter inviting them to participate in this study and undergo a pharmacist-led structured in-depth asthma review in the general practice setting. Patients who agreed to participate were asked to contact their GP practice to organise a time for a single 45-minute review visit during the specified period the specialist asthma pharmacist was available. Patients were asked to bring along their asthma medications and devices to the review visit. During the asthma review, data collected were entered by the pharmacist into an electronic database. At the end of the review, patients received appropriate education from the pharmacist and were encouraged to make a follow-up appointment with their GP to discuss the findings of the review. Each GP practice received an identical asthma review service.

Inclusion and exclusion criteria

Patients were included into the study if all the following criteria were met: they were aged 18–71 years at the time of the review, they had a current physician diagnosis of asthma, and they had received ≥2 prescriptions for FDC ICS/LABA medication in the previous 12 months. Patients were excluded from the study if they had a diagnosis of chronic obstructive pulmonary disease (COPD) or any other chronic respiratory disease other than asthma documented in their medical records, or were aged ≥40 years with a history of smoking and no
documentary evidence that COPD has been excluded either by spirometry or the International Primary Care Respiratory Group (IPCRG) recognised differential diagnosis questionnaire [28]. Patients were also excluded if they had received oral steroids and/or antibiotics for a lower respiratory condition in the two weeks preceding the review visit or they had received long-term systemic treatments for asthma including oral steroid, theophylline, leukotriene receptor antagonist or anti-IgE therapy. These exclusions were specified to minimise any potential confounding on disease stability and control by additional medications.

**Sample size**

Reviews of at least 196 asthma patients were needed in order to ensure that the results were generalisable to GP-managed Australian adults with asthma receiving FDC ICS/LABA therapy. This recruitment target was calculated based on the number of Medicare GP consultations claimed in 2010–2011 for asthma in Australia (approximately 2.64 million), within a 7% margin of error at 95% confidence interval [29].

**Asthma review**

The asthma review used questionnaire-led and pharmacist-led assessments to collect information about patient demographic and clinical characteristics, asthma symptoms, rhinitis symptoms, inhaler technique, and occurrence of exacerbations requiring a short course of oral steroid use in the previous 12 months. Asthma control was assessed using the four GINA criteria, which asked patients if they experienced the following during the previous week: daytime symptoms (more than twice/week), any night waking due to asthma, need reliever inhaler (more than twice/week), and any limitation in daytime activity. The presence of these four criteria determined the asthma symptom control category as follows: none of the above (controlled), 1 or 2 of the above (partially controlled), and 3 or 4 of the above (uncontrolled) [30]. Exacerbations were identified by one of the following patient-reported outcomes: hospital admission with breathing or chest problems, accident or emergency attendance related to asthma, or a short-term course (5–10 days) of oral steroids for worsening asthma. The number of exacerbations was taken from the 12-month period preceding the asthma review.

**Ethics and consent**

This study was approved by the University of Sydney Human Research Ethics Committee (Protocol Number 2012/967). All participants provided informed consent. Approval for use of the electronic database was granted by the Anonymised Data Ethics Protocols and Transparency committee and registered on the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) (as ENCePP/SDPP/9651).

**Data analysis**

Data collected were de-identified and analysed using SPSS (IBM® SPSS® Statistics) Version 22. Descriptive statistics were used to summarise patient demographics and clinical characteristics. The perception of asthma control was analysed by the GINA-defined control level and history of exacerbations using descriptive statistics. The relationship between GINA-defined control and incidences of asthma symptoms, indicators of acute exacerbations, incidence of rhinitis symptoms, patterns of preventer inhaler use and side effects from inhaled preventer medication was assessed using the Chi-Square test for independence. A significance level of \( p < 0.05 \) was used for all statistical procedures.

**Results**

**Patient population**

Of the nine GP practices approached, six agreed to participate in the study (participation rate, 66.7%). A total of 370 patients who met the inclusion criteria were identified by GPs from their practice databases and were invited to participate in the study. Of the 370 invited patients, the first 200 patients who agreed to participate were recruited into the study and underwent a pharmacist-led structured...
in-depth asthma review. Patient demographics and clinical characteristics are shown in Table 1. The mean age of patients was 47.7 (±15.8) years, 128 (64.0%) were females, 165 (82.5%) had been diagnosed with asthma for more than 10 years, 69 (34.5%) were obese (i.e., had a BMI ≥ 30) and 28 (14.0%) were current smokers.

### Asthma control

Overall, 23 (11.5%) patients had controlled asthma according to the GINA criteria, 77 (38.5%) had partially controlled asthma and 100 (50.0%) had uncontrolled asthma (Table 2). Over half of the patients (52.5%) had symptoms that interfered with daily activities, 114 (43.0%) had symptoms affecting their sleep and 106 (53.0%) had used their relievers three or more times in the week before the asthma review visit. Overall, 53 (26.5%) patients reported having used at least one short-term course of oral steroids for asthma in the previous 12 months, 54 (27.0%) reported having taken at least one day off work/education due to asthma, 23 (11.5%) reported having visited an emergency department and 12 (6.0%) reported having been hospitalised for asthma (Table 2).

### Asthma symptoms and exacerbations across control levels

Incidences of asthma symptoms and indicators of exacerbations across asthma control levels are shown in Table 2. Compared to patients with controlled asthma, those with uncontrolled asthma were more likely to have experienced acute exacerbations requiring short-term courses of oral steroids (13.0% vs. 40.0%, \( p < 0.001 \)), have taken time off work/education due to asthma (17.4% vs. 40.0%, \( p < 0.001 \)), or have been hospitalised due to asthma (8.7% vs. 10.0%, \( p = 0.018 \)) in the 12 months before the asthma review visit.

### Perception of asthma control

Overall, 133 (66.5%) patients considered their asthma to be well controlled in the past four weeks when in fact only 23 (11.5%) patients had asthma that was currently controlled according to GINA criteria (Table 3). Almost half of the patients (49.0%) with currently uncontrolled asthma according to GINA criteria considered their asthma to be well controlled. Of 133 patients who considered their asthma well controlled, 61 (45.9%) had used reliever medications more than twice a week, 52 (39.1%) had symptoms that interfered with normal activities and 39 (29.3%) had awoken at night due to asthma in the previous week. Moreover, almost half of the patients who had required oral steroid use and over one-third of those who had experienced acute exacerbations requiring emergency department visits or hospitalisations in the previous year regarded their asthma as well controlled (Table 3).

### Rhinitis symptoms across control levels and treatment use

Incidences of rhinitis symptoms overall and across GINA-defined asthma control levels are shown in Figure 1. While 180 (90.0%) patients reported having rhinitis symptoms, with 104 (57.8%) and 76 (42.2%) patients classified as having moderate–severe and mild rhinitis, respectively, 82 (45.6%) patients were without a diagnosis. A higher proportion of patients with uncontrolled asthma had moderate–severe rhinitis symptoms than those with controlled asthma (61.8% vs. 43.4%, \( p = 0.025 \)). Among the patients reporting rhinitis symptoms, 85 (47.2%) reported using oral antihistamines and 47 (26.1%) INCSs. However, 70 (67.3%) patients with moderate–severe rhinitis were not using the recommended INCS therapy.
Table 2. Indicators of asthma symptoms and exacerbations overall and by GINA-defined control levels.

<table>
<thead>
<tr>
<th>Control and indicators of symptoms</th>
<th>Overall (N = 200)</th>
<th>Controlled (n = 23)</th>
<th>Partially controlled (n = 77)</th>
<th>Uncontrolled (n = 100)</th>
<th>p Valuea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days with symptomsa</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>38 (19.0)</td>
<td>14 (60.0)</td>
<td>24 (31.2)</td>
<td>0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1–2 days</td>
<td>55 (27.5)</td>
<td>9 (39.1)</td>
<td>38 (49.4)</td>
<td>8 (8.0)</td>
<td></td>
</tr>
<tr>
<td>≥3 days</td>
<td>107 (53.5)</td>
<td>0</td>
<td>15 (19.5)</td>
<td>92 (92.0)</td>
<td></td>
</tr>
<tr>
<td>Normal activities affected by symptomsa</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>95 (47.5)</td>
<td>23 (100)</td>
<td>61 (79.2)</td>
<td>11 (11.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥1 day</td>
<td>105 (52.5)</td>
<td>0</td>
<td>16 (20.8)</td>
<td>89 (89.0)</td>
<td></td>
</tr>
<tr>
<td>Nighttime awakeninga</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>114 (57.0)</td>
<td>23 (100)</td>
<td>60 (77.9)</td>
<td>31 (31.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥1 day</td>
<td>86 (43.0)</td>
<td>0</td>
<td>17 (22.1)</td>
<td>69 (69.0)</td>
<td></td>
</tr>
<tr>
<td>Reliever inhaler usea</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>69 (34.5)</td>
<td>16 (69.6)</td>
<td>39 (50.6)</td>
<td>14 (14.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1–2 days</td>
<td>25 (12.5)</td>
<td>7 (30.4)</td>
<td>13 (16.9)</td>
<td>5 (5.0)</td>
<td></td>
</tr>
<tr>
<td>≥3 days</td>
<td>106 (53.0)</td>
<td>0</td>
<td>25 (32.5)</td>
<td>81 (81.0)</td>
<td></td>
</tr>
<tr>
<td>Acute exacerbations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral steroid for worsening asthmab</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥1 course</td>
<td>147 (73.5)</td>
<td>20 (87.0)</td>
<td>67 (87.0)</td>
<td>60 (60.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Days off work/education due to asthma</td>
<td>55 (26.5)</td>
<td>3 (13.0)</td>
<td>10 (13.0)</td>
<td>40 (40.0)</td>
<td></td>
</tr>
<tr>
<td>Emergency department visit due to asthma</td>
<td>146 (73.0)</td>
<td>19 (82.6)</td>
<td>67 (87.0)</td>
<td>60 (60.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hospitalisation due to asthma</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥1 stay</td>
<td>177 (88.5)</td>
<td>21 (91.3)</td>
<td>71 (92.2)</td>
<td>85 (85.0)</td>
<td>0.298</td>
</tr>
<tr>
<td>Notes. Data are shown as n (%) of patients.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GINA; Global Initiative for Asthma.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>aAt least one in the previous 7 days.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>bIn the previous 12 months.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c p value from Chi-Square test.</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Attitudes and behaviours regarding preventer inhaler use and side effects**

While the majority of patients (85.5%) stated that they found their preventer inhaler(s) easy to use and 146 (73.0%) felt that they had a ‘good’ or ‘excellent’ inhaler technique, an objective assessment of inhaler technique revealed that all 200 patients exhibited at least two errors and 114 (72.0%) exhibited five or more errors. The five most common errors performed included the following: does not have head tilted such that the chin is slightly upwards (93.5%), does not breathe out to empty lungs (88.5%), no breath-hold (or holds breath for less than 3 seconds) (88.5%), inappropriate inhalation technique (78.0%), and second dose within 30 seconds (37.0%). Only 82 (41.0%) of the FDC preventer medication users reported taking it everyday, 54 (27.0%) used it only when they had symptoms and 46 (23.0%) used it for some days; 12 (6.0%) had stopped taking it and six (3.0%) never took it at all (Figure 2). Compared to patients with controlled asthma, those with uncontrolled asthma were more likely

Table 3. Perception of asthma control for the overall population and by GINA-defined control levels and history of exacerbations.

<table>
<thead>
<tr>
<th>GINA-defined asthma control</th>
<th>Overall (N = 200)</th>
<th>Controlled (n = 23)</th>
<th>Partially controlled (n = 77)</th>
<th>Uncontrolled (n = 100)</th>
<th>Acute exacerbationsa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perception of asthma control</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not well controlled</td>
<td>67 (33.5)</td>
<td>2 (8.7)</td>
<td>14 (18.2)</td>
<td>51 (51.0)</td>
<td></td>
</tr>
<tr>
<td>Well controlled</td>
<td>133 (66.5)</td>
<td>21 (91.3)</td>
<td>63 (81.8)</td>
<td>49 (49.0)</td>
<td></td>
</tr>
<tr>
<td>Oral steroid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency department visits</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalisation</td>
<td></td>
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<tr>
<td>Notes. Data are shown as n (%) of patients.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>GINA; Global Initiative for Asthma.</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>aAt least one in the previous 12 months due to asthma.</td>
<td></td>
<td></td>
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</tbody>
</table>
to take their preventer medications only on some days but not on others (13.0% vs. 30.0%, \( p = 0.029 \)). The most common reasons selected for non-adherence included feeling worried about taking regular preventer medication (52.5%), forgetting to take it (46.0%) or just deciding to miss a dose (41.0%).

The rate of reported side effects experienced from the preventer inhaler use was high with 155 (77.5%) patients reporting that they had experienced at least one side effect (Figure 3), with 24 (12.0%) experiencing a maximum of four side effects. Incidences of side effects experienced from preventer medication use overall and by GINA-defined control levels are shown in Figure 4. Compared to patients with controlled asthma, those with uncontrolled and partially controlled asthma were more likely to have experienced at least one side effect (47.8% vs. 83.0% and 79.2%, \( p = 0.001 \)). In the past year, 190 (95.0%) patients had not had their inhaler technique checked by an HCP. Overall, 28 (14.0%) patients had seen a respiratory specialist for asthma outside the GP practice in the past year, with 91 (45.5%) having seen a specialist more than a year ago and 81 (40.5%) never having seen a specialist outside the practice.

**Figure 1.** Incidence of rhinitis symptoms overall and by GINA-defined control levels. GINA; Global Initiative for Asthma. Self-reported rhinitis symptoms by patients, in response to the question: ‘Do you have any of these symptoms: itchy, runny, blocked nose or sneezing when you don’t have a cold?’ with responses ranging from, \( \text{None} \) (no), \( \text{Occasionally and little bother} \), \( \text{Occasionally but quite a bother} \), \( \text{Most days but little bother} \), or \( \text{Most days and a lot of bother} \). Responses \( \text{None} \) and \( \text{Occasionally and little bother} \) were classified under ‘mild’ rhinitis symptoms and responses \( \text{Occasionally but quite a bother} \) and \( \text{Most days and a lot of bother} \) under ‘moderate–severe’ rhinitis symptoms. Patients classified as having mild symptoms: \( n = 76 \); moderate–severe symptoms: \( n = 104 \); Global Initiative for Asthma-defined controlled: \( n = 77 \); partially controlled: \( n = 100 \).

**Figure 2.** Patterns of preventer medication use overall and by GINA-defined control levels. GINA; Global Initiative for Asthma. Self-reported pattern of preventer medication use by patients, in response to the question: ‘Which statement best describes how you take your regular asthma treatment?’ with the above five options. Patients taking a preventer inhaler (overall; \( N = 200 \); Global Initiative for Asthma-defined controlled: \( n = 77 \); partially controlled: \( n = 100 \)).

**Figure 3.** Number of side effects experienced from preventer inhaler use overall and by GINA-defined control levels. GINA; Global Initiative for Asthma. Side effects experienced by patients from preventer inhaler use, in response to the question: ‘Do you experience any of these side effects from your preventer inhaler?’ with ‘yes’ or ‘no’ responses for the following side effects: continual sore mouth/throat; oral thrush; bruising; hoarse voice; abnormal weight gain and cough. Patients could indicate more than one side effect. Patients using a preventer inhaler (overall; \( N = 200 \); Global Initiative for Asthma-defined controlled: \( n = 23 \); partially controlled: \( n = 77 \); uncontrolled: \( n = 100 \)).

**Figure 4.** Incidences of side effects from preventer inhaler use overall and by GINA-defined control levels. GINA; Global Initiative for Asthma. Self-reported side effects of preventer inhaler use by patients, in response to the question: ‘Do you experience any of these side effects from your preventer inhaler?’ with ‘yes’ or ‘no’ responses for the following side effects: continual sore mouth/throat; oral thrush; bruising; hoarse voice; abnormal weight gain and cough. Patients could indicate more than one side effect. Patients using a preventer inhaler (overall; \( N = 200 \); Global Initiative for Asthma-defined controlled: \( n = 23 \); partially controlled: \( n = 77 \); uncontrolled: \( n = 100 \)).
Discussion

This study provided a unique ‘snapshot’ of the current asthma status of GP-managed patients receiving fixed-dose combination therapy, and insights into patient’s perceptions, attitudes and behaviour regarding preventer inhaler use. Our findings showed that the incidence of controlled asthma was low with a high risk of future asthma exacerbations, and a discrepancy between perceived and guideline-defined level of asthma symptom control. Undiagnosed and undertreated comorbid rhinitis was prevalent and asthma medication use was sub-optimal. Inhaler technique continues to be a major issue and medication concerns as well as not perceiving the importance of taking medication remain problematic. The side effects of medication were common and more frequently reported in patients with sub-optimal control. Taken together, the results from this study revealed the extent to which asthma management needs to be improved in this group of patients and highlights the numerous unmet needs regarding the current state of asthma care. This research provided valuable insight by utilising a structured in-depth asthma review approach and helped in identifying populations that should be targeted by tailored interventions to improve asthma management practices in the future.

The strength of this study lies in the fact that it is the first Australian cross-sectional observational study providing data on detailed assessment of asthma symptoms, indicators of acute exacerbations and levels of guideline-defined control among GP-managed patients receiving regular maintenance therapy. By utilising a comprehensive structured asthma review approach, the results of this study helped to identify populations that should be targeted by tailored interventions to improve practice. Moreover, this approach provided valuable insight into patient behaviour regarding inhaler technique which would have been impossible to obtain through other approaches such as online surveys utilised in other studies [13–20,24,25,27]. While many multinational studies have shown that poor asthma control remains prevalent, few studies have assessed asthma control in real-life clinical practice and none in the Australian population, a population with one of the highest asthma prevalence rates in the world (in 2015, there were 2.4 million Australians with a recorded diagnosis of asthma, i.e., 9.9% of the population) [2]. This study focused on those patients with recent general practice contact receiving combination preventer therapy, this being the most highly prescribed asthma medication type in Australia (prescribed in 49.5% of the GP encounters among Australian adults with asthma in 2011, and almost five times the proportion of encounters for asthma at which ICSs alone had been prescribed) [3]. Thus, the results of this study become highly relevant and translatable into current practice.

In this study, asthma control was defined based on the 2011 GINA report [30]. This particular framework for evaluating asthma control was used over other measures (e.g. the Asthma Control Test (ACT)) [37] due to the fact that it bases control assessment on symptoms and reliever use, independent of patient’s perceptions of their level of asthma control (a disadvantage of using the ACT which has the potential to overestimate the level of asthma control based on the influence of patient’s perceptions). This study revealed that in a population of patients with current asthma, asthma control remains sub-optimal with only 11.5% of the patients having controlled asthma as defined by GINA guidelines, despite being prescribed a combination therapy. A proportion of controlled patients also had acute exacerbations, emergency department visits and hospitalisations due to asthma over the previous year, increasing their future risk of exacerbation and adverse asthma outcomes [4–6]. Compared with other recent online surveys, the incidence of controlled asthma in our real-world study was lower than that reported by Reddel et al. using the ACT (54.7% had well-controlled asthma) [20] and in online surveys using GINA-defined criteria across Europe (20.1%) [24], Asia (17.8%) [25] and Australia (12.0%) [15]. This clearly identifies a trend in the Australian asthma cohort in which the incidence of controlled asthma achieved seems to be lower than that achieved internationally.

A major finding of this research is the lack of accurate perception of poor control and tolerance of symptoms on the part of the patient. Almost half of the patients with uncontrolled asthma believed that they had well-controlled asthma, even if they were symptomatic or limited in their daily activities. This acceptance of symptoms as the ‘norm’ may be due to low patient expectations, which, in turn, may be as a result of poor clinical care [27,38]. Almost half of the patients did not recognise the nighttime symptoms and the overuse of reliever medication as indicators of poor control, suggesting a continuous discrepancy between patient’s perception of control and guideline-defined control. This raises questions about patients’ understanding of the concept of asthma control, and factors being utilised by patients to gauge their level of asthma control. These findings are consistent with recent online surveys across Europe [24,27], Asia [25] and Australia [15]. It has been well documented that patients’ inaccurate estimation of their level of asthma control can create a barrier to the attainment of optimal asthma management [15,24,25,27,38]. Patients may benefit from a comprehensive structured asthma review, which offers self-management education including a written asthma action plan, self-monitoring
and regular medical review, to assist in addressing some of these areas [5,27,39]. A personalised written asthma action plan not only provides clear instructions on what to do for worsening asthma, but is also an effective tool which can be used to educate patients about the understanding of control and help raise patient’s expectations. Future research into factors associated with patient’s inaccurate perception of asthma control and predictors of uncontrolled asthma also needs to be investigated.

This study revealed that coexisting rhinitis was highly prevalent, yet underreported and undertreated. There was a discrepancy between diagnosis (49%) and prevalence (90%), with moderate–severe rhinitis symptoms more common among uncontrolled asthma patients. Of 104 (57.8%) patients with moderate–severe rhinitis, 70 (67.3%) patients were not using first-line INCS therapy [31]. Similar findings have been reported in a random sample of a Danish population, where 49.0% of the asthma patients had undiagnosed and untreated comorbid allergic rhinitis (AR) [40]. Up to 80% of the Australians with allergic asthma have coexisting AR and at least 30% with known AR also have asthma [5]. Both AR and non-AR are the risk factors for the development of asthma [31,41], and pose a significant socioeconomic burden on the individuals and society [42]. Given that AR and asthma are the manifestations of one chronic inflammatory process in two parts of a single airway [43], and that untreated or sub-optimally managed AR has been shown to be associated with worse asthma control [44], it is recommended that HCPs screen all patients with asthma for AR (and for asthma in AR patients). It is also recommended that HCPs raise awareness of the asthma and AR link, and use an integrated and unified approach in the management of both conditions [31,41].

Another significant yet disappointing finding in this study relates to the medication use. Despite the recommendations of evidence-based guidelines developed for primary care health providers [5], and the fact that this patient cohort engages with medical care, the medication use has yet again been identified as problematic, in terms of adherence, inhaler technique and patient understanding of the value of medicines and experiences of side effects. In this study, adherence rates to inhaled preventer therapy were low (41.0%), with uncontrolled asthma patients more likely to take preventer medication sporadically. Interestingly, half of the patients had concerns about taking regular preventer medication and almost 80.0% had experienced at least one side effect, possibly contributing to their reduced willingness to use them, and ultimately leading to poor control [26,45]. Moreover, not a single patient was able to demonstrate correct inhaler technique, even though most patients believed that their technique was satisfactory, highlighting the disparity between patients’ perceptions and reality. The results also demonstrate that poor adherence and poor inhaler technique coexist [46], and that little progress has been made in recent decades in improving patient adherence and inhaler technique in asthma management [15,20,27,36,47]. Our results strengthen the need to address and regularly review factors which contribute to poor asthma control before stepping-up treatment, those which might influence patient adherence, including medication side effects [48], and those which might influence inhaler technique maintenance [46]. As the majority of patients had not had their inhaler technique checked in the past year, there is an urgent need for HCPs to recheck the inhaler technique and provide education reinforced regularly, as recommended by current asthma guidelines [4,5], as well as intranasal device technique where appropriate [31,41].

There are some potential limitations to this study which are associated with the convenience sampling method, cross-sectional study design, and a reliance on patient recall for self-reported symptoms, exacerbations and medication behaviour that may have been under- or overstated by patients. Additionally, even though there were criteria to exclude people with COPD, and given that many patients were aged 50 years or more with a past or current smoking history (and at a greater risk of COPD), it may have been possible that people with both asthma and COPD were included and could have biased the results. In considering the results of this research, it is important to consider the patient population explored, a patient cohort of moderate–severe asthma-prescribed FDC ICS/LABA therapy, who had a recent GP contact as opposed to patients with milder disease who may not have a regular GP contact. However, there is a possibility that patients regularly seeking a GP might also be those who are not well controlled, thereby limiting the generalisability of our results. There is also a possibility that patients receiving FDC ICS/LABA therapy might have milder disease and are being overtreated due to failure in excluding poor inhaler technique, poor adherence or comorbidities. Despite these limitations, this research provided valuable insight by using a structured in-depth asthma review approach, and helped identify populations that should be targeted and the type of interventions needed in primary care, where most asthma is managed in Australia.

**Conclusions**

The results from this study confirmed that even amongst a cohort of adults with asthma who regularly seek care from a GP, the proportion of individuals with controlled
asthma was extremely low and the medication use was sub-optimal. The study revealed a consistent discrepancy between patient's perspectives and reality and their acceptance of asthma and rhinitis symptoms as well as medication side effects. This research highlights the urgent need for primary health practitioners to go back to basics with their patients and raise patient expectations, complete comprehensive reviews on an annual basis and better support patients to self-management more effectively. Not only there is a need for continuous education of patients, but also education of health care practitioners to better understand the way in which patient's perceptions impact on asthma management practices, incorporating these findings into clinical decision making.

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