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Patients with Asthma in Primary Care Versus a Salbutamol-Free Asthma Center Observational Study

Pacientes con asma en atención primaria versus un centro de asma sin salbutamol. Estudio observacional

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ABSTRACT

Introduction: Given the evidence against the prolonged use of short-acting beta2-agonists (SABAs), including an increased likelihood of exacerbations and mortality, the Global Initiative for Asthma (GINA) report no longer recommends SABA monotherapy. Since 2014, our asthma center at the Hospital from G. Baigorria (Argentina) has implemented a rescue strategy using budesonide/formoterol as anti-inflammatory maintenance and reliever therapy (AIR/MART), eliminating the use of SABAs. The Asthma Refer ID Questionnaire (ReferID) was designed to identify patients with uncontrolled asthma who should be referred to a specialist.

Objectives: To compare ReferID outcomes between a SABA-free asthma center and primary care using SABAs.

Materials and methods: This was an observational, cross-sectional, comparative study applying the ReferID questionnaire (which consists of four simple questions) between September 2020 and August 2021 at a public hospital in Buenos Aires, Argentina, and at the SABA-free asthma center between December 2021 and January 2022.

Results: The SABA-free asthma center achieved significantly better outcomes, including fewer courses of systemic corticosteroids (SCS) and fewer emergency department visits for asthma exacerbations. Eleven patients had been intubated before entering the SABA-free asthma center.

Conclusions: AIR/MART treatment without SABAs, combined with asthma specialist follow-up, significantly reduced SCS courses and emergency department visits compared with primary care management using SABAs.

Key words: asthma | anti-inflammatory reliever therapy | salbutamol

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RESUMEN

Introducción: Dada la evidencia en contra del uso prolongado de agonistas beta2 de acción corta (SABA), incluida la mayor probabilidad de exacerbaciones y mortalidad, el Informe de la Iniciativa Global para el Asma (GINA) ya no recomienda la monoterapia con SABA. Desde 2014, en nuestro centro de asma del Hospital de G. Baigorria (Argentina) implementamos una estrategia de rescate con budesonida/formoterol como mantenimiento y rescate antiinflamatorio (AIR/MART), eliminando el uso de SABA. El Cuestionario de Identificación de Derivación para Asma (REFID) se diseñó para identificar pacientes con asma no controlada que deben derivarse a un especialista.

Objetivos: Comparar los resultados del REFID entre un centro de asma sin SABA y la atención primaria con SABA.

Materiales y métodos: Estudio observacional, transversal y comparativo aplicando El REFID (consta de cuatro preguntas sencillas) entre septiembre de 2020 y agosto de 2021 en un hospital público de Buenos Aires, Argentina, y en el centro de asma sin SABA entre diciembre de 2021 y enero de 2022.

Resultados: El centro sin SABA logró resultados significativamente mejores, menos ciclos de corticosteroides sistémicos (SCS) y menos visitas a urgencias por exacerbaciones de asma. Los once pacientes que habían sido intubados; esto ocurrió antes de ingresar al centro sin SABA.

Conclusiones: El tratamiento AIR/MART sin SABA, junto con el seguimiento por un especialista en asma, redujo significativamente los ciclos de SCS y las visitas a urgencias en comparación con la atención primaria con SABA.

Palabras clave: asma | rescate antiinflamatorio | salbutamol

INTRODUCTION

Given the evidence against the prolonged use of SABAs, including an increased likelihood of exacerbations and mortality, the GINA report no longer recommends SABA monotherapy. In addition, the SABINA program indicated that overuse of SABAs remains a major global public health concern, highlighting a global burden, as 40% of the asthma population worldwide was prescribed three or more SABA inhalers annually.[2] Although there were differences in prescribing practices between primary care physicians (PCPs) and specialists, overprescription was common in both models of care. SABA monotherapy for mild asthma was prescribed at a higher frequency and volume by PCPs; conversely, SABA prescription rates for moderate-to-severe asthma were similarly high across both PCPs and specialists.[2] Only a small proportion of patients in the Latin American cohort were treated in primary care (11.8%). A greater proportion of these patients were prescribed ≥3 and ≥10 SABA inhalers (56.2% and 50.8%, respectively) compared with those who were managed by a specialist (37.3% and 21.9%, respectively). [3] Overprescription and over-reliance on SABAs are problems that affect everyone involved.

The ReferID questionnaire was designed to identify uncontrolled asthma requiring referral to a specialist.[4] ReferID consists of four questions, each with a yes/no recommendation for evaluation by a specialist. These four questions address the main risk factors associated with inadequate asthma management.

OBJECTIVES

To compare ReferID results in a tertiary hospital primary care setting with the specialty care provided by the world's first SABA-free asthma department.[5]

MATERIALS AND METHODS

Through an observational, cross-sectional, and comparative study, we aimed to highlight the advantages of the MART strategy, which remains underdisseminated and limited in availability, particularly in

countries such as Argentina.[1-3] Patients between 18 and 75 years of age with a diagnosis of asthma of at least 12 months of evolution were included in the study.

ReferID is a simple and concise tool that primary care physicians can use to quickly identify patients with uncontrolled or potentially severe asthma who may benefit from an evaluation by a specialist. The questions are as follows:

1) Has the patient received two or more courses of SCS or been on maintenance SCS therapy in the past 12 months?

2) Has the patient had two or more emergency or unscheduled visits for asthma within the last 12 months?

3) Has the patient ever required intubation or admission to an ICU due to asthma? 4) Has the patient used 3 or more SABA inhalers within the last 12 months?

The ReferID data was initially collected at a tertiary care level public hospital in Buenos Aires, Argentina, between September 2020 and August 2021. The population of patients with asthma using SABAs received care from general practitioners, internists, emergency department staff, and healthcare resources outside the hospital. The ReferID was also conducted at the public SABA-free asthma center between December 2021 and January 2022. Patients who had attended the SABA-free asthma center for at least 12 months completed the ReferID questionnaire. All patients at the SABA-free center received treatment with budesonide/formoterol as both maintenance and reliever therapy (AIR/MART).[6]

Statistical analysis

Quantitative variables with a normal distribution were expressed as the mean with standard deviation (SD). The Student's t-test for independent samples was used for continuous variables. A two-tailed Fisher's exact test was used to analyze the contingency tables, comparing the absolute numbers for each ReferID question between the hospital using SABAs and the center not using SABAs. The analysis was performed using GraphPad Prism 9 software (San Diego, CA, USA).

RESULTS

The hospital using SABAs included 105 patients with asthma, whereas the SABA-free center included 60. Table 1 shows demographic characteristics and main findings. Patients at the SABA-free asthma center received significantly fewer courses of systemic corticosteroids and made fewer emergency department visits or unscheduled consultations during the previous 12 months. Eleven patients in the non-SABA group required endotracheal intubation due to respiratory arrest before being admitted to the center. After admission, none of the patients required hospitalization.

DISCUSSION

This retrospective, observational study compared SABA-free asthma management with that of patients using SABA in primary care. It provides compelling evidence supporting the elimination of SABAs from asthma treatment protocols. Current guidelines do not recommend complete elimination of SABAs, despite evidence of a dose-response association with outcomes such as hospitalizations and mortality.[1-3] Particularly in resource-limited settings, such as low- and middle-income countries (LMICs), limited availability and

Table 1. Basal characteristics and main findings

ReferID Asthma Questionnaire	Hospital using SABAs	SABA-free hospital	*Difference
Sample size (males)	105 (31)	60 (18)	NS
Age in years (mean±SD)	43.82±16.2	45.5±14.6	NS
No. of patients on ICS/LABA	24	60	<.0001
Smoking: n (mean pack-years)	31 (10 pack-years)	22 (5 pack-years)	NS
≥2 courses of SCS the last 12 months: n	58	3	<0.0001
≥2 visits to the Emergency Department or unscheduled consultations the last 12 months: n	69	2	<0.0001
Intubation/admission to the ICU	14	11	0.4988
≥3 SABA units the last 12 months	76	0	N/A
Referral to a specialist is required	92 (87.6%)	11 (18%)	<0.0001

SD= standard deviation ICS/LABA: inhaled corticosteroids/long-acting beta-agonists ICU: Intensive Care Unit.

higher costs of inhaled corticosteroid-containing medications contribute to excessive reliance on SABAs. In addition, many physicians are unfamiliar with the evidence-based shift away from SABA monotherapy toward bronchodilator plus anti-inflammatory therapy as a safer and more effective option.[6] Our data support the SABA-free approach, specifically using the AIR/MART strategy at the Hospital of Granadero Baigorria in Argentina, which was associated with significantly better outcomes in patients with asthma.[7]

Despite the high standards of practice at their hospital, primary care physicians (SABA users) demonstrated poor asthma management. Simply eliminating SABAs from asthma treatment would improve most outcomes, as occurred with the hospitalization rate in the SABA-free asthma center.[7] Unfortunately, Montero Arias and colleagues showed that specialist care does not prevent SABA overprescription.[3] Indirectly, they showed that specialist care does not necessarily translate into better outcomes when SABA prescribing persists.

The most notable findings were substantial reductions in severe asthma exacerbations. Patients at the SABA-free asthma center received fewer courses of systemic corticosteroids (SCS) and had fewer emergency department visits compared with their counterparts in primary care who used SABAs. This indicates that combining a bronchodilator with inhaled corticosteroids (ICS), together with specialist follow-up, not only stabilizes asthma control but also reduces the burden on healthcare systems by minimizing acute exacerbations. The percentage of severe asthma cases that might require referral to an asthma specialist was significantly reduced compared with SABA users. Even more importantly, SABA users tended to overestimate asthma severity. Furthermore, the study highlights the effectiveness of the ReferID questionnaire in identifying uncontrolled asthma; however, excessive SABA use and overprescription may lead to an overestimation of the proportion of patients with severe asthma. This tool proved effective both in primary care and in the specialized center. However, the substantial improvement in patient outcomes observed at the SABA-free asthma center underscores the benefits of integrated specialist care combined with innovative management strategies.

Nevertheless, preventable asthma-related admissions and mortality continue to pose a public health challenge in Argentina.[8] The purpose of publishing this real-world experience was to disseminate optimized care strategies among local healthcare providers who lack direct access to these medications. According to GINA guidelines, Track 2 is the appropriate therapeutic pathway for Argentina, given its status as a developing nation.[1] Evaluating the ReferID tool was not our primary objective; however, the collected data proved highly effective for identifying and addressing entrenched clinical practices in Argentine primary care.

The elimination of SABAs in favor of a combined ICS/formoterol regimen is aligned with the latest recommendations of the Global Initiative for Asthma (GINA).[1] The findings support a paradigm shift in asthma management, advocating the abandonment of SABA monotherapy due to its associated risks of exacerbations and mortality. These findings have significant implications for clinical practice, suggesting that transitioning to SABA-free protocols may optimize patient outcomes.

Limitations

Although the ReferID tool has not undergone extensive psychometric validation comparable to the Severe Asthma Questionnaire (SAQ), it has been adapted and translated into 21 languages and is being implemented in more than 30 countries, suggesting strong face validity and clinical utility.[4]

The comparative analysis of ReferID in two distinct clinical settings introduces potential limitations related to contextual heterogeneity. Differences in healthcare infrastructure, staff training, patient demographic characteristics, and asthma management protocols may influence the performance and interpretation of the tool. Temporal bias was significant in the context of the pandemic. However, this favored our results because during 2020-2021 there was a marked reduction in asthma exacerbation rates; in this regard, it could be speculated that without the pandemic, the SABA group would have had

even worse outcomes.[9] Finally, the lack of pulmonary function testing and validated asthma questionnaires, such as the Asthma Control Test (ACT) must be considered.

CONCLUSION

This study provides further evidence that replacing short-acting beta-2 agonists with budesonide/formoterol, combined with specialized follow-up, improves asthma control and reduces severe asthma exacerbations in a low-income country. The complete elimination of salbutamol exceeds current guidelines and also offers an alternative approach to improving the quality of life of patients with asthma in Argentina.[6]

Conflict of interest

LJN received speaker fees from Novartis and AstraZeneca, and travel support from Boehringer Ingelheim and AstraZeneca. MS received fees for participating in medical education programs from AstraZeneca, GlaxoSmithKline, Sanofi, and ELEA. DP received fees as a speaker and for participating in advisory boards for GlaxoSmithKline, AstraZeneca, Sanofi, and ELEA. NB and OMF have no conflicts of interest to declare.

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