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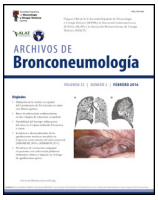

Special article

Expert Statement on the Single-Agent Use of Inhaled Bronchodilator in the Treatment of Stable Mild-Moderate Chronic Obstructive Pulmonary Disease☆

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ABSTRACT

Objective: To describe the evidence- and experience-based expert consensus on the use of single-agent bronchodilators in patients with stable mild-moderate chronic obstructive pulmonary disease (COPD).
Methods: Using Delphi methodology, a panel of 7 respiratory medicine experts was established, who, in the first nominal group meeting defined the scope, users, and document sections. The panel drew up 14 questions on the use of single-agent bronchodilators in patients with mild-moderate stable COPD to be answered with a systematic review of the literature. The results of the review were discussed in a second nominal group meeting and 17 statements were generated. Agreement/disagreement with the statements was tested among 16 different experts including respiratory medicine experts and primary care physicians. Statements were scored from 1 (total disagreement) to 10 (total agreement). Agreement was considered if at least 70% voted ≥7. The level of evidence and grade of recommendation of the systematic literature review was assessed using the Oxford Center for Evidence-based Medicine levels.
Results: A total of 12 of the 17 statements were selected. Specific statements were generated on different profiles of patients with stable mild-moderate COPD in whom single-agent bronchodilators could be prescribed.
Conclusions: These statements on the use of single-agent bronchodilators might improve the outcomes and prognosis of patients with stable mild-moderate COPD.

Documento de expertos del uso de broncodilatadores inhalados en monoterapia en el tratamiento de la EPOC estable leve-moderada

Palabras clave:
Enfermedad pulmonar obstructiva crónica
Broncodilatadores
Monoterapia
Aseveraciones

RESUMEN

Objetivo: Describir el acuerdo entre expertos basado en la evidencia científica y en la experiencia sobre el uso de broncodilatadores inhalados en monoterapia en pacientes con enfermedad pulmonar obstructiva crónica (EPOC) estable leve-moderada.

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Métodos: Se siguió la metodología Delphi. Se seleccionó un grupo coordinador de 7 neumólogos que, en una primera reunión nominal, definieron el alcance, los usuarios, los apartados del documento y generaron 14 preguntas sobre el uso de broncodilatadores inhalados en monoterapia en pacientes con EPOC estable leve-moderada para ser contestadas por una revisión sistemática. Los resultados de la misma se discutieron en una segunda reunión nominal del grupo, en la que se generaron 17 aseveraciones. El grado de acuerdo con las aseveraciones, que se extendió a 16 expertos más (neumólogos y médicos de atención primaria), se votó según una escala de 1 (total desacuerdo) a 10 (total acuerdo), definiéndose el acuerdo como una puntuación ≥7 por al menos el 70% de los participantes. El nivel de evidencia y el grado de recomendación de la revisión sistemática se clasificaron según el modelo del *Center for Evidence-Based Medicine* de Oxford.

Resultados: Finalmente se aceptaron 12 de las 17 aseveraciones. Incluye aseveraciones específicas sobre distintos perfiles de pacientes con EPOC leve-moderada estable sobre los que se puede pautar un broncodilatador inhalado en monoterapia.

Conclusiones: En los pacientes con EPOC leve-moderada estable estas aseveraciones sobre el uso de la broncodilatación en monoterapia pueden ayudar en el manejo de estos pacientes.

Introduction

Chronic obstructive pulmonary disease (COPD) is a highly prevalent disease among the Spanish population that places a heavy burden on both the patient and the health and social welfare system.[1–3] In Spain, the EPISCAN study reported a prevalence of 10.2% among the adult population aged between 40 and 80 years,[1,4,5] along with a high rate of underdiagnosis, particularly in individuals with mild disease and/or few symptoms.[6]

In recent years, new drugs and studies in patients with stable COPD have prompted several scientific societies and expert groups, both in Spain and in other countries, to draw up statements on the use of bronchodilators, which have been included in the consensus recently published by GOLD and other similar documents.[7–14] Professionals responsible for the care of COPD patients with stable disease are currently expressing interest in the need to define and clarify the role of bronchodilators in monotherapy, in dual therapy and even as part of triple therapy in combination with inhaled corticosteroids.[15]

This document aims to define the degree of agreement among experts, to describe the available evidence regarding the management of patients with stable mild-to-moderate COPD, defined as $FEV_1 \geq 50\%$, and to help clarify possible questions and areas of controversy in the use of single-agent bronchodilators. We present a series of statements that are intended to improve quality of care and assist in therapeutic decision-making, and should not be interpreted in any way as guidelines or as a COPD treatment protocol. In short, this document is presented as a tool that may optionally be adopted by clinicians involved in the management of these patients.

Methods

Nominal group techniques and Delphi methodology were used to prepare this document.[16] In short, this is an expert consensus document generated by a group of professionals who undertook an extensive, systematic review of the literature in order to draw up statements about topical and/or controversial aspects that may be of value to their colleagues involved in the treatment of these patients. We insist that this not a treatment protocol or guideline, but rather a clinical tool. The degree of agreement was established using Delphi methodology, and the existing level of evidence for each of the recommendations is described.

The document was prepared by distributing tasks and relaying comments to the participants, with the help of a systematic review of the literature.

The steps followed are set out in detail below, in Fig. 1.

Phase 1. First Nominal Group Meeting

A group of 7 respiratory medicine experts with recognized expertise in the management of COPD patients was initially selected on the basis of the following criteria: interest, demonstrated experience in the area, Medline publications in the last 5 years, participation in research projects in the specific area of the expert statement, membership of national or international scientific societies, and geographical diversity (in order to represent different organizational healthcare models).

The objective, scope, users, and sections of the document were defined in the first nominal group meeting. Participants also agreed to perform a systematic review of the literature on different aspects of bronchodilation in COPD patients, based on a list of research questions (Table 1). These questions were generated from a series of issues considered by the experts to be topical and/or controversial in the specific area of the expert statement.

Phase 2. Systematic Review of the Literature

A research protocol was established and the questions generated in the previous phase (Table 1) were used to define the PICO: population (P), intervention (I), comparison (C) and outcomes (O). The PICO was used to design the search strategy and the inclusion and exclusion criteria of the review were defined in depth. Studies were selected that included adults with stable mild-to-moderate COPD (according to the different criteria developed by GOLD over time, but primarily patients with $FEV_1 \geq 50\%$ predicted value), receiving long-acting muscarinic antagonists (LAMA) (tiotropium, glycopyrronium, aclidinium, umeclidinium) and/or inhaled long-acting β_2-agonists (LABA) (salmeterol, formoterol, vilanterol, indacaterol, olodaterol), irrespective of the dose, type, combinations with inhaled corticosteroids or other LABAs or LAMAs, versus a valid comparator group, placebo or other LABA or LAMA. These studies also had to include an analysis of clinical efficacy data, with at least one of the following parameters: dyspnea (functional class), exacerbation, quality of life, FEV_1, lung volumes, inspiratory capacity, physical activity, exercise capacity, hospitalization, comorbidities, anxiety/depression, safety (cardiovascular, osteoporosis, mortality, etc.), or cost-effectiveness. Finally, studies with the following designs were included: meta-analyses, systematic reviews, clinical trials (>1 week duration). With regard to observational studies (including cross-sectional studies), only good