Arch Bronconeumol. 2015;51(4):193–198

ARCHIVOS DE BRONCONEUMOLOGIA

www.archbronconeumol.org

Special article

"Correct Use of Inhaled Corticosteroids in Chronic Obstructive Pulmonary Disease": A Consensus Document☆

Bernardino Alcázar Navarrete,[a,*] Ciro Casanova,[b] Marc Miravitlles,[c] Pilar de Lucas,[d] Juan Antonio Riesco,[e] José Miguel Rodríguez González-Moro[d], on behalf of the Working Group "Consensus document on the appropriate use of inhaled corticosteroids in COPD"[◊]

[a] *Neumología, Área integrada de gestión de Medicina, Hospital de Alta Resolución de Loja, APES Hospital de Poniente, Granada, Spain*
[b] *Servicio de Neumología, Unidad de Investigación, Hospital Universitario Nuestra Señora de la Candelaria, Tenerife, Spain*
[c] *Servicio de Neumología, Hospital Universitari Vall d'Hebron, Barcelona, Spain*
[d] *Servicio de Neumología, Hospital General Universitario Gregorio Marañón, Madrid, Spain*
[e] *Servicio de Neumología, Hospital San Pedro de Alcántara, Cáceres, Spain*

ARTICLE INFO

Article history:
Received 25 July 2014
Accepted 6 November 2014
Available online 3 March 2015

Keywords:
Chronic obstructive pulmonary disease
Inhaled corticosteroids
Guidelines

ABSTRACT

Introduction: Indications for inhaled corticosteroids (IC) in combination with long-acting bronchodilators (LABD) are well defined in clinical practice guidelines. However, there are some doubts about their efficacy and safety. The aim of this document is to establish an expert consensus to clarify these issues.
Method: A coordinator group was formed, which systematically reviewed the scientific evidence with the aim of identifying areas of uncertainty about the efficacy of ICs, the adverse effects associated with their use and criteria for withdrawal. Their proposals were submitted to a panel of experts and the Delphi technique was used to test the level of consensus.
Results: Twenty-five experts participated in the panel, and consensus was reached on the use of IC in the mixed chronic obstructive pulmonary disease (COPD)-asthma phenotype and in frequent exacerbators, and on not using IC in association with LABD for improving lung function in COPD. There was no general consensus on restricting the use of IC to prevent adverse effects. The panel did agree that IC withdrawal is feasible but should be undertaken gradually, and patients who have discontinued must be evaluated in the short term.
Conclusions: Consensus was reached regarding the indication of IC in mixed COPD-asthma and frequent exacerbator phenotypes. The potential for adverse effects must be taken into consideration, but there is no consensus on whether limiting use is justified. The withdrawal of ICs was uniformly agreed to be feasible.

Documento de Consenso "Uso adecuado de los corticoides inhalados en la enfermedad pulmonar obstructiva crónica"

Palabras clave:
Enfermedad pulmonar obstructiva crónica
Corticoides inhalados
Normativas

RESUMEN

Introducción: Las indicaciones de los corticoides inhalados (CI) asociados a broncodilatadores de larga duración (BDLD) están bien definidas en las guías de práctica clínica. Sin embargo, existen áreas de incertidumbre acerca de su eficacia y seguridad. El objetivo de este documento es establecer un consenso de expertos acerca de estas áreas.

☆ Please cite this article as: Alcázar Navarrete B, Casanova C, Miravitlles M, de Lucas P, Riesco JA, Rodríguez González-Moro JM. Documento de consenso "Uso adecuado de los corticoides inhalados en la enfermedad pulmonar obstructiva crónica". Arch Bronconeumol. 2015;51:193-198.

* Corresponding author.
E-mail address: balcazar@telefonica.net (B. Alcázar Navarrete).

[1] The members of the Working Group "Consensus document on the appropriate use of inhaled corticosteroids in COPD" listed in Appendix A.

1579-2129/

Método: Se constituyó un grupo coordinador que realizó una revisión sistemática de la evidencia científica para proponer cuestiones que reflejaban áreas de incertidumbre relativas a la eficacia de los CI, los efectos adversos asociados a su empleo y los criterios para su retirada. Estas aseveraciones fueron sometidas a un panel de expertos mediante el método Delphi para comprobar el grado de consenso.
Resultados: Participaron en el panel 25 expertos, que alcanzaron el consenso en la indicación de CI en el fenotipo mixto EPOC-asma, en su empleo en el paciente con agudizaciones frecuentes y en no añadir CI a BDLD para mejorar la función pulmonar del paciente con EPOC. En general, no hubo consenso en restringir el uso de CI motivado por sus efectos adversos. En cambio, el panel alcanzó el consenso en que la retirada del CI es factible pero debe hacerse de forma gradual y evaluando a corto plazo a los pacientes a los que se les retire.
Conclusiones: Existe consenso en la indicación de CI en pacientes con fenotipo mixto EPOC-asma y agudizador frecuente. Se deben considerar los posibles efectos adversos, pero no existe consenso en sí justifican restringir su indicación. También existe consenso en que la retirada de CI es factible.

Introduction

Chronic obstructive pulmonary disease (COPD) is highly prevalent. Data from Spain, based on the EPISCAN study,[1] suggest that it affects 10.2% of Spanish adults aged between 40 and 80 years. Worldwide, it is the third cause of death[2] and the fifth most burdensome disease in terms of disability-adjusted life years.[3]

Spanish COPD guidelines (GesEPOC) recommend the use of long-acting bronchodilators (LABD) as first line treatment, alone or in combination with other drug families (long-acting beta-agonists [LABA] and long-acting muscarinic antagonists [LAMA]), reserving the use of LABA+inhaled corticosteroids (IC) for frequent exacerbators with FEV1 <60% or mixed COPD-asthma phenotype, irrespective of severity.[4] This is in line with the GOLD 2011 strategy that positions IC+LABA as treatment for patients with severe COPD with frequent exacerbations.[5]

Numerous Spanish and international observational studies performed in different care settings have detected intensive use of ICs alone or combined with LABD in COPD patients. In Spain, several studies[6–8] have shown that over 60% of patients with mild COPD receive ICs (alone or in combination with LABDs), generally at high doses, irrespective of the care setting. This is in stark contrast with studies indicating that the mixed COPD-asthma phenotype is identified in less than 20% of patients,[9] and that only one third of patients are frequent exacerbators.[10]

In some cases, COPD patients receive combination IC+LABD without a clear indication. Others return to clinical stability after an initially correct indication, but continue with the treatment in the long-term. The beneficial effect of IC in stable COPD in terms of reducing exacerbations and improving other health outcomes is widely supported in the literature. However, it remains unclear whether the response is universal or if it only occurs in a subgroup with certain characteristics, known as IC responders. Moreover, these benefits are accompanied by potentially serious side effects derived from long-term use. In view of these considerations, a consensus document has been developed with the aim of determining the level of agreement in various areas where the use of IC+LABD may be unclear, in order to establish criteria for the appropriate use of IC in stable COPD.

Material and Methods

This consensus document was drawn up by a group of professionals involved in the treatment and research of COPD with the aim of standardizing the use of IC in stable COPD. Members of the consensus panel were selected on the basis of their research activities in COPD, their active participation in scientific forums, and their involvement in scientific societies dedicated to COPD care. The consensus process took place in 2 phases: in the first phase, a coordinator group was set up, consisting of the 6 authors of the document. The scientific evidence for the use of ICs in stable COPD was systematically reviewed. Three areas of interest were defined: (1) clinical benefits of the use of IC+LABD in stable COPD; (2) associated risks; and (3) evidence for IC withdrawal in stable COPD. In a second phase, after review of the evidence, areas of uncertainty in which expert opinion might converge in a consensus were detected for each area of interest. A total of 20 statements addressing these areas of uncertainty were drawn up and submitted to the panel for consensus. These questions were formulated exclusively by the members of the coordinator group, without the help of any external advisors, and submitted to the working group along with the complete review of the scientific evidence. Comments and suggestions for amending certain areas of the document or re-wording the questions for better understanding were noted. The expert group was given sufficient time to analyze the information provided and to make suggestions to the coordinator group before the voting process commenced.

The Delphi method was used to determine the level of agreement of the experts with regard to the statements on the use of IC in stable COPD. In this method, a questionnaire completed by a panel of experts is used to explore a route map for change. A summary of the expert opinions (in the form of quantitative evaluations and written comments) is provided as feedback to the same experts as part of the next round of the questionnaire.[11] This methodology has already been used on other occasions in the area of COPD.[12,13]

The consensus participants individually assessed their level of agreement with each statement on a 9-point Likert scale, ranging from 1 (completely disagree with the statement) to 9 (completely agree with the statement). These scores were divided into 3 final groups: agree (7–9 points), neither agree nor disagree (4–6 points) and disagree (1–3 points). Voting took place in the first round in a face-to-face meeting using an interactive voting system (www.powervote.com). Any questions that did not achieve consensus in the first round of voting were submitted to a second, final round and drafted, compiled and analyzed using online survey software (www.surveymonkey.com). Consensus for each statement was established if at least 90% of the panel indicated their agreement with the statement in any of the 2 rounds, and the criterion for majority vote was met if at least 70% of the participants indicated agreement with the statement in any of the 2 voting rounds.