



REVIEW

# Long-acting bronchodilators improve Health Related Quality of Life in patients with COPD



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## KEYWORDS

Long-acting  
bronchodilators;  
COPD;  
Quality of life;  
Health status

## Summary

**Background:** Long-acting bronchodilators are first-line treatment for chronic obstructive pulmonary disease (COPD), and their efficacy on lung function and clinical parameters is recognized.

**Objective:** To explore the available evidence about the effects of long acting bronchodilators on Health Related Quality of Life (HRQoL) and Health Status (HS) in clinical research.

**Methods:** Randomized controlled trials published till December 2012 evaluating HRQoL/HS in COPD by means of validated questionnaires were analysed.

**Results:** Fifty-one trials on Long acting  $\beta_2$  agonist (LABA) and Long acting Anticholinergic (LAMA) met the inclusion criteria. A total of 37,225 moderate-severe COPD patients testing 6 drugs, 12 different devices and 22 different dosages, with a study duration ranging from 4 weeks to 4 years were studied. A statistical significant HRQoL/HS improvement was reached in 93% of the studies. Nevertheless, the Minimal Important Difference (MID) was reached in 70,6% of the studies considering the difference between baseline and end of the study, and in 50% when comparing active treatment and placebo.

**Conclusions:** The data coming from the review support the efficacy of long acting bronchodilators in improving HRQoL/HS of COPD patients. Further research evaluating HRQoL/HS as primary outcome and according to guidelines on Patient Reported Outcomes is needed.

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## Introduction

Health Related Quality of Life (HRQoL) and Health Status (HS) represent the Patient Reported Outcomes (PROs) most frequently assessed in chronic obstructive pulmonary disease (COPD). HRQoL refers to the impacts of a disease and its therapy upon a patient, as perceived by the patient himself [1–3]. HS is part of the broader concept of HRQoL, and can be defined as the ability of a subject to be skillful in a variety of physical, emotional and social activities [4]. Both PROs are assessed by means of validated questionnaires usable for all health conditions (generic questionnaires, e.g. SF-36, EQ5D) [5] or specifically addressed to COPD (specific questionnaires, e.g. the COPD-specific version of the St. George's Respiratory Questionnaire - SGRQ) [6].

HRQoL and HS are considered relevant in clinical research, daily practice and regulatory processes [7–16]. The European Medicines Agency (EMA) [14] suggests that, especially in non life-threatening chronic conditions, when two drugs show similar efficacy, PROs could be useful in defining the drug to be recommended. The role of patient's perspective is also underlined by the GRADE system [17], which includes all patients' preferences and values as cornerstones in the process of formulating recommendations, thus contributing to bring scientific research to real life.

Moreover, the "Global Initiative for Chronic Obstructive Lung Disease" (GOLD) guidelines have recently proposed that the classification of severity should consider, besides pulmonary function or exacerbation history, symptoms or HS [18].

The aim of the present review was to examine the available scientific evidences about the effects of long acting bronchodilators, the mainstay treatment in COPD [18,19], on HRQoL and HS in order to draw considerations useful in daily practice and suggest potential areas for future research.

## Search strategy

Randomized controlled trials evaluating HRQoL/HS in COPD by means of validated questionnaires and published till December 2012 were searched in PubMed, using the following key words:

- COPD
- Chronic obstructive pulmonary disease
- HRQoL
- Health Status (HS)
- Long acting  $\beta_2$  agonist (LABA) (salmeterol, formoterol, indacaterol, vilanterol)
- Long acting Anticholinergic = Long acting muscarinic antagonist (LAMA) (tiotropium, aclidinium, glycopyrronium)

For each selected study, the following issues were taken into account:

- HRQoL/HS Total and domains scores (when available)
- Minimal Important Difference (MID), that is the smallest difference that patients perceive as important [20] (reported by the authors or calculated by reviewers according to figures and tables).
- Presence of complete HRQoL/HS data at each scheduled visit
- HRQoL/HS total score mean change at the end of the study in the treatment group(s)
- Difference in HRQoL/HS total score between active and placebo group

## Results

A total of 44 trials evaluated the impact of LABA and LAMA on HRQoL and HS with validated questionnaires. Table 1 reports the characteristics of the questionnaires used in the 44 trials.

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