

Medications for chronic obstructive pulmonary disease: a historical non-interventional cohort study with validation against RCT results

Kevin Wing,^{1*} Elizabeth Williamson,²
James R Carpenter,² Lesley Wise,¹
Sebastian Schneeweiss,^{3,4} Liam Smeeth,¹
Jennifer K Quint⁵ and Ian Douglas¹

¹Department of Non-communicable Disease Epidemiology, Faculty of Epidemiology and Population Health, London School of Hygiene & Tropical Medicine, London, UK

²Department of Medical Statistics, Faculty of Epidemiology and Population Health, London School of Hygiene & Tropical Medicine, London, UK

³Department of Epidemiology, Harvard Medical School, Boston, MA, USA

⁴Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital, Boston, MA, USA

⁵National Heart and Lung Institute, Imperial College London, London, UK

*Corresponding author kevin.wing@lshtm.ac.uk

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Plain English summary

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Chronic obstructive pulmonary disease affects 3 million people in the UK and is characterised by breathing difficulties that get worse over time, with sudden acute symptoms (exacerbations), possibly requiring hospitalisation. The evidence for use of medicines for treating chronic obstructive pulmonary disease comes from randomised controlled trial results. Randomised controlled trials generally include younger people with severe disease who do not have any other illnesses apart from chronic obstructive pulmonary disease, meaning that the effectiveness of these trials in all people with chronic obstructive pulmonary disease is unknown. Very large databases of anonymous electronic health records captured during NHS consultations can be used to study patients excluded from trials. However, confidence in results from studies using these data can be low because of fears of unaccounted bias, as patients are not randomised to treatment. In this project, we selected a group of patients from a very large electronic health record database called the Clinical Practice Research Datalink who were very similar to participants in a well-known large chronic obstructive pulmonary disease randomised controlled trial [the TORCH (TOwards a Revolution in COPD Health) trial]. When we analysed data from these patients, we found very similar results to the TORCH trial in relation to the reduction of exacerbations, development of pneumonia and time until death, when comparing one chronic obstructive pulmonary disease treatment with another. Having shown that our methods could be trusted to produce valid results when comparing one chronic obstructive pulmonary disease treatment with another, we then went on to analyse patients in the Clinical Practice Research Datalink who would have been excluded from the TORCH trial for the following reasons: aged > 80 years, having asthma as well as chronic obstructive pulmonary disease, or having only mild chronic obstructive pulmonary disease. For exacerbations, we found that, for people with milder chronic obstructive pulmonary disease, one of the treatments we studied seemed to work better than in the trial. For the analysis of mortality, we found that, for people with asthma as well as chronic obstructive pulmonary disease, one of the treatments seemed not to work so well, with more people dying. Future studies are needed in different populations (such as in a database from another country) to confirm these results.

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