

Off-label drugs prescribed for breathlessness may do more harm than good, warn scientists

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Credit: Puwadon Sang-ngern from Pexels

A new study from King's College London shows that off-label prescriptions of a common antidepressant doesn't help breathlessness in patients with respiratory disease—and may cause side effects.

Researchers warn prescribing medicines for a use which it has not been licensed could make things worse, even though the prescriber was trying to help.

The findings, presented at the [ERS Congress](#) in Vienna and published in

The Lancet Respiratory Medicine, show the desperate need for options to treat the symptoms of severe breathlessness, as there are no drugs licensed for this in the UK or most countries.

The severe breathlessness caused by [chronic respiratory diseases](#) greatly impacts a patient's quality of life. As well as creating substantial clinical challenges and [health care costs](#). Most patients with diseases like this have few options to help with their symptoms.

Ahead of the trial, researchers surveyed doctors in respiratory and [palliative medicine](#) and found doctors were often using off-label prescribing—where a clinician prescribes a medicine for use in a different way than that stated in its license. Various off-label prescriptions were being used, including common anti-anxiety and anti-depressant drugs like benzodiazepines and SSRIs.

Mirtazapine, a common antidepressant, was one of the types of drugs being prescribed. Case series and [early studies](#) showed it had potential. However, in this international trial, the first large-scale study to be done, researchers found that mirtazapine does not improve breathlessness in patients with respiratory disease compared with placebo. They also found that patients receiving mirtazapine had slightly more side effects and needed more care from hospitals and family members.

Chronic respiratory diseases affect 454.6 million people worldwide, with numbers predicted to increase with an aging population. Over 217 million people globally have [chronic obstructive pulmonary disease](#) (COPD) or [interstitial lung disease](#) (ILD), both of which can cause severe breathlessness as they progress.

Off-label use can be as safe as on-label use if based on good evidence. It is often used when symptoms can't be controlled with licensed medicines, particularly in serious illnesses. This is common in severe

breathlessness care, making proper evaluation of medicines vital. Off-label prescribing doesn't mean a doctor is making a mistake; it often happens when there are no other options to manage symptoms like breathlessness.

First author Professor Irene Higginson, King's College London said, "Breathlessness is a widespread issue in palliative care as a symptom of respiratory diseases, heart disease and some cancers. When severe, it's distressing for patients, as well as their caregivers, family and friends. It diminishes people's quality of life and often leads to considerable health and social care use, including driving emergency hospital admissions.

"Despite being a widespread issue, we still don't have effective treatments available. As such, many doctors turn to off-label prescribing, trying to help their patients.

"Our earlier survey found that 19% of respiratory and 11% of palliative physicians frequently recommend antidepressants for severe breathlessness in COPD, so these medicines are already being used off-label.

"This new trial concludes that mirtazapine is not recommended for the treatment of breathlessness, that the use of unlicensed medicines should be approached with caution and that it's crucial to subject medicines in [palliative care](#) to rigorous trials.

"We need further research into potential therapies for severe breathlessness. In the meantime, we recommend clinicians use early identification and non-pharmacological approaches, such as those offered from breathlessness support services, to treat the [symptom](#)."

More information: Irene Higginson et al, *The Lancet Respiratory Medicine* (2024)

Provided by King's College London

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