

Researchers question safety of mist inhalers for delivering common drug for chronic lung disease

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People who use a mist inhaler to deliver a drug widely prescribed in more than 55 countries to treat chronic obstructive pulmonary disease (COPD) may be 52 percent more likely to die, new Johns Hopkins-led research suggests.

The findings, published by *BMJ*, the [British Medical Journal](#), raise concerns not only about the mist inhaler -- a device that delivers the soluble form of the medication tiotropium -- but also about the drug itself. The mist inhaler has not yet gained regulatory approval in the United States, but the drug in its powdered form is commonly used to treat COPD here.

"What we think is going on is that the mist inhaler is delivering a higher concentration of tiotropium than it should be and that may be increasing the risk of death," says Sonal Singh, M.D., M.P.H., an assistant professor of general internal medicine at the Johns Hopkins University School of Medicine and the lead author of the study.

COPD, the fourth leading cause of death worldwide, includes the chronic lung diseases [emphysema](#) and bronchitis, which are usually due to decades of smoking. Tiotropium is routinely given to COPD patients with symptoms such as [shortness of breath](#), and those with hospitalizations as a result of their [breathing problems](#).

Singh says the increased deaths linked to the inhaler are primarily from cardiovascular disease. Anticholinergics, the class of drugs that includes tiotropium, increase the risk of [heart rhythm disturbances](#) (arrhythmias), especially among those with existing [heart conditions](#).

In the United States and throughout the world, the medication is available in a powdered form and sold under the brand name Spiriva. Fifty-five countries now allow tiotropium to also be administered using the mist inhaler. Overseas, people with poor manual dexterity tend to be prescribed the mist inhaler because it is easier to use.

For the study, Singh and his colleagues from the United States and the United Kingdom reviewed and analyzed published findings comparing treatment with the mist inhaler containing tiotropium to treatment with a mist inhaler containing a placebo. They looked at five randomized, controlled trials, which included data on more than 6,500 participants. Both the drug and the placebo were delivered with the Respimat Soft Mist Inhaler. The results show a 52 percent increased risk of death among those who used the mist inhaler with tiotropium, as compared to the mist inhaler with placebo. Singh says his new research shows one excess death due to the mist inhaler for every 124 patients with chronic obstructive lung disease treated for one year.

What concerns Singh now is that there is a large, 17,000-patient, multicenter study underway in several countries, including the United States, comparing the two devices using the same drug.

"I'm worried about the participants assigned to the use of the mist inhaler," he says. "They are not fully informed about what could be serious safety issues with the device."

Singh emphasizes that while the current study only focused on tiotropium delivered through mist inhaler, the findings also raise serious

questions about whether the drug tiotropium, in particular, and the class of inhaled anticholinergics, in general, are safe for COPD patients, particularly those with known heart problems. The shortness of breath caused by COPD can be treated with other long-acting bronchodilators, such as the long-acting beta-agonists. The risk of additional hospitalizations for these chronic lung diseases can be reduced somewhat by other COPD inhalers. At this point, Singh recommends that patients discuss the risks and benefits of COPD treatments with their doctors.

In New Zealand, a warning about a possible link between cardiovascular death and the mist inhaler has been included in the package insert for the device. In the United Kingdom, health officials advise caution in prescribing the mist inhaler to patients with arrhythmias.

Provided by Johns Hopkins Medical Institutions

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