

Temple-led study finds no benefit in taking statin drugs for COPD exacerbation prevention

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A statin drug commonly used to lower cholesterol is not effective in reducing the number and severity of flare ups from chronic obstructive pulmonary disease (COPD), according to the results of a large multicenter clinical trial designed and directed by Gerard J. Criner, MD, Director of Pulmonary and Critical Care Medicine at Temple University Hospital in Philadelphia, PA.

Dr. Criner, who served as the study's Principal Investigator, will report the results on May 18 at the American Thoracic Society's annual international scientific meeting in San Diego, with simultaneous publication of the findings online in the *The New England Journal of Medicine*.

The study rigorously tested the hypothesis that statin drugs may be beneficial to persons with COPD because of the drugs' purported anti-inflammatory effect. COPD, an inflammatory disease of the airways and lungs, is the third leading cause of death in the U.S. An estimated 12 million Americans are diagnosed with the disease and nearly 12 million more have impaired lung function, which indicates an underdiagnosis of COPD.

The disease is characterized by acute exacerbations, or flare-ups, which send the patient into episodes of coughing with increases in mucus, shortness of breath, wheezing and a feeling of tightness in the chest.

COPD exacerbations can precipitate repeated trips to the emergency department, hospitalizations, disability and a diminished quality of life. Some [patients](#) need oxygen to help them breathe.

"This is the first randomized, controlled trial to examine the question of whether the class of drugs called statins (simvastatin) may be useful in preventing COPD exacerbations," said Dr. Criner, Director of Temple's Lung Center and Professor of Medicine at Temple University School of Medicine. Multiple previous studies, all retrospective in design, had suggested a potential significant benefit of statins in improving lung function and decreasing the morbidity and mortality associated with acute COPD exacerbations.

"That turns out not to be the case," Dr. Criner said. "This study suggests that statins' purported non-cholesterol-lowering anti-inflammatory effects do not extend to COPD."

The study, funded by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health, was carried out at 45 sites in the U.S. and Canada, with Temple leading the way in the number of enrolled participants. The Canadian Institutes of Health Research also provided funding for the Canadian clinical centers. Of the study's 877 participants, 430 took 40 mg. daily of simvastatin, a common statin drug used to prevent heart attack and stroke, and 447 took a daily placebo, or dummy pill. They were followed for at least 12 months, and some as long as 36 months.

The study enrolled patients with moderate to severe COPD who were not taking statins for other medical indications. Volunteers, ranging in age 40 to 80, were current or former smokers, and met one of the following other criteria: they used oxygen supplementation either currently or in the past, they were prescribed systemic corticosteroids and or antibiotics in the past year, or had been at the ER or hospitalized with a flare-up in

the past year. The study excluded patients with diabetes or coronary heart disease, as well as patients who were not taking a statin drug but should have been because of their cardiovascular risk profile.

The study's primary outcomes measure was the rate of exacerbation, defined as the number of exacerbation events per participant year. Secondary outcome measures included time to first exacerbation, severity of exacerbations, quality of life and changes in lung function as measured by spirometry. Study participants, who all continued with their usual COPD treatment and care, were tracked throughout the study by clinic visits every three months and monthly phone calls.

Among the findings:

- COPD exacerbation rates were similar in the two groups: 1.36 per year among those taking simvastatin and 1.39 per year for the placebo group.
- The median number of days to first exacerbation also did not differ significantly: 223 days for simvastatin and 231 days for placebo.
- The severity of exacerbation was not impacted by whether the patient took simvastatin or placebo.
- There was no effect of simvastatin on lung function or general or disease-specific quality of life.
- The rates of adverse events (such as pneumonia) and deaths were similar for the two groups.
- As expected, at one-year follow-up, patients on the statin drug had lower cholesterol and triglyceride levels than those on placebo.

The study was stopped early because an interim analysis conducted by the data safety monitoring board demonstrated futility for simvastatin to provide benefit for COPD.

"In conclusion, 40 mg of daily simvastatin added to usual care did not reduce exacerbation rate or prolong time to exacerbation in moderate to severe COPD patients at risk for exacerbation," the researchers reported. "Furthermore simvastatin had no effect on lung function, quality of life, severe adverse effects or mortality."

Dr. Criner cautioned, however, that the finding that the statin drug has no benefit for prevention of COPD exacerbations does not mean that COPD patients should stop taking statins prescribed for cholesterol lowering or other cardiovascular indications.

"COPD patients benefit from the use of statins just like any other group of patients that benefit from statins according to established indications to reduce cardiovascular risk," Dr. Criner said. "What this study shows is that patients who do not meet already established criteria for statin therapy should not take statins only to prevent COPD exacerbations."

Temple is sending a letter to its study participants to advise them of that fact.

Because the study was limited to predominately moderately to severely impaired patients, it is not possible to say whether statin drugs might have been useful in patients who were less impaired. Another limitation of the study was that researchers did not analyze a blood biomarker called C-Reactive Protein (CRP) as a measure of inflammation to select patients to be enrolled into the study.

Dr. Criner said that despite the clinical trial's finding that the statin drug did not help with COPD flare-ups, information gleaned from this study should help inform other research into the inflammatory nature of COPD.

"What this does is allow us to pursue other avenues of anti-inflammatory

treatment so we can develop new therapies that are so desperately needed," he said. "More work is currently being done and planned to be done that will target more viable pathways and mechanisms to prevent or alleviate the consequences of COPD exacerbations."

Approximately 75 percent of the annual \$49.9 billion expended on COPD care is attributed to caring for patients with acute exacerbations. There are approximately 715,000 annual hospitalizations for COPD exacerbation nationally and about 34,000 hospitalizations annually in Pennsylvania.

The Temple Lung Center is a recognized national leader in clinical care, research and education for patients with COPD. It also provides comprehensive care for a full range of other lung diseases.

The Bottom Line: Statin Drugs Not Helpful for COPD Exacerbations

- 40 mg. of daily simvastatin ([statin drug](#)) added to usual care did not reduce exacerbation rate or prolong the time to exacerbation in patients with moderate to severe COPD.
- Simvastatin had no effect on lung function, quality of life, severe adverse events or mortality.
- The data do not demonstrate a therapeutic benefit from statins in patients with moderate to severe COPD.

Source: The STATCOPE Trial (Simvastatin in the Prevention of COPD Exacerbations)

COPD Facts

What is it?

Chronic Obstructive Pulmonary Disease, or COPD, is a group of diseases that cause airflow blockage and breathing problems. It includes emphysema, chronic bronchitis and in some cases asthma.

What causes COPD?

Tobacco smoke is a key cause of the development and progression of COPD in the U.S. Exposure to air pollutants in the home and workplace, genetic factors, and respiratory infections also factor in. In the developing world, indoor air pollution is thought to play a larger role in COPD.

How common is it?

- Chronic lower respiratory disease, primarily COPD, is the third leading cause of death in the U.S., causing approximately 135,000 deaths annually.
- An estimated 12.7 million Americans have COPD, though close to 24 million U.S. adults have impaired [lung function](#), which indicates an underdiagnosis of COPD.

Who's at most risk?

- People aged 65-74 years.
- Current or former smokers.
- Patients with a history of asthma.
- Non-Hispanic whites.
- Women.
- Individuals who are unemployed, retired or unable to work.
- Individuals with less than a high school education.
- People with lower incomes.

How is COPD treated?

Patients should undergo a comprehensive evaluation by a physician. Treatment can alleviate symptoms, decrease the frequency and severity of exacerbations, and increase the patient's ability to exercise. Treatment strategies include:

- Smoking cessation.
- Avoiding tobacco smoke and removing other air pollutants from the patient's home or workplace.
- Using medications to treat symptoms such as coughing or wheezing.
- Pulmonary rehabilitation programs to teach patients breathing strategies and energy-conserving techniques.
- Annual flu shots.
- Antibiotics to treat respiratory infections when appropriate.
- Supplemental oxygen for patients who have low blood oxygen levels.

Provided by Temple University

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