

COPD patients breathe easier with Lung Flute

September 26 2014, by Ellen Goldbaum

Patients with chronic obstructive pulmonary disease (COPD) report improved symptoms and health status when they use a hand-held respiratory device called the Lung Flute[®], according to a new study by the University at Buffalo. Usually caused by smoking, COPD, which includes chronic bronchitis and emphysema, is the third leading cause of death in the U.S.

The Lung Flute, manufactured by Medical Acoustics, (Buffalo), uses sound waves to break up mucus in the lungs. The device allows patients to clear lung mucus simply by blowing into the hand-held respiratory device, which produces a low frequency acoustic wave.

Published on Sept. 23 in *Clinical and Translational Medicine*, the 26-week study demonstrates that patients using the Lung Flute experience less difficulty breathing and less coughing and sputum production than a control group, which saw no change in COPD symptoms.

"This study confirms that the Lung Flute improves symptoms and health status in COPD patients, decreasing the impact of the disease on patients and improving their quality of life," says Sanjay Sethi, MD, principal author of the study and professor and chief, division of pulmonary, critical care and sleep medicine in the Department of Medicine, UB School of Medicine and Biomedical Sciences.

Photos of the Lung Flute and Sethi are at

<http://www.buffalo.edu/news/releases/2014/09/051.html>.

The device is approved by the Food and Drug Administration (FDA) to treat COPD and other lung diseases characterized by retained secretions and congestion. It also is approved by FDA to obtain deep lung sputum samples for "laboratory analysis and pathologic examination."

Colleagues of Sethi's in the UB medical school are now studying the Lung Flute for use in improving symptoms in asthma. The device is also being investigated for diagnostic use in tuberculosis and lung cancer.

The study followed 69 patients with COPD for six months; it was conducted at the Veterans Affairs Western New York Healthcare System (Buffalo VA) by researchers at the UB medical school.

"This study confirms and extends the results of a previous, 8-week study of 40 patients that was conducted in 2010 to obtain FDA approval for the Lung Flute," says Sethi, whose clinical practice is at the Buffalo VA.

He has led a series of clinical trials demonstrating the safety and efficacy of the Lung Flute, including those that played a key role in the FDA's approval of the device for diagnostic and therapeutic uses.

Improvement in the current study was demonstrated by responses reported by patients on the Chronic COPD Questionnaire, which assesses changes in COPD symptoms and the St. George's Respiratory Questionnaire, which measures quality of life. On both questionnaires, patients using the Lung Flute reported significant improvements.

In addition, the Body-Mass Index, Airflow Obstruction, Dyspnea and Exercise Capacity (BODE) score was measured repeatedly in the study. "The BODE index provides a more comprehensive assessment of COPD patients," explains Sethi. "As the disease worsens, the BODE index goes

up as it did in the control group. But for patients using the Lung Flute, the BODE index stayed flat."

Sethi adds that the study points to a potential decrease in exacerbations, flare-ups of respiratory symptoms, as a result of using the Lung Flute. Researchers are planning longer-term studies that will focus specifically on how the device affects exacerbations, a key part of what makes COPD patients sicker and leads to health care utilization.

Sethi notes that while similar devices have been developed for cystic fibrosis, the Lung Flute is the only one that has undergone extensive testing specifically for COPD patients. In a previous study comparing a device developed for cystic fibrosis with the Lung Flute, the Lung Flute was superior for COPD patients.

"All therapeutic studies on using the Lung Flute for COPD have been done here in Buffalo," says Sethi. "We have the biggest database by far on using the device in COPD. The Lung Flute is the only one that has been tested and been clearly shown to benefit COPD patients."

The research is the result of a partnership between UB and Medical Acoustics.

"Medical Acoustics has worked closely with UB's medical school since the company's founding in 2002," says Frank Codella, chief executive officer at Medical Acoustics. "We are very fortunate to have had access to UB's vast resources, including medical researchers of the caliber of Sanjay Sethi and his team, to lead many of the Lung Flute's clinical trials.

"Dr. Sethi is recognized as one of the leading COPD research professionals in the United States," Codella continues. "His research has resulted in the Lung Flute receiving FDA clearances for both obtaining

deep lung sputum samples for diagnostic use and for airway clearance therapy as well as a series of Phase IV studies such as the one being reported this week."

Adds Sethi: "The people at Medical Acoustics are open-minded and I was willing to help because I saw an unmet medical need. Our relationship satisfies my goal of getting therapies to patients, while it helps the company succeed, satisfying their goals of creating a viable business. That's the way academia and industry partnerships should work."

Provided by University at Buffalo

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