Measures Predict Need for Ventilation in COPD

BY MITCHEL L. ZOLER
Philadelphia Bureau

PHILADELPHIA — Three easily obtained clinical measures can predict who will probably need mechanical ventilation among newly hospitalized patients with an acute exacerbation of chronic obstructive pulmonary disease, based on an analysis of data from almost 100,000 patients.

Patients presenting to an emergency department with an acute exacerbation of COPD with a BUN level above 25 mg/dL, altered mental status, and a pulse of more than 109 beats/minute had about an 11% rate of mechanical ventilation during their index hospitalization, Dr. Andrew F. Shorr reported at the annual meeting of the American College of Chest Physicians.

In contrast, similar patients who lacked all three of those clinical signs had a 0.3% rate of mechanical ventilation later during their hospitalization, said Dr. Shorr, associate director for pulmonary and critical care medicine at the Washington (D.C.) Hospital Center.

Determining a patient's risk for needing mechanical ventilation early during hospitalization is important, Dr. Shorr said in an interview, because "if you know there is a high risk, you can arrange closer monitoring and an earlier start to ventilatory support. That's better than waiting until the patient is so sick that intubation is tenuous."

Also, "you don't want to put a patient [who has a high risk for needing mechanical ventilation] in an unmonitored room," he added. "With identification of high risk, you can put them in higher-level care."

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DR. SHORR

Dr. Shorr and his associates reviewed 98,036 patients admitted to any of 191 U.S. hospitals for acute exacerbation of COPD during 2004-2006. The sample was randomly divided into a derivation cohort and a validation cohort.

The researchers then took the derivation cohort and used classification and regression tree analysis to assess a long series of demographic, clinical, and hospital characteristics to find parameters that best distinguished patients who required mechanical ventilation from those who did not.

That analysis showed that three parameters worked well together to segregate patients into low- and high-risk groups. The three parameters were then tested using the validation cohort, and the results confirmed the initial finding. (See box.)

In both cohorts, the three parameters were able to account for slightly more than three-quarters of the risk for mechanical ventilation, Dr. Shorr said.

"These three markers don't have anything to do with the lungs," he noted. "Our hypothesis is that they are simple markers for end-stage organ dysfunction." A BUN level of greater than 25 mg/dL is a marker for volume depletion. Altered mental status is a marker for a patient who is hypoxic or hypercarbic. And a pulse rate of more than 109 beats/minute is a marker for shock, hypoxia, or acidosis.

In addition, all three are simple measures that don't require blood gas measurements or invasive testing, and they can be assessed with little interobserver variability.

At last year's annual meeting of the American College of Chest Physicians, Dr. Shorr and his associates reported that the same three measures could help predict the risk of death in patients hospitalized for an acute exacerbation of COPD. Patients who met all three criteria had a mortality rate of nearly 14%, compared with a rate of less than 1% among patients who met none of the three criteria.

The new finding that the scoring method also helps predict need for mechanical ventilation "adds to the biologic validity" of the assessment, Dr. Shorr said, adding that predicting the need for mechanical ventilation can affect management of a patient as much as predicting a high risk of death. ■

Quantifying the Risk of Mechanical Ventilation In COPD Patients

Number of assessment measures positive at time of initial hospitalization	Mechanical ventilation rate during hospitalization in the derivation cohort	Mechanical ventilation rate during hospitalization in the validation cohort
0	0.3%	0.3%
1	1.2%	1.2%
2	5.4%	5.5%
3	10.1%	12.4%

Note: The three measures assessed for this analysis were BUN level > 25 mg/dL; altered mental status; pulse rate > 109 beats/minute.

Source: Dr. Shorr

Bronchial Valve Approved for Postoperative Air Leaks in Lung

BY ELIZABETH MECHCATIE
Senior Writer

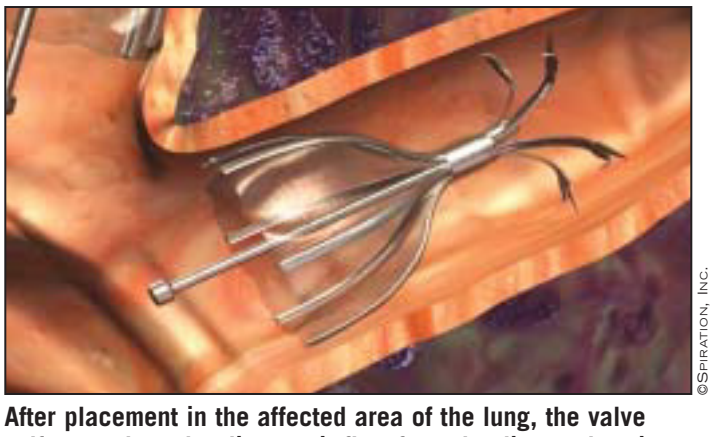
An implantable bronchial valve designed to control prolonged air leaks of the lung after lobectomy, segmentectomy, or lung volume reduction surgery has been approved by the Food and Drug Administration.

The IBV Valve System includes the valve, a catheter for inserting it, and a sizing kit to measure the target area for valve implantation, according to the FDA statement announcing the approval. The system is used to treat patients "who have undergone partial or total removal of a lung lobe or lung volume reduction surgery and who experience prolonged air leaks [present 7 days after surgery] or significant air leaks that may become prolonged," the FDA said.

The catheter containing the valve is passed through a bronchoscope, and the valve is then placed in the affected area of the lung, where it self-expands and redirects air flow from the diseased regions while allowing secretions and trapped air to pass through, according to Spiration Inc., the manufacturer. The valve expands and contracts with breathing and can be removed during a bronchoscopy.

The valve was approved under the Humanitarian Device Exemption program, which applies to devices for diseases or conditions that affect fewer than 4,000 people in the United States every year.

Approval was based on successful use of the valve in 58 patients with emphysema and 4 patients with prolonged air leaks, according to Spiration.



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After placement in the affected area of the lung, the valve self-expands and redirects air flow from the diseased regions while allowing secretions and trapped air to pass through.

The company plans to conduct a postapproval study to obtain more safety and efficacy information about the system.

The valve is being studied in a pivotal trial of U.S. patients with severe emphysema.

Patients aged 40-70 years with predominantly upper lobe emphysema and shortness of breath with exertion who have had inadequate responses to available medical treatments and who are either ineligible for or opposed to invasive surgery are being enrolled in the trial, according to Spiration.

The study is comparing response rates and serious adverse events at 6 months among those who have the valve implanted and controls, who undergo a diagnostic bronchoscopy with no valves implanted.

The approval "is an extremely important step for patients with emphysema," said Dr. Robert James Cerfolio, professor of surgery and chief of the section of thoracic surgery at the University of Alabama at Birmingham, who has had significant experience with these valves.

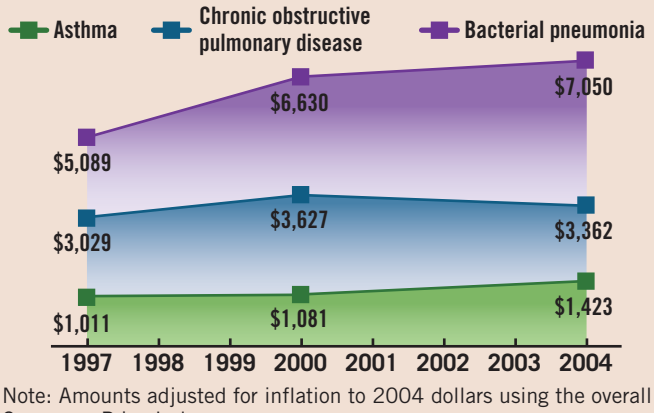
Dr. Cerfolio said in an interview that several well-designed studies have shown that "in properly selected patients, these one-way valves, which can be easily placed via a bronchoscope and which block the entry of air into emphysematous segments of the lung but allow for mucus exit, improve the breathlessness these patients experience." These studies include several presented in May 2008 at the American Thoracic Society meeting in Toronto.

"Although the mechanism of action is different than that seen in lung volume reduction surgery, the improvement in dyspnea in these patients may be just as good," Dr. Cerfolio noted in the interview, adding that the technique entails a 15- to 20-minute bronchoscopy, and thereby avoids the morbidity associated with surgery.

Dr. Cerfolio is an investigator in a study of the implantable bronchial valve. ■

DATA WATCH

Costs of Hospitalizations For Preventable Respiratory Conditions
(in millions of dollars)



Note: Amounts adjusted for inflation to 2004 dollars using the overall Consumer Price Index.
Source: Healthcare Cost and Utilization Project