

Gel Plugs Severe Air Leaks in Lung Surgery

BY MITCHEL L. ZOLER

FROM THE AMERICAN ASSOCIATION FOR
THORACIC SURGERY ANNUAL MEETING

TORONTO — A synthetic, absorbable gel designed to seal lung air leaks following lobectomy failed to produce a significant drop in all grades of air leaks during post-operative hospitalization in a randomized, multicenter study with 121 patients.

However, treatment with the gel significantly reduced the number of advanced, grade II and III air leaks compared with control patients in a post-hoc analysis that involved about two-thirds of the study's patients, Dr. Paul De Leyn said at the annual meeting.

This experience has guided Dr. De Leyn's use of the gel, PleuraSeal. "I use [the gel] in patients with a severe, grade II or III air leak," said Dr. De Leyn, a professor of thoracic surgery at University Hospital, Leuven, Belgium.

PleuraSeal applies to tissue surfaces as two separate liquids, a polyethylene glycol ester solution, and a trilycine amine solution. When mixed, the liquids form an absorbable hydrogel that adheres to the pleura surface, and then gradually absorbs over 4-8 weeks.

The study enrolled patients who developed intraoperative air leaks following lobectomy or segmentectomy at any of seven academic, tertiary thoracic units in five European countries. Randomization assigned patients to standard care or standard care plus application of the gel.

The 62 patients randomized to the gel group averaged 62 years, 98% underwent a lobectomy, and all had surgery for lung cancer. The 59 patients in the control group averaged 63 years, 98% underwent a lobectomy, and 97% had surgery for lung cancer.

The study design stratified patients by their risk scores, based on a combination of preoperative and intraoperative features, such as the patients' forced expiratory volume, whether they received preoperative chemo- or radiotherapy, and their number of leak sites.

High-risk patients made up 18% of the gel group and 10% of the control group. The air-leak grade before treatment averaged 2.4 in the control patients and 2.8 in the gel patients. After, the grades averaged 2.0 in the control patients and 0.4 in the gel-treated patients.

During the intraoperative period, gel treatment controlled all air leaks in 71% of patients, compared with 24% of control patients whose air leaks resolved, a statistically significant difference.

However, during the balance of their hospitalization, patients free from air leaks reached 31% in the control group and 42% in the gel-treated group, a difference that was not statistically significant for the study's primary end point.

Among the patients who began with grade II or grade III air leaks, 15% of the control patients and 44% of the gel-treated patients remained air leak free during hospitalization, a significant dif-

ference. Among patients with grade I air leaks, 50% of controls and 38% of the gel-treated patients remained air leak free during hospitalization, a non-significant difference.

There were no differences in air leak duration, time needed for chest-tube drainage, amount of fluid

removed via chest tubes, total duration of hospitalization, or complication rate.

No patient died while hospitalized, and none had an adverse event attributable to gel, including no effects on liver or kidney function, lung expansion or pneumothorax. ■

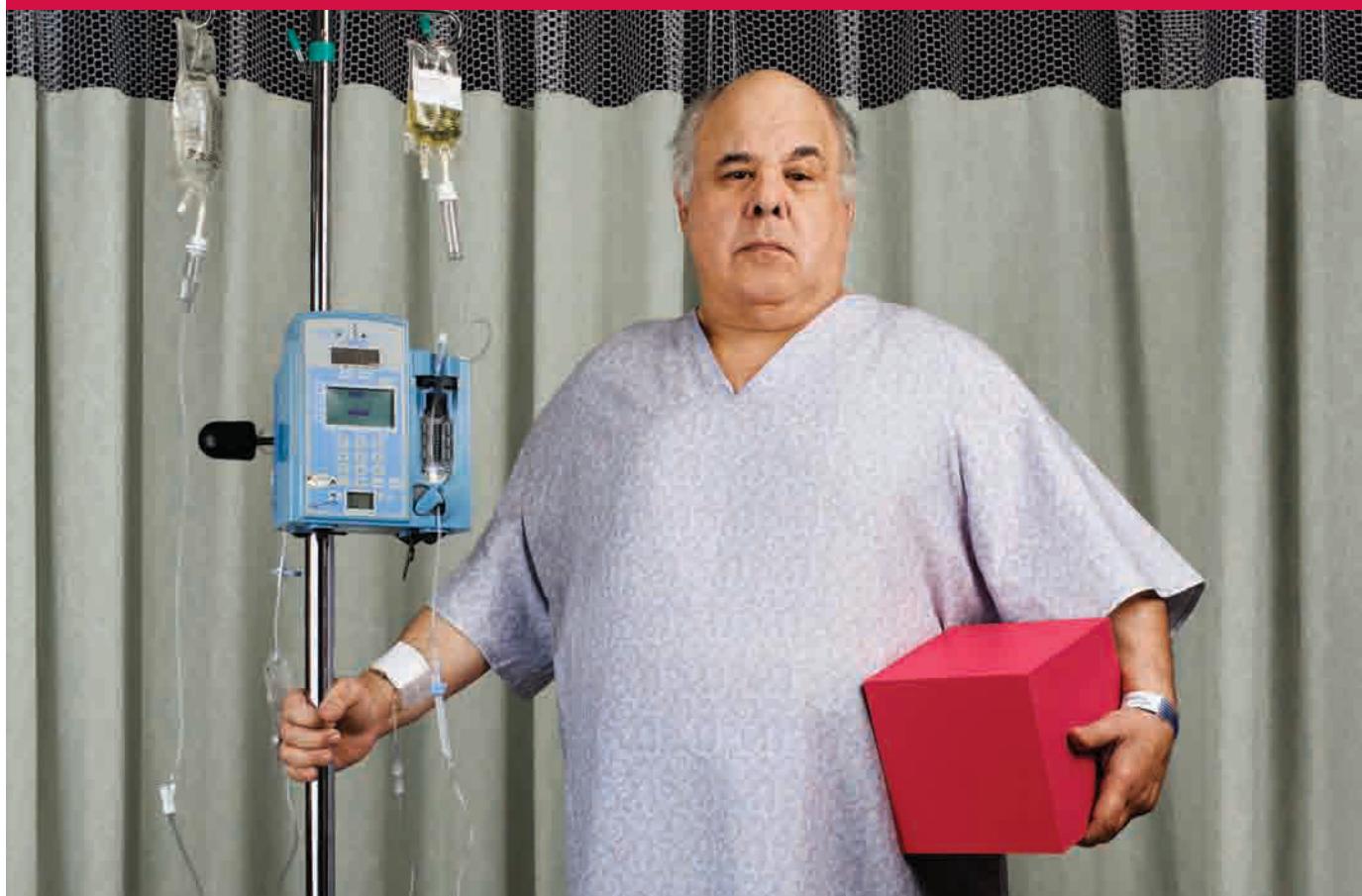
VITALS

Major Finding: Gel treatment of intraoperative air leaks during lung surgery led to a 42% rate of freedom from air leaks during hospitalization compared with a 31% rate in control patients, a difference that was not statistically significant.

Data Source: Multicenter, randomized controlled study with 121 patients undergoing lung surgery.

Disclosures: The study was sponsored by Covidien, the company that markets the tested gel. Dr. De Leyn said that he has been a consultant to Covidien.

IN THE TREATMENT OF MRSA BACTEREMIA AND MRSA COMPLICATED SKIN INFECTIONS



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- Landmark clinical trial of CUBICIN 6 mg/kg once daily demonstrated efficacy in *S. aureus* bacteremia caused by MRSA and MSSA
- Proven clinical success of CUBICIN 4 mg/kg once daily in *S. aureus* complicated skin infections—both MRSA and MSSA

INDICATIONS AND IMPORTANT SAFETY INFORMATION

CUBICIN is indicated for the following infections:

Complicated skin and skin structure infections caused by susceptible isolates of the following Gram-positive microorganisms: *S. aureus* (including methicillin-resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae* subspecies *equisimilis*, and *Enterococcus faecalis* (vancomycin-susceptible isolates only). Combination therapy may be clinically indicated if the documented or presumed pathogens include Gram-negative or anaerobic organisms.

S. aureus bloodstream infections (bacteremia), including those with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates. Combination therapy may be clinically indicated if the documented or presumed pathogens include Gram-negative or anaerobic organisms.

The efficacy of CUBICIN in patients with left-sided infective endocarditis due to *S. aureus* has not been demonstrated. The clinical trial of CUBICIN in patients with *S. aureus* bloodstream infections included limited data from patients with left-sided infective endocarditis; outcomes in these patients were poor. CUBICIN has not been studied in patients with prosthetic valve endocarditis or meningitis.

Patients with persisting or relapsing *S. aureus* infection or poor clinical response should have repeat blood cultures. If a culture is positive for

S. aureus, MIC susceptibility testing of the isolate should be performed using a standardized procedure, as well as diagnostic evaluation to rule out sequestered foci of infection. Appropriate surgical intervention (eg, debridement, removal of prosthetic devices, valve replacement surgery) and/or consideration of a change in antibiotic regimen may be required. CUBICIN is not indicated for the treatment of pneumonia.

Clostridium difficile-associated diarrhea (CDAD) has been reported with the use of nearly all antibacterial agents, including CUBICIN, and may range in severity from mild diarrhea to fatal colitis. CDAD has been reported to occur over 2 months post-antibiotic treatment. If CDAD is suspected, antibiotic treatment may need to be suspended.

Patients receiving CUBICIN should be monitored for the development of muscle pain or weakness, particularly of the distal extremities. In patients who receive CUBICIN, creatine phosphokinase (CPK) levels should be monitored weekly, and more frequently in patients who received recent prior or concomitant therapy with an HMG-CoA reductase inhibitor. In patients with renal insufficiency, both renal function and CPK should be monitored more frequently. Patients who demonstrate unexplained elevations in CPK while receiving CUBICIN should be monitored more frequently.

CUBICIN should be discontinued in patients with unexplained signs and symptoms of myopathy in conjunction with CPK elevation >1000 U/L (~5X ULN), or in patients without reported symptoms who have marked elevations in CPK >2000 U/L (≥10X ULN).

Most adverse events reported in CUBICIN clinical trials were mild to moderate in intensity. The most common CUBICIN adverse events were anemia, constipation, diarrhea, nausea, vomiting, injection-site reactions, and headache.

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Please see Brief Summary
 of Prescribing Information
 on adjacent page.