Gel Plugs Severe Air Leaks in Lung Surgery

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

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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.