The Emperor Wears No Clothes

To the Editor:

I would like to congratulate Ernst and colleagues1 for their report in CHEST (September 2008) concerning the development of a database for therapeutic bronchoscopic interventions. This database will include prospective information gathered from multiple institutions and may ultimately allow physicians to carefully assess patient outcomes from such procedures. The current article represents a robust first step, reporting results from 554 procedures performed at four different hospitals. The enthusiasm generated by this project must be mitigated by the reported results, however. The morbidity and mortality associated with these procedures were very high. The authors reported a complication rate of 19.8% and a 30-day mortality rate of 7.8%. Even in patients with “benign” disease, 13 of 302 patients died. The data in this study were uncontrolled so that the reader cannot compare the outcomes associated with performing these procedures to outcomes expected from a more conservative approach. The correlation of outcomes with scores from illness severity indexes or compelling statements that procedures were performed on an “urgent” basis should not dissuade the medical community from demanding controlled outcome data for high-risk procedures.

A few decades ago, the use of pulmonary artery catheters was widespread in ICUs. Today, such catheters are infrequently used, mainly because of controlled, prospective data that failed to show improvements in patient outcomes. Considerable time elapsed for this transition in practice to take place. Let us hope that we have learned from this lesson, and that patient outcomes from therapeutic bronchoscopic procedures are subjected to close scrutiny. In my opinion, such procedures should not be performed outside of centers of excellence, and such centers should enroll their patients in prospective controlled clinical trials.

Daniel R. Ouellette, MD, FCCP
Henry Ford Hospital
Detroit, MI

Response

To the Editor:

We appreciate the opportunity to reply to the letter by Dr. Ouellette1 in regard to our article2 on risk-adjusted outcome analysis after interventional bronchoscopic procedures. We are unclear what Dr. Ouellette means with the title of the letter and the statement that the data reported were “uncontrolled.” In our report,2 the data were collected prospectively, and all data fields were defined before the data-entering process started. The reported outcome data were clearly controlled for quality, patient illness, and intervention performed. This represents an enormous step forward in our field, in which most reported outcomes have been collected retrospectively and generally have been uncontrolled.

By “uncontrolled,” Dr. Ouellette might also mean that there was no sham control arm or nontreatment group. This was not a randomized controlled trial (RCT), but rather a prospective observational study to assess morbidity and mortality. Hence, there are no claims or assertions for the superiority of any particular treatment option. The evidence base in interventional pulmonology does not contain many RCTs, especially for well-established interventions, such as airway stenting and ablative techniques, such as Nd-YAG laser ablation. Most reports in the surgical literature also do not have RCT evidence. However, new interventions, such as bronchoscopic treatments for emphysema, have been designed with sham control arms and are underway.

But are RCTs always necessary for investigating all things? In our opinion, no. Indeed, such a claim misrepresents the evidence-based medicine approach. Evidence-based medicine does not limit itself to one method of investigation in order to draw inferences. Indeed, the American College of Chest Physicians lung cancer guidelines3 state that high-quality evidence includes RCTs without important limitations or overwhelming evidence from observational studies. The techniques used in our study are well-established therapeutic techniques that demonstrate a high level of directly observable effects. Patients in respiratory failure who stop receiving mechanical ventilation immediately after successful ablation and stent placement clearly constitute “overwhelming observational evidence.” This is not to say that all patients can benefit but is merely to state that in certain carefully selected patients there is overwhelming observational evidence that these techniques are of benefit (grade 1A). The majority of cases fall into a gray zone (ie, grade 1B, 1C, or even 2C), and much of the work of evidence-based medicine must therefore revolve around risk/benefit quantification for these groups. This highlights the importance of proper patient selection.

The assertion that this is analogous to prior arguments in favor of the use of pulmonary artery catheters is weak. The interventions described are therapeutic, whereas the pulmonary artery catheter is diagnostic. As such, the nature of the evidence, the reference standards of truth, and the definition of a proper control are different. Pulmonary artery catheters provide information but not treatment. The interventions described produce directly observable

Reference