elevated pulmonary arterial pressures were not required for enrollment in the Flolan International Randomized Survival Trial (FIRST). 2 However, all patients underwent right-sided heart catheterization, and most subjects (>75%) did, in fact, have PH as defined by mean pulmonary arterial pressure > 25 mm Hg. This makes it unlikely that epoprostenol is of significant benefit in patients with systolic heart failure and PH. The same is true for the Phosphodiesterase-5 Inhibition to Improve Clinical Status and Exercise Capacity in Diastolic Heart Failure (RELAX) trial. The rationale behind the RELAX trial was to target the pleiotropic (cardiac, vascular, and neurohormonal) effects of phosphodiesterase-5 inhibition on cardiovascular function in patients with heart failure with reduced ejection fraction regardless of the pulmonary pressures. 3 Based on echocardiographic estimates (which are admittedly imprecise), approximately two-thirds of subjects in this trial also had elevated pulmonary arterial systolic pressure (> 35 mm Hg).

Recently, Bonderman and colleagues 4 reported the results of the Left Ventricular Systolic Dysfunction Associated With Pulmonary Hypertension Rioconigat Trial (LEPHT). Riociguat, a guanylate cyclase stimulator, is efficacious in the treatment of pulmonary arterial hypertension and in PH due to chronic thromboembolic disease; it received US Food and Drug Administration approval for these indications in October 2013. LEPHT was a phase 2 trial that examined the hemodynamic effects of riociguat in patients with hemodynamically confirmed PH due to heart failure with reduced ejection fraction. In this study, riociguat failed to reduce mean pulmonary arterial pressure, and there was no significant improvement in N-terminal pro-brain natriuretic peptide or 6-min walk test distance after 16 weeks of treatment. On a more positive note, subjects receiving riociguat had significantly increased cardiac index and a decrease in the Minnesota Living With Heart Failure score.

To conclude, the clinical trials to date have been disappointing, and the use of PH-specific therapies for PH due to LHD should be discouraged outside of the context of clinical trials. We do agree with Dr Guglin that additional, adequately powered, trials looking at subgroups of patients with LHD and a fixed component of PH are needed.

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References


Just Because We Can Does Not Mean We Should
A Perspective on Combined Tracheostomy and Percutaneous Endoscopic Gastrostomy Tube Insertion

To the Editor:

We read with interest the article from Yarmus et al1 in CHEST (August 2013) about the feasibility of percutaneous endoscopic gastrostomy (PEG) tube insertion by interventional pulmonologists. For reasons that are unclear, a combination procedure of PEG and tracheostomy has been advocated by some. In the current work, more than one-half of the patients (n = 41) underwent a combined procedure. There is some historic observational data on the feasibility of this approach2,3; however, efficacy and safety of this approach has not been previously studied in prospective randomized trials.

Consensus guidelines would suggest that PEG tube insertion be considered for patients who are likely to have a requirement for enteral nutrition of > 30 days.4 PEG, while safe and reasonably well tolerated, is not a frivolous procedure. Thirty-day mortality after PEG tube insertion has been noted to range between 10% and 26% in some series, largely driven by poor patient selection.4,5 Indeed, in one of the largest published series, a 1-week mortality of 43% was seen in a national confidential inquiry into patient deaths in the National Health Service, of which 19% of procedures were deemed futile upon expert review.6 It is with this knowledge that the selection of critically ill patients undergoing tracheostomy as suitable subjects for PEG tube insertion needs to be questioned. By virtue of their complex critical illness, patients undergoing tracheostomy insertion are sick and not optimal subjects. Reported 30-day mortality rates after tracheostomy insertion alone vary but have been reported to be on the order of 30%.4,6 For similar reasons, the policy of placing PEG tubes in patients early in the course of their critical illness (as early as 4 days in the current report) and prior to declaration of medical stability is questionable.

In the current series, Yarmus et al1 reported mortality at 30 days of 11%. The mortality in the group that underwent simultaneous PEG and tracheostomy tube insertion was not reported; we would be interested to see these data.

PEG tubes were removed in 73% of surviving patients within a median of 76 days (range, 24-611 days). This would seem to
suggest that PEG tube insertion (and all of its attendant risks) may have been avoided completely in some patients by deferring simultaneous insertion.

Nasogastric feeding tubes are widely regarded as safe and should be the preferred option for short-term nutrition delivery. We feel that the policy of simultaneous PEG and tracheostomy tube insertion should not be advocated until it has been proven to be superior to a watch-and-wait approach in prospective randomized trials.

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REFERENCES


Response

To the Editor:

We thank Drs Slattery and Seres for their interest in our article regarding the placement of percutaneous endoscopic gastrostomy (PEG) tubes by interventional pulmonologists. Although there are no prospective randomized trials addressing the efficacy and safety of combined tracheostomy/PEG within critically ill patients, to our knowledge, no randomized data have demonstrated it as unsafe/unfeasible, and designing noninferiority studies of this type would be extremely difficult and expensive. We agree that, like tracheostomy placement, decisions regarding timing for PEG tube placement remain difficult for providers; PEG tube placement should be reserved for those likely to need enteral nutrition for >30 days. We believe our data suggest appropriate patient selection, with removal occurring in 73% of surviving patients (after a median 76 days) and long-term PEG tube utilization in an additional seven patients. Data on ICU admission to PEG placement time were not collected; rather, the time period cited is time to death or follow-up after placement. Unfortunately, 11% of this cohort died within 30 days (five patients receiving tracheostomy and PEG, three patients receiving PEG only); however, this remains favorable when compared with larger PEG studies.

We would like to point out that the main objectives of our article remain as discussed by Dr Kovitz in the accompanying editorial. Tracheostomy, once limited to surgeons, has experienced successful expansion to other subspecialties through the appropriate breakdown of health-care silos, potentially allowing for improved health-care efficiency and decreased costs. We believe this same approach can be taken with a procedure such as PEG placement (or combination tracheostomy/PEG) as described. The field of interventional pulmonology continues to expand, as does our role within the health-care system, and the main goal of this study was to show the safe and feasible performance of this procedure in the hands of trained interventional pulmonologists in a procedure historically limited in most institutions to gastroenterologists or surgeons.

Although not currently defined well in the literature, use of this approach may potentially decrease costs and expedite efficient patient care. As suggested, the procedural performance by one team at one encounter has potential for significant improvements in cost, decreased ICU stay, decreased anesthetic exposure, and so forth. The use of this team may also help expedite patient transfer to other levels of care. Within the authors’ current and previous practice environments, it remains the general practice of long-term ventilator facilities to refuse admission of patients to their facility without the placement of a long-term feeding tube. The continued use of a nasogastric tube only delays transfer and discharge from the hospital, often at a significantly higher cost to the health-care system.

We believe PEG tube placement remains a safe procedure when performed by an experienced team with careful regard to patient selection. We disagree with the complaint made by Drs Slattery and Seres of excessive mortality in this population. Mortality remains a poor marker for this procedure due to the critically ill nature of every patient within this cohort. We suggest further study to help answer these difficult questions of who would best be served by PEG placement as well as analyses of health-care costs.

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