Letter by Faul et al Regarding Article, “Percutaneous Femoral Arteriovenous Shunt Creation for Advanced Chronic Obstructive Pulmonary Disease: A Single-Center Safety and Efficacy Study”

To the Editor:

We were interested to read the recent article by Bertog et al., published in your journal. Bertog et al. report, for the first time, significant increases in cardiac output, mixed venous oxygen saturations, oxygen delivery, and functional capacity (significant reductions in New York Heart Association [NYHA] functional class) in patients with severe end-stage chronic obstructive pulmonary disease (COPD) with the use of the novel Rox procedure (percutaneous arteriovenous fistula creation).

Their interpretation that “the creation of an arteriovenous shunt in the setting of severe chronic obstructive pulmonary disease did not improve functional capacity” is not convincing, because the data prove the opposite: an improved NYHA functional class, which is not only clinically significant (improved from class III to II) but also statistically significant ($P<0.01$). Thus, the idea that an arteriovenous shunt (AVS) does not improve functional capacity is refuted by their data that demonstrate statistically significant improvements in NYHA functional class.

Although Bertog et al. did not demonstrate a significant change in 6-minute walking distance (6MWD) in this small feasibility study, it would seem premature to say the creation of an AVS does not improve 6MWD: (1) The observed changes in 6MWD were not statistically significant ($P<0.07$); therefore, the changes might have occurred through chance alone. (2) Patients with end-stage COPD who demonstrate relative stability in 6MWD over 12 months may reflect a successful outcome in comparison with a control group (the present study was uncontrolled). (3) Although 6MWD was used in this study as a measure of exercise capacity, many other measures (NYHA functional class, shuttle walk test, cardipulmonary exercise testing, treadmill testing, etc.) might show a beneficial effect of therapy that more closely reflects the clinical improvement that many of these patients experience. Our own patients (more than 180 patients have now received this therapy) report a range of benefits such as regaining the ability to wash and dress themselves without assistance, carry groceries, play with grandchildren, and so on, but these clinical benefits are not reflected by the 6MWD test. In support of this concept, Bertog et al report a statistically significant improvement in NYHA functional class that was not accompanied by a significant change in 6MWD. The failure of Bertog et al to demonstrate significant improvements in 6MWD might be explained by the fact that many of these subjects developed leg edema, a local effect that shortens walking distances.

Bertog et al have achieved considerable expertise in this technically challenging procedure, but their enthusiasm is tempered by concern about adverse effects. Surgical AVS are routinely created for dialysis patients, and the predicted venous stenosis rate is 35%. New medical devices are evaluated (in terms of feasibility, cost, efficacy, convenience, patient acceptability, durability, and adverse effects) in 2 stages: feasibility studies and controlled studies of clinical efficacy. Feasibility studies are designed as noncomparative studies that answer questions about patient selection, the development of techniques, patient experience, and complications. In a feasibility study of surgical fistula creation in patients with end-stage COPD, “oxygen responder” patients walked significantly further after creation of an AVS, but the hemodynamic and functional improvements seen in this feasibility study by Bertog et al are far greater, suggesting that the deployment of a device appears to provide superior outcomes in terms of hemodynamics and oxygen delivery. The differences might be explained by both differences in technique and patient selection. In our study most patients underwent open surgery and had more advanced COPD (FEV$_1$: 19% versus 32% predicted; average 6MWD on room air: 217 m versus 338 m). We believe that in expert hands, the percutaneous device implantation should carry a predictable (20%) risk of venous stenosis and achieve superior efficacy to the surgical creation of an arteriovenous fistula. Ongoing studies are trying to determine which patients gain most benefit and which are most likely to develop venous stenosis as a complication.

Given that Bertog et al. demonstrate that this new procedure is (1) technically feasible with a high success rate, (2) associated with improved oxygen delivery, (3) associated with improved NYHA functional class, and (4) associated with a number of predictable but manageable adverse effects, we suggest that this therapy be recommended for selected patients with progressive end-stage COPD who have few therapeutic options.

Disclosures

Dr. Faul is a founder of Rox Medical and holds patents for the creation of an arteriovenous fistula for COPD.

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References

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