though the authors of above study have found favorable comparison between the device and new anticoagulants in terms of follow-up, patient characteristics and time in therapeutic range. Also, the study is not powered enough to answer questions in specific subgroups (e.g. patients with prior history of TIA/stroke).

We believe that further studies with large number and long term follow-up will clarify whether use of such devices can be generalized. If approved, this therapy will not only revolutionize the management of AF (by minimizing issues like major bleed, drug interruption for surgical procedures and compliance) but also design studies targeting patients deemed in eligible to oral anticoagulation.

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Background: Although balloon pulmonary angioplasty (BPA) for inoperable patients with chronic thromboembolic pulmonary hypertension was first reported over a decade ago, its clinical application has been restricted because of limited efficacy and complications. We have refined the procedure of BPA to maximize its clinical efficacy.

Methods and results: Sixty-eight consecutive patients with inoperable chronic thromboembolic pulmonary hypertension (CTEPH) underwent BPA. We evaluated pulmonary artery diameters and determined the appropriate balloon size by using intravascular ultrasound. We performed BPA in a staged fashion over multiple, separate procedures to maximize efficacy and reduce the risk of reperfusion pulmonary injury. A total of 4 (2–8) sessions were performed in each patient, and the number of vessels dilated per session was 3 (1–14). The World Health Organization functional class improved from 3 to 2 (p < 0.01), and mean pulmonary arterial pressure was decreased from 45.4 ± 9.6 to 24.0 ± 6.4 mm Hg (p < 0.01). One patient died because of right heart failure 28 days after BPA. During follow-up for 2.2 ± 1.4 years after the final BPA, another patient died of pneumonia, and the remaining 66 patients are alive. In 57 patients who underwent right heart catheterization at follow-up, improvement of mean pulmonary arterial pressure was maintained (24.0 ± 5.8 mmHg at 1.0 ± 0.9 years). Forty-one patients (60%) developed reperfusion pulmonary injury after BPA, but mechanical ventilation was required in only 4 patients.

Conclusions: Our refined BPA procedure improves clinical status and hemodynamics of inoperable patients with chronic thromboembolic pulmonary hypertension, with a low mortality. A refined BPA procedure could be considered as a therapeutic approach for patients with inoperable chronic thromboembolic pulmonary hypertension.

1. Perspective

Pulmonary endarterectomy is the only potentially curative treatment for CTEPH. However, nearly one-third of CTEPH are not fit for this procedure because of various reasons. Although vasodilator therapy such as epoprostenol has been tried in such cases, they have very limited efficacy in terms of functional class or hemodynamics. Considering the high mortality of such patients when untreated an alternative therapeutic option is required. It is in this context that BPA can play some role.

BPA for a patient with CTEPH was first reported in 1988. In 2001, Feinstein et al reported improvement in hemodynamics in 18 inoperable cases of CTEPH. However, even after more than 20 years after the first report of BPA, it is still not widely accepted as a therapeutic option for inoperable patients with CTEPH because of the following reasons: 1) insufficient improvement in hemodynamics after BPA, 2) inaccurate estimate of balloon size based only on angiographic findings thereby leading to pulmonary artery rupture and 3) high incidence of pulmonary reperfusion injury and pulmonary edema.

The present study has tried to overcome these limitations by refining BPA by use of the following measures: 1) use of IVUS to provide more accurate estimates of the diameters of target pulmonary arteries, thereby preventing rupture of pulmonary arteries to a great extent, 2) BPA done in a staged fashion over multiple procedures to reduce the risk of pulmonary reperfusion injury while still achieving an effective therapeutic result. Also, in this study, a soft-tipped 6F guiding catheter, a thinner 0.014-inch wire and a low profile balloon were used, which potentiated the opening of completely obstructed lesions with a lower risk of perforation. All these armamentarium are commercially available and this procedure can be performed in any catheterization laboratory. After determination of the vessel diameter with IVUS, initial dilatation was done with a 2 mm balloon and the diameter of the balloon was gradually increased to a maximum size of not more than 90% of the original vessel diameter. This avoided rupture and dissection of the pulmonary artery. The procedure was repeated in multiple sessions until a sufficient amount of stenosis were dissolved. The more segments
were dilated, the larger the decrease in PA pressure was achieved. The mean PA pressure was reduced >20 mmHg to <25 mmHg. Though reperfusion pulmonary injury developed in 60% patients after BPA, only 6% patients (as compared to 17% in a previous study) required mechanical ventilatory support. I/V epoprostenol, methylprednisolone and NIPPV have all been tried to reduce it, but all have failed to do so. An attempt has been made, however, to reduce this complication by not dilating >2 vessels at the initial BPA and perform it in a staged fashion over multiple, separate procedures and also by doing limited BPA only within a single lobe at a time. The reduction in this complication with time also indicates a role for learning curve and proficiency of operators performing BPA.

Considering the fact that reperfusion injury is unavoidable despite best efforts, postprocedural intensive monitoring of hemodynamics and oxygenation at least for 72 h is necessary, even if the patient appears to be free from pulmonary injury after BPA.

In my opinion, refined BPA using the technique as in this study, can be used to remove stenosis in distal pulmonary arteries to obtain a substantial decrease in PA pressure and to improve WHO functional class in patients who are not candidates for either endarterectomy or lung transplantation. It is not that complicated procedure and it can be done by interventional cardiologist doing coronary intervention. However, there is definitely a learning curve and acquiring BPA technique and training is necessary, which is the case as with any procedure. Though the numbers in this study are small (68 patients) and follow-up was for 2.2 ± 1.4 years only, it has offered a ray of hope to inoperable patients and further larger studies with longer follow-up and randomized trials versus medical therapy is the need of the hour for such patients.

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Rate control is often the therapy of choice for permanent atrial fibrillation. The RACE II study was the first to evaluate the relative efficacy of strict rate control (resting heart rate <80 bpm and during moderate exercise <110 bpm) versus lenient rate control (resting heart rate <110 bpm) in patients with permanent AF. The study demonstrated that lenient rate control was not only easier to achieve but was non-inferior to strict rate control in reducing symptoms, improving the quality of life, exercise tolerance and survival. However, an important limitation was the marked discrepancy in the number of patients achieving target heart rate (THR), in the two groups. While only 67% achieved THR in the strict rate control group, almost all (98%) achieved THR in the lenient rate control group.

Since this could have influenced the outcome in favor of lenient rate control, the present post hoc analysis evaluated differences in outcomes in patients with successful strict (n = 203), failed strict (n = 98), and lenient rate control (n = 307). Patients in the strict rate control group who failed to achieve one of the heart rate criteria were classified as failed strict while the remaining patients were classified as successful strict rate control.

Nearly 80% of patients in the failed strict group had resting heart rate >80 bpm at the end of dose-adjustment phase. Reasons for failure to achieve strict rate control included drug-related adverse events in 25% and inability to achieve THR with drugs in another 20% patients.

Clinical characteristics and echocardiographic parameters (including left atrial and left ventricular dimensions and baseline EF) were similar amongst the three groups. Mean dosages of rate control drugs (beta blockers, verapamil and digoxin) as well as use of drug combination was significantly higher in successful strict and failed rate control as compared to lenient rate control groups. The number of additional hospital visits at 1 and 2 years of follow up were significantly more common in the successful strict and failed strict compared with the lenient group while there was no difference in additional visits between the successful strict and failed strict groups.

The primary outcome (composite of death from cardiovascular causes, hospitalization for heart failure, and stroke, systemic embolism, bleeding, and life-threatening arrhythmic events), all-cause mortality and quality of life scores were not significantly different amongst patients with strict, failed strict or lenient rate control. Separate analysis of patients with EF <40% also revealed no differences in the primary outcome. Whether use of more aggressive measures to achieve strict rate control or longer follow up would reveal any outcome differences remains to be studied further.

The study confirms that it is often difficult to achieve strict heart rate control in patients with AF with currently available anti-arrhythmic drugs. Not only do these patients require higher dosages of drugs and drug combinations, but the number of additional hospital visits is also more. Despite achieving pre-specified target heart rate, there was no difference in outcome between successful and failed strict rate control. Therefore a strategy of lenient rate control may continue to be the preferred strategy in patients with permanent AF. However in patients with intolerable rate related symptoms or onset of tachycardiomyopathy, lower heart rate targets may be reasonable.

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