The combined use of radiofrequency-ablation and balloon-dilation (CURB) in the creation of a stable inter-atrial communication: fist-in-man use for patients with severe pulmonary arterial hypertension

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Topic(s):
Pulmonary Circulation, Pulmonary Embolism, Right Heart Failure: Intervention

Citation:

Funding Acknowledgements:
National Natural Science Foundation of China (81670283) and Beijing Natural Science Foundation (7162160)

Background Recent preclinical research has suggested that combined use of radiofrequency-ablation and balloon-dilation (CURB) had the potential to create a stable inter-atrial communication. However, the related clinical data is still absent.

Purpose This study describes the first-in-man use of CURB in the patients with severe pulmonary arterial hypertension (PAH).

Methods Under the guidance of fluoroscopy and intra-cardiac echocardiography, CURB was attempted in 3 patients with severe PAH (age: 35.0±12.1 years, one idiopathic PAH and two PAH related to repaired congenital heart disease). With the aid of 3D location system, fossae ovalis was ablated with radiofrequency. Then the graded balloon-dilation was performed after transseptal puncture, and radiofrequency-ablation was repeated around the rim of fenestration created with balloon-dilation. The exercise capacity and fenestration-size were followed up.

Results CURB was performed successfully in all 3 patients, and pulmonary vascular resistance was 30.3±10.9 Wood units. The fenestration size was 5.0±1.0 mm (range: 4-6 mm), and systemic arterial oxygen saturation decreased by 4.7±0.6 % (range: 4-5%). World Health Organization functional class increased by 1.6±0.5 (P<0.001) and cardiac index increased by 0.58±0.34 L/min/m² (P<0.001). In addition, exercise capacity improved significantly (+63.7 meters, P<0.001). Follow-up (6.0±1.0 months; range: 5-7 months) showed that all fenestrations were stable (P=0.808), and no complication occurred.

Conclusions In patients with severe PAH, CURB is feasible and effective to create a stable inter-atrial communication. Further research was required to evaluate the long-term result of this novel approach. (ClinicalTrials.gov ID: NCT03554330)

Figure 1: The combined use of radiofrequency-ablation and balloon-dilation (CURB) was performed in the patient with severe PAH. Left figures showed the procedure of CURB. Middle figures showed the created fenestration with MSCT, and the morphology and size of fenestration was provided in the right-inferior panel. In addition, the sizes of right atrium and ventricle were alleviated with increase of left atrium. Right figures indicated that the fenestration-size was stable during follow-up (one week, one month and six months, respectively).
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