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Efficacy and safety of balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension guided by cone-beam computed tomography and electrocardiogram-gated area detector computed tomography

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ABSTRACT

Background: Chronic thromboembolic pulmonary hypertension (CTEPH) is a disease characterized by chronic obstructive thrombus and pulmonary hypertension. Balloon pulmonary angioplasty (BPA), an emerging alternative catheter-based treatment for inoperable patients with CTEPH, has not yet been standardised, especially for lesion assessment in distal pulmonary arteries. Recent advancement in computed tomography enables distal CTEPH lesions to be visualized.
Methods: We retrospectively studied 80 consecutive patients with inoperable CTEPH who received BPA guided by cone-beam computed tomography (CT) (CBCT) or electrocardiogram (ECG)-gated area detector CT (ADCT) for target lesion assessment. We collected clinical and hemodynamic data, including procedural complications, before BPA and at 3 months and 1 year after BPA.
Results: Three hundred eight-five BPA sessions (4.8 sessions/patient) were performed for the lesions of subsegmental arteries (1155 lesions), segmental arteries (738 lesions), and lobar arteries (4 lesions) identified by CBCT or ECG-gated ADCT. Significant improvements in the symptoms, 6-min walk distance, brain natriuretic peptide level, exercise capacity, and haemodynamics were observed 3 months and 1 year after BPA. No cases of death or cardiogenic shock with a low rate of severe wire perforation (0.3%) and severe reperfusion oedema (0.3%) were observed.
Conclusions: BPA guided by CBCT or ECG-gated ADCT is effective and remarkably safe in patients with CTEPH . These new advanced CT techniques may be useful in pre-BPA target lesion assessment.

1. Introduction

Chronic thromboembolic pulmonary hypertension (CTEPH) is a devastating disease with high pulmonary vascular resistance due to chronic organized thromboembolism, which leads to right heart failure and death, if untreated [1]. The gold standard treatment for CTEPH is pulmonary endarterectomy (PEA) [2]. However, one-third of patients with CTEPH is considered as inoperable according to the CTEPH international registry because of an anatomical reason and comorbidities [3]. Moreover, 30% of patients after PEA have residual pulmonary hypertension (PH) with limited exercise capacity and dyspnoea on effort [4]. Alternative treatment options for inoperable patients with CTEPH and residual PH after patients have undergone PEA have been anticipated.

Balloon pulmonary angioplasty (BPA) is a catheter-based invasive procedure for stenosis or obstructed lesions in the pulmonary artery with a balloon catheter (Fig. 1A–D) [5]. Feinstein et al. described a series of 18 patients with CTEPH treated with BPA, and they reported promising haemodynamic effects in 2001 [6]. Subsequently, mainly Japanese groups have developed BPA procedures [7–9]. Recent advances in BPA for CTEPH are promising

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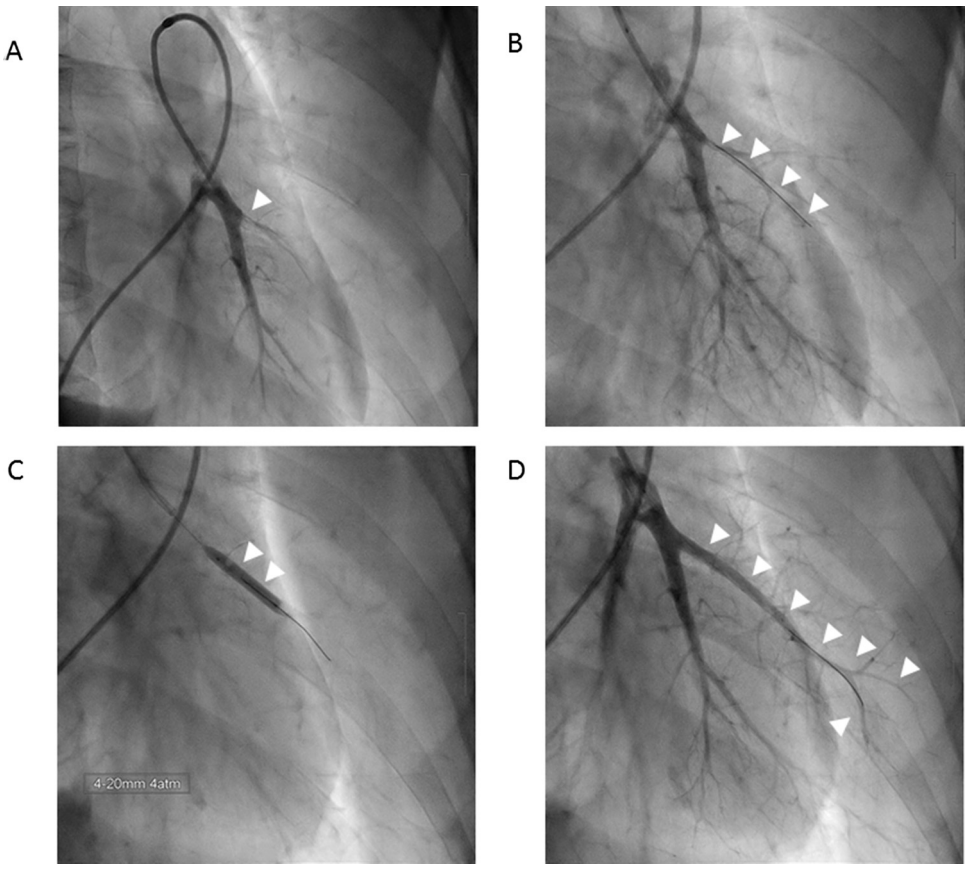

Fig. 1. Pulmonary angiograms during balloon pulmonary angioplasty. Selective pulmonary angiogram showing severe stenosis and slow flow of a branch of the right segmental pulmonary artery (A8, arrowhead) (A). A 0.014-inch wire was used during the intervention to cross the severe stenotic lesions in the target vessel (arrowhead) (B). Balloon (φ4 mm) dilatation performed at the stenotic lesion (arrowhead) (C). Improved pulmonary artery flow and enlarged pulmonary artery are shown after dilatation by balloon (arrowhead) (D).

in terms of clinical and haemodynamic effects [10–13], which has gained worldwide attention [14–16]. However, numerous issues remain unclear, especially target lesion assessment for BPA. There are no standard modalities for observing distal lesions in patients with CTEPH, although the main BPA target lesions are segmental and sub-segmental lesions. Pulmonary angiography (PAG) is the gold standard modality for diagnosing CTEPH . However, PAG is insufficient for showing detailed distal vessel lesions. Selective PAG during BPA can easily overlook distal lesions, and there is a potential risk for vessel injury due to the guiding catheter.

Recent CT imaging advancement has made it possible to show more details of the vessel anatomy. Previously, we reported that cone-beam computed tomography (CBCT) [17,18] and electrocardiogram (ECG)-gated area detector CT (ADCT) [19] can show precise organized lesions in the distal pulmonary artery of patients with CTEPH . We hypothesized that balloon angioplasty for web and slit lesions assessed by CBCT or ECG-gated ADCT effectively improve haemodynamics and reduce procedural complications, as intravascular imaging modalities, which potentially cause vascular injuries during BPA, are unnecessary. We investigated the efficacy and safety of BPA guided by CBCT or ECG-gated ADCT.

2. Materials and methods

2.1. Study patients

We retrospectively reviewed 80 consecutive patients (median age 68 years; 59 women) with inoperable CTEPH and residual PH after PEA who underwent CBCT guided BPA or ECG-gated AD

CT between June 2011 and October 2015. All patients complained of dyspnoea on effort that was more severe than World Health Organization functional class (WHO-FC) II. Patients were diagnosed as having CTEPH using the standard criteria and assessment. The technical and risk standpoint [20] of PEA operability was discussed by the multidisciplinary CTEPH team at our centre, which included radiologists and PEA surgeons [21]. Adequate anticoagulation therapy was maintained for at least 3 months before BPA, and it was continued thereafter. Written informed consent was obtained from all patients, and the institution's ethics committee approved the study.

2.2. Target lesion assessment

2.2.1. CBCT

CBCT was performed using a flat panel detector angiography system with motorized C-arms (Infinix Celeve-I INFX–8000 V; Toshiba Medical Systems, Tokyo, Japan). It has a sampling pitch of 291 × 291 μm and an array format of 1024 × 1024 pixels with synchronized radiography exposure and panel readout under continuous rotation of the C-arm. Forty-eight mL of contrast media (Iopamidol 300; Fuji Pharma Co., Ltd., Tokyo, Japan), containing 200 mg/mL of iodine diluted in saline at a rate of 8 mL/s with a 2 s scanning delay during the entire acquisition time of 4 s, was injected using a 5-French (Fr) angled pigtail catheter and a power injector. Three-dimensional datasets were obtained from a single rotation with a field of view of 298 × 298 mm using the floor-mounted C-arm with continuous breath-hold (longer than 10 s) [17]. One hundred eight projections were acquired at 27