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Case report

Paclitaxel-coated balloon dilation for central airway obstruction

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ABSTRACT

Introduction: Central airway obstruction (CAO) often requires repeated interventional procedures which offer variable efficacy, a time-limited effect, and have inherent limitations. Paclitaxel has been used to prevent restenosis in blood vessels. The literature describing the use of paclitaxel to prevent recurrent airway stenosis is limited. We sought to describe our experience using a paclitaxel-coated balloon (PCB) for CAO.

Material and methods: We performed a retrospective review of all patients who underwent PCB airway dilation. We collected: basic demographics, details of the CAO, details of the bronchoscopes used, PCB size, PCB dilation pressure, duration of PCB inflation, concurrent non-PCB interventions, estimated pre- and post-PCB CAO luminal diameter, follow up bronchoscopy date and luminal diameter, and spirometry results.

Results: PCB dilation was performed in 10 cases on 5 patients. Eight PCB dilations were performed for CAO related to distal airway stent stenosis. Concurrent non-PCB interventions were performed with 6 PCB dilations. Nine cases documented improvements and 1 was unchanged immediately post-PCB dilation. Median luminal diameter pre-PCB dilation was 2 mm. Immediately post-PCB dilation, the median change in luminal diameter was 2 mm. Follow up bronchoscopy information was available for 9 cases. For these 9 cases, luminal diameter was unchanged in 5 and worse in 4 when compared to immediate post-PCB dilation.

Conclusion: PCB dilation in benign CAO produced a modest effect in this cohort of challenging airways. Larger prospective studies are needed to assess how a PCB would perform when compared to a non-drug coated balloon.

1. Introduction

Central airway obstruction (CAO) can be from benign or malignant etiologies and is defined as occlusion of > 50% of the trachea, mainstem bronchus, bronchus intermedius, or a lobar bronchus [1]. Depending on the degree, extent, and severity of the narrowing, CAO can be functionally limiting and physically debilitating for patients. Benign strictures constitute the majority of benign forms of CAO and include airway stenosis related to post-intubation tracheal stenosis, post-tracheostomy tracheal stenosis, post-tuberculosis infection, transplant-related and idiopathic stenosis [1]. There are various methods for alleviating symptoms in patients with CAO, which include mechanical debulking, rigid bronchoscopic dilation, stent placement, and balloon dilation.

A balloon can be used to provide mechanical dilation of the stenotic or strictured airway segment, though the stenosis often recurs. Methods aimed at delaying or preventing recurrence include the topical use of mitomycin C and corticosteroid injection [2,3]. Paclitaxel-coated balloons (PCB) (IN.PACT Admiral, Medtronic, Santa Rosa, CA, USA) have been shown effective in preventing restenosis in the vascular setting [4]. PCBs have shown some efficacy in airway stenosis for lung transplant recipients [5], though there is still very limited data regarding PCBs for airway stenoses.

Paclitaxel is a hydrophobic and highly lipophilic antiproliferative drug that has been shown to prevent neointimal hyperplasia after endovascular balloon angioplasty by inhibiting cell division and assembly of microtubules [6,7]. The balloon coating consists of paclitaxel and a hydrophilic excipient urea which facilitates the transfer of paclitaxel from the balloon surface to the luminal surface [8]. Evidence suggests that the balloon delivers paclitaxel concentrations in the vascular wall via paclitaxel reservoirs. These reservoirs provide a source of soluble drug with extended drug availability allowing paclitaxel to exert its anti-proliferative effect for over 180 days [8]. PCBs have been described for the treatment of coronary and peripheral artery disease [6], dysfunctional dialysis access [9], in-stent restenosis in TIPS [10], and biliary anastomotic stricture after liver transplantation [11]. One study reported encouraging results describing the use of PCBs in 12 lung transplant recipients who developed treatment refractory non-anastomotic airway stenosis [5]. The aim of this study is to describe our experience with PCB airway dilation for CAO.

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Abbreviations

CAO	Central airway obstruction
PCB	Paclitaxel-coated balloon
YAP	Yttrium aluminum perovskite
LMB	Left mainstem bronchus
RMB	Right mainstem bronchus
BI	Bronchus intermedius
NK	Natural killer
RA	Rheumatoid arthritis
atm	Atmosphere
FEV1	Forced expiratory volume in 1 second

2. Materials and methods

We performed a retrospective case series review of all patients who underwent a PCB airway dilation of their CAO between March 2016 and July 2016. Five consecutive patients who developed recurrent CAO from a stenosis or stricture and underwent PCB airway dilation were included. There were no exclusion criteria. If documented in the electronic medical record, the following data points were collected: basic demographics, etiology of the CAO, prior CAO interventions attempted, CAO location, specific details of the bronchoscopes used, size of PCB used, duration of PCB inflation, PCB dilation pressure, non-PCB interventions performed concurrently, estimated pre- and post-PCB airway stenosis luminal diameter, follow up bronchoscopy date and estimated stenosis luminal diameter, and spirometry results. Rather than using radiographic software or expensive airway sizing instruments, the known outer diameter of the bronchoscope and/or other instruments used to traverse the stenosis or stricture was used as the estimated luminal diameter pre- and post-PCB dilation. The first bronchoscopy post-PCB was used for the follow up bronchoscopy data points.

In this report a 7 Fr 130 cm long catheter, 6.0 mm or 7.0 mm inflated balloon outer diameter, 40 mm balloon length, IN.PACT™ Admiral™ Drug-Coated Balloon (Medtronic; Minneapolis, MN) was advanced and inflated through the working channel of an adult therapeutic bronchoscope (Olympus T-180 Bronchoscope, Olympus USA). The balloon coated paclitaxel drug dose density was 3.5 μg/mm^2. All PCB dilations were performed at a nominal pressure of 8 atmospheres (811 kPa).

Informed consent was obtained from all patients prior to PCB airway dilation. This study was approved by the Mayo Clinic Institutional Review Board, #17-008149. Our retrospective review was deemed a minimal risk study and was granted consent waiver.

3. Results

There were 5 patients who underwent 10 separate PCB dilations. All 5 patients were female and had benign intrinsic CAO. Three patients had recurrent stent-related granulation tissue CAO and two patients had primary stenoses from benign inflammatory airway disease. All had at least one prior airway intervention and one non-drug coated balloon dilation attempt prior to PCB dilation.

One patient underwent 4 separate PCB dilations and another patient underwent 3 separate PCB dilations. Three patients had a single PCB dilation performed. Eight PCB dilations were performed for CAO related to stenosis that developed at the distal end of their silicone stent. A 7-mm PCB was used in 9 of 10 PCB dilations (Fig. 1). A 6-mm PCB was used in 1 case. Four cases described the duration and number of balloon dilations performed. Each case performed 2-3 PCB dilations for 2–3 minutes. Concurrent non-PCB interventions were performed for 6 PCB dilations. The non-PCB airway interventions included various size non-drug coated balloon dilations, yttrium aluminum perovskite (YAP) laser, and cryoprobe debulking.

Nine of 10 cases documented improvements in the airway stenosis immediately post-PCB dilation. One case was unchanged compared to pre-PCB dilation (Table 1). Median stenotic airway diameter pre-PCB dilation was 2 mm (mean, 2.5 mm; range, 1–5 mm). Immediately post-PCB dilation, the median improvement in the stenotic luminal diameter was 2 mm (mean, 2.5 mm; range, 0–6 mm). Nine cases had follow up bronchoscopy information available for review. For these 9 cases, stenotic airway luminal diameter was unchanged in 5 and worse in 4 when compared to immediate post-PCB dilation. There were no cases showing improvement from the time of post-PCB dilation and the follow-up bronchoscopy. Median follow up bronchoscopy was 20 days (mean, 24 days; range, 1–61 days). There were no significant peri- or post-procedural complications.

Four cases had pre- and post-PCB spirometry data available for comparison. Three patients showed improvement in their forced expiratory volume in 1 second (FEV1) with a median change of 0.13 liters (mean 0.16; range 0.03–0.33). The median number of days from PCB dilation to spirometry testing was 40.5 (mean, 40.5; range, 20-43). There was one patient who recorded worsening FEV1 of −0.24 liters at 61 days post PCB airway dilation.

4. Discussion

CAO can be very problematic for both the patient and the bronchoscopist. Optimal management of recurrent or refractory airway stenosis remains unclear; long-term endobronchial luminal patency rates are modest and repeated interventional procedures are often required. Currently, there are various treatment modalities that demonstrate efficacy, yet offer a time limited effect, and have inherent limitations. Non-drug coated balloon dilations represent the mainstay of treatment with silicone or self-expanding metal stents used as a last resort [5]. A well-documented drawback of placing a silicone stent in the airway is the development of excessive granulation tissue [12] which can occur in up to 50% of patients who have an airway stent [7].

We looked at 10 cases where a PCB was utilized to treat benign CAO. Nine cases documented a significant improvement in the stenotic

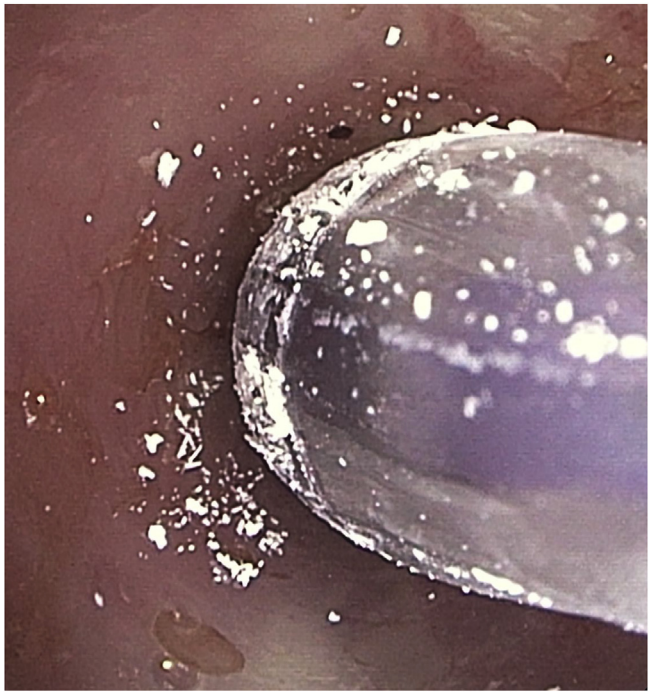

Fig. 1. Fully inflated size 7 mm paclitaxel-coated balloon airway dilation.