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### Case Report

## Stentless percutaneous coronary intervention with directional coronary atherectomy and drug-coated balloon angioplasty in worsening angina patients with metal allergies



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#### ABSTRACT

Metal allergy is a concern in percutaneous coronary intervention (PCI) with stent implantation because of its potential association with poor cardiovascular outcomes, such as stent thrombosis and recurrent in-stent restenosis requiring revascularization. Although stentless PCI with drug-coated balloon (DCB) angioplasty is theoretically useful for patients with metal allergies, DCB angioplasty alone for huge plaques in large vessels may yield inadequate luminal enlargement and coronary deep dissection, leading to insufficient results. Directional coronary atherectomy (DCA) is effective to reduce plaque volume. However, the efficacy of DCA followed by DCB (DCA/DCB) angioplasty in patients with metal allergies has never been described. We present two cases wherein stentless PCI with DCA/DCB angioplasty was an alternative revascularization strategy for patients with metal allergy and concomitant worsening angina pectoris involving proximal left anterior descending artery stenoses. Preoperative evaluation using coronary computed tomography angiography in Case 1 and intravascular ultrasound in Case 2 was useful to determine the possible use of the DCA/DCB procedure for huge plaques in large vessels.

**Learning objective:** Revascularization for patients with metal allergy with worsening angina pectoris due to stenoses of the proximal main arteries is often challenging because of the necessity to avoid stent implantation. As stentless percutaneous coronary intervention (PCI) is theoretically useful in such settings, PCI with directional coronary atherectomy (DCA)/drug-coated balloon angioplasty can be one of the treatable strategies. Preoperative evaluation of plaque morphology for the suitability of DCA procedure is important.

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#### Introduction

Metal allergy is a potential cause of stent failure after percutaneous coronary intervention (PCI) with stent implantation [1]. PCI with drug-coated balloon (DCB) angioplasty, a stentless revascularization technique, may be indicated in coronary artery disease (CAD) in patients with metal allergies because no stent-metal material is used.

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However, optimal lesion preparation prior to DCB angioplasty is challenging in cases of massive plaque volume in large vessels.

Directional coronary atherectomy (DCA) is reportedly effective in reducing plaque volume, resulting in the prevention of slow-flow phenomena and side-branch occlusion due to plaque shift or carina shift. DCA monotherapy presented high restenosis rates due to excessive intimal hyperplasia [2]. Recently, an improved DCA catheter (Atherocut<sup>™</sup>, NIPRO, Osaka, Japan) became available in Japan, and several DCA techniques, including tip detection method, can precisely reduce plaques [3]. DCA followed by DCB (DCA/DCB) angioplasty is an effective stentless PCI strategy, especially in main coronary artery stenosis cases involving bifurcation lesions, offering the combination of plaque debulking and suppression of neointimal proliferation; however, the efficacy of PCI with DCA/DCB angioplasty in patients with CAD with metal allergies has not been reported.

We report two cases of metal allergy, in which stentless PCI with DCA/DCB angioplasty for worsening angina pectoris resulted in complete revascularization.

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Abbreviations: CABG, coronary artery bypass grafting; CAD, coronary artery disease; CAG, coronary angiography; CCS, Canadian Cardiovascular Society; CCTA, coronary computed tomography angiography; DCA, directional coronary atherectomy; DCB, drugcoated balloon; ISR, in-stent restenosis; LAD, left anterior descending artery; PCB, paclitaxel-coated balloon; PCI, percutaneous coronary intervention; OM, obtuse marginal branch; RCA, right coronary artery; TIMI, thrombolysis in myocardial infarction. \* Corresponding author at: Division of Cardiovascular Medicine, Department of Internal

#### **Case report**

#### Case 1

A 66-year-old man with a history of hypertension, type 2 diabetes mellitus, and dyslipidemia had been diagnosed with definite nickel allergy through a patch test at another hospital. The patient presented with worsening exertional angina pectoris with Canadian Cardiovascular Society (CCS) classification 3. Coronary angiography (CAG) showed multivessel disease with a SYNTAX score of 15, including lesions in the proximal left anterior descending artery (LAD), proximal obtuse marginal branch (OM), and distal right coronary artery (RCA) (Fig. 1A-C). Considering his history of definite nickel allergy and complex multiple lesions, coronary artery bypass grafting (CABG) without the usage of metal alloy was recommended; however, the patient refused CABG and requested PCI. Therefore, we needed to investigate whether stentless PCI would be applicable. Coronary computed tomography angiography (CCTA) prior to PCI showed that the proximal LAD lesion consisted of a non-calcified, huge plaque in a large vessel (diameter > 3.5 mm), suggesting that it was suitable for stentless PCI with DCA/DCB angioplasty (Fig. 1D-F). Because of the patient's worsening symptoms and the patient's request, we decided to perform stentless PCI with DCA/DCB angioplasty after extensive discussion with the heart team.

First, PCI of the proximal LAD was performed via the right femoral artery using an 8-Fr guiding catheter. DCA using Atherocut<sup>™</sup> L in four sessions with 17 total cuts (maximum cutting pressure: 4 atm) could obtain optimal lesion preparation, in which intravascular ultrasound (IVUS) showed that the percent plaque volume was successfully reduced from preoperatively 83 % to postoperatively 42 % (Fig. 1G–H). Then, balloon angioplasty was performed with a 3.25/15-mm cutting balloon and 3.5/26-mm paclitaxel-coated balloon (PCB, SeQuent Please, B. Braun, Melsungen, Germany). After successful PCI with DCA/DCB angioplasty, subsequent PCI of the proximal OM lesion was performed with balloon angioplasty using a 2.75/10-mm cutting balloon and 2.75/25-mm PCB, leading to optimal luminal expansion with thrombolysis in myocardial infarction (TIMI) grade 3. Two

days later, a scheduled PCI for the distal RCA was performed via the right radial artery using a 7-Fr guiding catheter. Balloon angioplasty with a 2.25/10-mm cutting balloon and a subsequent 2.25/30-mm PCB was performed. Finally, stentless PCI with DCB angioplasty provided complete revascularization.

The patient was discharged 2 days later, and the clinical course after stentless PCI was uneventful. CAG, performed 8 months later, showed optimal results without restenosis, and the patient had no apparent angina symptoms for 33 months (Fig. 11–K).

#### Case 2

A 70-year-old woman with a history of hypertension and dyslipidemia presented with exertional angina pectoris (CCS classification 3). Exercise-stress cardiac scintigraphy showed significant myocardial ischemia with a total perfusion defect of 19 % in the anteroseptal left ventricle (Fig. 2A–B). Because of the patient's metal allergy concerns based on her history of contact dermatitis to metal, we performed patch tests for various metal alloys, which showed mercury, zinc, and nickel allergies (Fig. 2C). Thereafter, CAG showed the proximal LAD stenosis. Because of the patient's strong willingness to undergo stentless PCI and her refusal to undergo CABG, an additional IVUS examination for preoperatively evaluating plaque morphology revealed a soft plaque with mild superficial calcification, which was expectedly suitable for DCA (Fig. 3A–D). Based on these findings, the heart team elected to perform stentless PCI with DCA/DCB angioplasty as a revascularization strategy.

DCA was performed using Atherocut<sup>™</sup> L in six sessions with 30 total cuts (maximum cutting pressure: 4 atm), which enabled the optimal reduction in plaque volume from preoperatively 78 % to postoperatively 45 % on IVUS images (Fig. 3E). Balloon angioplasty with a 3.5/13-mm scoring balloon and 4.0/20-mm PCB was performed. Then, using a 2.25/10-mm cutting balloon and subsequent 2.5/30-mm PCB for the diagonal branch, the final CAG showed optimal results with TIMI grade 3.

The patient had an uneventful clinical course after stentless PCI, and CAG, 9 months later, showed no restenosis (Fig. 3F–H). The patient had no apparent angina symptoms for 30 months.

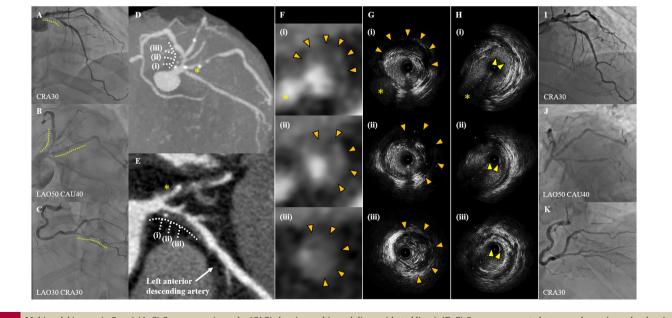
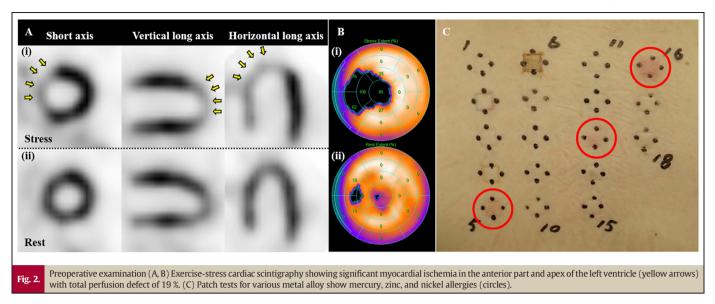


Fig.1. Multimodal images in Case 1 (A–C) Coronary angiography (CAG) showing multivessel disease (dotted lines). (D–F) Coronary computed tomography angiography showing non-calcified plaque in the left anterior descending artery (LAD). Massive plaque in the distal left main trunk extending from the proximal LAD (arrowheads). (G–H) Comparison of each lesion on intravascular ultrasound (G) before and (H) after directional coronary atherectomy (DCA). Resected region by DCA (arrowheads). (I–K) CAG performed at 8 months later, showing no restenosis. An asterisk indicates high lateral branch.



#### Discussion

The present cases demonstrated the efficacy of stentless PCI with DCA/DCB angioplasty in metal allergy patients with CAD involving proximal LAD stenoses. In Case 1, CCTA effectively suggested the suitability of DCA/DCB angioplasty for the proximal LAD and of DCB angioplasty for other lesions, resulting in complete revascularization. In Case 2, preoperative evaluation of plaque characteristics on IVUS was useful in determining the suitability of the DCA procedure, which could successfully guide stentless PCI.

Coronary stents consist of various metal alloys, including nickel, cobalt, and platinum. Metal allergies, reported in 14–20 % of cases in the

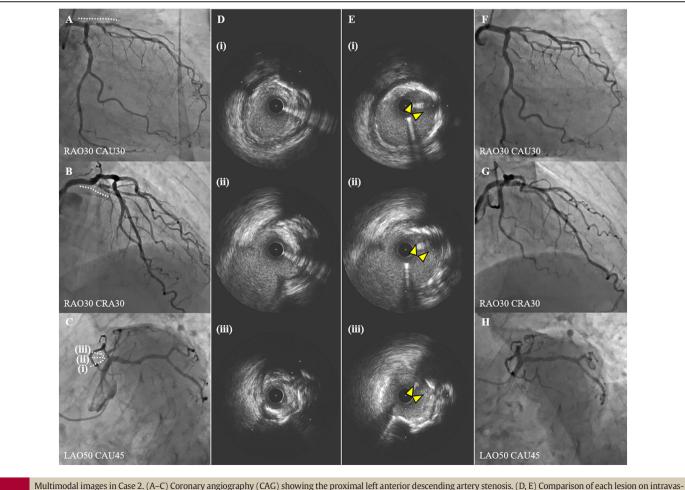


Fig. 3. Fig. 3. Fig. 3. Comparison of each lesion on intravasrestenosis. (*D*, *E*) Comparison of each lesion on intravasrestenosis. USA and Europe, have been associated with recurrent in-stent restenosis (ISR) and occlusion, leading to poor cardiovascular outcomes after PCI with stent implantation [4]. Therefore, a definite metal allergy confirmation prior to stent implantation is desirable. Although hyposensitizing treatment is a potential strategy for definite metal allergy cases, sufficient time is required to have effectiveness, which is unsuitable for patients with worsening angina pectoris [5]. Furthermore, the latent metal allergy detected by magnetic resonance imaging and fluorodeoxyglucose with positron emission tomography not by conventional patch tests, in patients with recurrent ISR of biodegradable polymer drug-eluting stent, was described [6]. In cases with recurrent ISR owing to potential hypersensitivity to metal allergy, medication therapy, including prednisolone and anti-allergic and anti-proliferative drugs, is reportedly effective; however, long-term immunosuppression therapy may be needed [7,8]. Considering the potential association between poor stent prognosis and metal allergy, the usefulness of a stentless strategy should be considered in patients with definite metal allergies or recurrent ISR history. Thus, stentless PCI is a treatable strategy in patients with metal allergies. However, CABG is recommended as a revascularization strategy for complex lesions, including the proximal LAD stenosis, as per guidelines; therefore, heart team should carefully discuss revascularization strategies while respecting the patient's willingness.

DCB angioplasty is a feasible strategy for stentless PCI. The efficacy of PCI with DCB angioplasty alone is non-inferior in patients with CAD in small vessels (<3.0 mm), ISR, and even ST-segment elevation myocardial infarction, than that of PCI with drug-eluting stent implantation, and DCB for large vessels is still off-label indication in Japan although several clinical trials showed its efficacy [9]. Lesion preparation before DCB angioplasty is important to achieve optimal vascular results, as the DCB consensus group recommends that lesion preparation prior to DCB angioplasty should be managed as angiographically <30 % stenosis without major dissection [9]. Additional interventions using coronary atherectomy procedures, such as DCA for non-calcified plaques, excimer laser coronary atherectomy for vulnerable plaque containing thrombotic lesions, and rotational atherectomy for calcified plaques, are effective in reducing plaque volume, resulting in achieving stentless PCI due to sufficient luminal expansion with a lower frequency of major coronary dissection induced by balloon angioplasty. Evaluating plaque morphology before PCI using coronary imaging, such as CCTA and IVUS, was useful in determining the suitability of the DCA procedure because the procedure is difficult for severely calcified, tortuous, diffuse (>30 mm) lesions or small vessels (<3.5 mm). In patients with metal allergies and unsuitable morphology for DCA, PCI with a bioresorbable magnesium scaffold (in some regions, except Japan) or minimally invasive CABG without the use of metal clips or implants may be alternative treatment strategies [10]. Additionally, although severe coronary dissection with flow delay is a rare complication, additional DCA for residual dissected plaques or long-time inflation using a perfusion balloon under mechanical circulatory supports can be feasible. If necessary, an emergency CABG may be required owing to the limitation of stent usage. Interventionalists should sufficiently inform patients of several DCA-related complications and bail-out methods before procedure.

Further investigations are warranted to determine the efficacy of stentless PCI with DCA/DCB in patients with CAD with metal allergies.

In conclusion, stentless PCI with DCA/DCB angioplasty under preoperative evaluation of plaque morphology by coronary imaging may be an acceptable strategy for patients with CAD with metal allergies.

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None.

#### Patient consent statement

Informed consent was obtained from the patients for publication of the case and accompanying images.

#### **Declaration of competing interest**

The authors declare that there is no conflict of interest.

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