



Local drug-delivery balloon for proliferative occlusive in-stent restenosis after drug-eluting stent

Gianluca Rigatelli, Paolo Cardaioli, Fabio Dell'Avvocata, Massimo Giordan

Cardiovascular Diagnosis and Endoluminal Interventions Unit, Rovigo General Hospital, 45100 Rovigo, Italy

Abstract

Drug-coated balloon has been developed as an alternative to drug-eluting stents for in-stent restenosis but the performance of drug infusion balloon in such setting has not been previously described. We present a case of particularly aggressive in-stent restenosis after drug eluting stent implantation treated with a new kind of drug infusion balloon developed in order to overcome the impossibility to inflate regular drug-coated balloon for several dilatation.

J Geriatr Cardiol 2011; 8: 65–66. doi: 10.3724/SP.J.1263.2011.00065

Keywords: angioplasty; stent; restenosis

1 Introduction

Drug-coated balloon has been developed as an alternative to drug-eluting stents (DES). Results of several preclinical and clinical studies indicate that short-term exposure of injured arteries to paclitaxel eluted from regular Percutaneous Transluminal Angioplasty and PTCA balloons may be sufficient to reduce late lumen loss and restenosis rates during a critical period of time after angioplasty of diseased coronary and peripheral arteries.^[1-2]

We present a case of particularly proliferative in-stent restenosis treated with a new type of drug eluting balloon.

2 Case report

A 68-year-old man with severe silent ischemia was admitted to our center for elective coronary angiography and percutaneous coronary intervention. The patient had bypass grafting of left anterior descending (LAD, with mammary artery), first obtuse marginal branch and right coronary artery (RCA) 6 years before. Three years after the surgical procedure, he developed unstable angina and angiography showed occlusion in both vein grafts. He underwent percutaneous transluminal coronary angioplasty

with DES in the obtuse marginal branch and left main and with a bare metal stents Vision 3.5 × 18 mm in the proximal and 3.0 × 23 mm (Abbot Vascular, Abbott Park, Illinois, USA) in the distal dominant RCA (Figure 1A and 1B). After one year, he had recurrent angina and a complete occlusion of previous bare-metal stents of RCA was noted. The patient underwent repeated coronary angioplasty with DES and extensive reconstruction of the RCA was accomplished using two Promus (Boston Scientific, USA) 3.5 × 28 mm and a 3.5 × 15 mm followed by another 3.0 × 12 mm from the proximal to the distal portion of RCA with excellent angiographic results (Figure 1C) after high pressure over-dilatation with 4.0 × 12 mm Sprinter NC balloon (Medtronic, Minneapolis, Minnesota, USA). Nevertheless after 8 mo the patient developed severe stress myocardial ischemia in the inferior territory associated with mild effort angina. The coronary artery angiography revealed diffuse proliferative and subocclusive in-stent restenosis of previous DES (Figure 1D). The patient was considered at risk for repeated bypass surgery, so a percutaneous ballaoon angioplasty with a medicated balloon was scheduled. Because the in-stent restenosis was too long to treat with a coated balloon, that usually can be used only one time for each inflation, an infusion balloon such as the Genie (Acrostak AG, Stegackerstrasse 14, Winterthur, Switzerland) was selected. The device is composed of a balloon with two heads at each distal extremity which allow for stopping the blood flow for at least 80 s (ideally 120 s) and a central chamber with micro-holes which is filled up with liquid paclitaxel (130-170 μmol) (Figure 1E), and can be implanted at a low pressure (2 atm). Treatment can be

Correspondence to: Gianluca Rigatelli, MD, FACP, FACC, FESC, FSCAI, Cardiovascular Diagnosis and Endoluminal Interventions, Rovigo General Hospital, 45100 Rovigo, Italy. E-mail: jackyheart@libero.it

Telephone: +39-44220164

Fax: +39-44220164

Received: November 20, 2010

Revised: March 16, 2011

Accepted: March 23, 2011

Published online: March 28, 2011

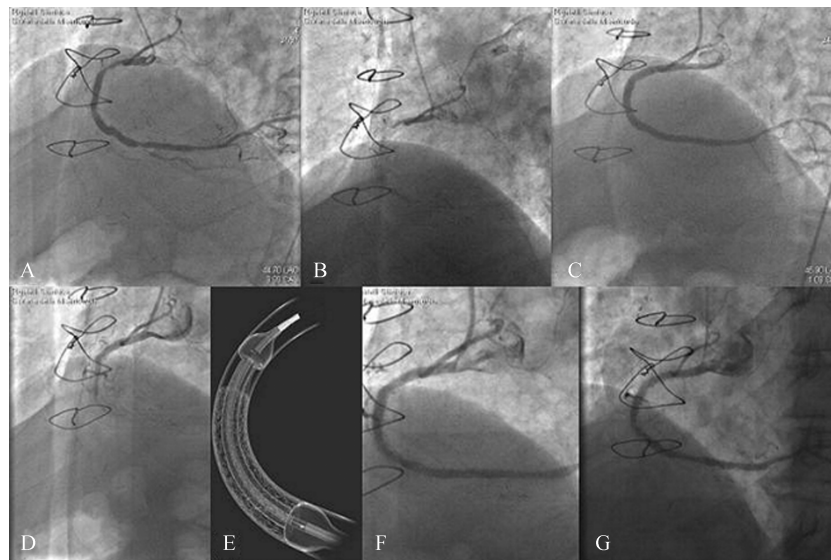


Figure 1. Angiographic appearance of in-stent restenosis after DES and subsequent treatment. (A): Native diffuse disease of the RCA treated with spot-stent with bare metal stent; (B): Restenosis and stent occlusion after bare-metal stenting; (C): angiographic appearance after DES extensive reconstruction; (D): Diffuse proliferative and subocclusive in-stent restenosis after multiple DES implantation; (E): the Genie Catheter for local anti-proliferative drug infusion; (F): Immediate angiographic results after Genie catheter application (four inflations from the distal to the proximal RCA); (G): six month angiographic control showing excellent result. DES: drug-eluting stents; RCA: right coronary artery.

repeated in long segment restenosis without using other balloon.

Thus, the RCA was wired and dilated with multiple inflation of a standard 3.0×30 mm Sprinter balloon and then, four dilatation along the entire RCA was accomplished with a 3.5×28 mm Genie catheter. The immediate final (Figure 1F) as well as 6 mo follow-up coronary angiographic results (Figure 1G) were excellent. The patient is free from symptoms and silent ischemia at 9 mo clinical and instrumental follow-up.

3 Discussion

The presented case suggests that drug-infusion balloon can offer an effective therapeutic option in selected patients with very extensive in-stent restenosis after DES implantation. Although the number of published trials and patients treated with drug eluting-balloon is still limited, and its effectiveness in treating in-stent restenosis, and in particular in the treatment of restenosis after DES has been only suggested but not yet proved, there is some promise for

drug-coated stent for such purpose. Most drug-coated balloon cannot be used for more than one inflation and thus resulted useless in long segment treatment. The Genie catheter has been used in in-stent restenosis after bare-metal stent implantation.^[3] However, to the best of our knowledge, this is the first report about its use in very long proliferative and occlusive in-stent-restenosis after DES treatment.

References

- 1 Scheller B, Speck U, Abramjuk C, *et al.* Paclitaxel balloon coating, a novel method for prevention and therapy of restenosis. *Circulation* 2004; 11: 810–814.
- 2 Fanggiday JC, Stella PR, Guyomi SH, *et al.* Safety and efficacy of drug-eluting balloons in percutaneous treatment of bifurcation lesions: the DEBIUT (drug-eluting balloon in bifurcation Utrecht) registry. *Catheter Cardiovasc Interv* 2008; 71: 629–635.
- 3 Herdeg C, Göhring-Frischholz K, Geisler T, *et al.* GENIE catheter for liquid local drug delivery. *EuroIntervention* 2007; 3: 286–268.