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# Kissing inflation is feasible with all second-generation drug-eluting balloons☆

Gregory A. Sgueglia*, Daniel Todaro, Andrea Bisciglia, Micaela Conte, Antonino Stipo, Edoardo Pucci

*UOC Emodinamica e Cardiologia Interventistica, Ospedale Santa Maria Goretti, Latina, Italy*

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**Abstract**

**Objective:** To assess the feasibility of kissing second-generation drug-eluting balloons (DEB), which have better mechanical properties than the first-generation DEB, in order to optimize provisional bare-metal stenting (BMS) when treating coronary bifurcation lesions in patients with contraindication to drug-eluting stents.

**Methods:** Consecutive patients with anticipated low compliance to dual antiplatelet therapy who are undergoing provisional stenting with an open-cell design BMS and final kissing balloon with second-generation DEB were enrolled in this feasibility study. Angiographic success and procedural success (i.e., angiographic success in absence of in hospital major cardiovascular events) were registered. Clinical follow-up was also attempted in all patients.

**Results:** A total of 14 patients (mean age 66±9 years, nine men) participated on the study. The DEB used were SeQuent Please (B. Braun Melsungen, Berlin, Germany) in six patients, In.Pact Falcon (Medtronic Invatec, Roncadelle, Italy) in four patients, New Dior (Eurocor, Bonn, Germany) in two patients and Pantera Lux (Biotronik, Berlin, Germany) in another two patients. All procedures, but one, were performed by transradial access through a 6-French high-flow guiding catheter. True bifurcation was present in 50% of the patients. Angiographic and procedural success was obtained in all patients. At a mean follow-up of 234±81 days, all contacted patients were asymptomatic and free from major adverse cardiac events (including cardiac death, nonfatal myocardial infarction and target bifurcation revascularization).

**Conclusion:** At the advent of dedicated bifurcation stents, kissing DEB appears safe and effective and can be used to implement innovative, simpler, safer and possibly more effective bifurcation techniques. These remarkable results have laid the ground for an ongoing prospective registry of the kissing DEB technique (KISSING DEBBIE study, ClinicalTrials.gov NCT01009996).



*Keywords:* Drug-eluting balloons; Kissing balloon; Coronary bifurcations; Provisional stenting; Bare-metal stents

## 1. Background

Bifurcations account for up to one fifth of all coronary lesions requiring interventional treatment, and percutaneous coronary interventions (PCI) involving bifurcation lesions are historically associated with lower angiographic success rate, a higher risk of procedural complications [1] and a greater restenosis rate than nonbifurcation lesions [2]. The

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* Corresponding author. UOC Emodinamica e Cardiologia Interventistica, Ospedale Santa Maria Goretti, Via Canova, 3-04100 Latina, Italy. Tel.: +39 077 36556217; fax: +39 07736556218.

*E-mail address:* g.a.sgueglia@gmail.com (G.A. Sgueglia).

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Table 1
Major advantages of DEB in bifurcation lesions as compared with DES according to their single components

| DES component | Related DEB advantage |
|---|---|
| Platform | Easy deliverability to the SB |
| | Preservation of the original vessel anatomy |
| Drug | Local drug delivery over a very short period of time, thus favoring endothelialization |
| | Drug concentration highest at the time of the injury due to angioplasty |
| | Homogeneous drug transfer to the whole bifurcation vessel wall |
| Polymer | Much lower inflammatory stimulus |
| | Anticipated lower rate of (very) late stent thrombosis and restenosis |
| | Shorter duration of dual antiplatelet therapy |

introduction of drug-eluting stents (DES) [3] and a variety of bifurcation-specific techniques [4,5] has improved procedural success, although actual evidence do not support any increased benefit of a two-stent technique over stenting the main vessel (MV) only [6,7]. The consequent widespread practice of provisional stenting is often associated with suboptimal angiographic results in the side branch (SB), thus leaving room for some improvement when percutaneously approaching such lesions.

Drug-eluting balloons (DEB) are a promising technology that has shown good results in the treatment of in-stent restenosis [8,9] and small vessels lesions [10]. After provisional bare-metal stenting (BMS), final kissing with two DEB would allow to achieve a homogeneous distribution of paclitaxel over the whole bifurcation, with results comparable with those obtained with DESs but without their drawbacks (e.g., prolonged dual antiplatelet therapy, increased risk of stent thrombosis). Table 1 outlines the advantages of an approach based on DEB in bifurcation lesions.

However, disappointing experience with first-generation DEB linked to poor mechanical properties has precluded this approach.

Second-generation DEB derive from established semi-compliant dilatation catheters that have better crossing profile than first-generation DEB but are still more rigid than their homonymous device because of the drug matrix on the balloon surface area [11]. We therefore performed a feasibility study of a kissing DEB strategy for the treatment of major bifurcation lesions with a standard approach in patients with contraindication to DES.

## 2. Methods

Patients with anticipated low compliance to prolonged dual antiplatet therapy and indication to percutaneous treatment of one major coronary bifurcation de novo lesion (visual reference vessel diameter ranging from 2.25 to 4.0 mm for both MV and SB) of the left coronary artery underwent provisional BMS and final kissing balloon with a second-generation DEB.

At the time of PCI, all patients were on dual antiplatelet therapy (aspirin, 100 mg daily, and clopidogrel, 300 mg loading dose on the day before the PCI). If a patient was already taking clopidogrel 75 mg daily for more than 3 days before the procedure, the 300-mg loading dose was not administered. After wiring both branches, predilation of the MV lesion was performed according to operator's judgment, while SB predilation was avoided to prevent possible vessel dissection and the risk of rewiring the SB through a dissection plane [12]. An open-cell design stent was always chosen to be implanted in the MV with the SB guidewire left in place. After MV stenting, guidewires were switched, with special care taken to recross through the stent strut closest to the carina, which has been shown to provide a far better stent scaffolding than proximal rewiring [12]. The procedure was then completed by kissing DEB to ensure homogenous medication of the whole bifurcation lesion. In this exploratory series, kissing balloon with conventional semicompliant balloons prior to kissing DEB was performed. A flowchart of the percutaneous bifurcation intervention is depicted in Fig. 1. After the procedure, dual antiplatelet therapy with aspirin 100 mg and clopidogrel 75 mg was prescribed for 3 months, according to the DEB instructions for use document, unless there is a different clinical requirement.

Angiographic success was defined by residual stenosis <20% in the MV and <50% in the SB with Thrombolysis in Myocardial Infarction (TIMI) 3 flow in both the MV and the

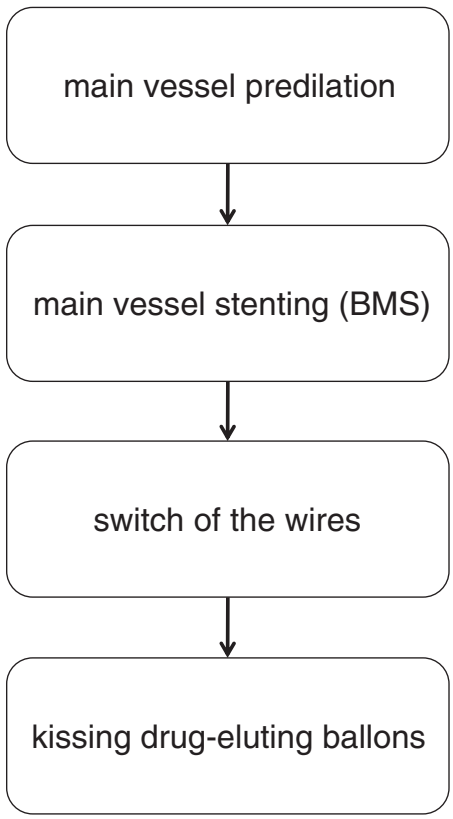


Fig. 1. Flowchart of the percutaneous bifurcation intervention.