

## PERCUTANEOUS CORONARY INTERVENTION

# Edge-to-Edge Technique to Minimize Overlapping of Multiple Bioresorbable Scaffolds Plus Drug Eluting Stents in Revascularization of Long Diffuse Left Anterior Descending Coronary Artery Disease

GIANLUCA RIGATELLI, M.D., Ph.D., F.A.C.C., F.E.S.C., F.S.C.A.I.,<sup>1</sup>

FABIO DELL'AVVOCATA, M.D.,<sup>1</sup> FEDERICO RONCO, M.D.,<sup>2</sup> MASSIMO GIORDAN, M.D.,<sup>1</sup>

LORIS RONCON, M.D.,<sup>1</sup> FRANCESCO CAPRIOGLIO, M.D.,<sup>2</sup> GIUSEPPE GRASSI, M.D.,<sup>2</sup>

GIUSEPPE FAGGIAN, M.D.,<sup>3</sup> and PAOLO CARDAIOLI, M.D.<sup>1</sup>

From the <sup>1</sup>Cardiovascular Diagnosis and Endoluminal Interventions Unit, Rovigo General Hospital, Rovigo, Italy; <sup>2</sup>Emodinamica Aziendale, ULS 12 Veneziana, Mestre-Venezia, Italy; and <sup>3</sup>Cardiac Surgery Institute, Verona University School of Medicine, Verona, Italy

**Background:** Implantation of Drug Eluting Stents (DES) plus bioresorbable scaffolds (BVS) in very long diffuse left anterior descending coronary artery (LAD) disease may be problematic because of multiple devices overlapping. We sought to assess the short and mid-term outcomes of combined implantation of DES and BVS using a novel "edge-to-edge" technique in patients with diffuse LAD disease.

**Methods:** Patients with long diffuse LAD disease were enrolled in a prospective registry from 1st August 2014 to 1st August 2015 and treated with IVUS-aided percutaneous coronary intervention using a DES plus a single or multiple BVS using a novel "edge-to-edge" technique. Clinical follow up and invasive follow up driven by clinical justification was performed.

**Results:** Twenty-three patients (5 females, mean age  $59.1 \pm 9.1$  years) were enrolled. Mean length of LAD disease was  $73.1 \pm 20.6$  mm. Mean number of DES and BVS implanted was  $1.2 \pm 0.4$  and  $1.7 \pm 1.3$ , respectively. At a mean follow-up of  $11.3 \pm 3.8$  months, no stent thrombosis or MACE were observed. Angiographic and IVUS follow-up at a mean of  $6.6 \pm 0.7$  months showed no significant angiographic restenosis and no appreciable stent gaps.

**Conclusions:** In revascularization of long diffuse disease of the LAD, the edge-to-edge implantation technique appears to be feasible resulting in no restenosis or thrombosis on the short-term follow-up. (J Intervent Cardiol 2016;29:275–284)

### Introduction

Current-generation drug-eluting stents (DES) hold several advantages over first generation DES and bare metal stents.<sup>1</sup> Permanent metallic stenting of the coronary vessel is perceived as a limitation, because it abrogates vasomotion, thereby preventing late

expansive remodeling. Bioresorbable scaffolds, and in particular the everolimus-eluting Absorb Bioresorbable Vascular Scaffold (BVS) (Abbott Vascular, Santa Clara, CA, USA), promise complete bioresorption after two to three years, vessel lumen enlargement, reduction of the plaque-media ratio, and restoration of vasomotion.<sup>2,3</sup> These characteristics may be particularly appealing when faced with very long, diffuse disease of main vessels unsuitable for surgery, such as the Left Anterior Descending coronary artery (LAD). In the real world a long LAD lesion is very often associated with disease of the proximal LAD bifurcation and some reports suggest the use of a hybrid strategy consisting of implanting a regular DES in the LAD-first Diagonal (D1) site and treating the rest of

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Address for reprints: Gianluca Rigatelli, M.D., Cardiovascular Diagnosis and Endoluminal Interventions, Rovigo General Hospital, Viale tre Martiri, Rovigo 45100, Italy. Fax: +390425394513; e-mail: jackyheart71@yahoo.it

the disease with a BVS.<sup>4,5</sup> Third-generation DES seem to offer very promising outcomes in simple and complex bifurcation lesions approached with a single or even double stent technique.<sup>6,7</sup> Multiple BVS implantation has been suggested anecdotally to be safe and effective.<sup>8,9</sup>

Outcomes of such a hybrid strategy have not yet been reported in a case series, nor has the impact of multiple BVS implantation and the ideal overlapping technique amongst BVS devices and between DES and BVS in such an anatomic picture (1 mm, or less, or no overlapping at all). We sought to assess the short and mid-term outcomes of a hybrid revascularization strategy consisting of the combined implantation of DES at the LAD-D site and BVS at the mid and distal LAD with a minimal or no –overlapping (edge-to-edge) technique in patients with diffuse LAD disease not suitable for surgery, in a prospective registry at two sites in Italy, the Rovigo General Hospital, Rovigo and the Mestre General Hospital, Mestre-Venice.

## Methods

Patients with long diffuse significant disease of the left anterior descending coronary artery which were not suitable for surgery on the basis of disease extension on coronary artery angiography were enrolled in a prospective registry from 1st August 2014 to 1st August 2015.

Clinical (cardiovascular risk factors, Canadian Cardiovascular Score class, EUROSCORE<sup>10</sup>) and angiographic characteristics (lesion/s location and severity according to the SYNTAX score<sup>11</sup> and MEDINA classification<sup>12</sup>) were analyzed by a Heart Team composed of the referral cardiac surgeon, the referral clinical cardiologist and the interventional cardiologist.

Exclusion criteria included: ST-elevation acute coronary syndrome with LAD as the infarcted artery, diameter of the proximal LAD >4 mm and of the mid-distal portion <2.25 mm after nitroglycerin intracoronary injection (200 micrograms), severe calcification of the mid-distal portions of the LAD not amenable to adequate lesion preparation, age >70 years old, clinical comorbidities causing inability to maintain double antiplatelet regimen for 12 months and life-expectance <2 years.

Patients not suitable for surgery underwent a percutaneous coronary intervention according to the current guidelines<sup>13</sup> using a drug eluting stent (Promus

Premier, Boston Scientific, Galway, Ireland) at the LAD-D bifurcation (distal left main shaft stenosis was not considered an exclusion criteria) plus a single or multiple BVS (Absorb, Abbot Vascular, Santa Clara, CA, USA) for the mid (LAD II) and distal portion of the LAD (LAD III). Additional significant lesions in other vessels were treated with staged procedures and a routine DES of the operator's choice (Promus Premier, Boston Scientific, Galway, Ireland; Orsiro, Biotronik, Bulack, Switzerland; Resolute Integrity, Medtronic Inc., Galway, Ireland). All patients signed the informed consent and the Hospital Editorial Board approved the study.

During PCI, patients were anticoagulated with unfractionated heparin (a bolus of 40 U/kg and additional heparin to achieve an activated clotting time of 250–300 seconds). All patients were advised to maintain the use of aspirin lifelong. Twelve-month Prasugrel or Ticagrelor treatment was recommended.

**PCI Protocol.** Steps included:

- 1) Coronary angiography with intracoronary nitroglycerin injection through a 6F femoral guiding catheter or through a 6 F right or left radial approach.
- 2) Intravascular ultrasound evaluation of the LAD diameter and lesion length: pre-dilation using non-compliant balloons (Sprinter NC or Euphonia, Medtronic, USA). The size was chosen on the basis of IVUS findings with 1:1 ratio at nominal atmospheres (atm) with increasing pressure until the rated burst pressure was reached or until the residual stenosis by QCA was less than 10%.
- 3) BVS size and length was chosen on the basis of IVUS findings following the company charts (2.25–2.5 mm, 2.5 mm device; 2.5–3.0 mm, 3.0 mm device; 3.0–3.5 mm, 3.5 mm device).
  - Minimal or no overlapping among BVS in the mid-distal portions of the LAD and between BVS and DES at the proximal LAD in order to prevent excessive strut protrusion within the vessel lumen.
  - DES at the LAD-D site was implanted following a standard protocol, as suggested by the European Bifurcation Club recommendations.<sup>14</sup>
  - Post dilation of BVS with non-compliant balloons not exceeding 0.5 mm of the

scaffold diameter at 20 atm. Post-dilation of DES at 20 atm with non-compliant balloons of diameter up to 1.5 mm exceeding the stent diameter.

- Control IVUS: eventual additional post-dilation at increasing pressure till the RBP was reached or until a residual stenosis of <10% was obtained or strut malapposition on IVUS was noticed.

**Overlapping Technique.** Choice of implanting the DES as the first step or the final step after BVS implantation was left to the operator's discretion on the basis of the LAD-D complexity on coronary angiography. Attention was required by the operators in order to leave minimal or no overlapping (edge-to-edge technique) between BVS and DES and among each BVS implanted.

In developing an ad hoc overlapping strategy, we considered some main concepts:

Firstly, it would be easier to position the BVS with the aid of the radio-opaque BVS balloon markers for overlapping of the fixed DES. Secondly, the BVS would lie on top of the metallic stent at the overlapped junction and would not cause any metallic strut disruption once the temporary scaffold was fully resorbed.

If the BVS was positioned first distally and then overlapped proximally with a DES, the thinner metallic struts would lie on top of the thicker BVS scaffold at the overlapped junction. Once the BVS scaffold beneath the metallic strut has resorbed, this would leave a segment of overhanging metallic strut which would not be apposed to the vessel wall. The longer the overlapping segment, the longer the length of potentially malapposed stent segment. The expansive remodeling property of the BVS may also contribute to the malapposition phenomenon at the DES-BVS overlap junction.

The current BVS has thicker struts and a larger crossing profile. From our experience with BVS implantation, we believe that crossing an already fully expanded DES can be very difficult and could damage the BVS struts, lengthening the procedural time and increasing the risk of complications.

To overcome all these issues, we employed a minimal (less than 1 mm) or no overlapping (edge-to-

edge technique) slightly different from the standard technique (Fig. 1):

- 1) Between two BVS: for scaffolds of any size the balloon of the implanting device was lined up not with the deployed scaffold marker beads, which should result in a 1 mm overlapping, but at the edge of the deployed scaffold marker beads, which should result in less than 1 mm or no overlapping;
- 2) Between the DES and the BVS:

- a) The balloon marker of the implanting DES was lined up with the second marker beads of the deployed scaffold in scaffolds 3.5 mm, in whom the marker is placed 1.4 mm inside from the outer edge proximally, which should result in less than 1 mm or no overlapping.

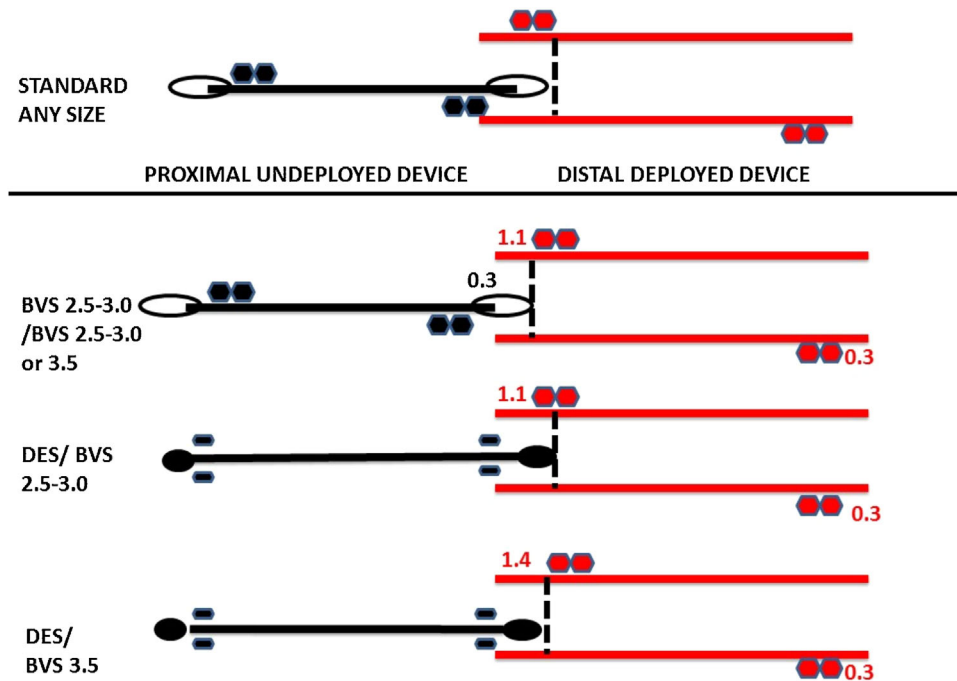
- b) The balloon of the implanting DES was lined up with the edge of the deployed scaffold marker beads in scaffolds 2.5–3.0 mm, in whom the marker is placed 1.1 mm inside from the outer edge proximally, which should result in less than 1 mm or no overlapping.

That obviously differs if another type of DES than Promus Premier has to be used, being the edge of the stent on the marker of the balloon in other types of stent.

**Angiographic Protocol.** For device implantation purposes, the LAD was divided in segments as following:

- LAD-D: LAD proximal + 10 mm distally from the first diagonal branch with diameter >2 mm.
- LAD II: 10 mm distally to the first diagonal branch with diameter >2 mm from the exit of the vessel from the sulcus arteriosus.
- LAD III: from the exit from the sulcus to the apex.

Quantitative coronary angiographic (QCA) analysis at baseline, post-stenting and at follow-up was performed using edge detection techniques (CAAS II 5.0 version; Pie Medical, Maastricht, Netherlands). Minimal lumen diameter (MLD), reference vessel



**Figure 1.** Schematic representation of the the standard technique (top of the figure) and the edge-to-edge overlapping technique in case of BVS/BSV any size (top-middle), DES/BVS 2.5–3.0 mm (middle-bottom), and DES/BVS 3.5 mm (bottom). On the right is represented the deployed scaffold (red colour) whereas on the left is represented the undeployed device (BVS or DES, black colour). The vertical broken line represented the point of lining up of devices.

diameter (RVD), segment length, and diameter stenosis ( $[1-MLD/RVD] \times 100$ ) were assessed.

Binary restenosis was defined as stenosis  $\geq 50\%$  of the luminal diameter in the target lesion.

**IVUS Protocol.** Intravascular Ultrasound examination was performed using the 3 F Opticross coronary IVUS catheter (Boston Scientific, Fremont, CA, USA) and automatic pull-back system (0.5 mm/s). On-line ultrasound assessment was performed in diastole. IVUS images were recorded after administration of 100–200 mg of nitroglycerin. The ultrasound catheter was advanced 0.5 mm beyond the lesion/stent and was pulled back to a point 0.5 mm proximal to the lesion/stent using motorized transducer pullback at 0.5 mm/s. IVUS was performed and interpreted by the treating physician and at least one experienced IVUS technician.

The lumen cross sectional area (CSA) at the stent level was assessed by planimetry at the interface of the blood and the stent, at multiple levels (at least three), and the smallest area was chosen. The proximal and distal reference lumen areas and diameters were also measured by manual planimetry. The reference

segments were selected as the most normal-looking cross section within 10 mm proximal and distal to the stent. To reduce the variability, all IVUS measurements were repeated, and the average of the two values was used in the analysis. Routine measurements were recorded pre- and post-stent implantation.<sup>15</sup> On follow-up IVUS control particular attention was carried out in determining stent thrombosis or restenosis and in evaluating the transition zone among DES and scaffolds.

IVUS parameters at baseline, post stent, and on eventual follow-up, were correlated to FFR to verifying the lesion significance<sup>16</sup> and the achieved results using the AVIO criteria.<sup>17</sup>

**Definitions.** Angiographic success was defined as a residual stenosis  $< 30\%$  by visual analysis in the presence of Thrombolysis in Myocardial Infarction (TIMI) 3 flow grade.

Thrombosis was defined as occurring within 24 hours of the procedure, subacute stent thrombosis from 1 to 30 days, and late stent thrombosis beyond 30 days. Probable stent thrombosis included all definite stent thrombosis, death of cardiac cause within

30 days of the index procedure, and Q-wave myocardial infarction (MI) attributable to the target vessel.

In-stent restenosis (ISR) was classified as focal (<10 mm long), diffuse (>10 mm long), proliferative (>10 mm long and extending outside the stent edges), or totally occluded.<sup>18</sup>

Major cardiac adverse event (MACE), including death, Q-wave MI, and target vessel revascularization (TVR). Death was all cause mortality. Cardiac death included all deaths where a non-cardiac cause could not be demonstrated. Q-wave MI was defined as an elevation in Troponin I level in the presence of new Q-waves on the electrocardiograph in >2 contiguous Leads, as measured at baseline and at 12 and 24 hours and daily if increased 2X the baseline level, following Thygesen K et al.<sup>19</sup>

Target lesion revascularization (TLR) was defined as revascularization, either percutaneous or surgical, for a stenosis within stent or in the 5 mm segments proximal or distal to the stent. TVR was defined as either percutaneous or surgical revascularization of the stented epicardial vessel.

**Clinical Follow-Up.** Per our institutional protocol, follow-up was conducted by physical examination at 1, 6, 12 months and then yearly. Induced ischemia test by means of Ergometric test, nuclear stress test or stress echocardiography was scheduled at 6/8 months. Transthoracic echocardiography was scheduled at 6 months. Angiographic and intravascular ultrasound control was scheduled at 6/8 months, at the time of additional vessel treatment or driven by clinical symptoms or instrumental evidence of myocardial ischemia. Information about in-hospital outcome was obtained from an electronic clinical database for patients maintained at our institution and by review of hospital records for those discharged to referring hospitals. Post-discharge survival status was obtained from the Municipal Civil Registries. Information on the occurrence of AMI or repeated interventions at follow-up was collected by consulting our institutional electronic database and by contacting referring physicians and institutions and all living patients.

## Results

Twenty-three patients (5 females, mean age  $59.1 \pm 9.1$  years), judged not to be candidates for surgery, were enrolled (Table 1). Calcification was

**Table 1.** Demographical and Clinical Data

	N° 23 (±DS or %)
Age (years)	59.1 ± 9.1
Male/female	18/5
Hypertension	20 (86.9)
Hypercholesterolemia	23 (100)
Diabetes	12 (52.1)
Smoking	18 (78.2)
Valvular heart disease	3 (13)
EF (%) (±SD)	40.2 ± 5.6
CCS class (±SD)	2.4 ± 0.7
Transient ischemic attack/stroke	1 (4.3)
Heart failure	0 (0)
Severe COPD	3 (13)
Peripheral arterial disease	3 (13)
Carotid artery disease	1 (4.3)
Rest angina	5 (21.7)
Non-ST elevation ACS	14 (60.9)
ST-elevation ACS	4 (17.4)
1-vessel disease	9 (39.1)
2-vessel disease	8 (34.8)
3-vessel disease	6 (26.1)
Additional Left main disease (>50%)	1 (4.3)
LAD-D1 Medina classification 1,1,1	10 (43.5)
SINTAX score	20.3 ± 7.2

ACS, acute coronary syndrome; CCS, Canadian Cardiovascular Score; EF, ejection fraction calculated from left ventricle angiography; SD, standard deviation.

apparent on angiography in the LAD-D segment in 22/25 patients (86.9%) and at LAD II in 7/25 patients (30.4%); no patients presented with calcification in the LAD III, confirming that the proposed strategy was feasible.

As assessed by angiography, the mean treated stenosis in LAD-D, LAD II, and LAD III were:  $88.4 \pm 1.1$ ,  $85.4 \pm 3.7$ , and  $87.6 \pm 5.6$  %, respectively. Percentage of Type C lesions was 89.9% (20/23), 69.5% (16/23), and 30.4 % (7/23) in LAD-D, LAD II, and LAD III, respectively. Mean length of LAD disease as assessed by IVUS was  $73.1 \pm 20.6$  mm (range 54–111 mm).

**Procedural Results.** In all cases the DES has been implanted at the last stent. Mean number of DES implanted in the LAD-D was  $1.2 \pm 0.4$ , whereas the mean number of BVS was  $1.7 \pm 1.3$  for a mean length of disease covered by DES and BVS of  $30.9 \pm 12.8$  and

44.5 ± 16.5, respectively (Fig. 2, Table 2). LAD-D bifurcation was treated by single-stent strategy in 20/23 patients (86.9%). Three patients required a double-stent strategy (13.0%).

Four patients (17.4%) experienced an increase in Troponin level × 2 compared to the baseline value: three patients had transient occlusion of the second Diagonal and third Diagonal branches resolved with rewiring and a 2.0 × 15 mm balloon dilation, whereas one patient developed BVS mild thrombosis during implantation of DES in a very lengthy procedure, resolved by a glycoprotein IIb/IIIa inhibitor 8 hour-long infusion.

Unintentional overlapping between BVS and DES and between BVSs <1 mm was observed in 6/23 patients (26.1%): interestingly these patients were the first 6 patients treated with this strategy. At the start of the study we tried to positioning the stent with regular fluoroscopy but the visualization of the marker was suboptimal. In the subsequent cases we used angiography with maximal image magnification which allowed for an optimal visualization of the stent markers.

**Clinical Follow-Up.** Clinical follow-up was available for 100% of patients. At a mean follow-up of 11.3 ± 3.8 months, no patient death, or MACE were observed. A slightly improvement of EF on echocardiography compared to baseline (40.2 ± 5.6 vs. 57.6 ± 7.1 %,  $P < 0.01$ ) and an improvement of CCS (2.4 ± 0.7 vs. 0.4 ± 0.8,  $P < 0.01$ ) were noticed.

**Angiographic and IVUS Follow-Up.** Angiographic and IVUS follow-up was available for 15/23

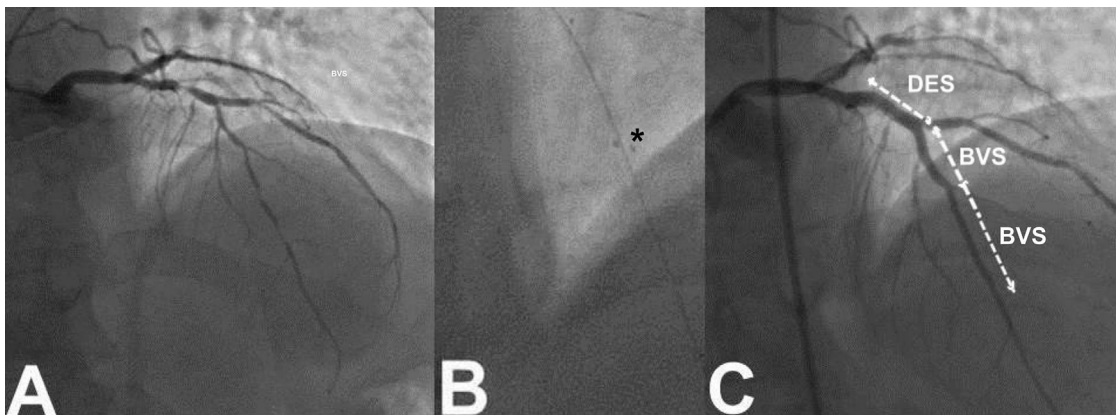
patients (65.2%) at a mean of 6.6 ± 0.7 months from the index procedure. The remainder of the patients were well with no symptoms or signs of reduced coronary reserve by stress test. Reasons for an invasive follow-up are detailed in Table 2.

No significant angiographic restenosis of DES was observed, whereas a moderate hyperplasia (<50%) of BVS was diagnosed in 2/23 patients (8.7%) on coronary angiography and confirmed by IVUS: these patients had unintentional overlapping on IVUS after stent deployment at time of the first procedure. They were treated conservatively and continued with clinical follow-up.

On IVUS, no appreciable gaps among BVS and between the BVS and DES was noticed (Figs. 3 and 4), No visible thrombus was noticed in any patients. Late lumen loss for segment LAD-D, LAD II, and LAD III, was 0.11 ± 0.42 mm, 0.12 ± 0.47 mm, 0.04 ± 0.28 mm, respectively. A comparison of QCA and IVUS findings at baseline, immediately after the index procedure and at follow-up examination in patients with invasive follow-up are summarized in Table 3.

## Discussion

Our small pilot study of this very challenging cohort of patients suggests that a hybrid revascularization strategy for the treatment of long, diffuse disease of the LAD using DES plus single or multiple



**Figure 2.** Coronary angiography in a 51-year-old male (patient n°14) with non ST-elevation ACS involving LAD as the culprit lesion: (A) Baseline Angiography Cranial AP view; (B) Edge-to-edge technique was used for stent overlapping: note the distance of the markers of the distal and proximal BVS, slightly longer than usually suggested by the company (asterisk); (C) immediate post-procedural result after implantation of 2.5 × 28 mm and 2.5 × 28 mm Absorb plus a 3.5 × 26 mm Promus Premier DES.

**Table 2.** Specific Data of the LAD Revascularization Procedure and Follow-Up

Pt	Indication	BVS (d × l, mm)	FU (Months)	Re-Cath Indication	Additional Tx
1	ACS	2.5 × 28/2.5 × 18	6	Staged PCI RCA	PCI RCA (DES)
2	ACS	2.5 × 28/3.0 × 18	6	Staged PCI RCA/LCx	PCI RCA/LCx(DES)
3	ACS	2.5 × 28	6	Staged PCI RCA/LCx PCI CDX CX (DES)	PCI RCA/LCx(DES)
4	ACS	2.5 × 28	6	Staged PCI RCA/LCx	PCI RCA/LCx(DES)
5	ACS	2.5 × 28	6	Staged PCI RCA/LCx	PCI RCA/LCx
6	ACS	2.5 × 28/3.0 × 18	6	Staged PCI RCA	PCI RCA
7	ACS	2.5 × 28/2.5 × 28	7	Nuclear stress test +	Clinical FU
8	ACS	2.5 × 28/2.5 × 28	7	Effort angina	—
9	ACS	2.5 × 28/2.5 × 28	Clinical FU	—	—
10	ACS	2.5 × 28	7	Nuclear stress test +	PCI LCx/RCA
11	ACS	2.5 × 28/2.5 × 28	Clinical FU	—	—
12	ST-el ACS*	2.5 × 28/2.5 × 28	Clinical FU	—	—
13	ST-el ACS*	2.5 × 23	6	Staged PCI RCA	PCI RCA
14	ACS	2.5+3.0 × 28/3.5 × 23	8	Effort angina	None
15	ACS	2.5 × 28	Clinical FU	—	—
16	ST-el ACS*	2.5 × 28/3 × 18/3.5 × 23	6	Staged PCI RCA	PCI RCA
17	ACS	2.5 × 23	Clinical FU	—	—
18	ACS	2.5 × 28	Clinical FU	—	—
19	ST-el ACS*	2.5 × 28/3 × 28/3.5 × 12	6	Staged PCI RCA	PCI RCA
20	ACS	2.5 × 28	Clinical FU	—	—
21	ACS	2.5 × 28/3 × 18	8	Nuclear stress +	—
22	ACS	2.5 × 28	8	Nuclear stress +	—
23	ACS	2.5 × 18/3.0 × 28	Clinical FU	—	—

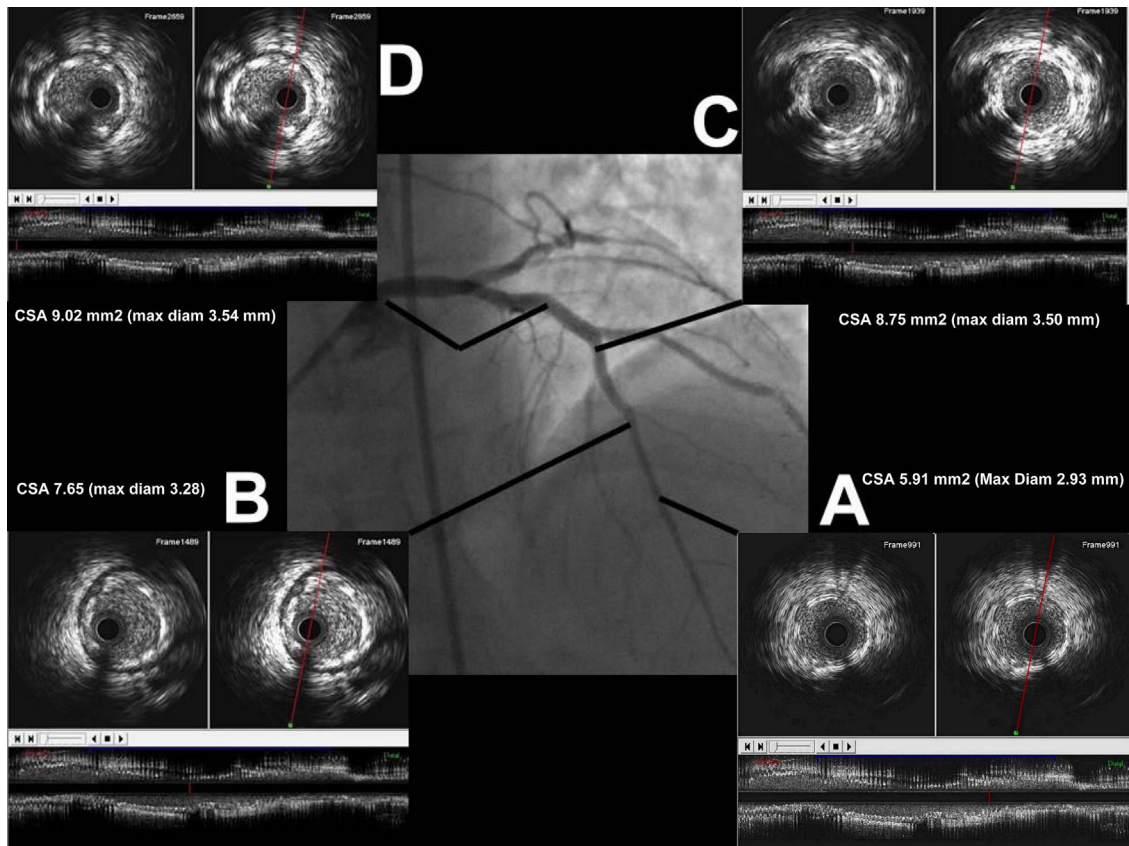
D × l: diameter × length; FU, follow up; LCx, left Circumflex coronary artery; PCI, percutaneous coronary interventions; RCA, right coronary artery. \*The infarcted vessel was LCx or Obtuse marginal branch.

BVS is feasible and relatively safe. Intriguingly, no death, thrombosis or acute myocardial infarction or TVR were experienced in a short-mid-term follow-up by any of the patients, despite a high percentage of multi-vessel disease treated. The edge-to-edge implantation technique resulted in no significant restenosis or thrombosis as assessed by angiography and IVUS examination in the patients with available follow-up.

Surgical treatment of long, diffuse LAD disease is still a matter of investigation. Sequential left internal mammary artery (LIMA) implantation, although feasible with good outcomes, is limited by the number of segments to be treated (usually no more than 2),<sup>20</sup> whereas the use of LIMA plus long segment endarterectomy has been proposed to be beneficial but is complicated by an operative mortality of 3.0 to 4.0% and a perioperative myocardial infarction rate of 4.0%.<sup>21</sup> The full-metal jacket technique using DES,

despite being considered relatively safe and effective, showed on long-term, rates of cardiac death, MI, TLR, and TVR of 6%, 6%, 27%, and 30%, respectively. The MACE rate was 15–34% in recent reports with a definite and probable stent thrombosis rate of 3–3.6%.<sup>21–23</sup>

It appears clear that the proposed strategy of combined third generation DES plus multiple BVS can be appealing, requiring nothing different than the usual antiplatelet regimen of multiple DES implantation. The obvious advantages could be to leave, in a relatively short time, a virtually naïve artery, maintaining the option of a LIMA implantation or a further stent procedure in case of new atherosclerosis onset in the index artery, and to ensure an optimal results at level of proximal LAD, which usually included an eventually calcified bifurcation, at the moment relatively contraindicated for BVS use.<sup>24</sup>



**Figure 3.** Follow-up at 7 months of the same patient: (central panel) Angiographic follow-up demonstrating vessel patency; IVUS examination confirming the absence of significant restenosis with no gap and no overlapping at both sites of BVS/BVS (B) and BVS/DES (C) transition zones and throughout the entire LAD from distal (A) to proximal (D). IVUS confirmed the angiographic good results following the AVIO criteria. CSA: stent cross sectional area; Max diam: maximum diameter.

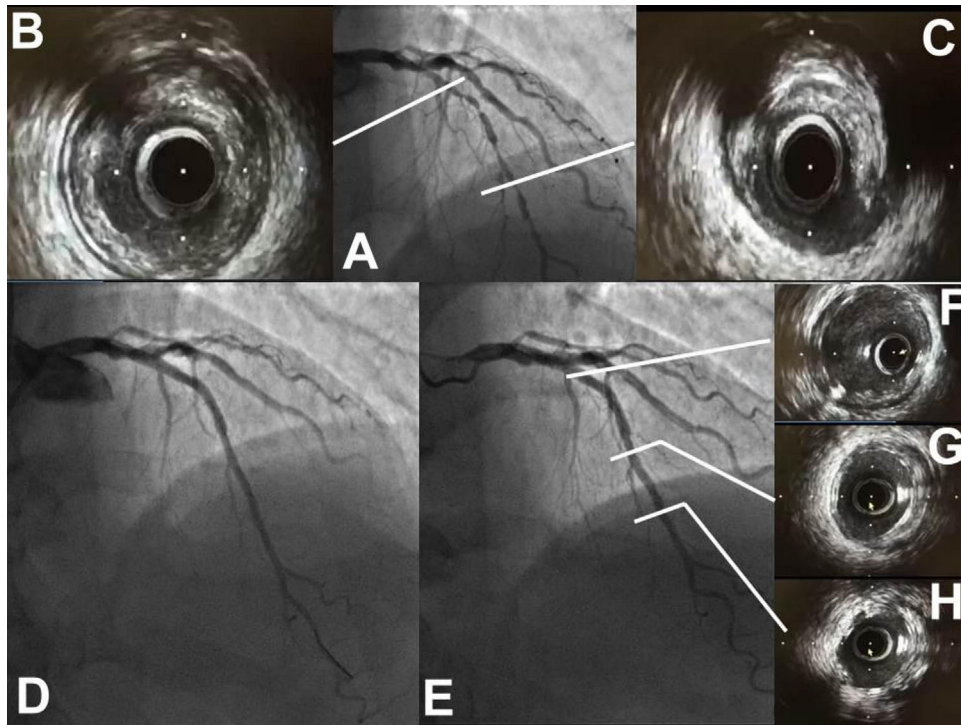
As expected, with a relatively short invasive follow-up period, mainly driven by clinical status or staged additional procedures, we did not observe vessel enlargement in the segment treated by BVS: the angiographic and IVUS parameters remained substantially unchanged. The time between the index procedure and the known reabsorption time of the BVS was too short to allow restoration of the functional properties of the vessels. In other words we assessed stented vessels rather than an already “cured vessels”. However, the invasive follow-up in half of the patients was useful, as we could assess the status of the transition zones between the stents and scaffolds and eventual restenosis or thrombosis.

An additional lesson learned in our brief experience in this challenging population, was to ensure that the procedure is as short as possible in order to

avoid perioperative troponin release and intraoperative stent or scaffold thrombosis. Repeated balloon dilation for lesion preparation and stent or scaffold post-dilation during deployment, heavily challenge the vessel, so meticulous ACT control during the procedure, short inflation and deflation times and methodically following all procedural steps, may help in maintaining short procedural times, thus decreasing the risk of thrombus formation or complications. Implantation of the BVS first and overexpansion, followed by DES deployment, avoiding difficulties in advancing the scaffolds even through an already well expanded DES, seem imperative in order to decrease long vessel manipulation and will expedite the procedure.

**Limitations.** Obviously our study suffers from several limitations including firstly the small population sample, which also reflects the very peculiar





**Figure 4.** Coronary angiography in a 55-year-old male (patient n°6) with non ST-elevation ACS involving LAD as the culprit lesion: (A) long and diffuse disease of the entire length of the LAD with a heavily diseased and calcified proximal LAD (B) and occlusion of D1. The disease extended up to the distal LAD (C); immediate result after implantation of Absorb  $2.5 \times 28$  mm,  $3.0 \times 18$  mm and a  $3.5 \times 28$  mm Promus Premier (D); follow-up at 6 month during staged PCI on RCA demonstrating vessel patency with no angiographic restenosis (E), and no stents malapposition throughout the length of the vessel (F–H).

anatomical presentation of our patients. Secondly, the study was conceived as non-randomized: randomization 1:1 with a full metal jacket technique, for itself still debated as standard of treatment in such patients, was thought not to be ethical because of the young age of the patients.

Thirdly, a lack of angiographic and IVUS follow-up for all the patients was clearly evident: for ethical and legal reasons a policy of submitting patients to coronary angiography and IVUS examination not-driven by clinical need was not feasible and perceived as potentially harmful. Fourthly, we have to

**Table 3.** Basal, Post-Stent Implantation and Follow-Up Angiographic and IVUS Examination Data in 12 Patients With Available Invasive Follow-Up

Vessel Segment	QCA					IVUS		
	Baseline			Post-PCI	FU	Baseline	Post-PCI	FU
	Ca	MLD	DS%	MLD	MLD	MLA	CSA	CSA
LAD D	13/15 (86.6)	$2.3 \pm 1.2$	$88.4 \pm 1.1$	$3.6 \pm 1.8$	$3.5 \pm 1.4$	$2.10 \pm 0.8$	$8.14 \pm 0.7$	$8.12 \pm 0.5$
LAD II	6/15 (40)	$1.9 \pm 1.4$	$85.4 \pm 3.7$	$2.8 \pm 3.5$	$2.7 \pm 3.1$	$1.87 \pm 0.6$	$4.7 \pm 1.8$	$4.6 \pm 1.5$
LAD III	0/15 (0)	$0.9 \pm 2.2$	$87.6 \pm 5.6$	$2.5 \pm 2.1$	$2.5 \pm 1.9$	$0.98 \pm 0.7$	$3.8 \pm 1.1$	$3.6 \pm 0.8$

Ca, calcification; CSA, stent cross sectional area ( $\text{mm}^2$ ); FU, follow-up; MLA, minimal lumen area ( $\text{mm}^2$ ); MLD, minimal lumen diameter (mm); DS%, Diameter stenosis.

acknowledge the lack of an optical coherence tomography investigation, which surely would add information on edge-to-edge technique and scaffold status: because of financial reasons and economic constraints, the already available IVUS equipment was preferred: in this sense the use of surrogate endpoints driven by IVUS findings is for itself a further limitation. Finally the assumption that overlapping between BVS and BVS and DES might be detrimental in term of risk of thrombosis and/or restenosis remains speculative since there are not definitive proof in current literature.

### Conclusions

Taking in account the clinical and anatomical picture of our study population, and that this represents the worst scenario for a relatively young patient, the outcomes appear promising, supporting the claim for further larger studies. The minimal or no-overlapping technique was shown not to impact the outcome, being relatively easy to perform after a short learning curve.

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