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Brief Rapid Report

Treatment of In-Stent Restenosis With Bioresorbable Vascular Scaffolds: Optical Coherence Tomography Insights

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See editorial by van Ditzhuijzen and Regar, pages 253-254 of this issue.

ABSTRACT

The role of the bioresorbable vascular scaffold (BVS) in patients with in-stent restenosis (ISR) remains unsettled. We present optical coherence tomography (OCT) findings in a series of 15 consecutive patients undergoing treatment of ISR with a BVS under systematic OCT guidance. OCT disclosed severe ISR in all patients (minimal lumen area [MLA], 1.3 ± 0.6 mm^2; stent obstruction 80% ± 10%). After the procedure, OCT MLA was 6.4 ± 2 mm^2 with a final BVS expansion of 79% ± 19%. "Angiographically silent" edge dissections (n = 6), intradevice dissections (n = 3), tissue prolapse (n = 3), and malapposition (n = 3) were also readily visualized. These findings underscore the diagnostic value of OCT in patients undergoing BVS implantation for ISR.

RÉSUMÉ

Le rôle de l'endoprothèse vasculaire biorésorbable (EVB) chez les patients subissant une resténose intrastent (RIS) n'est pas élucidé. Nous présentons les résultats de la tomographie par cohérence optique (TCO) d'une série de 15 patients consécutifs subissant un traitement de la RIS par EVB à l'aide de l'examen systématique de la TCO. La TCO révélait une RIS grave chez tous les patients (surface luminale minimale [SLM], 1,3 ± 0,6 mm^2; obstruction de l'endoprothèse, 80 % ± 10 %). Après l'intervention, la SLM à la TCO était de 6,4 ± 2 mm^2 et l'expansion finale de l'EVB, de 79 % ± 19 %. Les dissections de bords « muettes à l'angiographie » (n = 6), les dissections intradispositifs (n = 3), le prolapsus tissulaire (n = 3) et la malposition (n = 3) étaient également faciles à visualiser. Ces résultats soulignent la valeur diagnostique de la TCO chez les patients subissant l'implantation d'une EVB pour traiter la RIS.

Treatment of patients with in-stent restenosis (ISR) remains a clinical and technical challenge.[1] Different strategies have been proposed in this setting, but all suffer from relatively poor late clinical and angiographic results. Currently, the use of either the drug-eluting stent (DES) or the drug-coated balloon (DCB) is recommended in these patients.[1] Optical coherence tomography (OCT) provides unique insights into the underlying substrate of ISR and appears to be of value in optimizing the results of these interventions.[2,3] However, the value of the bioresorbable vascular scaffold (BVS) in this challenging anatomic scenario remains unsettled.[4,5] Furthermore, the potential value of systematic OCT guidance during this novel therapeutic strategy remains unknown. Therefore, we designed this prospective study to assess the value of OCT guidance during BVS treatment of patients with ISR.

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See page 259 for disclosure information.

Methods

We describe OCT findings in a prospective series of 15 consecutive patients with ISR treated with a BVS (ABSORB; Abbott Vascular, Santa Clara, CA). All patients presented with ISR (> 50% angiographic diameter stenosis on visual assessment) and were treated for symptoms or documented ischemia. Only the restenotic lesion (not the entire stent) was covered by the BVS. Special care was paid to predilate the lesion and, subsequently, to completely cover the injured segment to avoid the "geographic miss phenomenon." During the study period, 2 patients with ISR on small vessels were treated with DCB and therefore were not included in this series. All patients received dual-antiplatelet therapy before intervention. The ABSORB BVS consists of a semicrystalline polylactic acid backbone coated with a thin amorphous layer of poly(D-L- lactide) containing everolimus as an antiproliferative agent. Use of the BVS in patients with ISR was approved by our institutional ethics committee, and informed consent was obtained in all cases.

Quantitative coronary angiography was performed by experienced personnel using a validated edge-detection system (CASS II System, Pie Medical Imaging, Maastricht, The Netherlands). OCT (frequency domain system Dragonfly; St Jude Medical, St Paul, MN) was performed using a

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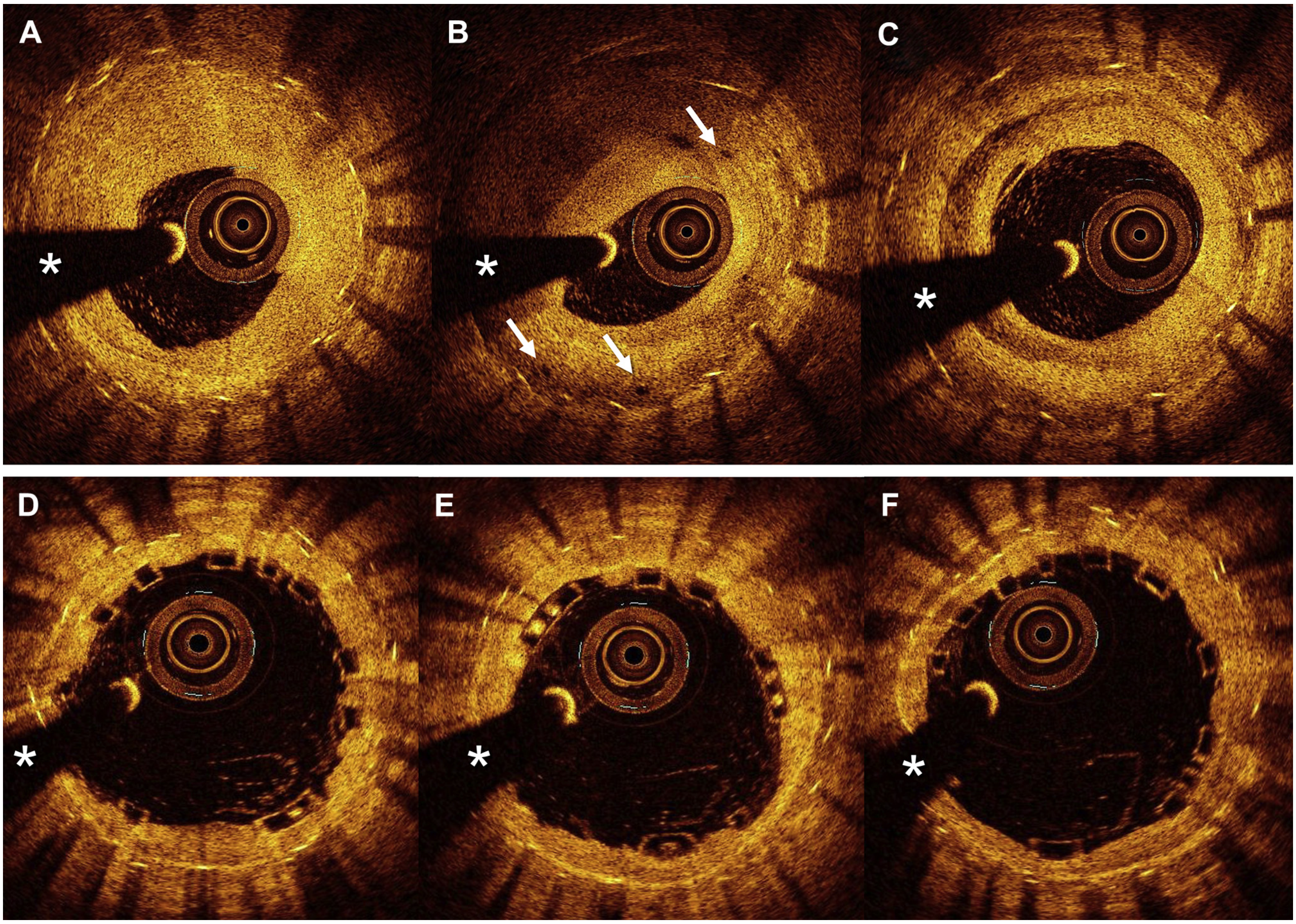

Figure 1. These optical coherence tomography (OCT) images are of the same patient and are matched in the same region of the lesion before and after bioresorbable vascular scaffold (BVS) implantation. (**A**) In-stent restenosis (ISR) with a typical uniform bright neointimal appearance. (**B**) OCT imaging showed the presence of neovascularization. (**C**) A layered neointimal pattern in the proximal area of ISR. (**D**-**F**) After high-pressure balloon predilation (26 bar) and BVS implantation, a satisfactory result (minimal lumen area, 4.4 mm^2) with complete strut apposition was obtained (**D**-**F**). The **asterisks** denote wire artifact. The **arrows** denote neointimal vascularization.

nonocclusive technique (automatic contrast medium injection of 10-12 mL at 4-5 mL/s) before and after intervention. OCT findings were analyzed using proprietary software (LightLab Imaging) after adjusting the z-offset for calibration and using standard criteria and recommendations.[6] Cross sections within the scaffolded segment and 10 mm proximal and distal to the BVS edges were carefully analyzed. Apposition was visually assessed strut by strut. Malapposition was defined as a break in continuity between the backscattering frame of the translucent strut and the vessel wall, appearing as a contrast-filled gap. The scaffold area was measured by joining the middle point of the black core abluminal side of the apposed struts or the abluminal edge of the frame borders in malapposed struts.

Data were analyzed with SPSS software (SPSS, Chicago, IL); categorical variables (n, %) were compared with the Fisher exact test, and continuous data were compared with the paired Student *t* test. A *P* value $\leq$ 0.05 was considered statistically significant.

Results

Fifteen consecutive patients with ISR were included. Mean age was 70 $\pm$ 10 years. Twelve patients were men and 3 were women. Nine patients had diabetes mellitus, 12 patients had hypertension, 14 patients had dyslipidemia, and 1 patient was a current smoker. Seven patients presented with acute coronary syndrome (2 had troponin elevation greater than normal values), and 8 patients presented with stable angina or silent ischemia. Nine patients had bare-metal stent ISR and 6 patients had DES ISR. Five lesions were located in the right coronary artery, 5 were in the left anterior descending artery, 2 were in saphenous veins grafts, and 1 was in the left main coronary artery. Two lesions had an ostial location and 3 lesions involved the bifurcation of a major side branch. Median size and length of the previous stent was 3.0 $\pm$ 0.8 mm and 15 $\pm$ 7 mm, respectively. The median elapsed time from initial stent implantation to ISR was 98 months.

OCT revealed severe ISR in all patients (mean minimal lumen area, 1.3 $\pm$ 0.6 mm^2; maximal stent obstruction, 80% $\pm$ 10%). A homogeneous bright image of neointimal proliferation was found in 3 patients. Twelve patients had a heterogeneous OCT pattern; of these 12 patients, 10 had findings highly suggestive of neoatherosclerosis (Figs. 1 and 2). Adequate OCT visualization of the entire stent length was obtained in all but 1 patient with an ostial stent location in whom the most proximal aspect of the stent was poorly