CLINICAL CASE

GuideLiner Catheter Facilitates Treatment of Calcific Ostial Circumflex Artery despite Severe Retroflexion

PHYSICIAN

Barry S. Weinstock, MD, FACC South Lake Hospital, Clermont, Florida

PRESENTATION

The patient is a woman with extensive cardiovascular history including prior CABG, porcine aortic valve replacement, chronic atrial fibrillation with AV node failure and subsequent permanent pacemaker placement. She also has hypertenstion, diabetes and a history of stroke. Due to severe left hip pain from degenerative joint disease, she was electively admitted for total hip arthroplasty. Post-operatively, she developed congestive heart failure and cardiac enzymes were consistent with a small peri-operative myocardial infarction. Cardiac catheterization was advised for further evaluation of her cardiac status.

INITIAL FINDINGS

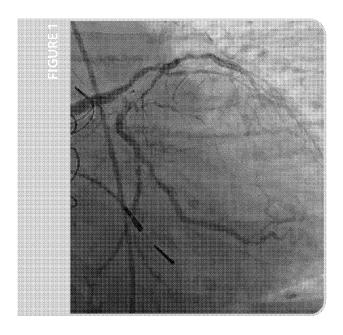
The patient underwent diagnostic catheterization (Figure 1) which demonstrated a patent left main coronary artery without significant disease. The left anterior descending artery had severe disease proximally with competitive flow from a bypass graft noted distal to the origin of a patent diagonal branch, which itself had severe ostial segment stenosis of 80-90%. The left circumflex artery had severe proximal tortuosity with retroflexion and a critical 95% stenosis at the origin followed by moderately severe disease proximally. A large 1st obtuse marginal branch had 70% proximal stenosis while a small 2nd obtuse marginal branch had 90% ostial segmental stenosis. The RCA had diffuse disease. The LIMA graft to the LAD was normal but all of the saphenous vein grafts were occluded. LV function was remarkably well preserved with EF of 55% with no significant wall motion abnormality. The culprit lesion for her MI was thought to be the critical ostial left circumflex stenosis and the patient was referred for intervention.

TREATMENT

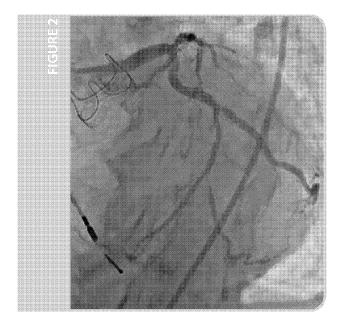
The ostial circumflex stenosis was approached using a 7F XB 3.5 guide catheter and the patient was anti-coagulated with bivalirudin. The circumflex was initially wired using a 0.014" Hi-Torque Whisper extra-support guidewire. The ostial stenosis was dilated using a 3.0 x 15mm Trek® PTCA balloon. A Promus® 4.0 x 28mm drug-eluting stent was inserted, but could be advanced only partially into the circumflex despite aggressive guide catheter positioning. The stent was removed and additional angioplasty was performed using a 3.5 x 20mm Apex® balloon catheter.

(continued on back)

VSIQXM_E00044658



DOCKET





Barry S. Weinstock, MD, FACC

Dr. Weinstock trained at Yale School of Medicine before completing his residency in internal medicine at the Hospital of the University of Pennsylvania. He completed his cardiology fellowship at Cedars-Sinai Medical Center and has been in practice as an interventional cardiologist since 1993. He currently practices with Mid-Florida Cardiology Specialists in Orlando and performs interventional procedures at three hospitals in the central Florida area.

TREATMENT (CONTINUED)

A second 0.014" ChoICE® PT Extra Support guidewire was delivered and the stent was re-advanced over the ChoICE PT wire. Again, it was not possible to pass the stent into the circumflex despite "deep-throating" the guide catheter. The first guidewire was removed, and a 7F-compatible GuideLiner was advanced without difficulty to the proximal circumflex artery. The 4.0 x 28mm stent was then advanced easily into the circumflex and the GuideLiner was removed. The stent was positioned at the ostium of the vessel and deployed. The 1st OM branch was then dilated using a 3.0 x 20mm Apex angioplasty balloon catheter which resulted in a moderate dissection. An attempt was made to pass a 3.0 x 23mm Promus stent into the OM branch but the stent would not pass through the ostial circumflex stent due to interaction with the stent struts. The stent was removed and the GuideLiner was re-advanced to the mid-circumflex artery. The 3.0 x 23mm Promus stent was then easily advanced into the OM branch and deployed.

Additional views of the left main coronary artery revealed mid-distal dissection, likely due to aggressive "deep-throating" of the guide catheter. The GuideLiner was re-advanced to the proximal circumflex and a 4.0 x 18mm Promus stent was advanced to the left main coronary artery with overlap distally into the ostial circumflex stent and deployed. The GuideLiner was removed and the left main artery and ostial / proximal circumflex were post-dilated using a 5.0 x 12mm NC Quantum[™] Apex balloon catheter. Final angiography confirmed excellent angiographic results in the left main, circumflex and first OM branch (Figure 2). The severe disease at the ostium of the small second OM branch was not treated.

SUMMARY

This patient had failure of all but one bypass graft and was extremely close to acutely occluding a large circumflex artery at its origin. The vessel's tortuosity, retroflexion and calcification combined to make stenting virtually impossible, despite use of a very strong guide catheter position and two extra-support wires. Using the GuideLiner device, it was possible to stent the ostial / proximal circumflex, a large OM branch after a balloon

angioplasty-induced dissection, and the protected left main coronary artery with highly important overlap of the ostial circumflex stent. This challenging case highlights the utility of the GuideLiner, a device which clearly was the difference between this procedure's failure and success.

GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement and exchange of guidewires and other interventional devices. Please see the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

GuideLiner is a registered trademark of Vascular Solutions, Inc. All other trademarks and registered trademarks are property of their respective owners.

DOCKET

ARM

©2016 Vascular Solutions, Inc. All rights reserved. ML2411 Rev. B 10/16



Vascular Solutions, Inc. 6464 Sycamore Court North Minneapolis, Minnesota 55369 USA Customer Service: United States: 888.240.6001 International: (001) 763.656.4298 customerservice@vasc.com www.vasc.com

VSIQXM E00044659

Find authenticated court documents without watermarks at docketalarm.com.