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Q1

The Contemporary Pulse of Bioresorbable-Scaffold Thrombosis Among Expert Operators

A European Survey

Fully bioresorbable scaffolds (BRS) represent a promising new technological frontier in percutaneous revascularization. BRS provide scaffolding properties and controlled release of antiproliferative agents followed by complete resorption of the backbone. The bioresorbable vascular scaffold (BVS) (Absorb BVS, Abbott Vascular, Santa Clara, California) has been the first BRS available for clinical use.

In 2014, we performed a survey (1) seeking to understand opinions and use of this technology. The fear for scaffold thrombosis was 1 of the most interesting findings of the survey—related at least in part to the GHOST-EU (Gauging coronary Healing with biOresorbable Scaffolding plaTforms in EUrope) registry findings (2). The survey highlighted how *scientific experts* (operators with scientific reputation but <20 BVS implantations) had less confidence with BVS use in complex settings as compared with *technical experts* (operators with >20 BVS implantations). Notably, technical experts expressed more concerns for scaffold thrombosis (3).

During the last 2 years, operator experience with BVS has increased and additional data has become available. A comprehensive meta-analysis showed a higher risk of definite/probable device thrombosis with BVS compared with drug-eluting stents (DES) at 1 year—with most events occurring during the first month after implantation (4). Conversely, a patientlevel meta-analysis of randomized trials including stable patients with at least 1 year of follow-up showed comparable efficacy and safety between BVS and DES (5).

Against this background, we conducted a follow-up survey of experts-defined as operators with at least 1 publication on BVS as first/corresponding author, or with documented experience of \geq 50 BVS

implantations. A list of centers using BVS was provided by the manufacturer, and a list of scientific experts was obtained through a PubMed search. Overall, 225 experts were identified, and an e-mail invitation was sent in September 2015. In case of no response, 2 additional reminders were sent 15 and 30 days after the initial invitation. Overall, 152 (67.6%) experts responded to the questionnaire.

A total of 40% of responders had implanted \geq 100 BVS and 50% had >2 years of experience, but 36% still used BVS rarely. With respect to complex/challenging settings, 43% of experts felt safe to use BVS during primary percutaneous coronary intervention, 33% in heavily calcified lesions, and 24% in bifurcations with side branch >2 mm.

Lesion preparation is considered mandatory by 83% of experts, but only 51% deem post-dilation essential with balloons 0.25 mm larger than the implanted device according to 57% of experts. Intracoronary imaging is employed in <20% of cases by 47% of experts, whereas it is used in >50% of cases by 27% of experts. Acute recoil is not considered an issue by 55% of experts, whereas 55% feel that any type of malposition might be an issue.

As it relates to scaffold thrombosis, 36% of experts never observed early, 63% never observed late, and 72% never observed very late events. As a result, 60% of experts do not consider scaffold thrombosis an issue, at least not more than with contemporary DES.

A section of the questionnaire was dedicated to optimal treatment strategies for scaffold thrombosis, as summarized in **Table 1**. About two-thirds of experts deem it necessary to investigate the possible mechanic etiology underlying the thrombotic event with intracoronary imaging. A total of 67% perform any type of thrombus aspiration, but only 29% use a glycoprotein IIb/IIIa inhibitor. A total of 33% perform balloon-only angioplasty, and 48% implant a DES. Only 23% believe that switching from clopidogrel to a more potent oral platelet inhibitor is important.

With respect to duration of dual antiplatelet treatment (DAPT), 90% of experts believe that a 12-month duration is mandatory. A marginal 8% always prolong DAPT beyond 12 months, and only 2% consider a 6-month duration to be sufficient.

ARTICLE IN PRESS

TABLE 1 Summary of Study Findings: How Experts Manage Scaffold Thrombosis Scaffold Thrombosis	9
Thrombus aspiration	67
OCT/IVUS (86%/14%)	65
Glycoprotein IIb/IIIa Inhibitor	29
DES	48
POBA	33
NC balloon	12
DEB	e
New BVS implantation	2
Clopidogrel switch to ticagrelor/prasugrel	23
DAPT longer than 12 months	27

Values are %.

BVS = biovascular scaffold; DAPT = dual antiplatelet treatment; DEB = drug-eluting balloon; DES = drug-eluting stent; IVUS = intravascular ultrasound; OCT = optical coherence tomography; POBA = percutaneous only-balloon angioplasty.

Conversely, 52% of experts believe that a BVS deserves longer DAPT than contemporary DES.

Regarding perception of future BVS penetration, 49% of responders believe that BVS use will increase in the next 12 months, 44% believe it will remain the same, and 7% expect a reduction.

In conclusion, experts that participated in this survey appear to be aware of safety concerns with currently available BVS suggested by recent published data. However, a good number of experts seem to believe that BVS thrombosis rates may be reduced by optimization of patient selection and implantation techniques.

[*] Bernardo Cortesq, MD	Q 7
Dario Buccherj, MD	
Giulio G. Stefaninį, MD, PhD	
Roxana Mehran, MD	
*Interventional Cardiology	
A.O. Fatebenefratelli Milano	
Bastioni di Porta Nuova 21	
20100 Milan	
Italy	<u>Q</u> 3
E-mail: bcortese@gmail.com	
http://dx.doi.org/10.1016/j.jacc.2016.03.576	

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