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# Bioresorbable Coronary Scaffold Thrombosis

## Multicenter Comprehensive Analysis of Clinical Presentation, Mechanisms, and Predictors

Serban Puricel, MD,[a] Florim Cuculi, MD,[b] Melissa Weissner, MTA,[c] Axel Schmermund, MD,[d] Peiman Jamshidi, MD,[b] Tobias Nyffenegger, MD,[b] Harald Binder, PhD,[e] Holger Eggebrecht, MD,[d] Thomas Münzel, MD,[c] Stephane Cook, MD,[a] Tommaso Gori, Dott Med Chir, PhD[c]

## ABSTRACT

**BACKGROUND** Recent reports suggest an elevated incidence of bioresorbable vascular scaffold (BVS) thrombosis (scaffold thrombosis [ScT]).

**OBJECTIVES** This study investigated occurrence rates, clinical and angiographic characteristics, and possible mechanisms of ScT in all-comer patients undergoing BVS implantation at 2 German and 2 Swiss hospitals.

**METHODS** A total of 1,305 consecutive patients (mean age 64 years, 78% male) who received 1,870 BVS (mean 1.4 ± 0.8 BVS/patient) were enrolled. Clinical/procedural characteristics, mortality, and ScT data at 485 days (range 312 to 652 days) were examined.

**RESULTS** ScT occurred in 42 patients. The incidence of probable and definite ScT was 1.8% at 30 days and 3.0% at 12 months, without differences among centers ($p = 0.60$). A total of 22 (52%) ScTs presented as ST-segment elevation myocardial infarction and 6 (17%) as sudden cardiac death. In multivariable analysis, ostial lesions ($p = 0.049$) and impaired left ventricular ejection fraction ($p = 0.019$) were independently associated with ScT. Nine (21%) of the ScTs occurred in patients who had suspended dual antiplatelet therapy, in 6 cases prematurely. Lower post-procedural minimum lumen and reference vessel diameters were hallmarks of ScT (all $p < 0.0001$). The risk of ScT appeared to rapidly increase for post-procedural minimum lumen diameters below 2.4 mm (for the 2.5- to 3.0-mm BVS) and 2.8 mm (for the 3.5-mm BVS). When a BVS-specific implantation strategy was implemented, 12-month ScT rates fell from 3.3% to 1.0%, an effect that remained significant when adjusted for multivariable propensity score ($p = 0.012$; hazard ratio: 0.19; 95% confidence interval: 0.05 to 0.70).

**CONCLUSIONS** The 12-month incidence of ScT reached 3% and could be significantly reduced when an optimized implantation strategy was employed. (retrospective multicentric registry and Mainz Intracoronary Database. The Coronary Slow-flow and Microvascular Diseases Registry [MICAT]; NCT02180178) (J Am Coll Cardiol 2016;67:921–31)


From the [a]Department of Cardiology, University & Hospital Fribourg, Fribourg, Switzerland; [b]Department of Cardiology, Luzerner Kantonsspital, Luzern, Switzerland; [c]Zentrum für Kardiologie, University Hospital Mainz, Mainz, Germany, and German Center for Cardiac and Vascular Research (DZHK), Standort Rhein-Main, Mainz, Germany; [d]Cardioangiologisches Centrum Bethanien, Frankfurt am Main, Germany; and the [e]Institute of Medical Biostatistics, Epidemiology and Informatics, University Hospital Mainz, Mainz, Germany. Dr. Cuculi has received lecture fees from Abbott Vascular; and has received unrestricted grants from Abbott Vascular and SIS Medical. Drs. Schmermund has received speakers' fees and travel expenses from Abbott Vascular. Dr. Eggebrecht has received unrestricted research grants from Abbott Vascular. Drs. Münzel and Cook have received speakers' fees from Abbott Vascular. Drs. Münzel and Gori receive funding from the Center for Translational Vascular Biology, Mainz. Dr. Gori has received speakers' honoraria from Abbott Vascular and St. Jude Medical. Abbott Vascular had no role in any phase of this research. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. Drs. Puricel and Cuculi as well as Drs. Cook and Gori contributed equally to the study.

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**ABBREVIATIONS AND ACRONYMS**

**ACS** = acute coronary syndromes

**BVS** = bioresorbable vascular scaffolds

**DES** = drug-eluting stents

**LVEF** = left ventricular ejection fraction

**MLD** = minimum lumen diameter

**QCA** = quantitative coronary angiography

**RVD** = reference vessel diameter

**ScT** = scaffold thrombosis

**STEMI** = ST-segment elevation myocardial infarction

Bioresorbable vascular scaffolds (BVS) have been introduced in interventional cardiology to address late-occurring complications of drug-eluting stents (DES) (1). Although the initial ABSORB cohort studies (2,3) and the recently published randomized trials ABSORB II and III (4,5) and EVERBIO-2 (Comparison of Everolimus- and Biolimus-Eluting Stents With Everolimus-Eluting Bioresorbable Vascular Scaffold Stents) (6) provided data in support of the safety of BVS, an unexpectedly high incidence of scaffold thrombosis (ScT) has been reported in single-center and multicenter observational studies (7–10) and in a recently published meta-analysis (11).

In particular, the 6-month incidence of ScT was 2% in the GHOST-EU (Gauging coronary Healing with biOresorbable Scaffolding platforms in EUrope) registry (7) and was as high as 3% in the academic medical center single-center registry (8). In the BVS EXAMINATION trial, a propensity score-matched analysis of ST-segment elevation myocardial infarction (STEMI) patients, a tendency toward higher rates of early ScT was observed in patients who received BVS compared with DES or bare-metal stents. Rates at 1 month were 2.1% for BVS, 0.3% for DES, and 1.0% for bare-metal stents ($p = 0.06$ for BVS vs. DES) (12).

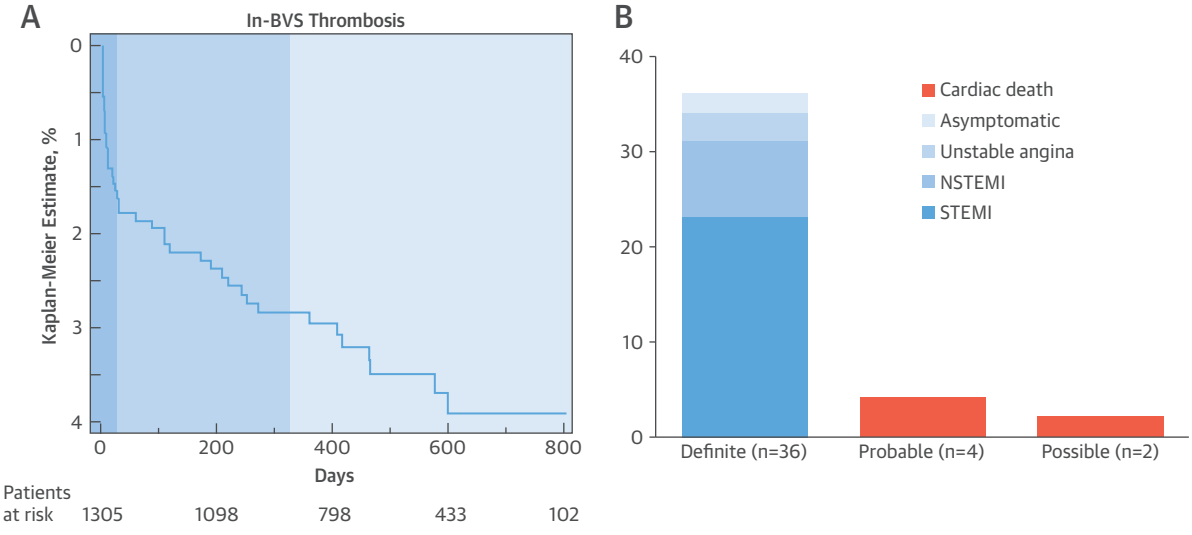
The existence of clinical or procedural predictors of ScT, and whether this incidence can be addressed, are unknown. The aim of this study was to describe the incidence and clinical presentation of ScT and to identify its clinical and procedural predictors in a large all-comer population.

SEE PAGE 932

## METHODS

**STRUCTURE OF THE DATABASE.** Patients were treated in each of the participating institutions according to clinical indications and underwent clinical follow-up at regular, pre-scheduled intervals. These data were acquired locally by trained medical staff using standardized questionnaires via clinical visits and through telephone contacts. Referring cardiologists, general practitioners, and patients were contacted whenever necessary for further information. All data were then internally audited in each center by staff who were not involved in data entry (T.G., M.W.), and they were retrospectively entered in the multicentric database in an anonymized way according to national privacy policies and laws and following the requirements of the ethics committee of the University Medical Center Mainz. Data were audited again centrally for consistency and plausibility, and queries were generated when necessary.

**FIGURE 1 Incidence and Clinical Presentation of ScT**




**(A)** Incidence of scaffold thrombosis (ScT). The different **shades of blue** identify early (<30 days from implantation), late (30 to 365 days), and very late (>365 days) thrombosis. **(B)** Clinical presentation and characterization of ScT. BVS = bioresorbable vascular scaffold; NSTEMI = non-ST-segment elevation myocardial infarction; STEMI = ST-segment elevation myocardial infarction.