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Clinical, Angiographic, and Procedural Correlates of Very Late Absorb Scaffold Thrombosis

Multistudy Registry Results

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ABSTRACT

OBJECTIVES The aim of this study was to identify independent correlates of very late scaffold thrombosis (VLST) from an analysis of consecutively treated patients from 15 multicenter studies.

BACKGROUND Recent analyses suggest an increased risk for VLST with the Absorb Bioresorbable Vascular Scaffold compared with drug-eluting stents, but insights as to correlates of risk are limited.

METHODS A total of 55 patients were identified with scaffold thrombosis. They were matched 2:1 with control subjects selected randomly from patients without thrombosis from the same study. Quantitative coronary angiography was available for 96.4% of patients. Multiple logistic and Cox regression analysis were used to identify significant independent outcome correlates from 6 pre-specified characteristics.

RESULTS Patients had scaffold thrombosis at a median of 20 months (interquartile range: 17 to 27 months). Control subjects were followed for 36 months (interquartile range: 24 to 38 months). For the combined groups, reference vessel diameter (RVD) was 2.84 ± 0.50 mm, scaffold length was 26 ± 16 mm, and post-dilatation was performed in 56%. Univariate correlates of thrombosis were smaller nominal scaffold/RVD ratio (linear $p = 0.001$; ratio <1.18:1; odds ratio: 7.5; $p = 0.002$) and larger RVD (linear $p = 0.001$; >2.72 mm; odds ratio: 3.4; $p = 0.001$). Post-dilatation at ≥16 atm, post-dilatation balloon/scaffold ratio, final percentage stenosis, and dual antiplatelet therapy were not correlated with VLST. Only scaffold/RVD ratio remained a significant independent correlate of VLST ($p = 0.001$), as smaller ratio was correlated with RVD ($p < 0.001$). Post hoc analysis of 8 other potential covariates revealed no other correlates of outcome.

CONCLUSIONS In the present analysis, the largest to date of its type, relative scaffold undersizing was the strongest determinant of VLST. Given current understanding of "scaffold dismantling," this finding likely has ramifications for all bioresorbable scaffolds. (J Am Coll Cardiol Intv 2018;11:638–44) © 2018 Published by Elsevier on behalf of the American College of Cardiology Foundation.

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Bioresorbable stents (BRS) were developed with the hope that they would attenuate the 1.5% to 3% annual risk for adverse events beyond 1 year following the implantation of metallic drug-eluting stents (DES) (1–3). Perhaps not unexpectedly given its large strut height and width, the BRS with by far the most clinical experience, the Absorb Bioresorbable Vascular Scaffold (BVS) (Abbott Vascular, Santa Clara, California) was shown to have an increased risk for 0- to 1-year thrombosis in comparison with the contemporary XIENCE DES (Abbott Vascular). An excess in events beyond 6 to 12 months, when the device was thought to have been well incorporated into the vessel wall, was not expected. Nonetheless, a 0.3% to 1.2% annual risk for very late scaffold thrombosis (VLST) with Absorb, more frequent than that seen with XIENCE, from 1 to 3 years has now been reported from several studies (4,5). Preliminary studies suggested a relation with larger diameter vessels (in contradistinction to the 0- to 1-year risk) (6), but rigorous analyses of the correlates of risk have not yet been forthcoming. Hence, the goal of this study was to carefully assess the correlates of VLST from data amalgamated from numerous well-conducted studies.

SEE PAGE 645

METHODS

STUDIES AND PATIENTS. In June 2016, we reviewed contemporary published research to identify high-quality randomized clinical trials and registries enrolling BVS patients with clinical follow-up in >95%, >12 months, and procedural quantitative coronary angiography (QCA) available either via the study directly or with willingness to send images to the Cleveland Clinic Core Angiographic Laboratory for review (which was done masked to clinical outcome). Nineteen studies were identified, and initially 15 agreed to participate. Formal case report forms, with study-specific definitions, were developed (7). This study was extended in the spring of 2017 to included follow-up through 4 years. One additional study contributed patients beyond 12 months, and 1 study had no follow-up beyond 12 months.

Consecutive cases of VLST (Academic Research Consortium definite or probable [8]) were identified. Control patients were selected 2:1 to cases, matched by site and requiring follow-up at least as long as their corresponding case, by a random number generator drawing from a consecutive list of patients without thrombosis.

STATISTICAL ANALYSES. Continuous variables are presented as mean ± SD or median as appropriate and were compared using parametric or nonparametric testing (chi-square, Fisher exact, or Kolmogorov-Smirnov). Categorical variables are presented as counts and percentages. For control patients undergoing BVS implantation at multiple sites, 1 was selected randomly to be the site of interest. Potential covariates were prioritized a priori for data analysis using an approximate 1:10 covariate/case ratio to minimize overmodeling (9). Chosen potential covariates were reference vessel diameter (RVD) and final post-implantation percentage stenosis by QCA, long-term and present use of dual antiplatelet therapy (DAPT), nominal scaffold/RVD ratio, post-dilatation at ≥16 atm, and post-dilatation with balloon/scaffold ratio >1.1:1. Continuous variables were assessing for possible dichotomization primarily by inspection of quintile data and also by spline analysis. Univariate and multivariate logistic regression and Cox proportional hazards analysis were performed to identify parameters possibly correlated with the endpoint. Models were assessed by multiple statistics, including log-likelihood, receiver-operating characteristic C-statistic, and McFadden's rho-squared testing. Interaction testing was performed to assess imbalances by study. Analyses were performed using SYSTAT version 13.0 (Systat, Richmond, California).

RESULTS

Of 7,578 consecutively treated (BVS implantation) patients, 55 had definite or probable scaffold thrombosis at a median of 20 months (interquartile range: 17 to 27 months). The timing of scaffold thrombosis in this series is shown in **Figure 1**. Because of the variable length of time of follow-up from the various studies, and within each study, these data should not be interpreted directly as the rate of VLST at various time points. Control patients were followed for a

ABBREVIATIONS AND ACRONYMS

BRS = bioresorbable stent(s)

BVS = Bioresorbable Vascular Scaffold

DAPT = dual antiplatelet therapy

DES = drug-eluting stent(s)

MLD = minimum lumen diameter

QCA = quantitative coronary angiography

RVD = reference vessel diameter

VLST = very late scaffold thrombosis

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