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# Bioresorbable coronary stent for the treatment of complex coronary lesions: Data from an all-comer registry

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ABSTRACT

*Background:* The study aimed to report the results from an all-comers registry of patients undergoing coronary angioplasty and treated with bioresorbable vascular scaffold (BVS).
*Methods:* Fifty-five consecutive patients with type B/C coronary lesions according to the AHA classification and treated with BVS were enrolled in the study. The clinical and procedural characteristics of enrolled patients were recorded. Fifty-five consecutive subjects with coronary lesions type B/C treated with everolimus eluting stent (EES) were used as control group.
*Results:* The incidence of adverse events was not statistically significant comparing subjects treated with BVS with those treated with EES. Non significant differences were also found in the follow-up considering the presence of diabetes, multivessel disease, use of more than one stent at the same time, diagnosis (STEMI vs UA/NSTEMI), use of coronary stents in overlapping.
The differences were significant considering the type of lesion (Log-Rank $p < 0.05$), stenoses treated in correspondence of a coronary bifurcation ($p < 0.05$), the SYNTAX score (cut off 22) ($p < 0.001$); after multivariable correction for age and gender, however, differences remained significant only for SYNTAX score.
*Conclusions:* The use of BVS in an all-comers registry of patients undergoing coronary angioplasty on complex coronary lesions is associated with a safety profile comparable to that obtained with EES; the use of BVS in particular conditions, such as very high SYNTAX score, should be further assessed.


## 1. Introduction

Coronary angioplasty (PCI) with drug eluting stent (DES) has been revolutionized in recent years by the introduction of bioresorbable vascular scaffold (BVS). The use of BVS DES was tested in the ABSORB study, which showed the safety and feasibility of everolimus BVS in patients with stable angina or silent ischemia and with de novo non thrombotic coronary artery lesions, with a low rate of major adverse cardiovascular events up to 4-year follow-up [1].

More recently, some studies have shown short-term safety and feasibility of BVS implantation in patients with acute coronary syndrome and acute myocardial infarction, with very encouraging results [2,3].

Less is known, however, on the safety and efficacy when BVS are used for complex coronary lesions, which are usually excluded from randomized controlled trials [4].

We therefore aimed to report clinical data coming from a monocentric registry enrolling all-comer patients treated with coronary angioplasty and BVS. We particularly focused on subjects treated with BVS, comparing follow up data with a historical cohort of control subjects treated with DES.

## 2. Methods

Fifty-five consecutive patients with complex coronary lesions and treated with Absorb™ BVS (Bioresorbable Vascular Scaffold, Abbott®, Santa Clara, California, USA) were enrolled in the study from May 2013 to April 2014. Inclusion criteria were coronary angioplasty on coronary lesion type B/C according to American Heart Association classification [5].

Exclusion criteria were: indication to oral anti-coagulant therapy, known neoplastic disease, active bleeding or anemia, left main stenosis, extended calcified lesions, vessel diameter <2.5 mm and >4.0 mm, and denied or withdrawn written informed consent.

Demographics, cardiovascular risk factors, diagnosis (STEMI vs UA/NSTEMI), number and characteristics of coronary lesions, SYNTAX score, AHA type of coronary lesions, presence of multi-vessel disease, angioplasty on coronary bifurcation, "overlapping" length and size of coronary stent used for coronary angioplasty, and left ventricular ejection fraction were recorded.

Incidence of adverse events (death, cardiovascular death, stent thrombosis, target lesion revascularization) was also recorded during follow up by direct clinical examination or telephone interview.

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Last fifty-five consecutive patients matching inclusion criteria and treated with everolimus drug eluting stent (EES) (Xience™ Abbott) before clinical implementation of BVS in our Institution were used as historical control group. All PCI procedures were performed by the same operators blind to the study. All the patients received dual anti-platelet therapy according to current guidelines, and atorvastatin 80 mg for at least 16 weeks.

The study was conducted according to declaration of Helsinki principles and, given its observational nature (clinical registry), not required explicit approval by local ethics committee. All participants gave a written informed consent.

### 2.1. Statistical analysis

Continuous variables were reported as mean ± standard deviation and compared with Student's *t*-test or Mann-Whitney *U* test as required, dichotomic variables with $\chi^2$ test.

The outcome of patients was described by means of Kaplan–Meier methodology, and statistical significance of differences in the combined clinical endpoint between groups of patients was tested using the Log-rank test. Multivariable Cox' analysis was used for correction for principal confounders.

A $p$ value $<0.05$ was considered as statistically significant.

### 2.2. Sample size

Given an expected incidence of adverse event with EES retrieved from prior studies [6], two groups of 55 patients are required to be 80% sure that the upper limit of a one-sided 95% confidence interval will exclude a difference between groups of >20%.

## 3. Results

Fifty-five consecutive subjects treated with coronary angioplasty and BVS were enrolled in the study and compared with 55 controls treated with EES, matchable for clinical and procedural characteristics (Table 1).

Mean age of patients who received a BVS was 55 ± 8 years, 16% had a diagnosis of STEMI, 42% had an AHA type of coronary lesion B, 58% type C, mean left ventricular ejection fraction was 50 ± 7%, mean SYNTAX score 15 ± 7, 58% had multi-vessel coronary heart disease, 60% received >1 BVS, 91% had lesions treated longer than 20 mm.

Incidence of adverse events among subjects treated with a BVS in a mean 417 ± 168-day follow up was 9%, 4% death, 4% cardiovascular death, 2% stent thrombosis (late thrombosis, 4 months after stent implantation), 4% target lesion restenosis.

The cumulative incidence of adverse events was not statistically significant comparing subjects treated with BVS with those treated with EES (Log-rank $p$ n.s., Fig. 1); differences remained statistically non significant even after correction for age, gender and anti-platelet therapy in multivariable Cox' analysis. Non significant differences were also found in the follow-up considering the presence of diabetes, multivessel disease, use of more than one stent at the same time, diagnosis (STEMI vs UA/NSTEMI), use of coronary stents in overlapping (Fig. 2).

The differences were however significant with worse outcomes with type C of lesion (vs type B, Log-Rank $p$ 0.0463, Fig. 2f), presence of coronary bifurcation stenting ($p$ 0.039, Fig. 2g), SYNTAX score >22 ($p < 0.001$, Fig. 2h). However, differences remained statistically significant after correction for age, gender and anti-platelet therapy (prasugrel/ticagrelor vs clopidogrel) only considering SYNTAX score >22 at multivariable Cox' analysis ($p < 0.001$).

**Table 1**
General characteristics of the population enrolled in the study.

| | All patients Mean | N 110 Std. dev. | EES Mean | N 55 Std. dev. | BVS Mean | N 55 Std. dev. | *p* |
|---|---|---|---|---|---|---|---|
| Age | 60.74 | 11.11 | 66.62 | 10.88 | 54.85 | 7.76 | <0.001 |
| Male | 83% | | 0,80 | | 0,85 | | 0.4538 |
| STEMI | 19% | | 22% | | 16% | | 0.4713 |
| NSTEMI | 35% | | 35% | | 35% | | 1.0000 |
| UA | 17% | | 18% | | 16% | | 0.8031 |
| SA | 29% | | 25% | | 33% | | 0.4057 |
| Hypertension | 68% | | 69% | | 67% | | 0.8396 |
| Diabetes | 31% | | 36% | | 25% | | 0.2194 |
| Dyslipidemia | 69% | | 64% | | 75% | | 0.2194 |
| Beta-blockers | 77% | | 87% | | 67% | | 0.3352 |
| ACEi/ARB | 83% | | 80% | | 85% | | 0.4802 |
| AHA type B1 | 1% | | 0% | | 2% | | 0.3195 |
| B2 | 45% | | 51% | | 40% | | 0.2546 |
| C | 54% | | 49% | | 58% | | 0.3436 |
| LVEF | 49.66 | 6.94 | 49.20 | 6.93 | 50.13 | 6.98 | 0.4862 |
| SYNTAX score | 15.87 | 6.89 | 17.11 | 6.43 | 14.64 | 7.17 | 0.0594 |
| LAD | 62% | | 56% | | 67% | | 0.2429 |
| LCX | 17% | | 15% | | 20% | | 0.4538 |
| RCA | 15% | | 16% | | 15% | | 0.7942 |
| 1-Vessel disease | 40% | | 38% | | 42% | | 0.7003 |
| 2-Vessel | 49% | | 53% | | 45% | | 0.4660 |
| 3-Vessel | 12% | | 11% | | 13% | | 0.7703 |
| Stent size | 2.87 | 0.40 | 2.83 | 0.43 | 2.9 | 0.37 | 0.3724 |
| # stents implanted | 1.75 | 0.59 | 1.84 | 0.60 | 1.67 | 0.58 | 0.1489 |
| Total stent length | 42.81 | 15.22 | 44.65 | 15.73 | 40.96 | 14.61 | 0.2050 |
| Bifurcation angioplasty | 26% | | 27% | | 25% | | 0.8306 |
| Lesion length > 20 mm | 91% | | 91% | | 91% | | 1.0000 |
| Chronic total occlusion | 7% | | 11% | | 4% | | 0.1446 |
| Overlapping stenting | 62% | | 65% | | 58% | | 0.4371 |
| Multiple stenting | 65% | | 71% | | 60% | | 0.2328 |
| Prasugrel | 20% | | 11% | | 30% | | 0.0136 |
| Ticagrelor | 18% | | 11% | | 26% | | 0.0428 |
| Clopidogrel | 62% | | 78% | | 44% | | 0.0003 |
| Death | 5% | | 5% | | 4% | | 0.6507 |
| Cardiac death | 3% | | 2% | | 4% | | 0.5625 |
| Stent thrombosis | 1% | | 0% | | 2% | | 0.3195 |
| TLR | 5% | | 5% | | 4% | | 0.6507 |
| Any adverse event | 8% | | 7% | | 9% | | 0.7309 |

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