CORONARY ARTERY DISEASE

Five-Year Clinical Outcome of Titanium-Nitride-Oxide-Coated Bioactive Stent Implantation in a Real-World Population: A Comparison with Paclitaxel-eluting Stents: The PORI Registry

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Aims: We sought to present the 5-year clinical outcome of the titanium-nitride-oxide-coated bioactive stents (BAS), as compared to paclitaxel-eluting stents (PES), in a real-world patient population.

Methods: From May 2003 to November 2004, we enrolled 405 consecutive patients who underwent percutaneous coronary intervention with either BAS or PES implantation. Patients were prospectively followed up for 5 years. The primary end-point was major adverse cardiac events (MACE) at 5-year follow-up including cardiac death, nonfatal myocardial infarction (MI), or target lesion revascularization.

Results: A total of 201 patients received BAS (218 lesions/221 stents) while 204 patients received PES (244 lesions/247 stents). Clinical follow-up for 5 years was completed in all patients. Cumulative MACE at the end of 5-year follow-up occurred in 34 (16.9%) patients in the BAS group, as compared to 53 (26%) in the PES group (OR 1.7, 95% CI 1.1–2.8, P = 0.03). This difference was mainly driven by a lower incidence of MI in the BAS group as compared with the PES group (9.5% vs. 20.6%, OR 2.5, 95% CI 1.4–4.4, P = 0.002). Stent thrombosis occurred in 16 (7.8%) patients in the PES group, while no one suffered stent thrombosis in the BAS group.

Conclusion: BAS implantation in a real-world patient population achieves an excellent clinical outcome over 5-year follow-up, with a significantly lower incidence of MI, MACE, and stent thrombosis as compared to PES. (J Interven Cardiol 2011;24:1–8)

Introduction

Coronary stent implantation has clearly improved procedural safety and promoted a better outcome of percutaneous coronary interventions (PCI) as compared to balloon angioplasty alone.1,2 Nevertheless, since the first introduction of coronary stents, in-stent restenosis (ISR) has always been the “Achilles’ heel” of this technique, ending up with repeat revascularization and a subsequent increase in health care cost.3,4 The incidence of ISR after bare metal stent implantation may approach 30% in several subgroups of patients, including diabetics, patients with small coronary vessels, and those with long lesions.5,6

The recent introduction of drug-eluting stents (DES) has, actually, revolutionized the practice of coronary angioplasty, since it has reduced the incidence of ISR by 50–70%.7,8 However, recent data from meta-analyses and registries have questioned the long-term safety of DES, raising concerns about a higher risk of late stent thrombosis (ST), a potentially life-threatening complication.9,11

The safety of titanium-nitride-oxide-coated bioactive stents (BAS) has been confirmed in several studies in real-life unselected populations, as well as in the most challenging indications such as diabetic patients, small coronary vessels, and acute myocardial
infarction (MI). Surprisingly, recent data have demonstrated an even “better” long-term outcome of BAS in comparison with paclitaxel-eluting stents (PES) in the real-world setting of unselected patients with high-risk clinical features and complex lesion characteristics. The purpose of this study was to present the 5-year clinical outcome of BAS implantation, as compared to PES, in this single-center, real-world population with unrestricted use of both types of stents.

Patients and Methods

Study Design and Patient Selection. The design of the original study has been previously reported. Briefly, the PORI Registry was a prospective nonrandomized single-center registry, with the chief aim to evaluate the efficacy and safety of BAS (Titan2®, Hexacath, Paris, France) as compared to PES in real-world unselected patients in everyday practice. From May 2003 to November 2004, we enrolled a total of 405 consecutive patients with symptomatic ischemic heart disease admitted to undergo PCI. We considered patients eligible for enrollment if they were above 18 years, with at least one significant de novo lesion (defined as at least 50% diameter stenosis by visual estimation) in a native coronary artery or coronary bypass graft. Treatment of more than one vessel was permissible and the stenting indication was determined by operator’s discretion. The study population included 201 patients who received BAS and 204 who received PES (Taxus™, Boston Scientific, Calway, Ireland). This patient population comprised 63% of all patients who underwent PCI during the index study period. Before inclusion, an informed written consent was obtained from each patient after full explanation of the study protocol. Collected data were given a code number for every patient to ensure patients’ anonymity. The study protocol was reviewed and approved by the Ethics Committee of Satakunta Central Hospital as it conforms to the ethical guidelines of the 1964 Declaration of Helsinki, as revised in 2002.

Device Used. A commercially available stainless steel tubular stent with the unique helicoidal design was used in this study. Titan2® stent is a thin strut (0.07–0.09 mm) balloon-expandable stent made of stainless steel and coated with titanium-nitride-oxide that completely prevents discharge of nickel, chromium, and molybdenum ions. The coating process is performed by plasma-enhanced vapor deposition of titanium in a prespecified gas mixture of nitrogen and oxygen in a vacuum chamber. Stents were available in lengths of 7, 10, 13, 16, 19, and 22 mm and in diameters of 2.5, 2.75, 3.0, 3.5, and 4.0 mm.

Coronary Stenting Procedure. All included patients were already pretreated with aspirin (100 mg daily). Oral clopidogrel was initiated in a loading dose of 300 mg before or immediately after the procedure and continued thereafter at a daily dose of 75 mg. For patients treated with PES, it was prescribed for a minimum of 6 months, according to randomized clinical trials. For patients treated with BAS, it was prescribed for at least 3 months. During the procedure, enoxaparine (1 mg/kg) was given intravenously. Use of periprocedural glycoprotein IIb/IIIa inhibitors was left entirely up to operator’s discretion. The medical treatment of coronary artery disease was optimized according to the contemporary guidelines.

Lesions were treated according to the contemporary interventional techniques. Predilatation was left to operator’s discretion. The operator decided the appropriate diameter to be implanted aiming at a stent: vessel ratio of 1.1:1 prior to stent placement (using nominal pressure). Stents were expanded by adjusting the balloon inflation pressure to achieve an angiographic appearance of the expanded stent slightly larger than the reference vessel segment. After stent deployment, postdilatation was allowed as necessary (at operator’s discretion). An additional stent could be deployed in overlap with the first one in case of edge dissection, incomplete lesion coverage, or otherwise suboptimal result (always dictated by operator’s discretion).

Clinical Follow-up. All patients were observed during hospital stay for the occurrence of the clinical end-points prespecified by the study protocol. Thereafter, patients were prospectively followed up by means of clinic visits or telephone interviews by cardiologists at 1, 3, and 5 years following the index procedure. Follow-up coronary angiography was performed for patients who develop recurrent symptoms during follow-up. The decision to perform further revascularization for the index lesion was based on clinical justification. All patient data available from hospital records, institutional electronic database, or referring physicians were entered into an electronic database, and checked at the end of the follow-up period (November 2009).

Study End-points and Definitions. The primary end-point was major adverse cardiac events (MACE), defined as the first occurrence of any of the following
during follow-up: cardiac death, nonfatal MI (including Q wave and non-Q wave MI), or target lesion revascularization (TLR). Q wave MI was defined as either (1) the occurrence of chest pain or other acute symptoms consistent with myocardial ischemia in the presence of new pathologic Q waves in ≥2 contiguous leads, or (2) elevated creatine kinase levels >2 times the upper limit of normal lab reference, associated with any elevation above the upper limit of normal of creatine kinase-MB levels, in the presence of new pathologic Q waves. Non-Q wave MI was defined as an elevated creatine kinase >2 times the upper limit of normal lab reference, associated with any elevation above the upper limit of normal of creatine kinase-MB levels. TLR was defined as any repeat intervention (surgical or percutaneous) to treat a significant luminal stenosis within the stent or in the 5-mm distal or proximal segments adjacent to the stent. Revascularization was regarded as “clinically-driven” if it was motivated by anginal symptoms and/or proven myocardial ischemia in the target vessel territory by non-invasive testing. ST was diagnosed by the occurrence of an acute coronary syndrome with angiographic evidence of either vessel occlusion or thrombus within the index stent, or in autopsy. Angiographic restenosis was defined as 50% diameter stenosis (by visual estimation) within the stent or in the 5-mm distal or proximal segments adjacent to the stent, at follow-up coronary angiography.

Statistical Analysis. Continuous variables were presented as mean ± SD, while categorical variables were described with absolute and relative (percentage) frequencies. Comparisons between the two individual groups were performed using the unpaired t-test for continuous, and the Pearson’s chi-square test or Fisher’s exact test for categorical variables. Propensity scores were used to adjust for potential bias in the comparison between nonrandomized BAS and PES groups. Propensity scores were calculated as the predicted probability that a patient was treated with PES as opposed to BAS using logistic regression. The differences between BAS and PES groups in outcome variables were compared after adjustment for propensity score (linear term) by using Cox regression analysis. Variables included in propensity score model and Cox regression models were age, gender, diabetes, current smoking, hypercholesterolemia, hypertension, previous MI, previous PCI, previous coronary artery bypass grafting (CABG), multivessel disease, acute ST-elevation MI, acute non-ST-elevation MI, unstable angina, stent diameter, stent length, and glycoprotein IIb/IIIa inhibitor. Receiver operating characteristic (ROC) curve analysis was used to estimate the area under the curve (AUC) of the model predicting the probability of being included in any of the study groups. The calculated propensity score was used for one-to-one matching as well as to adjust for other variables in estimating their impact on the postoperative outcome. Matching between study groups was done according to a difference in the propensity score <0.005. MACE, MI, TLR, and ST were analyzed by means of Kaplan–Meier survival curves during 5 years of follow-up and the differences between the groups were compared using log-rank test. Cox proportional hazards regression models were included in multivariable Cox regression analysis to identify independent predictors of clinical events during the 5-year follow-up. All tests were two-sided and a probability value of P <0.05 was considered statistically significant. All data were analyzed with the use of SPSS version 1119 and SAS system for Windows version 9.1 (SAS Institute Inc., Cary, NC, USA).

Results

Baseline Characteristics. Between May 2003 and November 2004, 201 patients (218 lesions/221 stents) were treated with BAS, and 204 patients (244 lesions/247 stents) with PES. Baseline clinical characteristics of the study population and the main angiographic and procedural characteristics have been previously detailed.17 Briefly, patients treated with BAS were older, had more often hypercholesterolemia and hypertension, presented more frequently with acute MI, and had more complex (type B and C) lesions, as compared to those treated with PES, however, the total stent length was, significantly longer in the PES group, as compared to the BAS group, as shown in Tables 1 and 2.

Five-Year Follow-Up Data. Clinical follow-up for 5 years was completed in all patients. Clinical follow-up data are presented in Table 3 and Figure 1. Cumulative MACE at the end of 5-year follow-up occurred in 34 (16.9%) patients in the BAS group, as compared to 53 (26%) patients in the PES group (OR 1.7, 95% CI 1.1–2.8, P = 0.03). Similarly, the incidence of recurrent MI alone was again significantly lower in the BAS group, as compared to the PES group (9.5% vs. 20.6% respectively, OR 2.5, 95% CI 1.4–4.4, P =
The c-statistic 0.84 for the propensity score model indicated good discrimination. Several baseline and procedural variables were imbalanced before adjusting for propensity score, but afterwards the differences between BAS and PES groups were nonsignificant, and the balance was achieved. Logistic regression identified the length of stent, ST-elevation MI, any previous MI, any previous PCI, hypercholesterolemia, hypertension as well as older age as independent risk factors of these patients for having been included in the BAS or PES groups. ROC analysis showed an AUC of the calculated propensity score of 0.75 (95% CI 0.70–0.83, S.E. 0.023, P < 0.001). After adjustment for propensity score, the differences in MACE (P = 0.005) and in MI or cardiac death (P < 0.001) between the two groups remained significant.

In multivariable analysis, older age (HR 1.04, 95% CI 1.02–1.07, P = 0.02), previous MI (HR 1.6, 95% CI 1.0–2.6, P = 0.03), non-ST-elevation MI as a presenting condition (HR 1.7, 95% CI 1.1–2.9, P = 0.02) and the use of PES (HR 1.8, 95% CI 1.1–3.0, P = 0.01) were independent predictors for MACE at 5 years, whereas MI or cardiac death was predicted by older age (HR 1.04, 95% CI 1.01–1.08, P = 0.001), previous PCI (HR 2.0, 95% CI 1.2–3.4, P = 0.01) and the use of PES (HR 3.1, 95% CI 1.6–5.4, P = 0.001). When multivariable models were adjusted for propensity score, the differences in MACE (HR 2.1, 95% CI 1.1–3.6, P = 0.009) and MI or cardiac death (HR 4.0, 95% CI 2.1–8.0, P < 0.001) between groups remain significant.

### Discussion

**Major Findings.** The current study presents the 5-year follow-up of the PORI registry comparing the use of BAS and PES in real-world everyday clinical practice. To the best of the authors’ knowledge, it represents the longest-term follow-up of such a comparison ever reported in literature. It has demonstrated that

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**Table 1. Baseline Clinical Characteristics of the 2 Individual Study Groups**

<table>
<thead>
<tr>
<th>Variable</th>
<th>BAS Group (N = 201)</th>
<th>PES Group (N = 204)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>67 ± 10</td>
<td>64 ± 10</td>
<td>0.022</td>
</tr>
<tr>
<td>Male gender</td>
<td>143 (71)</td>
<td>147 (72)</td>
<td>0.85</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>34 (17)</td>
<td>37 (18)</td>
<td>0.78</td>
</tr>
<tr>
<td>Current smoking</td>
<td>58 (29)</td>
<td>53 (26)</td>
<td>0.31</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>181 (90)</td>
<td>167 (82)</td>
<td>0.017</td>
</tr>
<tr>
<td>Hypertension</td>
<td>133 (66)</td>
<td>110 (54)</td>
<td>0.016</td>
</tr>
<tr>
<td>Prior MI</td>
<td>89 (44)</td>
<td>65 (32)</td>
<td>0.010</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>29 (14)</td>
<td>49 (24)</td>
<td>0.015</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>25 (12)</td>
<td>20 (10)</td>
<td>0.40</td>
</tr>
<tr>
<td>Acute STEMI</td>
<td>62 (31)</td>
<td>41 (20)</td>
<td>0.013</td>
</tr>
<tr>
<td>Primary angioplasty</td>
<td>22 (11)</td>
<td>10 (5)</td>
<td>0.024</td>
</tr>
<tr>
<td>Rescue angioplasty</td>
<td>40 (20)</td>
<td>31 (15)</td>
<td>0.21</td>
</tr>
<tr>
<td>Acute NSTEMI</td>
<td>52 (26)</td>
<td>49 (24)</td>
<td>0.67</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>20 (10)</td>
<td>20 (10)</td>
<td>0.96</td>
</tr>
</tbody>
</table>

Continuous variables are presented as mean ± SD, while categorical variables are presented as frequency (percentage). BAS = bioactive stent; CABG = coronary artery bypass grafting; MI = myocardial infarction; NSTEMI = non-ST-elevation myocardial infarction; PCI = percutaneous coronary revascularization; PES = paclitaxel-eluting stent; STEMI = ST-elevation myocardial infarction.

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**Table 2. Angiographic and Procedural Characteristics of 2 Individual Study Groups**

<table>
<thead>
<tr>
<th>Variable</th>
<th>BAS Group (N = 201)</th>
<th>PES Group (N = 204)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target vessel</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAD</td>
<td>100 (46)</td>
<td>124 (51)</td>
<td>0.29</td>
</tr>
<tr>
<td>LCx</td>
<td>48 (22)</td>
<td>37 (15)</td>
<td>0.060</td>
</tr>
<tr>
<td>RCA</td>
<td>54 (25)</td>
<td>68 (28)</td>
<td>0.45</td>
</tr>
<tr>
<td>Left main</td>
<td>7 (3)</td>
<td>7 (3)</td>
<td>7 (3)</td>
</tr>
<tr>
<td>Bypass graft</td>
<td>9 (4)</td>
<td>8 (3)</td>
<td>0.63</td>
</tr>
<tr>
<td>Lesion type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>26 (12)</td>
<td>54 (22)</td>
<td>0.004</td>
</tr>
<tr>
<td>B</td>
<td>137 (63)</td>
<td>171 (70)</td>
<td>0.10</td>
</tr>
<tr>
<td>C</td>
<td>55 (25)</td>
<td>19 (8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Reference vessel diameter (mm)</td>
<td>2.95 ± 0.34</td>
<td>2.97 ± 0.35</td>
<td>0.27</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>13.1 ± 3.4</td>
<td>13.5 ± 4.2</td>
<td>0.21</td>
</tr>
<tr>
<td>Stent diameter (mm)</td>
<td>2.98 ± 0.34</td>
<td>2.97 ± 0.34</td>
<td>0.83</td>
</tr>
<tr>
<td>Stent length (mm)</td>
<td>15.6 ± 3.5</td>
<td>21.2 ± 6.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total stent length per lesion (mm)</td>
<td>16.0 ± 4.0</td>
<td>21.4 ± 6.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Direct stenting</td>
<td>48 (22)</td>
<td>46 (19)</td>
<td>0.40</td>
</tr>
<tr>
<td>GP IIb/IIa inhibitor</td>
<td>54 (27)</td>
<td>49 (24)</td>
<td>0.38</td>
</tr>
<tr>
<td>Clopidogrel duration (months)</td>
<td>7.7 ± 3.3</td>
<td>8.2 ± 3.0</td>
<td>0.20</td>
</tr>
</tbody>
</table>

Continuous variables are presented as mean ± SD, while categorical variables are presented as frequency (percentage). LAD = left anterior descending; LCx = left circumflex; RCA = right coronary artery.
the implantation of BAS in de novo coronary lesions achieves a better long-term outcome as compared to PES. During a 5-year follow-up period, the use of BAS was associated with a lower incidence of MI and total MACE, in comparison with PES, a difference that occurred chiefly during the first 2 years of follow-up. Moreover, the present study demonstrated a “fairly high” rate of ST, associated with the use of PES in real-world practice. On the other hand, no ST occurred with the use of BAS over 5 years of follow-up.

**Late Stent Thrombosis after PES Implantation.**

The incidence of ST associated with PES implantation in the current study was higher than previously reported in studies and registries using PES.\(^20\)–\(^24\) This relatively higher rate of ST can be attributed, at least in part, to premature discontinuation of clopidogrel. In the current study, 9 patients in the PES group suffered ST after the clopidogrel discontinuation. Most of the patients actually received dual antiplatelet therapy for less than 12 months. Thus, the findings of the current work would also underscore the importance of extended dual antiplatelet therapy following DES implantation. Moreover, total stent length was particularly longer in the PES group in the current study as compared to the BAS group, a fact that might contribute to an elevated ST rate. Pooled analyses of randomized clinical trials of DES demonstrated that “on-label” use of DES culminates in ST rates identical to those reported with bare metal stents over a 4-year follow-up period.\(^20\),\(^21\) Yet, recent data on “unrestricted” use of first-generation DES in routine clinical practice have shown that late ST occurred at a steady rate of 0.6% per year at 4-year follow-up.\(^22\) Indeed, late ST has emerged as a distinct clinical feature of DES as compared to bare metal stents. Greater delay in arterial healing, as manifested by poor endothelialization and persistence of peristrut fibrin deposition, associated with the implantation of DES may extend the risk of ST far beyond 30 days. Other potential factors predisposing to late ST include stent-vessel mismatch, stent malaposition, overlapping stents, penetration of a necrotic core, excessive stent length, bifurcation lesions, hypersensitivity to drug or polymer, or a thrombogenic surface.\(^25\),\(^26\) Premature discontinuation of antiplatelet therapy was recently recognized as the most important predisposing factor for late ST.\(^27\) The obviously higher rate of late ST associated with the use of PES in the current study may well account for the increased rates of MI and total MACE in the PES group. Yet, the incidence of cardiac and all-cause death, and TLR was not different between the two groups. Nevertheless, it should be highlighted that DES are not equal, and the results of the current study—using PES—might not be extrapolated to the other DES. In this concern, recently released data from the TIDE trial similarly demonstrated an equivalent clinical outcome between titanium-nitride-oxide-coated BAS and a zotarolimus-based DES (Endeavor R⃝, Medtronic, Minneapolis, MN, USA) at 2-year follow-up, including death, MI, TLR, TVR, and ischemia-driven TVR. At 6–8 months angiographic follow-up, however, in-stent late loss was significantly lower in the zotarolimus-eluting stent group.\(^28\)

**Current Strategy for Reduction of Restenosis.**

Currently, the use of DES is the state-of-the-art means of reducing ISR in randomized clinical trials including selected patient populations.\(^7\),\(^8\),\(^29\) Several
randomized controlled studies comparing bare metal stents with the FDA-approved DES demonstrated a significant reduction of ISR with the use of DES, which translated into lower TVR and TLR rates. Nevertheless, after years of real-life experience with DES, the improvement of restenosis rate was not converted into a reduction of the most powerful “hard” clinical end-points: death and MI. Additionally, recent worrisome data showed a significant increase of such serious events with the use of DES in predetermined clinical scenarios and/or lesion or procedural characteristics, chiefly due to late and very late ST. Since the dawn of PCI, it was known that ISR is a “soft” nonlife-threatening event; otherwise, it would have been impossible for PCI to feasibly replace surgical revascularization. Therefore, in our search for a therapeutic strategy that effectively reduces ISR, we cannot accept any increase in the “hard” end-points as a price paid to reach such a goal.

Bioactive Stents. Titanium exhibits a better biocompatibility as compared to stainless steel, gold, or other surface coating materials. Metallic sheaths coated with titanium nitride or titanium oxide demonstrated higher endothelial cell density values on their surfaces in comparison with those without these coatings, suggesting that the use of stents covered with these coatings may accomplish an earlier complete endothelialization. The safety of titanium-nitride-oxide-coated BAS has been validated in several clinical trials in both unselected populations as well as in the most complex indications such as diabetic patients and those presenting with acute MI. Recently, a randomized study has demonstrated an even “better” outcome with BAS implantation in comparison with PES in patients presenting with acute MI.

Clinical Implications. A cost-effectiveness analysis of DES based on the BASKET trial justified the use of DES only in high-risk patients. Achievement of the goal of reducing TLR to a degree similar to DES, without taking the risk of life-threatening “hard” end-points of late and very late ST, would be an appealing strategy in combating ISR. Furthermore, unlike DES, which need maintenance clopidogrel therapy for at least 12 months (sometimes even for more extended periods), with BAS, this therapy is required for no more than 1 month. In this context, BAS appear to open a new “horizon” for revascularization of coronary atherosclerosis.

Study Strengths and Limitations. The strength of this single-center registry is the fact that Satakunta...
Central Hospital is the only center with a coronary angiography facility in the referral area. In this rural area, population is stationary enabling complete and extended follow-up of an unrestricted patient population undergoing coronary revascularization in daily clinical practice. The PORI registry was not randomized, and hence it was liable for selection bias. Propensity adjustment cannot be expected to completely compensate for group differences when one is dealing with only around 200 patients in each group with the relatively low incidence of end-points studied. Additionally, it bears an inherent limitation of any registry, namely, the non-blinded outcome assessment. Furthermore, whether the outcome of the PES in this registry can be extrapolated to the other “members” of the DES family remains to be determined. Finally, TLR was clinically driven, and this may underestimate the actual incidence of restenosis, however, it would avoid unnecessary interventions in borderline lesions due to the “oculostenotic reflex” or undue patients’ anxiety.

Conclusions

BAS implantation in a real-world patient population achieves an excellent clinical outcome over 5-year follow-up, with a significantly lower incidence of MI, MACE, and ST as compared to PES.

References


