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Real World Safety and Efficacy of the Janus Tacrolimus-Eluting Stent: Long-Term Clinical Outcome and Angiographic Findings from the Tacrolimus-Eluting Stent (TEST) Registry

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Objectives: We sought to evaluate the safety and performance of the Janus Tacrolimus-Eluting stent (TES) in an unselected population of patients, without application of restrictive clinical or angiographic criteria. Background: Continued attention to the safety, efficacy, and deliverability of first-generation drug eluting stents has led to the development of new antiproliferative agents with alternative stent platforms and different drug carrier vehicles. Methods: The TEST (Tacrolimus Eluting STent) registry is a prospective, nonrandomized single-center registry in which 140 consecutive patients who underwent single- or multi-vessel percutaneous coronary intervention between February 2005 and August 2005 were enrolled. Results: The composite rate of major adverse cardiac events (MACE) at 22 months clinical follow-up was 40.9%. The rate of mortality, myocardial infarction, and target lesion revascularization (TLR) were 5.5%, 11%, and 31.5%, respectively. Angiographic follow-up at 8 months was achieved in 74% of patients; binary restenosis occurred in 39.4% of lesions. Most restenosis lesions (94.6%) had a diffuse pattern, while focal restenosis was observed in 5.4% of cases. Definite or probable stent thrombosis was observed in 2.4% of patients. Conclusions: The present prospective, nonrandomized, TEST registry indicated high MACE and restenosis rates, and thereby rather discouraging long-term outcomes with use of the Janus TES in an unselected "real world" population of patients who underwent single- or multi-vessel percutaneous coronary intervention. © 2009 Wiley-Liss, Inc.

Key words: safety; tacrolimus eluting stent; restenosis

INTRODUCTION

Drug eluting stents (DES) significantly reduced the rates of restenosis and target lesion revascularization (TLR) compared with bare metal stents (BMS) in patients with symptomatic coronary artery disease [1–3]. Nevertheless, continued attention to the safety, efficacy, and deliverability of first-generation DES has led to the development of new antiproliferative agents with alternative stent platforms and different drug carrier vehicles.

The Janus® stent (Sorin Biomedica, Saluggia, Italy) uses a closed cell metal stent platform, has no polymer, and utilizes grooves that serve as reservoirs on the external surface of the stent struts [4]. These reservoirs are filled with tacrolimus, a cytostatic immunosuppressant drug that generally shares similar structure and biologic activity with antiproliferative and anti-inflammatory agent sirolimus [5]. The drug is released to the vessel wall at a rate of 2.3 μg/mm^2. Once tacrolimus is loaded into the reservoirs, the stent is coated with Carbofilm, a passive coating that intends to pre-

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vent thrombosis and enhances biocompatibility. The lipophilicity of tacrolimus may enhance its penetration in the vessel wall and limit loss in the blood stream.

To date, two clinical trials evaluating the safety and efficacy of tacrolimus-eluting stents (TES) have been completed: JUPITER I, a first-in-human-study, and JUPITER II, a randomized controlled study comparing the TES with the bare-metal Tecnic® stent. The results of the first two JUPITER trials indicate that Janus TES is a safe device for treating uncomplicated coronary lesions: at 6-month follow-up, major adverse cardiac events (MACE) occurred in 5.2% and 6.4% in the two trials, respectively.

The present TEST registry was initiated in order to investigate the safety and efficacy of this particular TES in an unselected population of patients, without the restrictive clinical or angiographic criteria applicable to previous trials.

METHODS

The TEST (Tacrolimus Eluting STent) registry was a prospective, nonrandomized single-center registry of 140 consecutive patients who underwent single- or multi-vessel percutaneous coronary intervention between February 2005 and August 2005. Inclusion criteria included patients eligible for coronary revascularization with one or more stenotic lesions to be treated with Janus carbostent in a vessel with a reference diameter $\geq$2.5 mm. Exclusion criteria included serious comorbidities with a life expectancy of less than 1 year, bleeding diathesis with anticoagulant or antiplatelet drug contraindication, and intolerance or allergy to aspirin or ticlopidine/clopidogrel treatment. The study was conducted according to the Declaration of Helsinki. Written informed consent was obtained from every patient.

Implantation Procedure

Stent diameter and length availability of Janus Carbostent are shown in Table I. Interventional procedures and adjuvant therapies were performed according to international guidelines [6]. All patients were pretreated with aspirin (100–200 daily) and ticlopidine (250 mg twice daily) or clopidogrel (75 mg daily). During the procedure, patients received intravenous unfractionated heparin dose (70 IU/kg) plus additional boluses to maintain activated clotting time between 250 and 300 sec. A loading dose of 300 mg of clopidogrel was given to patients not previously taking the agent, whereas glycoprotein IIb/IIIa inhibitors were administered at the physician's discretion. Predilatation or direct stenting and the use of ablative devices were at discretion of the operator. Angiographic optimization was performed by high-pressure dilation to achieve $<$10% residual stenosis by visual estimate after stent implantation. All patients were advised to maintain lifelong aspirin therapy. Clopidogrel 75 mg/day or ticlopidine 250 mg twice daily was prescribed for 6–9 months.

TABLE I. Diameter and Length Availability of Janus Carbostent

Diameter (mm)	Length (mm)
2.5	12–15–19–25
2.75	12–15–19–25
3.0	12–15–19–25–31
3.5	12–15–19–25–31
4.0	12–15–19–25–31

Follow-up

Information concerning in-hospital events was obtained from a centralized informatics database of our Institution for those patients who stayed in our hospital and from the hospital records or by telephone contacts for those transferred to another affiliated hospital after the procedure.

The clinical follow-up data related to medications and clinical status were prospectively collected through scheduled outpatient clinic evaluations. Referring cardiologists, general practitioners, and patients were contacted for further information. All repeated coronary intervention (surgical and percutaneous) and rehospitalization data were prospectively collected during follow-up using the centralized informatics system of our institution or contacting directly the hospitals were the patients were admitted.

Angiographic follow-up was suggested at 6 and 9 months after the index procedure in all patients, but it was performed at an earlier time if clinically indicated. Angiographic analysis was done with a computer-assisted system with automated edge detection algorithm (QCA-CMS® Version 5.2, MEDIS, The Nederland, USA). All clinical events were adjudicated by an independent, blinded end points committee.

End Points and Definitions

The primary end point of the TEST registry was the rate of major adverse clinical events (MACE) at 22 months, defined as the composite of death, nonfatal myocardial infarction (MI) or TLR. The secondary end-point was 8 months rate of angiographic restenosis within the segment treated with the stent.

A non-Q-wave MI was defined as creatine kinase-MB enzyme elevation $\geq$3 times the upper limit of the normal value; when in addition to enzyme elevation, there were new pathological Q waves in the electrocardiogram, the

TABLE II. Clinical Characteristics

	$n = 140$
Age, mean ± SD (years)	62 ± 10
Male gender, *n* (%)	114 (81.4)
Diabetes, *n* (%)	33 (23.6)
Unstable angina, *n* (%)	66 (47.1)
Recent myocardial infarction, *n* (%)	28 (20.0)
Previous myocardial infarction, *n* (%)	69 (49.3)
Previous CABG, *n* (%)	19 (13.6)
Baseline LVEF, mean ± SD (%)	51 ± 10
Number of diseased vessel, *n* ± SD	2.0 ± 0.9

CABG, coronary artery bypass graft; LVEF, left ventricular ejection fraction.

event was defined as a Q-wave MI. TLR was defined as any repeat percutaneous revascularization or surgical bypass of the original target lesion site. Target vessel revascularization (TVR) was defined as a reintervention driven by any lesion located in the same coronary artery. Restenosis was defined as the diameter stenosis of $\geq$50% within the stent or in the 5-mm distal or proximal edge segments adjacent to the stent.

Stent thrombosis was defined as an acute coronary syndrome with angiographic documentation of either vessel occlusion or thrombus within or adjacent to a previously successfully stented vessel [7]. Stent thromboses were categorized according to the timing of the event into intraprocedural, subacute thrombosis (from the end of the procedure to 30 days), late stent thrombosis (>30 days), and very late stent thrombosis (>365 days). The stent thrombosis is additionally reported according to the Academic Research Consortium (ARC) definitions for definite or probable stent thrombosis.

Statistical Analysis

Baseline characteristics of patients were summarized as frequencies and percentages for categorical variables and as means with standard deviations for continuous variables. Cumulative and subcomponents event-free survival was summarized as Kaplan-Meier estimates. All data were processed using the Statistical Package for Social Sciences, version 15 (SPSS, Chicago, IL, USA).

RESULTS

A total of 140 patients were recruited to the TEST Registry, and a total of 188 lesions were treated. The rates of completed clinical and angiographic follow-up were 91% (127 patients by 22 ± 4 months) and 74% (104 patients, 142 lesions by 8 ± 3 months), respectively.

Patient and lesion characteristics are summarized in Table II. The mean age was 62 ± 10 years, 24% of patients had diabetes mellitus, 47% had unstable angina, and 20% had evidence of a recent MI. Of the

TABLE III. Angiographic and Procedural Characteristics (Lesion Based)

	$n = 188$
Vessels treated, *n* (%)	
Left main coronary artery	6 (3.2)
Left anterior descending artery	82 (43.6)
Left circumflex artery	46 (24.5)
Right coronary artery	50 (26.6)
Saphenous vein graft	4 (2.1)
Internal mammary artery	0 (0)
Lesions characteristics, *n* (%)	
Ostial location	7 (3.7)
Bifurcation	30 (16.0)
B2 or C type[a]	125 (66.5)
In-stent restenosis	1 (0.5)
Thrombus	9 (4.8)
Chronic total occlusion	2 (1.1)
Procedural characteristics, mean ± SD	
Stent length per lesion (mm)	26 ± 15
Stents per lesion, *n*	1.5 ± 0.8
Reference vessel diameter (mm)	3.0 ± 0.4
Minimal lumen diameter (mm)	0.5 ± 0.4
Diameter stenosis (%)	82 ± 12
Lesion length (mm)	21 ± 13
Long lesions (>20 mm), *n* (%)	92 (48.9)
Small vessels (<2.5 mm), *n* (%)	44 (23.4)

[a]Based on American College of Cardiology/American Heart Association classification.

188 lesions treated, 67% were of B_2/C type by the American College of Cardiology (ACC) and American Heart Association (AHA) classification [8], and 16% were at a bifurcation. The left anterior descending artery was the vessel treated in 44% of cases. The mean lesion length was 21 ± 13 mm, and the average reference vessel diameter was 3.0 ± 0.4; lesion length was > 20 mm in 48.9% of patients, and the reference vessel diameter was 2.5 mm in 23% of cases (Table III).

Procedural Characteristics and Angiographic Outcomes

The average number of Janus stent per target lesion was 1.5 ± 0.8, and at least 2 stents were placed in 36% of lesions. The average stent length was 26 ± 15 mm. For the treatment of 97.9% of the lesions, the Janus TES was the only device implanted, whereas for the treatment of 2.1% of the lesions, it was implanted together with a different DES, because of length or size device unavailability. The device deployment success rate achieved 100%. Use of GPIIb/IIIa inhibitors was 17.1%. Intraprocedural thrombosis occurred in 2.1% of patients.

Angiograms at follow-up were per-protocol in 75% of patients. Late luminal loss was 0.96 ± 0.91 mm. Binary restenosis within the treated segment occurred in 47 patients (45.2%) and 56 lesions (39.4%). Most lesions (94.6%) had a diffuse pattern of restenosis, four were totally occluded. Focal restenosis was

TABLE IV. In-Hospital and Long-Term Outcome

	$n = 140$
In-hospital adverse event rates, *n* (%)	
MACE	5 (3.6)
Death	2 (1.4)
Cardiac death	2 (1.4)
MI	3 (2.1)
Q wave	0 (0)
Non-Q wave	3 (2.1)
Emergency CABG	0 (0)
Intraprocedural ST, *n* (%)	3 (2.1)
TLR	0 (0)
Long-term adverse event rates, *n* (%)[a]	
MACE	52 (40.9)
Death	7 (5.5)
Cardiac death	7 (5.5)
MI	14 (11.0)
Q wave	6 (4.7)
Non-Q wave	8 (6.3)
TLR	40 (31.5)
TVR	41 (32.3)
CABG	2 (1.6)

MI, myocardial infarction; CABG, coronary artery by-pass graft; MACE, major adverse cardiac events; TLR, target lesion revascularization; ST, stent thrombosis.
[a]127/140 (90.7%) patients with clinical follow up at 22 months.

observed in 5.4% of cases. Patients were generally asymptomatic or suffered from stable angina. Five (11%) experienced acute myocardial infarction as clinical presentation.

In-Hospital and Clinical Outcome

During hospitalization, the rate of MACE was 3.6%, mainly driven by the occurrence of non-Q wave MIs after the procedure (2.1%; Table IV). At follow-up the rate of MACE was 40.9% (Table IV, Fig. 1), of which 32.7% were observed during the first 4 months after the initial procedure and 80.7% during the first year.

At late follow-up, there were 7 deaths (5.5%) and 14 cases of MI (11%), of which 6 had a new Q wave (4.7%). The rate of TLR at 22 months was 31.5%, consisting of 38 cases of angioplasty and 2 cases of CABG of the target lesion. TVR rate was 32.3%.

Stent thrombosis according to ARC definitions are stratified in Table V. Definite late stent thrombosis was observed in 2 patients (1.6%) with a new Q-Wave MI, whereas probable subacute stent thrombosis occurred in 1 patient (0.8%), who died at 5 days from the index procedure. Thus, the cumulative incidence of definite or probable stent thrombosis at 22 months was 2.4%.

Of note, the slope of the linear portion of the cumulative events incidence curve decreased across the different time intervals after the initial procedure. The incidence of MACE was 3.2% per month between time of the initial procedure and 4 months, 2.6% per month between 4 months and 8 months, 2.8% per month between 8 months and 12 months, 1.5% per month between 12 months and 16 months, 0% per month between 16 months and 20 months, and 0.6% per month between 20 months and 24 months (Fig. 2).

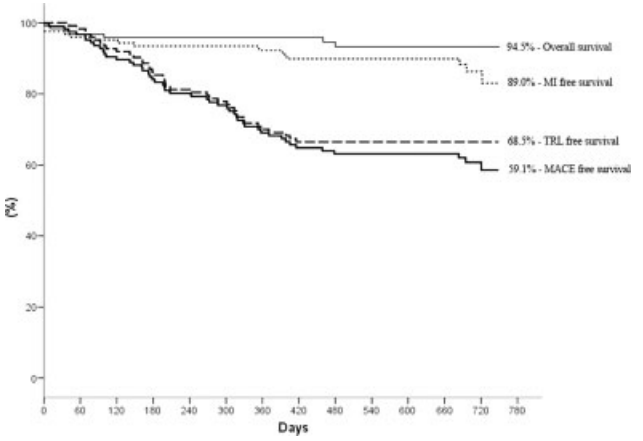

Fig. 1. Kaplan Meyer estimates to 22 ± 4 months for 127 of the 140 enrolled in the TEST registry and receiving the Janus tacrolimus-eluting stent (Sorin Biomedica, Saluggia, Italy). MACE, major adverse cardiac events; MI, myocardial infarction; TLR, target lesion revascularization.

TABLE V. Stent Thrombosis According to ARC Definitions

	Definite	Probable	Possible
Acute ST	0 (0)	0 (0)	0 (0)
Subacute ST	0 (0)	1 (0.8)	0 (0)
Late ST	2 (1.6)	0 (0)	0 (0)
Very late ST	0 (0)	0 (0)	0 (0)
Overall ST	2 (1.6)	1 (0.8)	0 (0)

ST, stent thrombosis.

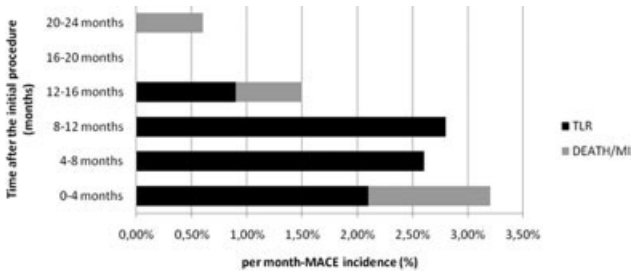

Fig. 2. MACE monthly incidence at different time intervals after the index procedure. MACE, major adverse cardiac events; TLR, target lesion revascularization; MI, myocardial infarction.

DISCUSSION

In the JUPITER-I study, a total of 65 Janus TES were implanted in 58 patients, of whom 19% were acute coronary syndrome (including 6.9% of acute myocardial infarction). The target lesions included

only 27% complex lesions of type B_2/C, the rest being simple. The use of the stent was associated with a 100% procedural and clinical success and no MACE at 30-day follow-up. There was 1 death at 6 months, and 2 patients (4.9%) underwent repeat revascularization. Analysis on the basis of the presence or absence of diabetes found that the rate of TLR was considerably higher in the former than in the latter (18.6% vs. 4.2%, respectively).

In the JUPITER-II randomized trial, 163 patients treated with TES were compared with 163 patients treated with the same stent without the drug. Patients eligible for enrollment had to have lesions suitable for direct stenting in a target vessel with a reference diameter between 2.7 and 4.0 mm. Clinical outcomes at 1-month follow-up demonstrate high procedural and lesion success together with a low rate of MACE in both treatment groups. At 6-month follow-up (data available for 327 patients), MACE rates were low in both groups (Tecnic, 10.6% vs. Janus, 6.4%, P = NS). There was no significant difference in the rate of TLR between the Tecnic and Janus stent groups (10.6% vs. 5.7%, P = NS, respectively) and there were no cases of subacute or late thrombosis. The rates of death and myocardial infarction (MI) at 6-month clinical follow-up were minimal.

Acute coronary syndromes accounted for only 27.6% of patients in Janus group in JUPITER-II. Non ST and ST-segment elevation MI presentations were all excluded, together with those patients with ostial lesions, left main diseases, chronic total occlusions, bifurcations, lesion in small vessels, long and thrombotic lesions. The target lesions included only 34.9% complex lesions of type B_2/C. Consequently, the validity of extrapolating the safety and efficacy results of JUPITER-II to day-to-day practice with the Janus TES has been uncertain.

Compared with Jupiter I and II studies, the population in the TEST registry included patients at high risk of restenosis, reflecting the ''real world'' of clinical practice.

Garcia-Tejada et al. [9] described the results of a series of 50 real-world patients who were treated with the Janus TES. During a follow-up period of 10 months, 8 (16%) MACE occurred: 1 patient died (2%) and 5 patients (10%) required revascularization because of restenosis. The relatively small number of patients and the absence of an angiographic control in the follow-up were the main limitations of this study.

Han et al. [10] recently reported midterm outcomes of a single center study, in which 200 unselected patients were randomized to TES ($n = 100$) or Tecnic ($n = 100$). The rate of MACE at an average of 246-days follow-up was 6% with the TES stent and 15% with the Tecnic Carbostent ($P = 0.038$). Because of the limited observation time, angiographic follow-up was low (19%).

The TEST registry benefits from a long-term clinical (90.7%) and mid-term angiographic (74.3%) follow-up. To the best of our knowledge, no other reports on the TES in the scientific literature have a longer follow-up.

In our series, the long-term rate of MACE for the 127 patients receiving the Janus TES was high at 40.9%, with an initial steep rise with 36% of cases occurring within 4 months (before the beginning of the angiographic follow-up period), followed by an almost linear increase in the remaining events up to 12 months and a plateau up to 22 months. This rate was mainly driven by need for repeat revascularization (31.5%) because of clinical symptoms, acute presentation, or diffuse restenosis at angiographic follow-up. Notably, despite a large mean reference vessel diameter of 3.0 ± 0.4 mm, the restenosis rate was even higher than that reported for BMS [1,3].

The extensive angiographic follow-up, although it is known to accentuate the rates of repeat revascularization compared with clinical follow-up alone [11], has provided important findings on the actual performance of the new device even in asymptomatic patients, showing a significant late loss and very high rate of TLR and binary restenosis, which were different from those reported for other unselected populations undergone to DES implantation [1–3,12].

Moreover, among patients with angiographic restenosis, 23 had ≥ 2 lesions. Of those, 9 (39.1%) developed binary restenosis on all their lesions treated with Janus TES, suggesting an individual incremental risk following implantation in selected subsets of patients.

The issue of stent thrombosis raises some other concerns about safety of Janus TES in clinical practice. Two cases of angiographically proven late stent thrombosis (1.6%) were observed at 42 and 121 days from the index procedure. One other case of probable stent thrombosis was registered at 5 days. All patients developed Q wave MI, two died. Of note, all these patients were on dual antiplatelet therapy when ST occurred.

CONCLUSIONS

Despite early encouraging reports from initial randomized trials and registries on the early and midterm efficacy and safety of the Janus stent, the analysis of data from a group of patients enrolled in the prospective, nonrandomized, TEST registry has demonstrated discouraging long-term outcomes for the Janus TES in a real world population of patients who underwent single-vessel or multivessel percutaneous coronary intervention.

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