Carbon-coated Stents in Patients with Acute Coronary Syndromes

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ABSTRACT

Background: For patients with ST elevation myocardial infarction (STEMI) or non-ST elevation myocardial infarction (NSTEMI), rapid restoration of coronary blood flow is the primary therapeutic goal. Because of the acute nature of this clinical presentation, bleeding risks may not be adequately evaluated, limiting the use of drug-eluting stents, since premature discontinuation of antiplatelet therapy strongly predicts stent thrombosis. We evaluated angiographic and clinical results of non-drug-eluting carbon-coated stents.

Methods: In this prospective observational study, angiographic and clinical 6-mo results of a carbon-coated stent for treatment of acute lesions in native coronary arteries were evaluated. Angiographic main outcome measures included in-stent late loss and binary restenosis rate. Major adverse cardiac events (MACEs) were defined as any death, Q-wave myocardial infarction (MI), and target lesion revascularization.

Results: We included 320 patients with STEMI ($n = 205$) or NSTEMI ($n = 115$) with 360 lesions. Reference vessel diameter was 2.93 ± 0.53 mm and stented length 22.7 ± 13.8 mm. Angiographic follow-up was available in 220 of 360 lesions (61%). In-stent late loss was 0.69 ± 0.75 mm, with a binary restenosis rate of 19.1%. For the total segment late loss was 0.74 ± 0.77 mm and binary restenosis rate 21.4%. Clinical follow-up for 97.4% of discharged patients was available. Hierarchical MACEs were death in 14 patients (4.4%), Q-wave MI in 3 patients (0.9%), and target lesion revascularization in 39 patients (12.2%).

Conclusion: In this prospective, observational study, the use of a carbon-coated stent for treatment of lesions in patients with STEMI or NSTEMI was associated with a low late loss, translating into a low binary angiographic restenosis rate within a 6-mo follow-up.

Key words: acute coronary syndromes, myocardial infarction, clinical trials, catheterization, angiography

For patients with ST elevation myocardial infarction (STEMI) or non-ST elevation myocardial infarction (NSTEMI), the primary therapeutic goal is the rapid restoration of coronary blood flow by percutaneous coronary intervention (PCI). In this clinical scenario, the use of drug-eluting stents (DESs) was associated with a lower revascularization rate during a 12-mo of follow-up.^{1,2} Nevertheless, concerns have been raised regarding the safety of DES.^{3,4} An acute myocardial infarction (AMI) was an independent predictor of stent thrombosis with primary PCI using DES.⁵ Furthermore, the premature discontinuation of dual antiplatelet therapy was a very strong predictor regarding stent thrombosis.^{5–7} Potential bleeding risks in sedated and hemodynamically unstable myocardial infarction (MI) patients impeding the long-term dual antiplatelet therapy may not be adequately evaluated. Hence, in this special patient population the use of non-DES will continue. On the other hand, the occurrence of restenosis has been associated with the clinical presentation of acute coronary syndromes (ACSs) in about one-third of patients⁸ and has been linked to an increased mortality.⁹

In the Jupiter II trial, a carbon-coated stent was associated with comparable angiographic results to a tacrolimus-eluting

stent.¹⁰ Interestingly, the late loss of the carbon-coated stent was lower compared with the bare-metal stent arms of the TAXUS-IV,¹¹ SIRIUS,¹² and ENDEAVOR-II trials.¹³ Whether the carbon-coating has a positive impact on long-term angiographic outcome has not been addressed so far.

This prospective, observational study was conducted to evaluate the angiographic results of a carbon-coated stent for treatment of lesions in native coronary arteries in a patients with STEMI or NSTEMI.

Materials and Methods

Study Design

Patients with STEMI or NSTEMI undergoing cardiac catheterization and stent implantation were included in this prospective, observational study. For stenting, only the Tecnic stent (Sorin Biomedica Cardio S.r.l., Saluggia, Italy) was used. This is a balloon-expandable, stainless steel, tubular coronary stent with an innovative cellular geometry. Cells are connected at the midpoint of the longest curved segments to create elastic joints that increase overall stent flexibility, and to allow almost no shortening on expansion. The entire surface of the stent is mirror-like polished, and the edges are rounded to optimize deliverability and

minimize the likelihood of trauma to the vessel wall. Strut thickness is 100 μm (3.0–4.0 mm stent diameter) or 90 μm (2.25–2.75 mm stent diameter). Strut width is 90 μm . Stent struts are coated with a high-density, ultrathin film (0.3–0.5 μm) of turbostratic carbon. Exclusion criteria were left main disease, lesion within saphenous vein grafts, and contraindication to acetylsalicylic acid, clopidogrel, or heparin. Loading dose of clopidogrel was 300 mg. A combined antiplatelet therapy with ≥ 100 mg of acetylsalicylic acid and 75 mg clopidogrel daily was prescribed for 3–9 mo.

Patients with hypertension were on antihypertensive drug treatment due to well-known arterial hypertension, or in the case of newly diagnosed arterial hypertension, had resting systolic (diastolic) blood pressures >140 (90) mm Hg. Patients with hyperlipidemia were on lipid-lowering drug therapy due to well-known elevated lipid levels, or their low-density lipoprotein (LDL) cholesterol level was >2.5 mmol/L. Patients with diabetes were on antidiabetic drug therapy due to well-known diabetes mellitus; otherwise, diabetes mellitus was diagnosed if fasting glucose level was 2 times >7.0 mmol/L. Cardiogenic shock was defined as a systolic blood pressure <90 mm Hg and the need of supportive measures to maintain sufficient circulation.

Patients were scheduled for a 6-mo angiographic and clinical follow-up. Clinical follow-up was performed to analyze the occurrence of major adverse cardiac events (MACEs). A MACE was defined as all-cause death, any Q-wave MI, and target lesion revascularization within the total segment representing the stent, plus 5 mm proximal and distal to the stent. Angiographic main outcome measures included the late loss and binary restenosis rates within the stented segment. Stent thrombosis was determined as the occurrence of an acute clinical ischemic event and angiographic documentation of partial or total thrombotic stent occlusion, or evidence of thrombotic material in the distal vessel (definite stent thrombosis). Stent thrombosis was classified according to the timing of occurrence into acute (within 24 h), subacute (2–30 d), and late (beyond 1 mo). The study was ethically approved and patients gave their written informed consent.

Quantitative Coronary Angiography

Coronary angiography of the culprit lesion before and after angioplasty, and at follow-up was performed in the same projections after intracoronary application of glycerol trinitrate. Angiographic measurements were done with Pie Medical Software 2.1 (Pie Medical Imaging, Maastricht, the Netherlands). Quantitative coronary measurements were performed in the same 2-orthogonal views. Measurements were reported separately for the stent section and for the total segment. The total segment included the 5-mm segments proximal and distal to the stent. The segments

proximal and distal to the stent were analyzed in case of a stenosis with more than 50% luminal narrowing. Restenosis was defined as diameter stenosis of more than 50% at follow-up angiography. Acute gain was calculated as the difference in minimal lumen diameter (MLD) after and before the procedure, and the late loss as the difference between MLD postintervention and MLD at 6 mo. Late loss index was calculated as the ratio of late loss and acute gain.

Statistical Analysis

Continuous variables are presented as mean ± 1 standard deviation. Discrete variables are expressed as counts and percentages compared by means of χ^2 analysis. Statistics were calculated with Statistica release 6.1 (StatSoft Inc., Tulsa, OK, USA).

Results

Baseline Characteristics

Within 18 mo (May 2004–October 2005), 320 patients were included. Of these, 205 patients suffered from STEMI and 115 patients from NSTEMI. Baseline characteristics are given in Table 1. A total of 360 lesions were treated with 489 carbon-coated stents. Median time from symptoms to PCI was 7.3 h (mean 13.9 ± 19.9 h). Median time difference for STEMI patients was 5.4 h and for NSTEMI patients was 12.0 h. None of the patients received preprocedural fibrinolysis. Total occlusions were present in 39%. Mean lesion length in nonoccluded stenoses was 11.6 ± 8.2 mm. Baseline angiographic data are shown in Table 2.

Procedural Data

In 1 vessel, it was not possible to advance a stent to the culprit lesion. This stenosis was treated by plain balloon angioplasty. Another 4 stents could not be advanced to the target lesion due to vessel tortuosity (delivery success 99.0%). These lesions were successfully treated with shorter carbon-coated stents. The postprocedural reference vessel diameter was 2.98 ± 0.47 mm. With a mean 1.4 stents per lesion, the stented segment was a mean 22.7 ± 13.8 mm. Procedural data are given in Table 3.

Angiographic Results

Angiographic follow-up with quantitative coronary analysis was available in 220 of 350 lesions (61%) after median 193 d, which is detailed in Table 4. In-stent late loss was 0.69 ± 0.75 mm, resulting in a binary restenosis rate of 19.1%. For the total segment, late loss was 0.74 ± 0.77 mm, and the binary restenosis rate was 21.4%. Median and interquartile range (IQR) for diameter stenosis was in-stent 24% (30%), and for the total segment 25% (33.5%). Median and IQR for late loss were within the stent 0.53 (0.85), and for the total segment 0.57 (0.98); numbers for late loss index were 0.24 (0.38) and 0.26 (0.42), respectively.

Table 1. Baseline clinical characteristics

Number of patients	320
STEMI, N (%)	205 (64.1)
NSTEMI, N (%)	115 (35.9)
Age, years	61.8±12.7
Male sex, N (%)	211 (65.9)
Hypertension, N (%)	203 (63.4)
Hyperlipidemia, N (%)	268 (83.8)
History of smoking, N (%)	144 (45.0)
Diabetes mellitus, N (%)	66 (20.6)
Requiring insulin	22 (6.9)
Body mass index, kg/m ²	27.8±4.5
Multivessel disease, N (%)	193 (60.3)
Cardiogenic shock, N (%)	20 (6.3)
Cardiopulmonary resuscitation, N (%)	15 (4.7)
<i>Abbreviations:</i> NSTEMI = non-ST elevation myocardial infarction; STEMI = ST elevation myocardial infarction.	

In diabetic patients the postprocedural reference diameter was 2.94 ± 0.41 mm with an in-stent late loss of 0.69 ± 0.75 mm, a late loss index of 0.31 ± 0.36 mm, and a 25.6% binary restenosis rate.

Angiographic results did not differ in lesions with STEMI or NSTEMI. Reference vessel diameter prior to PCI was 2.94 ± 0.54 mm in STEMI lesions versus 2.88 ± 0.51 mm in NSTEMI lesions ($p = 0.22$). Numbers for late loss were 0.66 ± 0.73 versus 0.73 ± 0.77 mm ($p = 0.51$). Late loss index 0.30 ± 0.36 versus 0.35 ± 0.36 ($p = 0.41$), and binary angiographic restenosis rate 18.1% versus 20.7% ($p = 0.43$), respectively.

Stent Thrombosis

There were a total of 9 stent thromboses (2.5%) in 8 patients (2.5%). In 1 patient with stenting of the proximal and distal right coronary arteries, both lesions were thrombotic occluded. There were 3 acute (0.83%) and 6 subacute (1.67%) stent thromboses. All patients with stent thrombosis underwent repeat coronary interventions. There were 1 death and 1 Q-wave MI. Patients with stent thrombosis showed a significantly lower implantation pressure, a severely depressed left ventricular function significantly more often, and a higher frequency of left anterior descending coronary artery (LAD) lesions, and total occlusions compared with patients without stent thrombosis (Table 5).

Table 2. Lesion characteristics

Number of lesions	360
Target vessel, N (%)	
LAD	142 (39.4)
CX	66 (18.3)
RCA	152 (42.2)
De-novo lesion, N (%)	349 (96.9)
Restenotic lesion, N (%)	11 (3.1)
Length of stenosis, mm	11.6±8.2
Total occlusion, N (%)	139 (38.6)
Reference vessel diameter, mm	2.93±0.53
Minimal lumen diameter, mm	0.34±0.39
Stenosis, % of luminal diameter	88.2±13.5
TIMI pre PCI, N (%)	
0–1	152 (42.2)
2–3	208 (57.8)

Abbreviations: CX = circumflex coronary artery; LAD = left anterior descending coronary artery; PCI = percutaneous coronary intervention; RCA = right coronary artery; TIMI = thrombolysis in myocardial infarction.

Clinical Follow-up

To show that the patient population with clinical follow-up was quite comparable to the patient group with angiographic follow-up, we compared the data detailed in Tables 1–3 of the groups. Regarding these variables, there were only some differences found: patients with clinical follow-up were older and had less frequent hyperlipidemia, a higher percentage of cardiogenic shock and cardiopulmonary resuscitation, and a lower frequency of postprocedural thrombolysis in MI (TIMI) 3 flow.

During their hospital stays, 14 patients with 15 treated lesions died. In all, 306 patients (95.6%) were discharged from the hospital on dual antiplatelet therapy. Clinical follow-up was available in 298 of the 306 (97.4%) discharged patients. During follow-up, no deaths occurred. There were 2 Q-wave MIs. Also, 31 patients underwent a repeat revascularization procedure for 33 restenotic lesions, and 3 patients underwent re-PCI for stent thrombosis after discharge.

During the total follow-up period, including in-hospital events and clinical follow-up, hierarchical MACEs were death in 14 patients (4.4%), Q-wave MI in 3 patients (0.9%), and target lesion revascularization in 38 patients (11.9%; 31 due to restenosis and 7 due to stent thrombosis). In addition,

Table 3. Procedural data

Number of lesions	360
Stents per lesion, N	1.4±0.8
Length of stented segment, mm	22.7±13.8
Number of inflations, N	3.4±2.6
Maximum inflation pressure, atm	17.1±2.8
High pressure inflation ≥16 atm, N (%)	263 (73.1)
Maximum balloon diameter, mm	3.0±0.4
Balloon to artery ratio	1.1±0.2
Final reference vessel diameter, mm	2.98±0.47
Final minimal luminal diameter, mm	2.62±0.50
Final stenosis, % of luminal diameter	12.0±11.1
Acute gain, mm	2.28±0.62
TIMI 3 post, N (%)	351 (97.5)
Abbreviations: TIMI = thrombolysis in myocardial infarction.	

there were 6 PCIs not related to the target lesion, resulting in a target vessel revascularization rate of 13.8% (44 of 320).

Discussion

In this prospective observational study, the use of carbon-coated stents for treatment of acute lesions in patients with STEMI or NSTEMI was associated with a low late loss, translating into a low binary angiographic restenosis rate within 6 mo of follow-up.

In-stent binary angiographic restenosis rate was 19.1% in the present study compared with 24.4% (72 of 294) in a study using the same carbon-coated stent exclusively in STEMI patients.¹⁴ The present study extends this knowledge with detailed angiographic data, showing a late lumen loss of 0.69±0.75 mm for the in-stent segment and 0.74±0.77 mm for the total segment, including the 5 mm proximal and distal to the stent. Of note, quantitative coronary analysis was modified compared with the present standard technique. The proximal and distal segments to the stent were analyzed in the presence of a stenosis with more than 50% luminal narrowing. Thus, late lumen loss, as well as binary angiographic restenosis rate, was higher for the total segment compared with the in-stent segment. This approach represents a more clinically relevant angiographic analysis compared with the academic measurements of late loss in the total segment, irrespective of luminal narrowing.^{10–13}

In the present trial, the late lumen loss of the carbon-coated stent was lower compared with data of other non-drug-eluting stents in patients with ACSs, with

Table 4. Angiographic measures at 6 mo

Angiographic follow-up, n	220/360
Reference diameter, mm	2.84±0.55
Minimal lumen diameter, mm	
In-stent	1.95±0.84
Total segment	1.90±0.86
Stenosis, % of luminal diameter	
In-stent	32.4±25.3
Total segment	33.7±25.7
Late loss, mm	
In-stent	0.69±0.75
Total segment	0.74±0.77
Late loss index	
In-stent	0.32±0.36
Total segment	0.34±0.37
Binary-restenosis rate, N (%)	
In-stent	42 (19.1)
Total segment	47 (21.4)

0.87±0.57 mm,¹⁵ 0.88±0.92,¹⁶ and 0.83±0.52 mm.² In patients with predominantly stable angina treated with primary, elective, or provisional stenting, the use of carbocarbon-coated stents did not differ from stainless steel stents regarding angiographic results.¹⁷ In this study, 2 stent types were mixed in the carbocarbon-coated group, and the included lesion types did not deal with the thrombogenic milieu of ACS lesions. Thus, the results cannot be translated to the setting of our study. With modern stent designs, there have been several reports about a low late loss with carbon-coated stents in patients with noncomplex lesions. In-stent late lumen loss was 0.66±0.53 mm based on 168 lesions in the JUPITER II trial, with mainly direct stenting,¹⁰ and 0.7±0.9 mm based on 80 patients in the Phantom IV study.¹⁸ This data supports the idea that the carbon-coating may have a positive influence on the restenotic mechanisms. Late loss in the non-drug-eluting stent arm of JUPITER II with the use of the carbon-coated stent was 0.66±0.53 mm,¹⁰ in TAXUS IV with use of the Express stent 0.92±0.58 mm,¹¹ in SIRIUS with the use of the BX Velocity stent 1.00±0.70 mm,¹² and in the ENDEAVOR-II with the use of the Driver stent 1.03±0.58 mm.¹³

Strut thickness also influences the occurrence rate of restenosis with use of bare-metal stents. In the Intracoronary Stenting and Angiographic Results Strut Thickness Effect on Restenosis Outcome (ISAR STEREO) II trial, 611

Table 5. Differences between patients with and without stent thrombosis

	Without stent thrombosis	With stent thrombosis	p-value
Implantation pressure, atm	17.2±2.8	14.9±3.3	0.016
Severely depressed left ventricular function, n (%)	37 (11.8)	3 (42.9)	0.014
Total occlusions, n (%)	133 (37.9)	6 (66.7)	0.08
LAD lesions, n (%)	137 (39.0)	5 (55.6)	0.32

Abbreviations: LAD = left anterior descending coronary artery.

patients were randomized to receive a thin strut (50- μ m) stent or a thick strut (140- μ m) stent.¹⁹ Stent designs were different. Binary angiographic restenosis rate after 6 mo was 31.4% with use of the thick strut stent and significantly less, 17.9%, with use of the thin strut stent ($p < 0.001$). In ISAR STEREO, 2 stents with comparable design but different strut thicknesses were analyzed. The thin strut stent was also associated with a lower binary angiographic restenosis rate compared with the thick strut stent.²⁰ Nevertheless, the data of both ISAR trials cannot be translated to our population including patients with STEMI or NSTEMI. In ISAR STEREO, 94 patients suffered from AMI, and in ISAR STEREO II there were only 75 patients, centering the better results of the thin strut stent to predominantly nonacute coronary lesions in native coronary arteries. At least from a theoretical consideration, the combination of thin struts being presently available with cobalt-chromium stents in combination with a passive surface coating might merge both positive effects.

The question of different clinical outcomes of various non-drug-eluting stents in AMI lesions has been recently raised in an editorial by van de Werf.²¹ In 2 randomized trials, the sirolimus-eluting Cypher and the paclitaxel-eluting Taxus stent have been shown to reduce the need for repeated revascularizations.^{1,2} Furthermore, no difference was observed regarding the occurrence of stent thrombosis between the drug-eluting stent and bare-metal stent arms in the PASSION,¹ as well as in the TYPHOON² studies during 12 mo of follow-up. Stent thrombosis in PASSION was 1.0% in the drug-eluting stent arm and 1.0% in the bare-metal stent group. Numbers in TYPHOON were 3.4% and 3.6%, respectively. Nevertheless, the premature discontinuation of dual antiplatelet therapy was a very strong predictor regarding stent thrombosis with use of drug-eluting stents.⁶ In patients with ACS, in particular STEMI, with limited chance to definitely exclude individuals with a possible bleeding risk due to sedation or hemodynamic instability, the use of non-drug-eluting stents should be preferred. Of note, the late lumen loss values shown for the carbon-coated stent were only somewhat higher compared with the 0.61 ± 0.46 mm reported for a zotarolimus-eluting stent in a less complex patient population.¹³ Nevertheless, the potential benefit of a carbon-coated stent with a

modern design regarding reduced occurrence of restenosis compared with noncoated bare-metal stents has to be proven in a randomized trial.

No intravascular ultrasound was used to assess neointimal formation. Angiographic follow-up rate was only 61%. This might be explained by the inclusion of patients with STEMI or NSTEMI. Nevertheless, a lower angiographic follow-up rate shifts the results to patients with more complaints possibly being associated with a higher restenosis rate. This shift would lead to a higher and not lower late loss, supporting our main study result and interpretation. Still, angiographic analyses were based on 220 lesions.

Conclusion

The use of a carbon-coated stent for treatment of acute lesions in patients with STEMI or NSTEMI was associated with low late loss, translating into a low binary angiographic restenosis rate within 6 mo of follow-up.

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