Low Target Vessel Revascularization after Intracoronary Silicon Carbide Coated Stent Implantation

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Introduction

Most studies conducted to assess the outcome after implantation of a particular intracoronary stent are using stringent in- and exclusion criteria. Often only a limited number of the patient scheduled for coronary bypass angioplasty fulfill these criteria. Therefore, it is difficult to transfer the results of these studies into daily praxis. To evaluate the results of intracoronary Silicon Carbide coated stent implantation in the heterogeneous group of patients treated in daily practice, we conducted an observational study.

Methods

Patients population

Records of 157 consecutive patients who received Silicon Carbide coated intracoronary stents (Tenax®, BIOTRONIK, Germany) at the Catharina Hospital in Eindhoven, between July 1997 and October 1998, were analyzed. Consecutive patients, also those receiving stents for acute or threatened closure, during rescue percutaneous transluminal coronary angioplasty (PTCA) and within 24 hours after prior balloon angioplasty were included. Baseline characteristics, including risk factors, were collected for all patients. Clinical follow up was performed including angina score, myocardial infarction, death, angiographic data, and any subsequent revascularization procedures.

Stent Placement

Stent implantation was performed using the Silicon Carbide coated balloon expandable Tenax® (BIOTRONIK, Germany) coronary stent according to the standard protocol. In case of elective stent implantation, the decision for performing predilatation was left to the discretion of the operator. In our study, both pre-mounted and hand crimped stents were used. Intravascular ultrasound guidance of the stent implantation was not mandatory, nor restricted. Anticoagulation regimen was 80 mg of aspirin, and for 15 days 250 mg ticlopidine daily.

Follow-up

Unless clinically indicated, no angiographic follow-up was scheduled. Telephone interviews of the patients were conducted between 60 and 495 days (mean 146 days) post stent implantation. At follow-up patients were assigned an angina score using the standard Canadian Cardiovascular Society system. Furthermore interval myocardial infarction, angiography, revascularization and death were recorded. In case of any adverse event, the referring physician of the patient was contacted and the patient file was analyzed. For purposes of analysis, patients reporting no angina at follow-up were assigned a score of 0. Endpoints in the analysis were (sub-) acute stent thrombosis, target vessel revascularization, and death. Acute or sub-acute stent closure was defined as angiographic proven stent occlusion within 30 days post implantation. In case of bail out stent implantation for acute closure not resulting in restoration of flow, vessel closure was not considered stent related.

Results

Patient characteristics

The clinical characteristics of the patient group are shown in Table 1. Pre-intervention 55% of the patients had stable angina CCS class 2 or 3. Thirty-eight percent of the patients had unstable angina, of which 8% was post-infarct angina. In 3% of the patients, the stent was implanted during rescue PTCA. In the majority of patients (57 %) indication for stent implantation was dissection. Six percent of the stents were implanted in venous bypass grafts, distribution in the native coronary tree was 43% Left Anterior Descending, 32% Right Coronary Artery, and 19% Ramus Circumflexis.

Total number of patients	157
Number of Tenax stents	168
Follow-Up completed in	147
Time of follow up	146 ± 99 days
Male	71%
Age	61 ± 10 years
Smoker	33.6%
IDDM*	7.8%
NIDDM*	7.8%
Hx of hypertension	42.5%
Hypercholesterolaemia	50%
Fam Hx of CAD*	55.6%
Peripheral arterial disease	19.4%

* IDDM: Insulin dependend diabetes mellitus
NIDDM: Non-IDDM
CAD: Coronary artery disease

Table 1. Clinical Characteristics

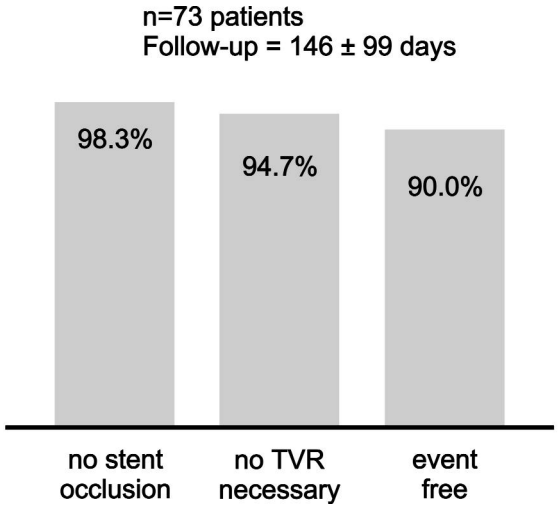

Figure 3. Clinical results with TENAX â

Implantation was successful in all patients. However, in three patients receiving stents for acute closure insufficient restoration of flow was achieved, these patients underwent bypass graft surgery.

Follow-up

In 147 of the 157 patients follow-up data are completed. An average follow up of 146 ± 99 days was obtained. At follow up serious adverse event included two myocardial infarctions and four deaths. One myocardial infarction might be attributed to the non-compliance of the patient to the anti-thrombotic regimen. Three death are definitely not attributable to failure at the stent site (cerebrovascular accident, renal failure, progressive heart failure), one death is of unknown origin. Seventy-five percent of the patients was free of anginal complaints at follow-up, 17% was in CCS class 1 or 2, and 7% in CCS class 3. The average angina score at follow up was 0.5 ± 0.9. Five patients underwent target vessel revascularization (TVR), 3 PTCA and 2 CABG, thus resulting in a TVR rate of 5.3%.

in %	Tenax	PS stent [1]	CR/Flex [2]	NIR [3]	Micro [4]
Stent occlusion	1.7	3.5	4.8	0	5
TVR	5.3	10	14.5	11.9	20
Event free	90	79.9	83	76.5	75

CR/Flex : Flexible tantalum Cordis stent.

Table 2. Comparison of event-rates (in %) of several stents

Discussion and Conclusion

Our study shows an extremely favorable TVR rate for patients treated with the silicon carbide coated intracoronary Tenax® stent. Comparing our data to other data in the literature, our patients had, despite less favorable pre-procedural characteristics lower TVR rates, and higher event-free survival (Table 2). Ninety percent event free survival is, considering the patient and lesion characteristic of our study population, a very promising number. However to fully evaluate the ideal applications and benefits of this stent further investigation is warranted. The clinical experiences with the Tenax® are summarized in Figure 1.

References

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