Coated Stents in Small Coronary Vessels - A Successful Strategy?

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Summary

Coronary stenting has increased tremendously over the past few years. There is supporting evidence for a number of indications, while the justification of others has not yet been proven compellingly. Among the latter indications is stenting of vessels with a diameter of less than 3.0 mm. A special silicon carbide (a-SiC:H) coated stent that reduces thrombogenesis and might thus lead to lower restenosis rates is compared with balloon angioplasty in small vessels in a prospective randomized trial. In each group, 250 patients were enrolled. This paper presents the initial results of the study. So far, 342 patients have been analyzed. There were no differences between the baseline characteristics of both groups. Complications during hospitalization occurred at equal rates in both groups. Major adverse cardiac events were observed in 7.3 % of the balloon group, and 4.3 % of the stent group (p = NS). Further results have to be awaited, but stenting of small vessels appears to be safe.

Key Words

Coronary stenting, small vessels, stent coating, stent thrombosis

Introduction

The first prospective randomized trials comparing conventional percutaneous transluminal coronary angioplasty (PTCA) and coronary stenting have led to an almost unlimited use of stents, due to their positive results in favor of stenting [1,2]. In many centers in Europe and the USA, intracoronary stents are used in 70 % to 80 % of the intracoronary procedures performed. The positive results of the aforementioned studies, which were performed in highly selected patient populations, have been assumed to hold true in the general daily praxis, without any actual evidence to this fact. It is questionable whether stenting in other subsets of patients with different anatomies is as beneficial as it is in short lesions in larger vessels. For instance, subanalyzing the larger studies suggests that elective stenting in small coronary arteries has a worse result than elective stenting in larger coronary arteries [3]. However, the results might still be favorable when compared to balloon angioplasty. Furthermore, the development of newer stent designs has not only simplified stent placement by their greater flexibility and better attachment to the delivery system, thus reducing acute complications, but the newer designs and coatings might also play an important role in reducing restenosis rates. The specific silicon carbide coating (a-SiC:H) described elsewhere theoretically holds the promise of reducing early and late complications after stenting [4]. Our study investigated the usefulness of stenting smaller coronary arteries (2.0 mm to 3.0 mm diameter) with silicon carbide coated stents as compared to balloon angioplasty in a prospective randomized way. A follow-up period of one year with an angiographic follow-up at 6 months is part of the study design. In this report, the procedural outcome and the 30-day follow-up results will be described.

Materials and Methods

Patients with symptomatic coronary artery disease and lesions in a vessel with a diameter of less than 3.0 mm and a lesion length of less than 15 mm were eligible for this study. Exclusion criteria were acute myocardial infarction (MI) within 48 hours before the intervention and unwillingness or inability to provide written

informed consent for participation in the trial. All patients were randomly assigned to either balloon angioplasty or stent placement (Tenax, Biotronik, Germany) by the use of a central telephone number. Patients also gave consent to routine angiography at 6 months. The study was conducted according to the principles of the declaration of Helsinki and was approved by the ethics committees at each participating center.

Procedure

During the intervention, patients received heparin and aspirin. Online quantitative coronary angiography (QCA) was performed proximal of the lesion to determine the vessel diameter. After the procedure, all patients continued with aspirin, and those receiving a stent were given 250 mg ticlopidine twice a day for 6 weeks. Stents were placed with intermediate pressures of 10 to 14 atm. The procedural success was assessed by angiography.

Endpoints

The primary endpoint of this study is the absence of angiographic restenosis at the 6-month follow-up. Angiographic restenosis is defined as a stenosis of > 50 % of the vessel diameter at the treated site. The secondary endpoint is the absence of major adverse cardiac events (MACE), defined as:

- urgent coronary artery bypass graft (CABG),
- nonfatal Q- or non-Q-wave MI,
- repeat revascularization, and
- cardiac death.

Angina scores will be determined at the 30-day, 6-month, and 12-month follow-up examination. The angina score will be assessed by using the Canadian Cardiovascular Society angina classification for stable, and the Braunwald classification for unstable angina pectoris. The angiographic minimal lumen diameter (MLD) will be determined after the procedure and as part of the 6-month follow-up angiography. Angiographic procedural success is defined as a residual stenosis of < 50 % in the PTCA group, and of < 20 %, in the stent group.

Statistical Analysis

Based on several substudies, angiographic restenosis rates of 50 % for conventional PTCA and 35 % for stent implantation are expected. To obtain a 90 % confidence level with a two-tailed error of 0.05, two groups of 226 patients each are required. With an estimated loss of approximately 10 % of the analyzable patients, a total of 500 patients will be required.

Results

Patient Characteristics

Of the 342 patients included to date, 168 were randomized to PTCA, and 174 to stent implantation. Most of the subjects, 70.2 %, were men, equally distributed in the two groups, with 73.2 % vs. 67.2 % in the PTCA group and the stent group, respectively (p = 0.2). The mean age was 60.4 ± 10.1 years and 61.1 ± 9.5 years for the PTCA group and the stent group, respectively. The incidence of diabetes was comparable for the two groups: 14.2 % vs. 16.1 %, (p = NS) for the PTCA group and the stent group, respectively.

Procedural Characteristics

The vessels treated were small coronary arteries, with an identical pre-procedural proximal reference diameter for the two groups of 2.4 mm ± 0.3 mm. The target lesion distribution was right coronary artery (RCA) in 20.9 % vs. 20.1 % of the patients; circumflex artery (CX), in 42.5 % and 37.4 %; and left anterior descending artery (LAD), in 36.5 % vs. 42.5 %, for the PTCA group and the stent group, respectively. Cross-over from the PTCA to the stent group occurred in 22.6 % of the patients, in the majority of cases this was due to severe dissection. In 4.0 % of the patients randomized to stent implantation, no stent was delivered. Procedural success was achieved in 96.4 % of the PTCA patients and 98.3 % of the stent patients.

Outcome

During hospitalization, 6.1 % of the patients experienced a MACE, 7.3 % vs. 4.3 % (p = NS) in the PTCA group and the stent group, respectively. The MACE consisted of death with 0.6 % vs. 0 %, MI with 4.5 % vs. 2.2 %, CABG with 0.6 % vs. 0.5 %, vessel occlusion with 0.6 % vs. 1.1 %, and repeat PTCA with 1.1 % vs. 0.5 % for the PTCA group and the stent group, respectively.

The 30-day follow-up was completed in 308 patients. In the time between hospital discharge and 30-day follow-up, an additional 1.9 % of the patients experienced a MACE, 1.4 % vs. 2.6 % (p = 0.7) for the PTCA group and the stent group, respectively. In the PTCA group, the MACE were death in 0.7 % and vessel

	PTCA (%)	Stent (%)	P-value (%)
In-hospital MACE	7.3	4.3	0.2
Death	0.6	0.0	0.3
MI	4.5	2.2	0.2
CABG	0.6	0.5	1.0
PTCA	1.1	0.5	0.6
Vessel occlusion	0.6	1.1	0.6
30 day FU MACE	1.4	2.6	0.7
Death	0.7	0.0	0.3
MI	0.0	0.0	1.0
CABG	0.0	0.0	1.0
PTCA	0.0	1.9	0.2
Vessel occlusion	0.7	0.7	1.0
Cumulative MACE	9.8	7.7	0.5
Death	1.3	0.0	0.2
MI	5.2	2.6	0.2
CABG	0.7	0.7	1.0
PTCA	1.3	2.6	0.4
Vessel occlusion	1.3	1.9	0.7

Table 1. Incidence of MACE following PTCA and stenting (in percent). MACE = major adverse cardiac event, MI = myocardial infarction, CABG = coronary artery bypass graft, PTCA = percutaneous transluminal coronary angioplasty, FU = follow-up.

occlusion in 0.7 % of the patients. In the stent group, MACE consisted of stent occlusion in 0.7 % and repeat target vessel intervention in 1.9 % of the patients. The cumulative incidence of MACE was 9.8 % for the PTCA group and 7.7 % for the stent group (p = NS) at the 30-day follow-up. Anginal complaints were nearly absent in 91.5 % vs. 90.1 % of the patients in the PTCA group and the stent group, respectively (Table 1).

Discussion and Conclusion

The presented preliminary results show that implantation of a silicon carbide coated stent in coronary arteries < 3.0 mm is a safe and effective treatment when compared to PTCA alone. Therefore, previous considerations concerning the high risk of stent thrombosis in small coronary arteries [3] were not confirmed by this study. However, further results concerning the long-term efficacy of Tenax stent implantation in small coronary arteries as compared to PTCA have to be awaited.

References

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