Preliminary Experience with the TENAX Coronary Stent

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Summary

The Tenax® coronary stent is laser sculpted from high-precision 316 L stainless steel using advanced production procedures. An a-SiC:H (hydrogen rich amorphous silicon carbide) coating reduces thrombogenicity and improves biocompatibility. From April until July 1998, 235 patients (62.7 ± 10.5 years) were implanted with 256 Tenax® coronary stent in five French centers (1.09 stents/pt). The clinical indication for intervention was unstable angina (33.2%) and recent myocardial infarction (28.5%) in the majority of cases. Most lesions (59.4%) had complex characteristics (class B2 or C). Target vessel was LAD in 42.2% and right coronary artery in 37.5% of all cases. Four primary stent deployment failures occurred and implantation was successful in 252/256 stents (98.4%). No death, no Q wave myocardial infarction or emergency CABG occurred during hospital stay. Clinical success, defined as successful deployment without procedural or clinical event occurred in 214/230 pts (93%). The clinical and angiographic outcomes of our study suggest that the hybrid, amorphous hydrogenated silicon carbide coated design is promising needing further evaluation in larger clinical trials.

Key Words

Angioplasty, coronary stenting, coronary artery disease, registry.

Introduction

In recent years, the beneficial effects of intracoronary stenting in reducing acute complications and restenosis rates of conventional percutaneous transluminal coronary angioplasty(PTCA) have been reported. The aim of this prospective study was the evaluation of acute clinical and angiographic outcomes after the planned use of the Tenax® coronary stent.

Materials and Methods

Stent Design

The tubular slotted design of Tenax® contains multiple segments connected by 0.75 mm articulations. The articulation sites are crossed over by overlapping segments to avoid tissue prolaps. The combination of segment and articulation design provides Tenax® with a high longitudinal and axial flexibility and conformability. Tenax® coronary stent is laser sculpted from high-precision 316 L stainless steel using advanced production procedures. An a-SiC:H (hydrogen rich amorphous silicon carbide) coating reduces thrombogenicity and improves biocompatibility. The stent is available in sizes ranging from 15 to 30 mm long and in diameters ranging from 2.5 to 4.5 mm.

Stent implantation procedure

In a majority of cases (72.8%), the Tenax® stent delivery system was not used as a primary dilatation device. So, lesion predilatation was performed using the physician's balloon-catheter of choice. In general, initial vessel dilatation was performed with a balloon-to-vessel diameter ratio of 1:1. After positioning the balloon with the premounted stent in the target lesion, the stent was expanded and deployed with a single or double inflation at 10 -12 atm for 60 seconds.

Medical Regimen

All patients received aspirin (250 mg/day) within 24 hours prior to the angioplasty. During the procedure, 10.000 units of heparin were given intravenously. Following the procedure, all patients received 500 mg ticlopidine/day for 2 months. Patients who had not

	n=235 (%)
Mean age ± SD(years)	62 ± 10
Male	193 (82)
Stable angina	63 (26.8)
Unstable angina	78 (33.2)
Recent myocardial infarction	67 (28.5)
Acute myocardial infarction	19 (8.1)
Silent ischaemia	8 (3.4)
Multi vessel disease	115 (49)
Indications for stenting	
Primary implantation	124 (52.8)
Incomplete result	68 (28.9)
Bail out/Dissection	38 (16.2)
Restenosis	5 (2.1)
Target lesion location	
Left anterior descending	108 (42.2)
Circumflex artery	48 (18.8)
Right coronary artery	96 (37.5)
Vein saphenous graft	3 (1.2)
Left main	1 (0.4)
Modified AHA/ACC classification	
Type A-B1	104 (40.6)
Type B2-C	152 (59.4)
Acute occlusion	17 (6.6)
Chronic occlusion	9 (3.5)
Calcification	88 (34.4)
Lesion in bend (> 45°)	46 (18)
Ostial	16 (6.3)
Bifurcation	12 (4.7)

Table 1. Baseline clinical and angiographic characteristics.

taken ticlopidine before the procedure were put back on heparin infusion for 72 hr. The aspirin dose was reduced to 100 mg/day 24 hr after the procedure and was continued indefinitely.

Quantitative Coronary Angiography

All the coronary angiograms were recorded on cine-films and analyzed in a central cath-lab (CHU Caen, France) where QCA/CMS Medis system (Medical Imaging Systems) was available.

Stent length	n=256 (%)
15 mm	200 (78.1)
20 mm	38 (14.8)
25 mm	17 (6.6)
30 mm	1 (0.4)
Stent diameter	
2.5 mm	1 (0.4)
3 mm	116 (45.3)
3.5 mm	103 (40.2)
4 mm	34 (13.3)
4.5 mm	2 (0.8)
Procedure	
Single stent implantation	159 (66)
Other PTCA	33 (14.8)
Other Stenting	43 (19.1)
QCA Analysis	(73/235 pts)
Reference vessel diameter (RVD)± SD mm	
pre-procedure	2.99 ± 0.48
post-procedure	3.08 ± 0.45
Minimal lumen diameter (MLD) ± SD mm	
pre-procedure	0.80 ± 0.42
post-procedure	2.51 ± 0.42
Percentage diameter stenosis (% DS)	
pre-procedure	73.34 ± 13.38
post-procedure	17.84 ± 9.69
Stent deployment success	252 (98.4)
Asymptomatic procedural complications	
no reflow	3
lateral occlusion	4
dissection	7
Acute or sub-acute occlusion	2
Death, QMI, emergency CABG	0

Table 2. Procedural characteristics and in-hospital clinical and angiographic outcomes.

Reference diameter (RD), minimal lumen diameter (MLD), and percent diameter stenosis (% DS) were calculated before and after stenting.

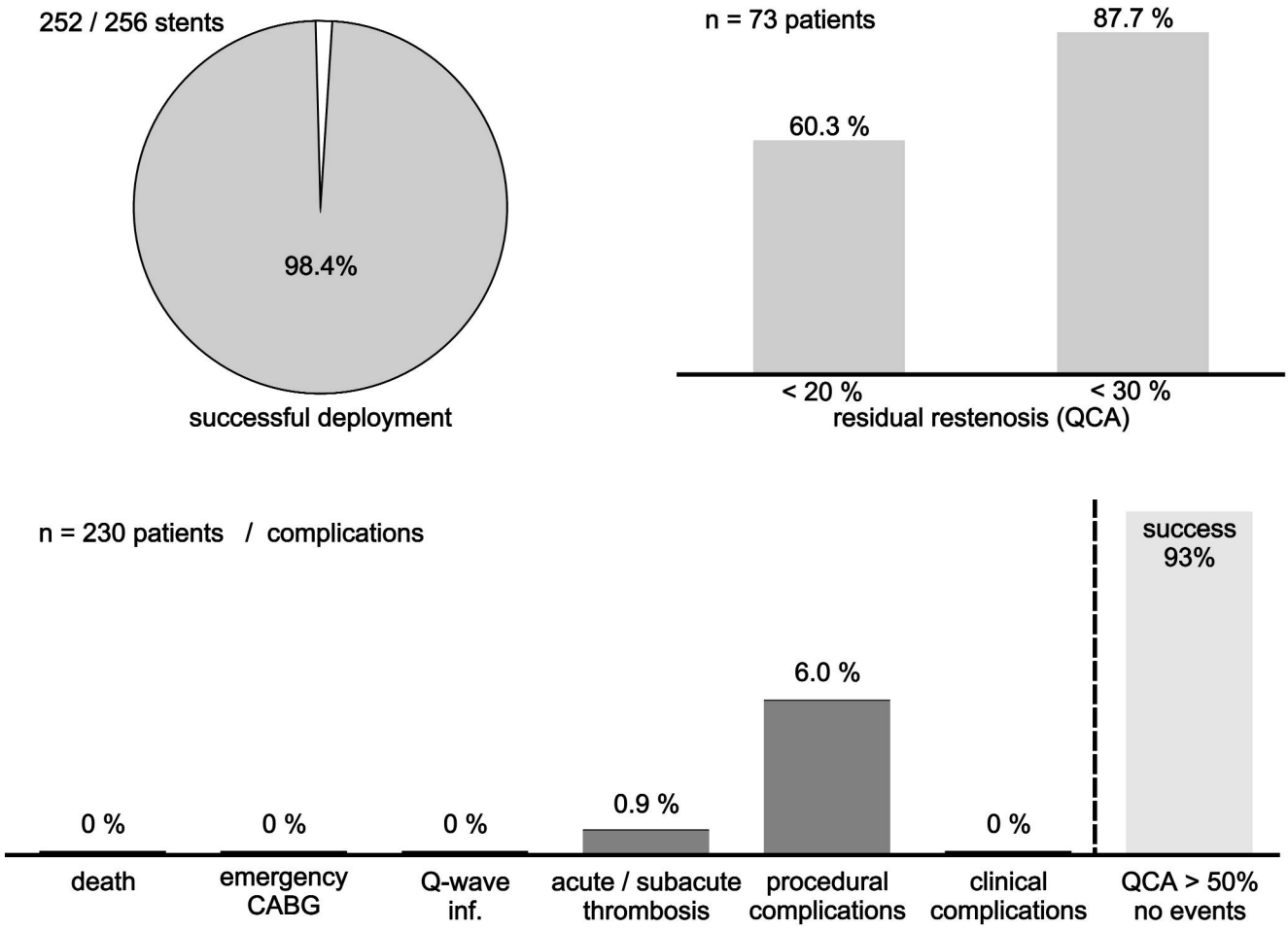

Figure 1. Clinical experience with the a-SiC:H coated Tenax® (BIOTRONIK, Germany) coronary stent: (a) successful deployment. (b) residual restenosis (QCA). (c) complications / success

Definitions

Failure was defined as failure to deploy the stent or residual stenosis > 50%. Optimal acute angiographic result means successful stent deployment associated with a residual stenosis < 30%, and no acute closure within 24 hr of stent deployment. Subacute stent closure means occlusion of the stented vessel from 24 hours to 2 weeks after the procedure.

Major adverse coronary events included: 1) death, 2) myocardial infarction, defined as the development of new pathological Q-waves or elevation of CK over twice the upper limit of normal level with an elevated CK-MB fraction, 3) repeat coronary angioplasty, 4) coronary bypass surgery and 5) bleeding that required blood transfusion or surgical repair at entry site.

Results

From April until July 1998, 235 patients (62.7 ± 10.5 years) were implanted with Tenax® coronary stents in five French centers (Cäen, Clermont-Ferrand, Metz, Mulhouse, Toulouse). Table 1 summarizes patient baseline clinical and angiographic characteristics. The clinical indication for intervention was unstable angina (33.2%) and recent myocardial infarction (28.5%) in the majority of cases. The target vessel for stenting was left anterior descending in 42.2% of cases and the right coronary artery in 37.5%. The majority of lesions (152 / 256, 59.4%) had complex characteristics (class B2 or C).

Procedural characteristics and in-hospital clinical and angiographic outcome are summarized in Table 2.

235 patients were implanted with 256 stents (1.09 stents/patient). Four primary stent deployment failures occurred, implantation was successful in 252/256 stents(98.4%). After procedure, angiography showed residual stenosis < 20% in 60.3% of patients and < 30% in 87.7% . No death, no Q wave myocardial infarction or emergency CABG occurred during hospital stay. Two patients underwent acute or sub-acute thrombosis and were treated medically. Fourteen patients had procedural complications after successful implantation (no-reflow: 3 pts, lateral branch occlusion: 4 pts and dissection: 7 pts), but no clinical complication occurred. Finally, clinical success defined as successful deployment without procedural or clinical event occurred in 214/230 pts (93%) implanted with Tenax® system.

The clinical experience with the Tenax® coronary stent is summarized in Figure 1.

Discussion

Despite sufficient biocompatibility currently available, coronary stents have less-than ideal hemocompatibility. As a consequence of inherent thrombogenicity, coronary stenting is associated with a significant number of acute and subacute thromboses. The heavy anticoagulation necessary to avoid stent thrombosis can lead to major bleeding events and vascular complications, often requiring surgical repair. Strategies such as stent placement guided by intravascular ultrasound, approach through the radial artery, restriction of stent placement to arteries > 3 mm in diameter, high pressure implantation, and "overdilatation" have been suggested to overcome these major limitations. However, due to increases in cost and a decrease in the spectrum of indications, the therapeutic strategies mentioned above are generally not enough to solve the problem. Improvement of the hemocompatibility of the materials themselves is a new concept that deals with stent thrombosis directly.

By the highly biocompatible and hemocompatible a-SiC:H coating of the Tenax® stent, preliminary clinical results indicate reduced complication rates as compared to uncoated metallic stents. In this pilot study, our initial results demonstrate that the Tenax® coronary stent can be safely and successfully (98.4%) implanted in patients with a variety of clinical and angiographic findings. Despite the frequently unfavorable angiographic characteristics of the lesions, subacute stent thrombosis occurred only in two patients (0.8%) and no death, no myocardial infarction and no emergency CABG occurred during in-hospital outcome.

Conclusion

The Tenax® coronary stent showed to be safe and efficacious in the treatment of coronary lesions, even in the presence of unfavorable characteristics. It has a very low profile (0.040"), excellent flexibility, trackability and scaffolding after deployment. The deposition of a-SiC:H on metallic stent surfaces forms a hybrid designed device, which promises reduced complication rates. The clinical and angiographic outcomes of our study suggest it is a promising design that needs further evaluation in larger clinical trials.