Primary Stenting with no Predilatation – A Pilot Study with the TENAX Coronary Stent

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Summary

Primary stenting is a new technique, which has been proven to be very useful in acute situations. Due to its time and cost saving properties there is a strong interest to use primary stenting in other types of lesions. This study evaluates the feasibility and safety of primary stenting using a new stent (Tenax®, BIOTRONIK, Germany). During the first phase of the study, 86 patients with accessible lesions received a stent. In 44 cases Tenax® stents were implanted. No complications occurred during the procedures or at clinical follow up after one month. No deaths occurred. These preliminary results are encouraging for the use of primary stenting in selected lesions.

Key Words

Primary stenting, stenosis, calcification

Introduction

Primary stenting — i.e., stenting of lesions with no prior balloon dilatation — is a new technique which offers a less expensive and faster alternative to the contemporary accepted technique. Although it was originally used for acute myocardial infarction [1,2] there is an interest in applying primary stenting to other indications in order to reduce the risks, costs, and time of the procedure.

The aim of this pilot study was to evaluate the feasibility and safety of primary stenting using a new stent system (Tenax®, BIOTRONIK, Germany). This new stent has a hemocompatible surface coating of amorphous silicon carbide. Thus, it is expected that the Tenax® is well suited for primary stenting. Over a period of 2 months (Oct. 10 1998 to Dec. 10, 1998) 277 PTCA procedures were performed. In these patients, direct stenting was performed in 86 cases. In 44 cases Tenax® stents were implanted. All procedures followed the primary stenting protocol.

Methods

Patients

44 patients received the Tenax® stent. 37 of these patients were male (84%). The mean age was 62 years ranging from 37 to 80 years. Patient characteristics and target vessel distribution are listed in Table 1. All patients gave oral or written consent. The study protocol was approved by the local ethics committee. The study was performed according to the declaration of Helsinki.

Characteristics of the Lesions

Lesions were classified according to AHA/ACC lesion type (types A, B1, B2, and C). Percentage diameter stenosis (%DS) was evaluated using quantitative coronary angiography of 35 mm cineangiograms with a MEDIS system. Both parameters are listed in Table 2. Thirty-four percent of the lesions showed small or regular calcifications. Nine percent of the stents were implanted in bifurcation lesions and two were ostial lesions. Sixty-one percent of the cases had a lesion length of 5 - 9 mm and 39% were 10 - 20 mm in length. The mean value was 9.09 mm.

Materials

The Tenax® stent has a slotted-tube design with multiple segments separated by 0.75 mm articulations. Tenax® has a high longitudinal and axial flexibility and is manufactured from 316 L medical grade stainless

Indication	
Stable angina pectoris	27%
Instable angina pectoris	59%
Acute myocardial infarction	9%
Silent ischemia	5%
Target vessels	
Left anterior descending	30%
Circumflex	54%
Right coronary artery	16%

Table 1. List of indications and target vessels of the 44 patients included in this study.

Type of lesion	
Type A	25 %
Type B1	31 %
Type B2	30 %
Type C	14 %
Percentage diameter stenosis	
70-79 % DS	25 %
80-89 % DS	34 %
90-99 % DS	27 %
100 % DS	14 %

Table 2. Type and severity of lesions that were treated with a stent.

steel with an amorphous silicon carbide (a-SiC:H) coating to improve its hemocompatibility. Three stent lengths were used (15 mm in 84% of the cases, 20 mm in 12%, 25 mm in 4%). The stent was used as a system, pre-mounted on a balloon delivery system. The three balloon diameters used were 3 mm (34%), 3.5 mm (41%) and 4 mm (25%).

Procedure

All patients were given aspirin (250 mg/day) at least 24 hours before the procedure. At the beginning of the procedure, patients received 10000 units of intravenous heparin. After stenting the patients received 500 mg ticlopidine/day for 2 weeks. Aspirin was reduced to 100 mg/day after the procedure. All patients remained on aspirin indefinitely.

High pressure balloons were used for stent deployment with a mean inflation pressure of 14.1 bar and an average inflation time of 23 seconds. Eighty-eight percent of the patients underwent an individual inflation deployment, while 12% required one secondary dilatation.

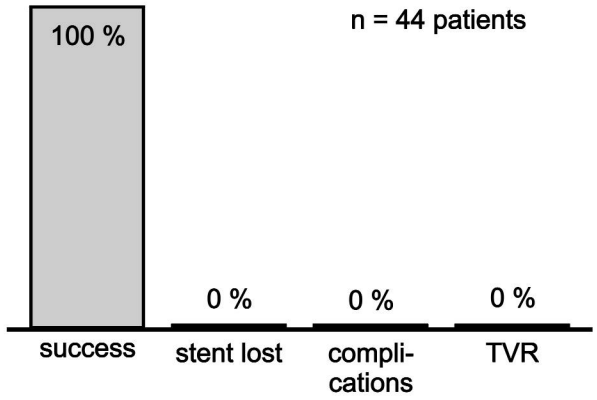

Figure 1. Clinical experience with the Tenax® coronary stent in direct stenting.

Results

All 44 cases were successful. No stents were lost during the procedures and no stenoses was found after stenting. No adverse events or complications were observed at clinical follow-up after a period of one month. There were no occurrences of dissection, target vessel revascularization, or death. The clinical experience in summarized in Figure 1.

Discussion

While this study has a limited patient population and only medium-term clinical follow-up, the preliminary results are promising. The procedural and cost advantages are clear, but there may also be significant long-term advantages in outcome with primary stenting. Animal studies [3,4] have established the role of vessel injury and endothelial denudation as critical factors in determining acute thrombosis and long-term restenosis, and some initial clinical evidence has been collected to support the concept [5,6]. Primary stenting has the theoretical effect of reducing the endothelial damage caused by balloon dilatation by shielding sections of the vessel wall with the stent struts and by reducing the abrasion and impact velocity of the balloon against the endothelial cell layer. By reducing the exposure of thrombogenic lesion tissue and coagulation factors to the blood stream, primary stenting may reduce acute thrombosis. Stent implantation without predilatation may also reduce restenosis by limiting the extent of vessel injury and the release of growth factors.

It has also been observed that primary stenting improves the chance of procedural success in cases where

PTCA alone might lead to extensive dissection [7]. While the traditional approach is to dilate a lesion and save stenting for emergency bailout, primary stenting is technically easier than bailout stenting and initial results have shown an improved short-term clinical outcome. However, primary stenting is not applicable in all lesions. Careful selection of lesions for primary stenting is critical. Overuse of primary stenting can lead to considerably worse scenarios than bailout stenting of PTCA.

Conclusion

Although the number of patients in this initial study was limited, some preliminary inferences can be drawn. Primary stenting is a new and very promising technique. Using the new Tenax® stent, it is cost effective and safe. Due to its simplicity and practicality, primary stenting should be encouraged for use in other types of lesions when prior balloon dilatation is not required to introduce the stent.

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