Low rates of clinical restenosis with the new flexible stainless steel tube intracoronary stent: the R Stent. A six-month safety and feasibility study

Arie HM Knook1, Alexander J Wardeh1, Benno J Rensing1, David P Foley1, Willem J van der Giessen1, Marcel van den Brand1, Pim J de Feyter1, H Richard Davis2, Gary J Becker3 and Patrick W Serruys1

INTRODUCTION: Coronary stents have been used with increasing frequency and in increasingly complex coronary lesions for the treatment of symptomatic coronary artery disease. A new stainless steel coronary stent, the R Stent, has been designed to provide maximum flexibility for tracking and high radial strength post-deployment.

AIMS: To assess the safety and feasibility of the R Stent in patients with coronary artery disease. Specific objectives were to assess the R Stent’s deployment success, angiographic and procedural success (<90% residual stenosis and TIMI 3 flow), safety (absence of complications), 30-day and six-month clinical follow-up.

METHODS: Between April 1998 and January 1999, stent deployment was attempted in 36 lesions in 30 patients with stable (43%) or unstable (57%) angina pectoris and 29/36 of the lesions were anatomically complex. Treated lesions were in the LAD (n = 15), RCA (n = 13) or LCX (n = 8).

RESULTS: Stent deployment was achieved in 97% with one crossing failure in a patient with a long, calcified, proximal LAD lesion. After the procedure, patients were scheduled for one- and six-month clinical follow-up. One patient experienced a non-Q-wave myocardial infarction in hospital. At one month, there were no additional complications. Only one patient experienced recurrence of angina (CCS class 2) within the 30 days. At six-month follow-up, one sudden death had occurred. Three (10%) patients had anginal complaints, one of them received target lesion repeat PTCA. All other patients (87%) were event- and angina-free.

CONCLUSION: This first clinical experience with the R Stent shows acceptable feasibility and safety with good long-term clinical results. (Int J Cardiovasc Intervent 2000; 3: 91–95)

Keywords: coronary disease – stenosis – stents

Introduction

Since their first introduction into clinical practice more than a decade ago, the use of coronary stents has increased rapidly. The introduction of newer, more versatile stent designs has enabled interventional cardiologists to apply coronary stent technology to an extended range of lesion subsets.

More than 60 different coronary stents are available nowadays in Europe.1 Multiple design changes were made in order to render stents more flexible for use in long or calcified lesions and in tortuous vessels.2–7 With the recent improvements in deployment techniques and adjunctive pharmacological therapies, manufacturers and interventional cardiology have re-focused their attention on the design of stents, particularly in relation to properties such as the trade-off between flexibility and radial strength. The goal remains to achieve the ideal stent.1

A new stainless steel stent, the R Stent (Orbus Medical Technologies, Fort Lauderdale, Florida) has been designed to improve the treatment of complex coronary lesions. The structural symmetry of the stent is achieved through two distinctive design components: a spiraling dual helix, which courses through the entire length of the stent, and a
series of sinusoidal support rings. This design is aimed to provide both a high radial strength and flexibility to attempt complex coronary anatomy.

The aims of this study were to assess the safety and feasibility and the clinical behavior of the R Stent for the treatment of complex coronary lesions.

**Materials and methods**

**Patient selection**

Between April 1998 and January 1999, 30 patients undergoing coronary angioplasty because of stable or unstable angina were enrolled in the study. Patients were included with lesions located in coronary arteries with a reference diameter of 2.5–4.0 mm, treatable with a stent length of 16 mm or 25 mm. Patients with ostial, restenotic and bifurcation lesions were included. Patients were excluded if they were under the age of 18 years or unable to obtain written informed consent. Patients were excluded if they had a myocardial infarction 72 hours prior to inclusion, stroke or gastrointestinal bleeding within the past six months or an ejection fraction of less than 30%. Patients with contraindications to anti-platelet therapy and patients unsuitable for emergent coronary bypass surgery were excluded as well as lesions in saphenous vein grafts. This trial was approved by the Medical Ethics Committee of the University Hospital Rotterdam. Written informed consent was obtained from each patient before enrollment in the trial.

**Stent design**

The R Stent is a balloon-expandable device fashioned from 316LVM stainless steel tubing (Figure 1). The stent includes three different zones, the two end zones located at the extremities of the stent, and the center zone. The end zones anchor the entire structure of the stent during deployment and enable the operator to place and deploy the stent within the lesion. In addition, the end zones provide the R Stent with squared ends, which may help to avoid inexact positioning and uneven support at the ends. The center zone of the R Stent consists of a continuous dual helix lattice. This configuration provides optimal balance between flexibility and radial strength.

**Procedure**

Percutaneous transluminal coronary angioplasty (PTCA) was performed using the femoral approach. Six, 7, or 8 F. guiding catheters supplied by six different manufacturers were used. Predilation of the lesion was performed with standard balloon angioplasty. Thereafter the stent was mounted on appropriate semi-compliant balloons, followed by manual crimping. After implantation at high pressure, additional balloon inflations with standard angioplasty balloon catheters were performed when necessary to achieve an optimal final result (DS < 20%).

Aspirin (250 mg) and heparin (10 000 ui) were administered to all patients at the beginning of the procedure. Periprocedural supplemental doses of heparin were given to maintain an activated clotting time of > 300 seconds. Intracoronary isosorbide-mononitrate (2 mg) was given before each protocol mandated cine-angiogram. Following the procedure, all patients were given 1000 mg ticlopidine orally, followed by 250 mg ticlopidine twice a day for the period of two weeks. Aspirin 80 mg/day was continued indefinitely.

CPK was obtained six and 12 hours after the procedure.

**Definitions and end-points**

Angiographic success was defined as < 20% residual stenosis on visual assessment and TIMI flow 3. Procedure success was defined as angiographic success without the occurrence of in-hospital major adverse cardiac events (death from any cause, myocardial infarction, target lesion repeat PTCA or coronary artery bypass surgery).

Q-wave myocardial infarction was defined as the presence of new Q-waves (according to the Minnesota code) in two or more electrographic leads and an elevation of creatine kinase or its muscle/brain (MB) isoenzyme of at least twice the upper limit of normal. Non-Q-wave myocardial infarction was defined as an elevation of creatine kinase or its MB isoenzyme of at least twice the upper limit of normal.

Extreme vessel tortuosity was defined as the presence of two successive angulations of ≤ 90° of the proximal vessel or at the stenosis site or a single acute angle ≤ 60°, judged in the most unfavorable projection and before wire insertion. Calcium was identified as readily apparent radiopacities within the vascular wall at the site of the stenosis. Flow was graded according to the Thrombolysis in Myocardial Infarction study criteria. Arterial lumen dimensions were obtained using selected end-diastolic cine frames so that
the stenosis was demonstrated in its most severe and non-foreshortened projection. The same projections were used to measure final results.

Three principal end-points were defined for assessment at one- and six-month follow-up after the index procedure: death, myocardial infarction and target lesion revascularization. Secondary end-points were defined as the occurrence of bleeding and vascular complications.

**Results**

**Baseline characteristics**

Baseline clinical characteristics of the study population are summarized in Table 1. The lesion characteristics and results of the acute quantitative coronary angiography are presented in Table 2 and Table 3, respectively.

**Procedural success**

R Stent models 225–161 (16 mm length, 2.5–3.0 mm diameter) and 225–251 (25 mm length, 2.5–3.0 mm diameter) were used. Thirty-six R Stents were implanted in the coronary arteries of 30 patients. Nine additional stents were implanted in seven patients: eight NIR Stents (Medinol/SciMed Life Systems, Maple Grove, MN, USA) and one Wallstent (Schneider/SciMed Life Systems, Maple Grove, MN, USA). These additional stents were implanted when the R Stent was too short for the lesion. The type of additional stent was left to the discretion of the operator. All stents were deployed using high pressure (>14 atm.).

Stent deployment was accomplished successfully in 29 of 30 (97%) patients. There was one deployment failure of a 25 mm R Stent. It could not be successfully tracked through a tortuous, long, heavily calcified proximal left anterior descending (LAD) coronary artery lesion. A dissection beyond the treated segment occurred in two patients (6%).

In all 29 successfully treated patients, TIMI 3 was achieved. No adverse cardiac events occurred.

**In-hospital complications**

One patient experienced a non-Q-wave myocardial infarction post-procedure owing to rupture of the balloon. The peak value of creatine kinase (CK) was 380 iu/l (upper limit of normal 190 iu/l) and the CK-MB fraction was 59 iu/l (upper limit of normal 24 iu/l). Other in-hospital complications did not occur.
Clinical follow-up at one month and six months

At one-month follow-up, there were no deaths, additional MIs, repeat percutaneous or surgical interventions. One patient (3.3%) had recurrence of angina with CCS class 2 symptoms. This is the same patient who experienced a small non-Q-wave myocardial infarction.

At six-month clinical follow-up, two other major adverse cardiac events occurred. At five months, one patient (3.3%) experienced a sudden death while skiing. An autopsy was not performed. Three patients (10%) had recurrent angina; one had a total coronary occlusion treated by repeat PTCA and the other two were treated medically (Table 4). The remaining patients (87%) were event- and angina-free (Table 5).

Discussion

The implantation of the R Stent was successful in all but one patient with just one in-hospital complication. This high rate of success (97%) compares very well to the 94–98% reported for the Palmaz-Schatz coronary stent,\textsuperscript{10,11} the ACS Multi-link coronary stent\textsuperscript{12} and other trials.\textsuperscript{13–15,18,19} However, these trials excluded ostial, restenotic and bifurcation lesions, whereas in this study, lesions with such high complexity could be included. The high success rate could be achieved because of the flexibility, low profile and high radial strength of this stent. Compared to the other stent trials, we can also report a low incidence of major adverse cardiac events (MACE) and recurrent angina after six months. Although the other trials treated single lesions and in this study multi-vessel stenting was performed in 23.3%, clinical results are similar. The 90% free from major clinical events survival rate is slightly better than previously reported in the STRESS trial\textsuperscript{16} (80.5%) and the BENESTENT-II trial\textsuperscript{17} (79.9%); however, this study was not randomized and the number of patients included is rather small. This may justify a randomized trial between the R Stent and the currently used stents. The DIRECTOR study, a randomized trial comparing pre-dilatation with direct stenting with the R Stent is now in its enrollment phase.

Study limitations

This study is a non-randomized trial with a small sample size. Furthermore, no follow-up angiography was performed to obtain detailed information about restenosis rates.

Conclusions

This first clinical feasibility experience with the R Stent indicates that its use is safe and feasible even in complex coronary lesions. A randomized trial comparing the safety and efficacy of the R Stent to other contemporary stents is required to confirm the role of this stent in coronary interventions.

References


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<tr>
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<th>6-month follow-up</th>
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<td>Sudden death at 5-month FU</td>
<td>TLR</td>
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Table 4
Total events in R stent study. TLR, target lesion revascularization.

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<tr>
<th>1-month follow-up</th>
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<tr>
<td>n (%)</td>
<td>n (%)</td>
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<tr>
<td>Death</td>
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<tr>
<td>Myocardial infarction</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>CABG</td>
<td>0</td>
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<tr>
<td>Target lesion repeat PTCA</td>
<td>0</td>
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<tr>
<td>Freedom of MACE</td>
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<tr>
<td>Freedom of MACE + angina</td>
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Table 5
One-month and six-month clinical outcome.


