Randomised comparison of coronary stenting with and without balloon predilatation in selected patients

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Abstract

Background—The SWIBAP (stent without balloon predilatation) prospective randomised trial was designed to compare direct coronary stenting with stenting preceded by lesion predilatation with an angioplasty balloon.

Objective—To determine the feasibility and safety of direct stenting in non-complex coronary lesions in a prospective study.

Patients and design—All patients < 76 years of age scheduled to undergo angioplasty of a non-complex, non-calcified lesion in a coronary artery of > 3.0 mm, who granted their informed consent, were randomised into the trial. In group I, the stent was placed without balloon predilatation, while in group II stent implantation was preceded by balloon predilatation. The primary end point was the angiographic result according to procedure assigned by randomisation. An intravascular ultrasound substudy was performed in 60 patients.

Results—Stent implantation was successful without predilatation in 192 of the 197 group I patients (97.5%), and with predilatation in 197 of the 199 group II patients (99%) (NS). No in-hospital stent thrombosis or death occurred. Overall procedural times, fluoroscopy times, and volumes of contrast agent given (mean (SD)) in group I were 23.50 (13.54) min v 27.96 (15.23) min (p = 0.002), 6.04 (4.13) min v 6.67 (3.65) min (NS), and 135 (65) ml v 157 (62) ml (p < 0.001), respectively. No major adverse cardiovascular events had occurred by 30 days.

Conclusions—The feasibility and safety of direct stenting of selected and non-complex coronary lesions is confirmed. This technique was as successful as the conventional approach and was associated with a minor reduction in fluoroscopic exposure and procedure time and the administration of less contrast agent.

(Heart 2001;86:302–308)

Keywords: coronary artery angioplasty; stent; coronary artery ultrasound

Methods

PATIENT INCLUSION AND EXCLUSION CRITERIA

Eligible patients were men and women less than 76 years of age scheduled to undergo coronary angioplasty and stent implantation; they had stable or unstable angina pectoris or a recent myocardial infarct and no contraindication to inhibition of platelet function with aspirin and ticlopidine or clopidogrel. The protocol required that the patients had a single American College of Cardiology/American Heart Association (ACC/AHA) task force classification type A or B1 non-calcified target lesion, situated in a vessel of > 3.0 mm diameter and free of sharp angulation. Patients scheduled to undergo angioplasty of multiple lesions were eligible for randomisation into the study; however, a single lesion was prospectively included in the analysis, the others being dilated by standard methods, with or without stent implantation. Excluded from the study were patients with acute myocardial infarction or highly unstable angina pectoris refractory to medical treatment, lesions that could not be covered by a single 9 mm or 16 mm stent, lesions situated at a bifurcation with a side branch > 2.0 mm in diameter, left
main coronary artery lesions, and restenotic lesions.

The study protocol was approved by the ethics review committee of the University Hospital of Rennes, and the study was conducted according to the guidelines listed in the declaration of Helsinki. Written informed consent was obtained from all participating patients.

RANDOMISATION PROCEDURE
Randomisation to stenting without (group I) versus with (group II) balloon predilatation was assigned by telephone communication. To guarantee a balanced randomisation scheme at each enrolling centre, treatments were assigned to each site in blocks of four.

PROCEDURAL PROTOCOL
In the group of patients randomised to stent placement preceded by balloon dilatation (group II), coronary angioplasty was performed by the femoral approach using standard techniques, with a balloon size chosen according to the angiographic arterial diameter. One or more inflations were performed to obtain a visually estimated residual vessel stenosis of < 30%, following which the stent was implanted. Identical techniques were used in group I, except for implantation of the stent without balloon predilatation. Crossover to balloon predilatation was allowed when the stent could not be successfully advanced through the lesion.

In both groups, an inflation pressure of at least 10 atm was recommended. NIR stents (Medinol, Tel Aviv, Israel) were used in all patients. Stent dimension (9 or 16 mm) was chosen according to the length of the stenosis. The stent was premounted on a Viva Primo balloon (Boston-Scimed, Galway, Republic of Ireland), which includes two radio-opaque markers between which the stent was inserted.

INTRAVASCULAR ULTRASOUND STUDY
In two participating study centres, an intravascular ultrasound (IVUS) substudy, which included 60 patients, was performed with single element 30 MHz transducers rotating at 1800 rpm, withdrawn automatically at a speed of 0.5 mm/s within a 3.2 French monorail imaging system (Cardiovascular Imaging Systems, Sunnyvale, California, USA). IVUS was performed before intervention and after stent placement in the 60 patients, as well as after balloon angioplasty in the 30 patients randomised to predilatation. Complete imaging sequences were obtained—from beyond the lesion, or stent, to the guiding catheter. The images were recorded on high resolution s-VHS tapes for off-line analysis.

ANTITHROMBOTIC REGIMEN
All patients received aspirin 160 mg/day and ticlopidine 250 mg twice daily, or clopidogrel 75 mg once a day for one month after stent implantation. A single intravenous bolus of 10 000 units of heparin was given at the beginning of the procedure.

DEFINITIONS
Procedure time was defined as the time interval between placement of the arterial sheath and removal of the guiding catheter. Immediate angiographic success was defined as stent placement with < 30% residual stenosis and a normal arterial flow (TIMI (thrombosis in myocardial infarction) flow grade 3). Primary success was defined as immediate angiographic success without major in-hospital complications, including death, myocardial infarction, stent thrombosis, or emergency coronary artery bypass surgery. Lesions were classified according to the definitions recommended by the ACC/AHA task force.

STUDY END POINTS
Primary
The primary end point of the study was the immediate angiographic success after proper positioning and deployment of a 9 or 16 mm NIR stent, according to the procedure assigned by randomisation.

Secondary
The following variables were measured and compared: fluoroscopy and overall procedure times; amounts of contrast agent given; residual dissections after stenting and need for a second stent; creatine kinase concentrations at 24 hours; and ischaemic event rates at 30 days, including death, myocardial infarction, readmission to hospital for unstable angina, and the need for additional target vessel revascularisation.

QUALITATIVE AND QUANTITATIVE CORONARY ANGIOGRAPHY AND ANALYSIS
Coronary angiograms were performed before balloon predilatation or stent placement, and immediately after stent placement in all patients. Standard acquisition procedures were followed for qualitative and quantitative coronary angiography analysis. To improve the accuracy and reproducibility of measurements, intracoronary linsidomine (1 mg) or isosorbide dinitrate (1–3 mg) was given before the initial and before the final poststent placement angiograms. Data collection included assessment of TIMI flow grade, lesion eccentricity, estimation of thrombus load, and AHA/AACC classification. An independent laboratory (Lille Core Laboratory, Lille, France) performed routine qualitative coronary angiography measurements with a Medis System (version 3.32.6, MEDIS Medical Imaging Systems, Leiden, Netherlands). Two orthogonal angiographic views which minimised vessel foreshortening were obtained, and the cineangiogram showing the most severe stenosis was selected for quantitative coronary angiography. Postprocedure angiograms, which duplicated the initial orthogonal views, were obtained after the removal of the balloon and guide wire.
Table 1 Baseline clinical data

<table>
<thead>
<tr>
<th></th>
<th>Stenting without predilatation (n=197)</th>
<th>Stenting with predilatation (n=199)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) (mean (SD))</td>
<td>59.7 (10.6)</td>
<td>60.5 (10.9)</td>
<td>0.468</td>
</tr>
<tr>
<td>Sex (M/F)</td>
<td>152 (77)/45 (23)</td>
<td>166 (83)/33 (17)</td>
<td>0.117</td>
</tr>
<tr>
<td>Risk factors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>25 (12.7)</td>
<td>27 (13.6)</td>
<td>0.796</td>
</tr>
<tr>
<td>Hypertension</td>
<td>84 (42.6)</td>
<td>81 (40.7)</td>
<td>0.696</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>126 (64.0)</td>
<td>131 (65.8)</td>
<td>0.697</td>
</tr>
<tr>
<td>Current smoker</td>
<td>52 (26.4)</td>
<td>53 (26.6)</td>
<td>0.957</td>
</tr>
<tr>
<td>Family history of CAD</td>
<td>59 (30.0)</td>
<td>55 (27.6)</td>
<td>0.612</td>
</tr>
<tr>
<td>Clinical presentation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable angina</td>
<td>63 (32.0)</td>
<td>74 (37.2)</td>
<td>0.276</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>78 (39.6)</td>
<td>82 (41.2)</td>
<td>0.744</td>
</tr>
<tr>
<td>Recent MI (&lt; 1 month)</td>
<td>48 (24.4)</td>
<td>39 (19.6)</td>
<td>0.252</td>
</tr>
<tr>
<td>Silent ischaemia</td>
<td>8 (4.1)</td>
<td>4 (2.0)</td>
<td>0.234</td>
</tr>
<tr>
<td>Coronary history</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>37 (18.8)</td>
<td>38 (19.1)</td>
<td>0.936</td>
</tr>
<tr>
<td>Coronary angioplasty</td>
<td>21 (10.7)</td>
<td>24 (12.1)</td>
<td>0.661</td>
</tr>
<tr>
<td>Coronary bypass surgery</td>
<td>6 (3.1)</td>
<td>5 (2.5)</td>
<td>0.747</td>
</tr>
</tbody>
</table>

Values are n (%) unless stated.

Table 2 Angiographic characteristics

<table>
<thead>
<tr>
<th></th>
<th>Stenting without predilatation</th>
<th>Stenting with predilatation</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary artery disease (n (%))</td>
<td>119 (60.4)</td>
<td>128 (64.3)</td>
<td>0.635</td>
</tr>
<tr>
<td>Two vessel</td>
<td>61 (31.0)</td>
<td>53 (26.6)</td>
<td></td>
</tr>
<tr>
<td>Three vessel</td>
<td>17 (8.6)</td>
<td>18 (9.4)</td>
<td></td>
</tr>
<tr>
<td>LV EF (% (SD))</td>
<td>63.3 (11.0)</td>
<td>63.6 (9.9)</td>
<td>0.769</td>
</tr>
<tr>
<td>Target vessel (n (%))</td>
<td>69 (35.0)</td>
<td>86 (43.2)</td>
<td>0.326</td>
</tr>
<tr>
<td>Left circumflex</td>
<td>50 (25.4)</td>
<td>40 (20.1)</td>
<td></td>
</tr>
<tr>
<td>Right coronary</td>
<td>76 (38.6)</td>
<td>72 (36.2)</td>
<td></td>
</tr>
<tr>
<td>Saphenous vein graft</td>
<td>2 (1.0)</td>
<td>1 (0.5)</td>
<td></td>
</tr>
<tr>
<td>ACC/AHA lesion type (n (%))</td>
<td>A</td>
<td>79 (40.1)</td>
<td>0.183</td>
</tr>
<tr>
<td></td>
<td>B1</td>
<td>118 (59.9)</td>
<td></td>
</tr>
</tbody>
</table>

ACC/AHA, American College of Cardiology/American Heart Association; LAD, left anterior descending coronary artery; LV EF, left ventricular ejection fraction.

PATIENT FOLLOW UP

All major clinical events—including death, myocardial infarction, readmission to hospital for unstable angina pectoris, and the need for additional revascularisation of the target vessel—were monitored by telephone inquiry up to 30 days after the procedure.

STATISTICAL ANALYSIS

The estimate of the sample size was based on the primary end point—angiographic success with respect of the procedure allocated by randomisation. Using a two sided test for differences of independent binomial proportions at a 5% significance level with a power of 90%, 400 patients (200 in each arm) were required to detect a 5% difference between the two procedures. Descriptive statistics were performed by group (mean (SD)) for quantitative variables and absolute and relative frequencies for qualitative variables. The variables in the two groups were compared using Student's t test for quantitative variables and the χ² test or Fisher's exact test for qualitative variables. The α level of significance used was 5%.

Results

CHARACTERISTICS OF THE PATIENTS

Four hundred patients were randomised between April 1998 and December 1999. Four patients did not undergo percutaneous transluminal coronary angioplasty (PTCA) or withdrew their informed consent. The final study population included 396 patients, 197 randomised to group I and 199 to group II. The patients’ baseline clinical and angiographic characteristics are presented in tables 1 and 2. Their mean (SD) age was 60 (10) years, 80% were men, 40% had unstable angina, and 62% had single vessel disease. The left anterior descending and right coronary arteries were the most common target vessels. Stenosis of a vein graft was present in three patients. The two randomised groups were strictly comparable for all baseline clinical and angiographic characteristics.

PROCEDURAL OUTCOMES

A single NIR stent was implanted in each of the 396 patients. Approximately two thirds of patients received a 16 mm stent, one third a 9 mm stent, and a single patient received a 32 mm stent. The size of the guiding catheter was 6, 7, or 8 French in, respectively, 77%, 15.5%, and 7.5% of cases (the same proportions in both groups). The mean balloon inflation pressure was 12.14 (2.24) atm (12.44 (2.28) atm in group I vs 11.85 (2.18) atm in group II (NS)). Stent implantation (9 or 16 mm NIR stent) was successfully completed without balloon predilatation in 192 of 197
up with the guiding catheter and three to a dis-
tal location of the stenosis in a tortuous vessel. In
those five cases, the stent was safely retrieved
and successfully implanted after balloon pre-
dilatation.

In one patient from group II, balloon angio-
plasty caused dissection of a length requiring a
32 mm NIR stent. In one other group II
patient, balloon dilatation was preceded by
rotablation with a 1.5 mm burr because of pri-
mary failure to cross the lesion with the
balloon. In a third group II patient, acute stent
occlusion required reopening of the vessel by
balloon angioplasty.

Four patients in group II needed an addi-
tional stent for a residual dissection and no patient
in group I needed this. Angioplasty of another vas-
cular segment was performed in 14 group I
patients and eight group II patients, followed by
successful stent implantation in 19 patients.

The mean duration of the procedure was
significantly longer in group II (27.96 (15.23)
mins) than in group I (23.50 (13.54) mins) (p = 0.002). Likewise, fluoroscopic exposure
was longer in group II (6.67 (3.65) min v 6.04
(4.13) min), though the difference was not
significant. Finally, the amounts of contrast agent
given were 135 (65) ml in group I versus 157
(62) ml in group II (p < 0.001; table 3).

**ANGIOGRAPHIC RESULTS**

The values of the angiographic variables are
listed in table 4. No differences were found
between the two groups in minimum lumen
diameter, per cent stenosis diameter, or
reference diameter before angioplasty. The
acute gain, minimum lumen diameter, and
residual stenosis after stenting were compara-
ble in the two groups.

**IVUS RESULTS**

Stent deployment with or without predilatation
at identical inflation pressures yielded statisti-
cally comparable results in both groups of
patients (table 5). The degree of plaque
remodelling after coronary stenting with or
without predilatation, gauged as the changes in
segment dimensions at proximal and distal
reference and lesion sites, confirmed that
predilatation did not modify the vessel wall
response to coronary stenting (table 6).

| Table 6 Variations in intravascular ultrasound data with or without predilatation at proximal and distal reference sites and at the lesion site |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
|                  | Stenting without  |                  | Stenting with     |                  |                  |                  |
|                  | predilatation     |                  | predilatation     |                  |                  |                  |
|                  | **Size** | VCSA (mm²) | V (mm²) | *p Value* | **p Value†** |                  |
|                  |                  |                  |                  |                  |                  |                  |
| Proximal         | EEM               | 15.7 (4.5)   | 0.7 (3.2) | 17.0 (5.2) | −0.9 (4.3) | 0.09  | 0.31  |
|                  | L                  | 8.3 (2.7)    | 0.2 (4.2) | 9.0 (4.1)  | −0.1 (2.9) | 0.74  | 0.48  |
|                  | P                  | 7.3 (3.0)    | 0.5 (4.3) | 8.0 (5.1)  | −0.9 (2.6) | 0.12  | 0.54  |
| Lesion           | EEM               | 15.4 (7.2)   | −3.7 (5.7) | 14.8 (5.9) | −2.4 (6.8) | 0.49  | 0.71  |
|                  | L                  | 1.8 (0.7)    | −3.7 (2.1) | 1.7 (0.6)  | −3.6 (2.5) | 0.85  | 0.85  |
|                  | P                  | 13.6 (6.8)   | 0.02 (6.9) | 13.1 (5.8) | −1.2 (6.3) | 0.50  | 0.72  |
| Distant          | EEM               | 11.6 (4.2)   | −0.6 (4.2) | 13.5 (5.3) | −1.8 (4.2) | 0.30  | 0.12  |
|                  | L                  | 6.3 (2.7)    | 0.2 (3.0)  | 7.6 (3.1)  | −1.1 (3.2) | 0.12  | 0.09  |
|                  | P                  | 5.3 (3.1)    | −0.18 (3.7) | 5.9 (4.0)  | −0.6 (3.5) | 0.87  | 0.49  |

Values are mean (SD).

*p Value between variations; †p value between baseline data.

EEM, external elastic membrane; L, lumen; P, plaque; V, variation.
CLINICAL OUTCOMES

In hospital

No death, Q wave myocardial infarction, subacute stent thrombosis, or need for emergency coronary artery bypass graft occurred during hospital admission. Non-Q wave myocardial infarction occurred in two patients in group I (1%). The primary success rate according to procedure allocated by randomisation was 96.5% in group I versus 99% in group II (NS). Mean creatine kinase enzyme concentrations at 24 hours were 73.8 (80) IU/l (group I) versus 77.7 (58.8) IU/l (group I vs group II; NS). Mean durations of hospital admission were also comparable (2.30 (1.27) days and 2.40 (1.59) days, respectively).

At 30 days

No major cardiovascular event—including death, myocardial infarction, stent thrombosis, or need for additional target vessel revascularisation—occurred within 30 days of follow up. One patient developed ticlopidine induced hepatitis.

Discussion

This prospective randomised trial confirmed the feasibility and safety of coronary artery stenting without balloon predilatation in simple, non-calcified lesions. Its primary success rate was high, close to that measured by conventional techniques. This high success rate is concordant with previously published reports and one randomised study of 122 patients. Except for the results of the earliest report—that of Figulla and colleagues in 1998, where the Palmatz-Schatz stent was used in more than half the patients—angiographic success rates have varied between 93% and 97%, reaching 100% after balloon predilatation when the lesion could not be crossed. In the randomised trial reported by Danzi and associates, and in our present study, the lesions were selected and were mainly of type A or B1 of the ACC/AHA classification. On the other hand, in the other studies, 22–60% of lesions were of the more complex B2 or C types. However, the lesions were short, with no major angulations proximal to or at the level of dilatation, and without severe calcification. The success rates reported reflect the results of procedures in which these characteristics were present. Thus the patients included in those studies represented only 21–50% of those undergoing stent implantation during the same period of observation.

LESION CROSSING FAILURES

In previously published studies, failures to cross the lesions were observed in 44 of 657 attempts (7%). Few factors predictive of unsuccessful lesion crossing were identified, owing to the infrequency of failures and the selection of lesions. In the study by Figulla and colleagues, calcifications and older age were more common when the lesion could not be crossed. On the other hand, the severity of stenosis was not predictive of procedural failure. In nearly all failed attempts, the stent could be retrieved and reimplanted after balloon dilatation.

INTRAVASCULAR ULTRASOUND STUDY

IVUS is considered the method of choice to confirm satisfactory implantation of coronary stents. Our study is the first to include IVUS data in two comparable groups of patients undergoing stent implantation with or without predilatation. Its main finding was the absence of any difference between the two groups in the degree of lesion dilatation and plaque remodelling. At identical inflation pressures, the results of stent deployment with or without predilatation were comparable. The response of the vessel wall to coronary stenting was independently related to the technique used. In our IVUS study, lumen cross sectional area (mm²) after stenting was smaller than reported in the comparable series by Laskey and colleagues (7.2 mm²) and Nakamura and associates (6.9 mm²), perhaps because of methodological differences among the studies and wide variations in the measurements of the endovascular surface. The obliqueness of the struts and the width of the echo, reflecting the lateral response of the system, complicated the interpretation of the images. In echographic imaging, the struts appear as small segments of a straight line, variably oriented toward the arterial wall. In our measurements, the most endoluminal point of each echo was used as the limit of the lumen cross sectional area.

QUALITY OF STENT IMPLANTATION

The absence of balloon predilatation combined with the use of comparable inflation pressures for placement of the stent may raise concerns about whether the device expanded correctly. However, these concerns are not supported by available angiographic and ultrasound data. In the study by Danzi and colleagues, which included a single angiographic evaluation, stenting with and without predilatation was associated with 7 (4%) and 7 (5%) mean residual stenosis, respectively (mean (SD))..

Wilson and associates compared the results of stent implantation in 777 patients with predilatation and in 3176 patients without, and found residual diameter stenosis of 3.7 (11.2)% and 4.3 (10.7)%, respectively.

RESIDUAL DISSECTION AFTER STENT IMPLANTATION

As observed in our study and by others, the lack of predilatation of stenosis in direct stenting may decrease the occurrence of residual dissection after stenting and the need for additional stent implantation. The use of stents in bail out situations after dissection has been associated with a worse outcome, supporting the possibility that predilatation may be harmful in a small number of patients.

EVENT RATE AT 30 DAYS

The absence of serious cardiovascular events at 30 days among our patients undergoing direct stenting is in agreement with previous reports.
of comparable rates of major early ischaemic events among patients treated with direct stenting and those receiving stents after balloon predilatation.7,8

ADVANTAGES OF DIRECT STENTING

Direct stenting potentially shortens the overall duration of the procedure and fluoroscopic exposure. However, the shortening observed in this study was not significant and was less than that reported by Danzi and colleagues.6 In SWIBAP, foregoing balloon predilatation only reduced fluoroscopic exposure on average by 0.7 minutes (a 10% reduction), as opposed to four minutes in the Italian study (36% reduction). Direct stenting also reduced the amount of contrast agent given in our study by 14%, and in the Italian study by 20%. Finally, this strategy saves the cost of the balloon used in the predilatation procedure. Danzi and colleagues have estimated a mean saving of $775 per procedure, a noteworthy figure if extrapolated to the total number of procedures performed annually.4

The additional potential benefit of a reduction in intrastent restenosis has been suggested by the experimental study of Rogers and colleagues.13 However, this hypothetical benefit has not been confirmed in any clinical study. In the report by Wilson and associates, one year survival free of major cardiac events (death, myocardial infarction, or need for revascularisation) was strictly comparable among patients who underwent stent implantation with or without balloon predilatation. Finally, it has been hypothesised that predilatation of unstable plaques in the context of unstable angina or myocardial infarction may facilitate embolisation of cholesterol and necrotic debris and increase the likelihood of no reflow.7 Topol and Yadav have recently underscored the importance of embolisation during percutaneous coronary interventions.14 In a series of 22 patients undergoing direct stenting during the acute phase of myocardial infarction, no distal embolisation was observed, and TIMI grade 3 flow was re-established in all patients.15 However, a significant decrease in distal embolisation and the no reflow phenomenon by direct stenting remains to be confirmed by ongoing large randomised studies of patients with unstable angina or acute myocardial infarction.

LIMITATIONS OF DIRECT STENTING

This therapeutic approach has several limitations. First, the choice of a stent of optimal length and diameter is limited by the absence of previous exposure to a balloon of known dimensions. Second, the stent position may be uncertain if it is occlusive across a tight stenosis, particularly if only 8–9 mm long, and in absence of any anatomical landmark such as a small collateral vessel. In all cases, the best catheter back up should be in place. Finally, several anatomical presentations are unfavourable, including severe calcification, pronounced vessel angulation, bifurcation lesions, and complete occlusions. Few data are available on ostial or lengthy lesions.

STUDY LIMITATIONS

The 400 randomised patients—enrolled over a 20 month period in 15 medical centres performing > 400 coronary angioplasties annually—were highly selected. The results of this analysis cannot, therefore, be immediately extrapolated to the overall population of patients undergoing coronary artery stenting, limiting the accuracy of any cost effectiveness estimates of this strategy.

The IVUS substudy clearly showed an underexpansion of stents in both groups. However, this was only an observational study and not a guided IVUS stent deployment study.

CONCLUSIONS

Direct stenting of non-complex and non-calcified coronary lesions is feasible and safe. The main advantage of this strategy is economic, saving overall procedural time, contrast agent, and balloons. A hypothetical advantage relating to reduced intimal hyperplasia or intrastent restenosis will only be demonstrable by a detailed angiographic examination at six months, including quantitative measurements of the severity and length of restenosis and a qualitative description of their location (that is, within the stent or elsewhere). The application of direct stenting to more complex lesions should be applied with caution, as it requires a more rigorous scrutiny of this new technique.

We wish to thank Ms Marie Hélène Chevalier and Ms Jeanne Brunet for their help in the development and monitoring of the study.

The following institutions and investigators participated in the SWIBAP trial (the number of patients enrolled at each centre is shown in parentheses): Clinique St Martin, Caen (90); P Commes, M Sureau, J F Morelle; Centre Hospitalier Universitaire, Rennes (71); M Bedossa, C Leclercq, D Boulmier, H Le Breton; Nouvelles Cliniques Nantaises—St Henri, Nantes (50); P Brunel, B Laurent, Y Bans; Centre Hospitalier Universitaire, Brest (44); J Boschat, M Gilard; Clinique du Grand Lest, Brest (29); C Breut, E Gestin; Clinique St Gatien, Tours (28); O Bar, A Bonnemarou, D Blanchard; Centre Hospitalier Universitaire, Angers (27); P Geslin, A Fieber; Centre Hospitalier Universitaire, Nantes (19); P Crochet; Centre Hospitalier Universitaire, Tours (11); L Maillard, L Quilliet, B Desseaux, P Raynaud; Clinique La Reine Blanche, Orleans (11); B Moquet; Hopital Beauregard, Marseille (9); P Barragan; Centre Hospitalier Universitaire, AP-HP, Creteil (7); P Dupouy, J L Dubois-Rande; Centre Hospitalier Universitaire, Caen (5); G Grollier, M Hamon; Clinique St Hilaire, Rouen (3); J Berland; Clinique St Laurent, Rennes (2); P Drueille, Y Biron, C Descaves, C Pico-Bourdouanne; Centre Hospitalier St Philibert, Lomme (1); R Rihani.


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Systemic sclerosis involving the heart

A 39 year old woman with systemic sclerosis (scleroderma) presented with four months of dyspnoea. Initial investigation including coronary angiography, echocardiography, and cardiovascular magnetic resonance (CMR) without contrast were normal. Over three months she became more breathless and developed arrhythmias. CMR was repeated with contrast. The right ventricle was now dilated with poor function. There was reduced left ventricular function and bilateral pleural effusions were present. The myocardium enhanced greatly with gadolinium at 20 minutes in a heterogeneous pattern, suggesting a patchy process such as fibrosis or infiltration (below left). One month later, despite treatment, the patient entered a terminal low output state with malignant arrhythmias. At postmortem examination the myocardium was grossly abnormal. Large islands of normal myocardium were interspersed with areas of myocardial oedema with myocyte loss, while other areas showed extensive sheets of fibrosis (below right).

Systemic sclerosis is an uncommon cause of cardiomyopathy, although cardiac involvement in systemic sclerosis may be under recognised clinically. Vasospasm and fibrosis occur throughout the body and in the heart this may result in patchy perfusion defects, diastolic dysfunction, arrhythmias, and systolic cardiac failure. In this case, heterogeneous myocardial gadolinium contrast enhancement correlated with postmortem findings of patchy myocardial oedema and fibrosis with interspersed normal myocardium. Late contrast enhancement with gadolinium is known to characterise fibrosis and necrosis in myocardial infarction and ischaemic cardiomyopathy. These images show the potential of the technique in other cardiomyopathies and for the assessment of cardiac systemic sclerosis.

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