Outcomes in Patients With De Novo Left Main Disease Treated With Either Percutaneous Coronary Intervention Using Paclitaxel-Eluting Stents or Coronary Artery Bypass Graft Treatment in the Synergy Between Percutaneous Coronary Intervention With TAXUS and Cardiac Surgery (SYNTAX) Trial

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Background—The prospective, multinational, randomized Synergy Between Percutaneous Coronary Intervention With TAXUS and Cardiac Surgery (SYNTAX) trial was designed to assess the optimal revascularization strategy between percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG), for patients with left main (LM) and/or 3-vessel coronary disease.

Methods and Results—This observational hypothesis-generating analysis reports the results of a prespecified powered subgroup of 705 randomized patients who had LM disease among the 1800 patients with de novo 3-vessel disease and/or LM disease randomized to PCI with paclitaxel-eluting stents or CABG in the SYNTAX trial. Major adverse cardiac and cerebrovascular event rates at 1 year in LM patients were similar for CABG and PCI (13.7% versus 15.8%; Δ2.1% [95% confidence interval −3.2% to 7.4%]; P=0.44). At 1 year, stroke was significantly higher in the CABG arm (2.7% versus 0.3%; Δ=2.4% [95% confidence interval −4.2% to −0.1%]; P=0.009), whereas repeat revascularization was significantly higher in the PCI arm (6.5% versus 11.8%; Δ=5.3% [95% confidence interval 1.0% to 9.6%]; P=0.02); there was no observed difference between groups for other end points. When patients were scored for anatomic complexity, those with higher baseline SYNTAX scores had significantly worse outcomes with PCI than did patients with low or intermediate SYNTAX scores; outcomes for patients with CABG did not correlate with baseline SYNTAX score, but baseline EuroSCORE significantly predicted outcomes for both treatments.

Conclusions—Patients with LM disease who had revascularization with PCI had safety and efficacy outcomes comparable to CABG at 1 year; longer follow-up is required to determine whether these 2 revascularization strategies offer comparable medium-term outcomes in this group of complex patients.

Clinical Trial Registration—http://www.clinicaltrials.gov. Unique identifier: NCT00114972.
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Key Words: stents coronary artery bypass grafting angioplasty, transluminal, percutaneous coronary

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meta-analyses that reported similar mortality rates between LM stenting and CABG after several years of follow-up.22,23

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The majority of reports comparing PCI to CABG for LM stenting were single-center studies, and the patient populations in all but 1 of these studies were not randomized, thus introducing a potential bias in patient selection that may confound interpretation of the results; moreover, some trials included both bare metal stents and drug-eluting stents.4,6–12 In addition, the only published randomized study, the Prospective, Randomized Trial of Stent Implantation Versus Bypass Graft Surgery in Patients With Left Main Coronary Artery Disease (LEMANS) study, was small, consisting of ~50 patients in each treatment group.5 For this reason, consensus treatment guidelines continue to recommend CABG as the “gold standard” for revascularization of unprotected LM stenosis but note that PCI is feasible and may be a promising strategy in selected patients.24 In the absence of a large randomized controlled trial, it has been difficult for interventional cardiologists to establish where the upper boundary of safety and efficacy lies in using PCI for revascularization of LM patients, with or without multivessel disease, and to develop objective evidence-based criteria for determining the optimal revascularization strategy for a given patient.

The SYNTAX trial is the first large trial (N=1800) to randomize patients suitable for revascularization by either CABG or PCI using drug-eluting stents for the treatment of LM and/or 3-vessel disease (3VD). The results of the overall population have been reported previously.25 This article presents outcomes in the prespecified subgroup of patients (n=705) with LM disease in the SYNTAX trial.

Methods

The study design and methods of the SYNTAX trial have been described previously in detail and are summarized here.26

Study Design

SYNTAX is a randomized, prospective, multicenter trial conducted in 17 countries in Europe and the United States. The study used an intended “all-comers” design consisting of a cohort of patients randomized to either PCI or CABG and nested registries for patients considered unsuitable for randomization (PCI registry for CABG-ineligible patients and CABG registry for PCI-ineligible patients). The institutional review board at each participating center approved the protocol, and all patients provided written informed consent. The institutional review board at each participating center approved the protocol, and all patients provided written informed consent. The primary end point was not met25; therefore, this analysis is noninferiority between PCI and CABG for the overall population.26

Comparisons between treatment groups by baseline SYNTAX score subgroups of isolated LM, LM with 2VD, and LM with 3VD.

The primary end point was the composite of major adverse cardiovascular and cerebrovascular events (MACCE) at 1 year, which included all-cause death, cerebrovascular accident/stroke (CVA), MI, and repeat revascularizations. Patients will continue to be followed up for up to 5 years. All MACCE events were adjudicated by an independent clinical events committee. Definitions of clinical events have been previously described.25,26,28

Statistical Methods

The primary end point analysis for the overall population at 1 year included a hierarchical statistical approach that prespecified statistical testing on the LM subgroup only after the demonstration of noninferiority between PCI and CABG for the overall population.26

The primary end point was not met25; therefore, this analysis is intended for descriptive and hypothesis-generating purposes only. Data were analyzed as both the overall LM population, and as the subgroups of isolated LM, LM+1VD, LM+2VD, and LM+3VD. Comparisons between treatment groups by baseline SYNTAX score were also prespecified in the analysis plan.

Mean±SDs were calculated for continuous variables, and discrete variables were reported as total events and percentages. For Kaplan-Meier analyses, event-free patients with >365 days of follow-up were censored at 366 days. For binary analyses, event-free patients who did not have adequate follow-up of 335 days were not included in the rate calculation. Two-sided 95% confidence intervals (CIs) were calculated on binary rates as the difference between groups ±1.96 SE of the mean unless an exact method was required. Exact 95% CIs are from the difference of the 2 binomial proportions based on the standardized statistic and inverting a 2-sided test. The Greenwood formula for the SE was used to calculate the 2-sided 95% CI of the Kaplan-Meier event rates. Patients were also analyzed post hoc by baseline SYNTAX score tertile (low ≤22, intermediate 23 to 32, and high ≥33) for 1-year MACCE outcomes. Differences between groups were considered statistically significant if the 95% CI around the difference of the means did not contain zero. In a prespecified analysis, baseline predictors (using both patient and procedural characteristics) for 12-month MACCE were
identified using multivariate logistic regression with stepwise model selection. Treatment assignment was forced into the overall model. The predictors in the final model were selected in a stepwise procedure with a significance level of 0.10 for entry and 0.10 for exit, and no interaction terms were considered as candidate variables in the multivariate modeling.

Results

Participants

In the SYNTAX trial, 705 patients had LM disease reported by the individual sites: 348 in the CABG arm and 357 in the PCI arm (Figure 1). Baseline patient and lesion characteristics were well balanced between groups (Table 1). Although patients without distal LM stenosis would have been permitted under the protocol definition of LM disease (LM equivalent disease), in actuality no patients with LM equivalent disease were enrolled. The CABG group had a higher proportion of current smokers (24.0% CABG versus 17.9% PCI) and a lower proportion of patients with hyperlipidemia (75.4% CABG versus 81.0% PCI). In the LM subset, 2 patients randomized to CABG received medical treatment (worsening clinical status, n=1; investigator decision that patient was not suitable for surgical treatment, n=1), and 5 received PCI (worsening clinical status, n=1; patient preference, n=3; disappearance of LM stenosis on second angiogram, n=1). In the PCI arm, 3 patients received medical therapy (patient preference, n=1; disappearance of LM stenosis on second angiogram, n=2) and 5 received CABG (patient preference, n=3; investigator decision that patient was not suitable for PCI, n=2).

In the PCI group, time from randomization to procedure, procedure duration, and hospital stay after the procedure were all significantly shorter compared with the CABG group (Table 2). Significantly more patients treated with CABG had complete revascularization (72.5%) than patients treated with PCI (64.5%; Δ=8.0% [-14.9%, -1.1%]; P=0.02). In the PCI arm, ~80% of patients were revascularized using a T-stenting technique (Table 2).
Study Outcomes
MACCE rates were comparable between CABG and PCI for overall LM disease (13.6% CABG versus 15.8% PCI; Figure 2A). Among the MACCE components, there was no observable difference between CABG and PCI in terms of all-cause death (4.4% CABG versus 4.2% PCI; Δ−0.2 [95% CI −3.2 to 2.8]; Figure 2B), cardiac death (2.4% CABG versus 3.9% PCI; Δ−1.6% [95% CI −1.0% to 4.2%]; P=0.24), nor MI (4.1% CABG versus 4.3% PCI; Δ0.2 [95% CI −2.8 to 3.2]; Figure 2C); however, at 1 year, the rate of CVA was significantly greater in patients with CABG compared to those with PCI (2.7% CABG versus 0.3% PCI; Δ−2.4% [95% CI −4.3% to −0.5%]; P=0.009; Figure 2D), and repeat revascularization was significantly increased in patients with PCI compared with CABG (6.7% CABG versus 12.0% PCI; Δ5.3% [95% CI 1.0% to 9.6%]; P=0.02; Figure 2E). Of the repeat revascularizations, the majority were via repeat PCI, with only 3.1% (11/355) of LM patients initially treated with PCI undergoing repeat revascularization by CABG within 12 months. For the combined safety end point of all death/CVA/MI, regardless of the extent of vessel involvement. Revascularization was significantly higher in PCI patients with LM+2VD or +3VD compared with CABG but not for patients with isolated LM or LM+1VD (Table 3). There was no significant difference between groups for the composite safety end point of death/CVA/MI, regardless of the extent of vessel involvement. Patients with isolated LM or LM+1VD were comparable between PCI and CABG with either low or intermediate baseline SYNTAX scores (Figure 3A and 3B), with the exception of significantly increased all-cause death in CABG patients with an intermediate SYNTAX score compared with PCI patients with an intermediate SYNTAX score (Figure 4). In the tercile with the highest baseline SYNTAX score, MACCE outcomes were significantly higher for patients treated

| Table 2. Procedural Characteristics in Left Main Patients |
|---------------------------------|--------------|----------------|----------------|----------------|----------------|
| Variable*                        | CABG (n=348) | PCI (n=357)    | Difference (95% CI) | P Value |
| Time to procedure, d             | 14.7±27.8    | 6.0±11.0       | −8.7 (−11.8 to −5.5) | <0.001 |
| Procedure duration, hr           | 3.3±1.2      | 1.5±0.8        | −1.8 (−2.0 to −1.7) | <0.001 |
| Post-procedure hospital stay, d  | 13.6±9.6     | 6.1±5.5        | −6.4 (−14.9 to 1.1) | <0.001 |
| Complete revascularization,† %   | 72.5         | 64.5           | −8.0 (−14.9 to 1.1) | 0.02   |
| Bifurcation‡ stenting technique (n=312 lesions) |     |                |                  |        |
| Provisional T-stenting, %        | 61.5%        | N/A            | N/A              |        |
| Classic T-stenting, main vessel first, % | 10.9%        | N/A            | N/A              |        |
| Classic T-stenting, side branch first, % | 5.1%        | N/A            | N/A              |        |
| Modified T-stenting, %           | 1.9%         | N/A            | N/A              |        |
| Culotte or trousers, %           | 8.7%         | N/A            | N/A              |        |
| Skirt, %                         | 0%           | N/A            | N/A              |        |
| Crush, %                         | 6.1%         | N/A            | N/A              |        |
| Y-stenting, touching stents      | 0.6%         | N/A            | N/A              |        |
| Y-stenting, trouser legs and seat, % | 0%           | N/A            | N/A              |        |
| V-stenting: kissing stents/gun barrel, % | 5.1%        | N/A            | N/A              |        |

*No. (percent) or mean±SD based on an intent-to-treat analysis.†Per protocol: “Complete revascularization was defined as the treatment of any lesion with >50% diameter stenosis in vessels ≥1.5 mm diameter as estimated on diagnostic angiogram during the local heart team conference.” Completeness of revascularization was assessed postprocedure by the operator (surgeon or interventional cardiologist).‡Includes all bifurcated lesions.

Outcomes Stratified by LM and Multivessel Disease
Overall 1-year MACCE rates were higher in the CABG arm than the PCI arm in patients with isolated LM or LM+1VD but higher in the PCI arm than the CABG arm for patients with LM+2VD or LM+3VD (Table 3). There was no significant difference between groups for the composite safety end point of death/CVA/MI, regardless of the extent of vessel involvement. Revascularization was significantly higher in PCI patients with LM+2VD or +3VD compared with CABG but not for patients with isolated LM or LM+1VD (Table 3). Interaction P values were not significant for treatment versus the extent of vessel involvement; however, it is important to remember that the limited statistical power of this subset analysis means that, despite the negative interaction findings, a positive interaction effect cannot be ruled out.

Outcomes Stratified by Baseline SYNTAX Score
Patients were subdivided by baseline SYNTAX score into 3 terciles: low (Syntax score 0 to 22), intermediate (23 to 32), or high (≥33) scores. In the LM subgroup, MACCE outcomes at 1 year were comparable between PCI and CABG with either low or intermediate baseline SYNTAX score (Figure 3A and 3B), with the exception of significantly increased all-cause death in CABG patients with an intermediate SYNTAX score compared with PCI patients with an intermediate SYNTAX score (Figure 4). In the tercile with the highest baseline SYNTAX score, MACCE outcomes were significantly higher for patients treated...
with PCI (Figure 3C). Increased MACCE rates in the highest SYNTAX score tercile were driven primarily by significantly increased repeat revascularization in the PCI group (Figure 4).

**Multivariate Predictors of MACCE at 1 Year**
Emergent revascularization priority, medically treated diabetes mellitus, and higher baseline EuroSCORE were significant predictors of increased MACCE at 1 year for the overall population, whereas female sex significantly predicted reduced MACCE (Table 4). Treatment group (CABG or PCI) did not significantly predict MACCE at 1 year ($P=0.14$). In the CABG arm, significant predictors for increased MACCE at 1 year were emergent revascularization priority and higher baseline EuroSCORE. In the PCI arm, significant multivariate predictors for increased MACCE at 1 year were prior transient ischemic attack, higher baseline SYNTAX score, and higher baseline EuroSCORE (Table 3). The Parsonnet score did not appear to be a significant predictor of MACCE at 1 year for any of the 3 models (overall cohort, CABG arm, or PCI arm; data not shown).

**Discussion**
In the SYNTAX trial, although the LM group was prespecified and sufficiently powered to detect overall MACCE, the statistical analysis plan used a hierarchical approach that allowed testing of the LM group only if PCI was shown to be noninferior to CABG in the overall population. Because this condition was not met, this analysis of the LM group should be considered only observational. With this caveat, patients with LM disease had comparable overall 12-month MACCE in both the PCI and the CABG group (14% CABG versus 16% PCI). This result is consistent with the findings of the only other randomized LM trial to compare PCI to CABG. Similarly, nonrandomized registries have also generally reported equivalent or improved safety (determined by rates of death, MI, or MACCE) at 1 year with PCI compared with CABG, with the exception of one small single-center study. Furthermore, some nonrandomized trials have also observed significantly higher revascularization rates for PCI versus CABG in LM patients. Additionally, rates of death/CVA/MI and target lesion revascularization similar to SYNTAX at 1 year were found in patients with unprotected LM disease treated with either paclitaxel- or sirolimus-eluting stents in the Intracoronary Stenting and Angiographic Results: Drug-Eluting Stents for Unprotected Coronary Left Main Lesions (ISAR-LM) study. Subgroup analyses by LM in the presence or absence of multivessel disease suggest that the outcomes of PCI relative to CABG are also good in patients with isolated LM or LM+1VD. However, the number of patients in these subgroups is small, so these results must be interpreted with caution. In contrast, outcomes in patients with LM+2VD or LM+3VD demonstrated equivalent safety outcomes but higher rates of repeat revascularization compared with PCI. The variability within these subgroup analyses, although undoubtedly influenced by the small number of patients in some subgroups, may suggest that lesion complexity has a greater effect on outcomes in these patients than does the absolute number of vessels treated.
In this regard, use of the SYNTAX score may better stratify the patients according to risk than does the division into isolated LM, or LM+1VD, 2VD, or 3VD. Analyses of SYNTAX score by baseline tercile demonstrated the excellent concordance between clinical outcomes and baseline SYNTAX score. In addition, the baseline SYNTAX score was also a significant predictor of outcomes after PCI by multivariate analysis. These results are similar to those reported for 3VD patients revascularized with sirolimus-eluting stents in the Arterial Revascularization Therapies (ARTS) II trial, in which patients with higher SYNTAX scores had higher MACCE rates at 30 days and also death/CVA/MI.30

The baseline SYNTAX score was also a significant predictor of outcomes after PCI by multivariate analysis. These results are similar to those reported for 3VD patients revascularized with sirolimus-eluting stents in the Arterial Revascularization Therapies (ARTS) II trial, in which patients with higher SYNTAX scores had higher MACCE rates at 30 days and also death/CVA/MI.30

One-year MACCE outcomes after CABG in the current study did not stratify according to the underlying baseline SYNTAX score tercile. This is not surprising given that the SYNTAX score is a measure of lesion complexity which, though an essential consideration for PCI, is less material to CABG based medicine into patient care. These results reflect current practice and indicate that there is a broad need to continue incorporating standards of evidence-based medicine into patient care.

Some reports have suggested that the incidence of ST in the LM, and consequently cardiac or sudden death, were low and compared favorably to non-LM lesions.26 Overall ST rates (definite, probable, possible) in patients with unprotected LM stents have been reported to range from 0% to 4%.14,15,17 In this analysis, the overall angiographic ST rate was 3% per patient and the Academic Research Consortium definite rate was somewhat higher (4% per patient, 1% per stent) at 1 year. Angiographic graft occlusion rate was 4% per patient. The consequences of ST and graft occlusion are unlikely to be equivalent, as suggested by some studies showing that the clinical cost of ST may be more severe than that after graft revascularization, were used suboptimally in comparison with the currently recognized standards of optimal care, and this may have affected outcomes within the surgical group. Nonetheless, these results reflect current practice and indicate that there is a broad need to continue incorporating standards of evidence-based medicine into patient care.

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In this LM analysis, no increase in mortality or MI rates was noted in the PCI cohort when compared with CABG. The incidence of very late (ie, 1 year) ST and graft occlusion also remains to be determined in this trial.

**Study Limitations**

The hierarchical primary end point testing of the study only allowed the LM subgroup of the SYNTAX study to be tested if the overall comparison reached statistical significance. Because this was not the case, results from this analysis should be considered hypothesis generating only and need to be confirmed in an additional dedicated LM trial. Although the study was adequately powered to test the difference in MACCE between groups, it is underpowered to detect differences in the individual components of MACCE, so these results must be interpreted with caution. It is also important to note that the subset of LM patients in this study was a heterogeneous group that consisted of patients with isolated LM disease or LM plus additional disease. Per the trial design, the clinical events committee did not adjudicate repeat revascularizations according to lesion location (ie, LM or elsewhere), which may have confounded the results presented here. Additionally, completeness of revascularization was determined by each investigator and not by the core laboratory and may therefore have been affected by interobserver variability. Finally, to date, follow-up is available only through 1 year. It is possible that, with time, differences in outcomes between patients treated with CABG and patients treated with PCI will begin to emerge.

**Figure 4.** One-year incidence of A, all-cause death; B, MI; C, CVA; D, death/CVA/MI; and E, repeat revascularizations in patients with low (0 to 22), intermediate (23 to 32), or high (≥33) baseline unadjusted SYNTAX score. Values are binary means presented with the 95% CI around the difference of the means.
Table 4. Multivariate Baseline Predictors of 1-Year MACCE in Patients With Left Main Disease

<table>
<thead>
<tr>
<th>Baseline Variable</th>
<th>Coefficient</th>
<th>Odds Ratio (95% CI)</th>
<th>P Value</th>
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</thead>
<tbody>
<tr>
<td>Overall predictors (n=705)</td>
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<tr>
<td>Emergent revascularization priority</td>
<td>1.17</td>
<td>3.22 (1.12, 9.31)</td>
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<tr>
<td>Medically treated diabetes mellitus</td>
<td>0.56</td>
<td>1.76 (1.04, 2.97)</td>
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<td>Additive euroSCORE</td>
<td>0.19</td>
<td>1.21 (1.12, 1.32)</td>
<td>&lt;0.001</td>
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<td>Women</td>
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<td>0.50 (0.27, 0.91)</td>
<td>0.02</td>
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<td>Group (CABG or PCI)*</td>
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<td>1.44 (0.89, 2.32)</td>
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<td>CABG predictors (n=348)</td>
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<tr>
<td>Emergent revascularization priority</td>
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<td>6.27 (1.62, 24.22)</td>
<td>0.008</td>
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<tr>
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<td>1.19 (1.04, 1.35)</td>
<td>0.009</td>
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<tr>
<td>COPD</td>
<td>0.92</td>
<td>2.52 (0.94, 6.73)</td>
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<tr>
<td>Medically treated diabetes mellitus</td>
<td>0.72</td>
<td>2.05 (0.91, 4.62)</td>
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<td>PCI predictors (n=357)</td>
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<tr>
<td>Prior TIA</td>
<td>1.16</td>
<td>3.19 (1.03, 9.86)</td>
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<tr>
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<td>1.12 (1.00, 1.25)</td>
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<td>SYNTAX score (corelab)</td>
<td>0.03</td>
<td>1.03 (1.01, 1.05)</td>
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<tr>
<td>Creatinine &gt;200 μmol/L</td>
<td>1.82</td>
<td>6.17 (0.92, 41.54)</td>
<td>0.06</td>
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</table>

COPD indicates chronic obstructive pulmonary disease; TIA, transient ischemic attack.
*Indicates variable was forced into the model.

Conclusions

In this observational analysis, patients with LM disease who had revascularization with TAXUS Express stents had safety and efficacy outcomes comparable to CABG at 1 year; longer follow-up is needed to confirm this early analysis.

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Disclosures

Drs Serruys and Mohr were the SYNTAX study principal investigators, and Drs Kappetein and Morice were co-principal investigators. Drs Leadley and Dawkins report being full-time employees of Boston Scientific, and Drs Kappetein and Morice were co-principal investigators. Drs Serruys and Mohr were the SYNTAX study principal investigators. Drs Leadley and Dawkins report being full-time employees of Boston Scientific, and Drs Kappetein and Morice were co-principal investigators.

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