Comparison of the Long-Term Safety and Efficacy of Drug-Eluting and Bare-Metal Stent Implantation in Saphenous Vein Grafts

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Background—Concerns about the long-term safety of drug-eluting stents (DES) in saphenous vein grafts has become an area of controversy and uncertainty.

Methods and Results—In this retrospective registry, we compared the outcomes in 127 patients (143 lesions) treated with DES from April 2002 to June 2006 (DES group) with 131 patients (160 lesions) treated with bare-metal stents in the preceding 36 months (bare-metal stent group). End points analyzed were cumulative death, myocardial infarction, and target vessel revascularization at 2 years after stent implantation. The DES group was significantly (P<0.05) more complex with a greater frequency of diabetes (33.1% versus 15.3%), older grafts (11.6±5.3 years versus 9.6±5.2 years), restenotic lesions (23.8% versus 4.4%), total occlusions (7.7% versus 1.2%), and smaller grafts (3.16±0.66 mm versus 3.44±0.76 mm) treated with longer stents (34.1±25.1 mm versus 22.7±11.6 mm). At 2 years, there was no statistical difference in death (8.7% versus 7.8%), myocardial infarction (6.3% versus 9.4%), or target vessel revascularization (19.7% versus 24.2%) between DES and bare-metal stents, respectively. A propensity analysis to adjust for baseline differences suggested that there was no observed association between DES and increased mortality (hazard ratio, 0.72; 95% CI, 0.21 to 2.44; P=0.60) but possibly an association with a reduction in target vessel revascularization (hazard ratio, 0.31; 95% CI, 0.14 to 0.66; P=0.002).

Conclusions—Despite being implanted in patients and lesions more complex than the bare-metal stent group, there was no observed association between DES implantation in saphenous vein grafts and an increase in late mortality. DES may maintain their efficacy in reducing revascularization rates in diseased saphenous vein grafts over a 2-year follow-up period. (Circ Cardiovasc Interv. 2010;3:249-256.)

Key Words: stents ■ angioplasty ■ stent thrombosis ■ saphenous vein graft

Saphenous vein grafts (SVGs) remain the commonest conduit used in coronary artery bypass surgery. The graft attrition rate is high and the risks of repeat surgery are not negligible. Therefore, percutaneous intervention is the preferred therapeutic modality for graft failure in the majority of cases. Unfortunately, bare-metal stents (BMS) in SVGs are associated with a high incidence of restenosis.1-3 The excellent results of drug-eluting stents (DES) in reducing restenosis and repeat revascularization in selected lesions have encouraged their use in this lesion subset.4-7 Currently, the available data are limited, and there are concerns about the durability of the restenosis reduction and the possibility of an increased mortality associated with DES, in particular with sirolimus-eluting stents (SES; Cypher, Cordis Corp, Johnson & Johnson, Warren, NJ).4 In light of the paucity of long-term data in this important lesion subset and the concerns over long-term outcomes, we analyzed our experience of DES in SVG lesions.

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Methods

All consecutive patients successfully treated with either paclitaxel-eluting stent (PES; Taxus, Boston Scientific, Natick, Mass) or SES implantation between April 2002 and March 2006 were considered in this retrospective analysis. This study period was selected because DES became available for clinical use in our institution in early 2002.
and allowed us to have a minimum of 2-year follow-up on all patients. We thus identified 127 consecutive patients (with 143 lesions in 131 grafts) who underwent percutaneous revascularization in SVG lesions with DES (DES group). A control group (BMS group) was composed of 131 consecutive patients (with 160 lesions in 137 grafts) who underwent percutaneous treatment in SVG lesions with BMS in the 36 months immediately before the introduction of DES. During both periods of the study, SVG interventions accounted for 3.5% to 4% of percutaneous coronary intervention procedures performed annually at our institution. Patients were excluded if any of the following was present: an acute myocardial infarction (MI) <1 week before the index procedure, implantation of a covered stent, or inability to cross the lesion with a guide wire. In particular, we excluded 8 patients (4 BMS and 4 DES) with a chronically occluded SVG in whom we could not cross the occlusion with a guide wire. In the DES era of the study, BMS were implanted in ~98% of SVG interventions, and reasons for not implanting DES in these patients included a contraindication to prolonged dual antiplatelet therapy, large SVGs with no appropriately sized DES available, primary percutaneous coronary intervention for acute MI, awaiting surgery, or requirement for long-term anticoagulation.

All patients provided informed consent for both the procedure and subsequent data collection and analysis for research purposes. Diabetes mellitus was defined as fasting blood glucose ≥126 mg/dL, self-reported diabetes, or being treated with antidiabetic medications. Hypercholesterolemia was defined as total serum cholesterol >240 mg/dL, self-reported history of hypercholesterolemia, or current lipid-lowering treatment. All patients were pretreated with aspirin and either ticlopidine or clopidogrel. A 300-mg loading dose of clopidogrel before the index procedure was administered if patients were not pretreated. Intravenous heparin was administered to maintain an activated clotting time >250 s during the procedure. Platelet glycoprotein IIb/IIIa receptor inhibitors, interventional approach, and intravascular ultrasound were used at the operator’s discretion. After the procedure, all patients were prescribed life-long aspirin therapy and clopidogrel or ticlopidine for at least 6 to 12 months after DES implantation and for at least 1 month after BMS implantation.

**Clinical Definitions and Follow-Up**

Clinical follow-up was performed by telephone contact or office visit at 1, 6, 9, 12, 18, and 24 months after the index procedure. Angiographic follow-up was encouraged for all patients between 6 and 9 months. All adverse events were verified by reviewing the medical records of the patients followed at our institution or by contacting the patients’ physicians and reviewing the hospital records of patients followed elsewhere. Because of the different time periods in which stents were implanted in the 2 groups and resultant marked difference in clinical follow-up duration available, we censored events occurring after 2 years, in both groups.

Clinical end points included major adverse cardiac events (MACEs), which included all-cause mortality, all nonfatal MI (including periprocedural MI), and target vessel revascularization (TVR), that were evaluated on a per patient basis. Target lesion revascularization (TLR) and TVR were also analyzed separately on a per lesion basis. All deaths were considered cardiac unless a clear noncardiac cause could be established. Specifically, any unexpected or unwitnessed death was considered of cardiac origin. Creatinine kinase (CK) is routinely measured after percutaneous coronary intervention in all patients at our institution and CK-MB is obtained only if total CK is >2 times the upper limit of normal. Percutaneous MI was defined as an elevation of CK-MB activity ≥3 times at 20% with Thrombolysis in Myocardial Infarction flow 3.13

**Quantitative Coronary Angiography Analysis**

Coronary angiograms were analyzed using a validated edge detection system (CMS, version 5.2, MEDIS, Leiden, The Netherlands).11 Minimal lumen diameter (MLD), reference vessel diameter (RVD), and percent diameter stenosis at baseline, at postprocedure, and at follow-up were measured, respectively. Acute gain was defined as the difference between the MLD immediately after the procedure and the baseline. Late lumen loss was defined as the difference between the MLD immediately after the procedure and at follow-up. Loss index was defined as the ratio between late lumen loss and acute lumen gain. Angiographic restenosis was defined as diameter stenosis ≥50% by quantitative coronary angiography within a previously stented segment (stent and 5 mm proximal and distal) at the follow-up angiogram. Restenosis patterns were assessed using the Mehran classification system.12 Angiographic success was defined as a final residual stenosis <20% with Thrombolysis in Myocardial Infarction flow 3.13

**Statistical Analysis**

Continuous variables are presented as means±SD or medians (interquartile range) and categorical variables as frequencies (%). Continuous variables were compared using the Mann–Whitney U test. Categorical variables were compared with χ² statistic. Patients lost to follow-up in whom no event had occurred before the follow-up windows were not included in the denominator for calculations of binary end points.

Multivariable Cox proportional-hazards regression modeling was performed to determine the independent predictors of MACE, using purposeful selection of covariates. Variables associated at univariate analysis with MACE (all with a P value <0.1) and those judged to be of clinical importance from previous published literature were eligible for inclusion into the multivariable model-building process. Candidate variables included age, sex, stent type, diabetes, ejection fraction, age of grafts in years, glycoprotein IIb/IIIa inhibitors, embolic protection devices, stent diameter, and stent length. Goodness of fit of the Cox multivariable model was assessed with the Grønnesby-Borgan-May test.14,15

To account for potential differences between the DES and BMS cohorts, a propensity analysis was performed on a patient-based setting for MACE, death, and TVR and on a lesion-based setting for TLR and restenosis.16,17 These were performed using stratified Cox regression with stent type as fixed dummy covariate and propensity score quintiles (propensity to be treated with DES estimated by nonparsimonious multivariable logistic regression) as stratification variable. Variables included in the propensity model were diabetes, restenotic lesions, hypercholesterolemia, occluded grafts, age of grafts in years, glycoprotein IIb/IIIa inhibitors, embolic protection devices, native vessel on which the graft was placed, stent length, reference vessel diameter, and number of stents implanted. In the lesion-based analysis, because observations recorded in the same patient cannot be considered independent,18 the sandwich estimator of variance–covariance matrix was used to take into account clustered data (more lesions within the same subject). The discrimination and calibration ability of the propensity score model was assessed by means of the c-statistic and the Hosmer-Lemeshow statistic.19

The results of the Cox proportional-hazards analyses are reported as adjusted hazard ratios (HRs) with associated 95% CI and P value. A P value of <0.05 was considered to be statistically significant and all reported P values are 2 sided. Statistical analysis was performed using STATA 9.0 (Stata Corporation, College Station, Tex).

The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agreed to the article as written.
Results
A total of 127 patients with 143 lesions in 131 grafts were treated with a DES. The BMS control group consisted of 131 patients with 160 lesions in 137 grafts.

Baseline Clinical Characteristics
The baseline clinical characteristics are presented in Table 1. The 2 groups were similar except for a significantly higher incidence of diabetes (33.1% versus 15.3%; \( P<0.001 \)) and hypercholesterolemia (78.0% versus 57.3%; \( P=0.001 \)) in the DES group. Clinical follow-up was available in 98.8% of patients.

Angiographic and Procedural Characteristics
Angiographic and procedural characteristics are shown in Table 2. Angiographic success was achieved in all the lesions treated in the DES group and 159 lesions (99.4%) in the BMS group. Grafts treated in the DES group were older than those treated in the BMS group. The percentage of restenotic lesions and occluded grafts was significantly higher in the DES group than the BMS group (23.8% versus 4.4%; \( P<0.001 \) and 7.7% versus 1.2%; \( P=0.02 \)). In the DES group, SES were implanted in 71 patients with 82 lesions (56%) and PES in 56 patients with 61 lesions (44%). Compared with the BMS group, the stents inserted in the DES group were of smaller diameter and longer, and more stents were inserted per lesion. DES were implanted more frequently after predilatation and at a higher inflation pressure. In the DES group, the intervention was performed more frequently with an embolic protection device and intraprocedural glycoprotein IIb/IIIa inhibitor usage. Slow flow or no reflow occurred in 4 patients (3.1%) in the BMS group and 6 (4.7%) in the DES group (\( P=0.71 \)), including 1 patient in the BMS group where the procedure was complicated by no reflow and intraprocedural ST and accounted for the only in-hospital death in this cohort. The rate of periprocedural MI after SVG intervention was similar in the BMS and DES groups (3.1% [4] versus 2.4% [3]; \( P=1.0 \)).

Serial Quantitative Coronary Angiography Analysis
Serial quantitative coronary angiography analyses are shown in Table 3. The mean MLD was 0.95 mm for the DES group and 1.24 mm for the BMS group (\( P<0.001 \)). The DES group also had a significantly smaller reference vessel diameter compared with the BMS group (3.16±0.66 versus 3.44±0.76; \( P=0.005 \)). Postprocedural reference vessel diameter and MLD were significantly larger in the BMS group.

Angiographic follow-up was available in 112 lesions in the DES group (78.3%) and 111 lesions in the BMS group (70.7%). The median duration of angiographic follow-up was similar in the BMS (200 days; interquartile range, 148 to 435) and DES groups (233 days; interquartile range, 174 to 392; \( P=0.65 \)). Late lumen loss (0.94±1.30 versus 1.27±1.44; \( P=0.17 \)) and the loss index (0.47±0.67 versus 0.60±0.84; \( P=0.36 \)) were not significantly different in the DES and BMS groups. The cumulative rate of angiographic restenosis during the 2-year follow-up period of the study was similar in the 2 groups (BMS 34.2% versus DES 29.5%; \( P=0.64 \)). There was no statistical difference regarding the incidence of graft occlusion during follow-up (14.4% versus 9.8%; \( P=0.40 \)). However, the angiographic patterns of restenosis were different with the 2 stent types. In the DES group, the majority of restenoses were focal (61% versus 27%; \( P=0.001 \)), whereas in the BMS group, the majority of restenoses were occlusive or diffuse (59% versus 36%; \( P=0.004 \)).

Clinical Follow-Up Outcomes
Cumulative outcomes at 30-day, 1-year, and 2-year clinical follow-up are shown in Table 4. The cumulative rate of MACE, MI, TLR, and TVR was similar in both groups at 2 years after stent implantation. Importantly, there were no statistically significant differences in the cumulative incidence of all cause mortality or cardiac death between the 2 groups at all time points in the study. At the 2-year end point of the study, the mortality rate was 7.8% in the BMS group and 8.7% in the DES group (\( P=0.99 \)).

According to the Academic Research Consortium definition of ST, the rate of definite/probable ST was 0.8% in both the BMS and DES groups (\( P=1.0 \)). In the BMS group, there was 1 definite subacute ST (3 days) and no cases of probable ST. In the DES group, there was 1 very late (431 days).
probable ST in a patient who had an acute MI after stopping dual antiplatelet therapy for a surgical procedure.

Multivariable Cox regression analysis was used to identify independent predictors of MACE. The final multivariable model included age, gender, diabetes, stent diameter, and the stent type (ie, BMS versus DES) implanted. The significant predictors of MACE during the 2-year follow-up period were diabetes (HR, 1.96; 95% CI, 1.21 to 3.18; \( P \leq 0.006 \)) and the usage of BMS (HR, 1.98; 95% CI, 1.22 to 3.21; \( P \leq 0.005 \)).

The Grønnesby-Borgan-May test \( P \) value was 0.72 confirming the goodness of fit of the proportional hazards model.

To account for possible baseline differences between the 2 stent groups, we also performed a propensity analysis. The c-statistic for the propensity score model was 0.87, indicating excellent discrimination. The Hosmer-Lemeshow goodness-of-fit test \( P \) value was 0.68, confirming good calibration and fit of the multivariable model that estimated the propensity score. Table 5 reports the results of the unadjusted and propensity analysis–adjusted HRs. The propensity-adjusted Cox proportional-hazards analysis confirmed that even after adjusting for baseline differences, there was no observed association between DES and increased mortality (HR, 0.72; 95% CI, 0.21 to 2.44; \( P = 0.60 \)). Furthermore, the propensity-adjusted analyses demonstrated that DES were associated with a lower rate of MACE (\( P = 0.001 \)), TVR per patient (\( P = 0.002 \)), TLR per lesion (\( P = 0.006 \)), and angiographic restenosis (\( P = 0.005 \)) during the 2-year follow-up period. Exploratory subgroup analyses for MACE (Figure) showed a similar result in most subgroups to the overall effect of DES, except in diabetics, small vessels, and short lesions where the analyses may have been limited by the small numbers in these subgroups.

**Discussion**

The most important finding of this study was that despite being implanted in more complex patients and lesions, there was no observed association between DES implantation in SVGs and an increase in death, MI, or ST at long-term (2-year) follow-up when compared with BMS. Furthermore, after adjustment for these important baseline differences, DES seem to maintain their efficacy in reducing repeat revascularization.
The current available literature on DES in SVG is limited by the small sample sizes and short follow-up periods. A number of retrospective studies have been performed with conflicting results with some showing a benefit from DES and others suggesting no difference between DES and BMS. Indeed, even the 2 randomized trials performed in this challenging subset have demonstrated somewhat contradictory results. The first randomized trial, RRISC (Reduction of Restenosis In Saphenous Vein Grafts with Cypher sirolimus-eluting stent), to be performed in SVGs was also limited by small numbers (n = 75). This trial confirmed the efficacy of SES in reducing restenosis (13.6% versus 32.6%; P = 0.031) and repeat revascularization (5.3% versus 27%; P = 0.012) at 6 months. However, a secondary ad hoc analysis at a median follow-up of 32 months showed that this initial benefit was lost (TVR, 34% SES versus 38% BMS; P = 0.74), and SES were associated with a 29% absolute increase in mortality. A second randomized trial, SOS (Stenting of Saphenous Vein Grafts), compared PES with a similar BMS in 80 patients. PES were associated with an 82% relative reduction in restenosis at 12 months (9% versus 51%; P = 0.0001) without any evidence of attenuation of this benefit during follow-up. During a median follow-up of 1.5 years, the PES patients had less TLR (28% versus 5%; HR, 0.38; 95% CI, 0.15 to 0.74; P = 0.003), and importantly, mortality was similar between the 2 groups (BMS 5% versus 12% PES; HR, 1.56; 95% CI, 0.72 to 4.11; P = 0.27).

An important caveat to be taken into account when interpreting the results in our study is that there were important differences in baseline clinical, procedural, and lesion characteristics between the groups. Of note, there were more patients with diabetes and dyslipidemia in the DES group, and DES were implanted more often in older grafts, restenotic lesions, and totally occluded grafts. Moreover, as these 2 groups were from different time periods, there were important differences in how the procedure was performed that reflect changes in interventional practice. This is particularly reflected by the greater use of embolic protection devices in the DES group. In general, when DES are implanted, longer stents are placed to completely cover the lesion, and stents are deployed at higher pressure. The number of stents implanted was also greater in the DES group, probably reflecting the fact that more complex lesions were treated such as totally occluded grafts. The finding that we would like to highlight is the fact that despite the higher risk profile of patients treated with DES, they did not show any increase in mortality or MI, even without adjustment. To correct for these baseline differences, we also performed a propensity analysis, which confirmed that at long-term follow-up, there was no observed association between DES

### Table 3. Serial Quantitative Coronary Angiography Analysis

<table>
<thead>
<tr>
<th></th>
<th>BMS n=157 Lesions</th>
<th>DES n=143 Lesions</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RVD, mm</td>
<td>3.44±0.76</td>
<td>3.16±0.66</td>
<td>0.005</td>
</tr>
<tr>
<td>MLD, mm</td>
<td>1.24±0.65</td>
<td>0.95±0.57</td>
<td>0.001</td>
</tr>
<tr>
<td>Diameter stenosis, %</td>
<td>64.7±16.2</td>
<td>69.6±17.0</td>
<td>0.02</td>
</tr>
<tr>
<td>Mean lesion length, mm</td>
<td>12.5±7.8</td>
<td>14.0±9.6</td>
<td>0.37</td>
</tr>
<tr>
<td>Post procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RVD, mm</td>
<td>3.67±0.70</td>
<td>3.44±0.56</td>
<td>0.01</td>
</tr>
<tr>
<td>MLD, mm</td>
<td>3.27±0.74</td>
<td>3.00±0.53</td>
<td>0.01</td>
</tr>
<tr>
<td>Diameter stenosis, %</td>
<td>11.1±12.1</td>
<td>12.4±9.1</td>
<td>0.84</td>
</tr>
<tr>
<td>Acute gain, mm</td>
<td>2.03±0.82</td>
<td>2.05±0.68</td>
<td>0.57</td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RVD, mm</td>
<td>111 (70.7)</td>
<td>112 (78.3)</td>
<td>0.17</td>
</tr>
<tr>
<td>MLD, mm</td>
<td>3.45±0.70</td>
<td>3.30±0.67</td>
<td>0.36</td>
</tr>
<tr>
<td>Diameter stenosis, %</td>
<td>2.11±1.26</td>
<td>1.97±1.31</td>
<td>0.76</td>
</tr>
<tr>
<td>Mean lesion length, mm</td>
<td>45.9±35.4</td>
<td>42.2±35.7</td>
<td>0.39</td>
</tr>
<tr>
<td>Late lumen loss, mm</td>
<td>7.68±5.95</td>
<td>7.91±6.21</td>
<td>0.92</td>
</tr>
<tr>
<td>Angiographic restenosis</td>
<td>38 (34.2)</td>
<td>33 (29.5)</td>
<td>0.64</td>
</tr>
<tr>
<td>Occlusion at follow-up</td>
<td>16 (14.4)</td>
<td>11 (8.8)</td>
<td>0.40</td>
</tr>
</tbody>
</table>

Values are presented as n (%) or mean±SD.
and an increased risk of mortality. Furthermore, after adjusting for the increased complexity in the DES group, it would seem that the benefits of DES in reducing revascularization were sustained. However, we cannot exclude that the longer duration of dual antiplatelet therapy prescribed in the DES group may have had an impact of reducing event rates. Finally, it should be noted that periprocedural MI rates were relatively low in both groups, and this is probably related to the fact that CK-MB was measured only in patients with elevated CK levels.

Thus, it is reassuring that in this large cohort, there was no observed association between DES implantation in SVGs and an increase in MI, ST, or death. The data from our study add to the body of evidence suggesting that DES maintain their superior efficacy over BMS even in the complex subset of SVGs without major safety concerns. However, a large randomized trial powered for a clinical end point is needed to settle the controversy and confirm the long-term beneficial effect of DES over BMS in SVGs.

### Study Limitations

The main limitation of this study is its retrospective design and lack of randomization. Another limitation is the use of a historical control group instead of studying the contemporary usage of these 2 stent types. These 2 factors resulted in important differences in baseline characteristics between the groups. Although there was some contemporaneous use of BMS in some patients with SVG lesions, since DES became available at our center, we excluded these patients from this study. This fact may be perceived as a selection bias. If anything, these patients had very focal lesions or lesions located in large SVGs for which no appropriately sized DES were available (this group represents a lower risk cohort for TLR) or had some comorbidity or contraindication to prolonged dual antiplatelet therapy. Moreover, the DES group included 2 different types of DES. Our rate of angiographic follow-up may also be considered a limitation, although the rates of angiographic follow-up were similar in the 2 groups.
and are quite high for a registry study. The sample size may be considered a limitation and make the study prone to Type II error. However, this is 1 of the largest cohorts of DES and BMS implantation in SVGs. The final limitation that we should point out is that the follow-up in our study is truncated at 24 months in comparison with the median of 32 months in the DELAYED RRISC (Death and Events at Long-term follow-up AnalySis: Extended Duration of the Reduction of Restenosis In Saphenous vein grafts with Cypher stent) trial. It may be possible that the survival curves will separate only after 2 years with a difference in mortality apparent only at 3 years.

Conclusions

In our study, there was no observed association between DES implanted in diseased SVGs and an increase in late mortality, as compared with BMS. SVGs remain a complex lesion to treat percutaneously with a high rate of MACE irrespective of the stent type implanted. Large randomized controlled trials powered for a clinical end point and with long follow-up periods are needed.

Disclosures

None.

References


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**CLINICAL PERSPECTIVE**

Concerns have been raised about the long-term safety of drug-eluting stents (DES) in saphenous vein grafts and as a result, the implantation of DES in this lesion subset has become an area of controversy and uncertainty. In this retrospective registry, we compared the outcomes in 127 patients (143 lesions) treated with DES from April 2002 to June 2006 (DES group) with 131 patients (160 lesions) treated with bare-metal stents in the preceding 36 months (bare-metal stent group). There were important differences in baseline clinical, procedural, and lesion characteristics between the groups. The DES group was more complex with a greater frequency of diabetes, older grafts, restenotic lesions, total occlusions, and smaller grafts treated with longer stents. At 2 years, there was no statistical difference in death (8.7% versus 7.8%), myocardial infarction (6.3% versus 9.4%), or target vessel revascularization (19.7% versus 24.2%) between DES and bare-metal stents, respectively. In an adjusted analysis, there was no observed association between DES implantation in saphenous vein grafts and an increase in late mortality. Saphenous vein grafts remain a complex lesion to treat percutaneously with a high rate of major adverse cardiac event irrespective of the stent type implanted. Large randomized controlled trials powered for a clinical end point and with long follow-up periods are needed.
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Circ Cardiovasc Interv. 2010;3:249-256; originally published online May 4, 2010;
doi: 10.1161/CIRCINTERVENTIONS.109.929042

Circulation: Cardiovascular Interventions is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-7640. Online ISSN: 1941-7632

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