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Vessel Size and Outcome After Coronary Drug-Eluting Stent Placement

Results From a Large Cohort of Patients Treated With Sirolimus- or Paclitaxel-Eluting Stents

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OBJECTIVES This study sought to investigate the influence of vessel size on the outcomes of patients after drug-eluting stent (DES) implantation.

BACKGROUND There are no dedicated studies on the influence of vessel size on the outcomes of patients treated with different DES.

METHODS The study population was composed of 2,058 consecutive patients who received sirolimus-eluting stents (SES) or paclitaxel-eluting stents (PES). Patients were grouped into tertiles according to vessel size (<2.41 mm in the lower tertile, 2.41 to 2.84 mm in the middle tertile, and >2.84 mm in the upper tertile). The primary end point was target lesion revascularization (TLR). Secondary end points were binary angiographic restenosis and the composite of death or myocardial infarction.

RESULTS Vessel size did not influence the composite end point of death and myocardial infarction. The TLR rates were higher among patients in the lower tertile (12.1%) as compared with the middle (8.4%) and upper (8.0%) tertiles ($p = 0.02$). In a multivariate analysis, vessel size emerged an independent predictor of TLR ($p = 0.009$). The model showed also a significant interaction between DES type and vessel size regarding TLR ($p = 0.008$). There was a significant difference in TLR rates among patients treated with SESs (8.6%) and PESs (16.4%) in the lower tertile ($p = 0.002$), but not in the middle and upper tertiles.

CONCLUSIONS The influence of vessel size on restenosis is related to the specific DES used, with SESs providing better outcomes than PESs in small but not in large coronary vessels. (J Am Coll Cardiol 2006;48:1304–9) © 2006 by the American College of Cardiology Foundation

Vessel size is an important determinant of outcomes in patients who undergo percutaneous coronary interventions (1–4). Small reference diameter has been associated with an increased risk of restenosis. In patients treated with bare-metal stents (BMS), the impact of vessel size is quite obvious because of the limited ability of small size vessels to accommodate for the neointimal proliferation that develops after stent implantation (5,6). This explains the failure of several studies to establish the superiority of BMS over plain balloon angioplasty in patients treated for lesions located in small coronary vessels (5,7–11).

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Several drug-eluting stent (DES) platforms have been very successful in reducing restenosis risk compared with BMSs after implantation in patients with coronary artery disease (12–18). The advantages of DES over BMS have been shown in different subsets of patients and lesions, including that of small coronary vessels (7,19–22). The antirestenotic efficacy of DES is achieved through inhibition of neointimal proliferation, which is shown angiographically by the reduced degree of late lumen loss. Because of the much lower lumen loss rates achieved with DES as compared with BMS, some have suggested that the impact of vessel size may be attenuated or even cancelled after DES implantation (23). Recent analyses have shown that vessel size plays a major role even in the DES era (20,24). However, previous studies have included only small to moderate numbers of selected patients, who have been treated with a single type of DES. It is also not known whether the influence of vessel size is related to the type of DES used.

The objective of this study was to investigate the impact of vessel size on the clinical and angiographic outcomes after coronary implantation of the 2 U.S. Food and Drug Administration–approved DES, the sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES), in a large series of consecutive patients.

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Abbreviations and Acronyms
BMS = bare-metal stent
DES = drug-eluting stent
PES = paclitaxel-eluting stent
SES = sirolimus-eluting stent
TLR = target lesion revascularization

METHODS

Patient population. The study population was composed of 2,058 consecutive patients who received polymer-based SES (Cypher, Cordis Corporation, Miami Lakes, Florida) or PES (Taxus, Boston Scientific Corporation, Natick, Massachusetts) in Deutsches Herzzentrum and First Medizinische Klinik rechts der Isar, Munich, Germany, from August 2002 through March 2005. Excluded from this study were patients with cardiogenic shock, acute ST-segment elevation myocardial infarction, or target lesion located in unprotected left main coronary artery or venous bypass graft. A loading dose of 600 mg clopidogrel was administered to all patients at least 2 h before coronary angiography. Periprocedural antithrombotic therapy consisted of intravenous aspirin and heparin. After the intervention, the protocol mandated antiplatelet therapy consisting of aspirin 100 mg twice per day indefinitely as well as clopidogrel 75 mg twice per day until discharge and 75 mg per day for at least 6 months.

Follow-up protocol. After the stenting procedure, all patients remained in the hospital for at least 48 h. Electrocardiograms were recorded, and blood was collected for determination of creatine kinase and its MB isoenzyme before stenting, every 8 h for the first 24 h after the procedure, and daily afterward. A telephone interview after 30 days was done to assess each patient's clinical status. All patients were asked to return for coronary angiography between 6 and 8 months after the procedure or earlier if anginal symptoms had developed. Phone interviews were repeated at 9 months after the intervention. All patients with symptoms considered to be possibly cardiac in origin underwent a complete clinical, electrocardiographic, and laboratory evaluation at the outpatient clinic. When necessary, an angiographic study was performed. Relevant data were prospectively collected and entered into a computer database by specialized personnel.

Quantitative coronary angiography evaluation. Baseline, postprocedural, and follow-up coronary angiograms were digitally recorded and assessed off-line in the Quantitative Angiographic Core Laboratory (Deutsches Herzzentrum, Munich, Germany) with the use of an automated edge detection system (CMS version 6.0.10.0, Medis Medical Imaging Systems, Nuenen, the Netherlands) by experienced personnel. The complexity of the lesions was defined according to the modified American College of Cardiology/American Heart Association grading system (25). All measurements were performed on cineangiograms recorded after intracoronary nitroglycerin administration. The same single, worst-view projection was used at all time points. The contrast-filled nontapered catheter tip was used for calibration. The parameters that were measured included the reference diameter of the vessel, the minimal lumen diameter, percent diameter stenosis (difference between the reference diameter and minimal lumen diameter divided by the reference diameter and multiplied by 100), and late lumen loss (difference between minimal lumen diameter at the end of the procedure and minimal lumen diameter at follow-up). Quantitative analysis was performed in the in-stent area (in-stent analysis) and in the in-segment area including the stented segment as well as both 5-mm margins proximal and distal to the stent (in-segment analysis).

Study end points and definitions. The primary end point of the study was the need for target lesion revascularization (TLR), which was defined as any revascularization procedure, percutaneous or surgical, involving the target lesion performed in the presence of symptoms or objective signs of ischemia during the 9-month follow-up interval. Secondary end points were in-segment binary angiographic restenosis, defined as a diameter stenosis $\geq$50% at control angiography, and the composite of death or myocardial infarction. The diagnosis of myocardial infarction during the follow-up required the presence of new Q waves in the electrocardiogram and/or an elevation of creatine kinase or its MB isoenzyme to at least 3 times the upper limit of normal in at least 2 blood samples.

Statistical analysis. Statistical analysis was performed using a per-patient approach. In patients with a multilesion intervention, only 1 lesion was selected randomly for analysis. The random selection was performed before the analysis of the data by assigning a random number to each lesion and selecting for analysis the lesion with the smallest random number among patients with multilesion intervention. The adequacy of this method was checked by evaluating the reproducibility of the results after selecting the lesion with the greatest random number.

To study the clinical and angiographic outcome for different ranges of vessel size, we grouped the study population in tertiles according to the reference diameter. The cutoff points of reference diameter that divided the population into 3 equally sized groups were 2.41 and 2.84 mm: the lower tertile included patients with vessel size $<$2.41 mm; the middle tertile included patients with vessel size 2.41 to 2.84, and the upper tertile included patients with vessel size $>$2.84 mm. Data are expressed as mean values $\pm$ SD for continuous variables and as percentages for discrete variables. Differences between groups were assessed using ANOVA test for continuous and chi-square test for categorical variables.

Multivariable logistic regression was used to investigate potential independent risk factors for TLR. Baseline clinical and angiographic characteristics as well as procedural variables were entered into the model. Differences were considered to be statistically significant when the p values were $<$0.05.

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Table 1. Baseline Characteristics of the Patients and Lesions

Characteristic	Lower Tertile <2.41 mm (n = 678)	Middle Tertile 2.41 to 2.84 mm (n = 692)	Upper Tertile >2.84 mm (n = 688)	p Value
Age, yrs	66.3 ± 9.5	66.1 ± 10.7	65.6 ± 10.9	0.17
Women, no. (%)	172 (25.4)	161 (23.3)	118 (17.2)	<0.001
Diabetes mellitus, no. (%)	233 (34.4)	186 (26.9)	176 (25.6)	<0.001
Current smoker, no. (%)	68 (10.0)	103 (14.9)	114 (16.6)	0.001
Arterial hypertension, no. (%)	406 (60.0)	425 (61.5)	393 (57.1)	0.26
Hypercholesterolemia, no. (%)	500 (73.7)	500 (72.3)	509 (74.0)	0.73
Unstable angina, no. (%)	173 (25.5)	186 (26.9)	223 (32.4)	0.01
Prior myocardial infarction, no. (%)	274 (40.4)	276 (40.0)	237 (34.5)	0.04
Prior aortocoronary bypass surgery, no. (%)	86 (12.7)	68 (9.8)	48 (7.0)	0.002
Multivessel disease, no. (%)	585 (86.3)	563 (81.4)	567 (82.4)	0.04
Left ventricular ejection fraction, %	55.5 ± 12.7	55.1 ± 12.6	55.2 ± 12.8	0.63
Target vessel				<0.001
Left anterior descending coronary artery, no. (%)	355 (52.4)	316 (45.7)	289 (42.0)	
Left circumflex coronary artery, no. (%)	219 (32.3)	200 (28.9)	146 (21.2)	
Right coronary artery, no. (%)	104 (15.3)	176 (25.4)	253 (36.8)	
Complex (type B2/C) lesions, no. (%)	499 (73.6)	521 (75.3)	526 (76.5)	0.47
Chronic occlusions, no. (%)	71 (10.5)	49 (7.1)	37 (5.4)	0.001
Lesion length, mm	13.3 ± 7.8	14.2 ± 8.0	13.8 ± 7.1	0.22
Minimal lumen diameter before procedure, mm	0.83 ± 0.33	1.04 ± 0.40	1.28 ± 0.51	<0.001
Diameter stenosis before procedure, %	60.9 ± 15.4	60.4 ± 14.9	60.2 ± 15.1	0.36

Plus-minus values are mean ± SD.

RESULTS

Baseline characteristics. Basal clinical and angiographic characteristics are shown in Table 1. There were significant differences across groups with respect to several variables such as gender, presence of diabetes mellitus, smoking status, prior coronary bypass surgery, and so on. There were no differences across study groups with respect to lesion length and complexity or to preprocedural diameter stenosis. Procedural characteristics are shown in Table 2.

The proportion of patients with multilesion intervention was 14.7% in the lower tertile, 12.4% in the middle tertile, and 11.2% in the upper tertile ($p = 0.14$). When patients with multilesion intervention were analyzed separately by including all stented lesions and according to the stent type received, there were no significant differences between the SES and PES groups regarding important characteristics such as frequency of diabetes ($p = 0.85$), vessel location of the lesion ($p = 0.32$), frequency of chronic occlusions ($p = 0.24$) and complex lesions ($p = 0.80$), vessel size ($p = 0.25$), and length of stented segment ($p = 0.26$). Lesion length tended to be greater among patients with multilesion intervention who received SES as compared with those who received PES ($p = 0.07$).

During the first 30 days after the procedure, there were 7 (1.0%) cases of stent thrombosis among patients grouped in the lower tertile, 2 (0.3%) cases in the middle tertile, and 4 (0.6%) cases in the upper tertile ($p = 0.22$).

Angiographic outcome. Follow-up angiography at a median of 193 days (interquartile range 175 to 205 days) was carried out in 1,666 patients (81%). Angiographic outcome is presented in Table 3. In-stent late lumen loss was not statistically different between the 3 groups ($p = 0.29$). The lack of dependence of late lumen loss on vessel size was seen irrespective of the type of DES used (Fig. 1). Diameter stenosis at follow-up showed significant variation between groups ($p < 0.001$), having the highest values among

Table 2. Procedural Characteristics

Characteristic	Lower Tertile <2.41 mm (n = 678)	Middle Tertile 2.41 to 2.84 mm (n = 692)	Upper Tertile >2.84 mm (n = 688)	p Value
Maximal balloon pressure, atm	13.9 ± 2.8	14.6 ± 2.9	14.9 ± 2.8	<0.001
Balloon-to-vessel ratio	1.23 ± 0.13	1.14 ± 0.09	1.10 ± 0.08	<0.001
Sirolimus-eluting stents, no. (%)	373 (55.0)	371 (53.6)	395 (57.4)	0.36
Length of stented segment, mm	22.8 ± 10.0	23.3 ± 8.9	23.0 ± 8.6	0.66
Minimal lumen diameter after procedure				
In-stent, mm	2.17 ± 0.26	2.52 ± 0.23	3.0 ± 0.32	<0.001
In-segment, mm	1.72 ± 0.35	2.11 ± 0.35	2.62 ± 0.44	<0.001
Diameter stenosis after procedure				
In-stent, %	6.7 ± 7.2	7.9 ± 6.5	9.4 ± 5.8	<0.001
In-segment, %	26.1 ± 6.2	23.0 ± 7.2	20.7 ± 8.3	<0.001

Plus-minus values are mean ± SD.

Table 3. Results of Quantitative Angiographic Analysis at Follow-Up

Characteristic	Lower Tertile <2.41 mm (n = 548)	Middle Tertile 2.41 to 2.84 mm (n = 562)	Upper Tertile >2.84 mm (n = 556)	p Value
Late lumen loss				
In-segment, mm	0.21 ± 0.58	0.20 ± 0.57	0.24 ± 0.62	0.29
In-stent, mm	0.38 ± 0.57	0.32 ± 0.58	0.34 ± 0.57	0.29
Minimal lumen diameter				
In-segment, mm	1.53 ± 0.54	1.91 ± 0.54	2.38 ± 0.61	<0.001
In-stent, mm	1.80 ± 0.60	2.20 ± 0.59	2.66 ± 0.64	<0.001
Diameter stenosis				
In-segment, %	35.18 ± 20.93	31.26 ± 18.21	28.27 ± 16.43	<0.001
In-stent, %	23.68 ± 23.67	20.60 ± 19.94	19.76 ± 17.30	0.002
Angiographic restenosis				
In-segment, no. (%)	107 (19.5)	75 (13.3)	55 (9.9)	<0.001
In-stent, no. (%)	75 (13.7)	52 (9.3)	41 (7.4)	0.002

Plus-minus values are mean ± SD.

patients grouped in the lower tertile. The incidence of the angiographic secondary end point of the study, in-segment binary restenosis, was significantly different between groups ($p < 0.001$).

Clinical outcome. After 9 months of clinical follow-up, the number of patients who suffered death or myocardial infarction was not different across study groups: 40 (5.9%) in the lower tertile, 35 (5.1%) in the middle tertile, and 36 (5.2%) in the upper tertile ($p = 0.77$). Similarly, a comparable proportion of patients died in each vessel size tertile (2.8% in the lower, 2.6% in the middle, and 2.8% in the upper tertile; $p = 0.97$).

The incidence of the primary end point of the study, TLR, was significantly different between the 3 study groups: 82 (12.1%) patients in the lower tertile compared with 58 (8.4%) patients in the middle tertile and 52 (8.0%) patients in the upper tertile required repeat revascularization procedures ($p = 0.02$). Most of the revascularization procedures consisted of repeat percutaneous interventions (11.5% among patients in the lower tertile, 7.7% in the middle tertile, and 7.6% in the upper tertile; $p = 0.01$). In the multivariate analysis that included all variables shown in Tables 1 and 2, vessel size tertile remained an independent predictor of clinical restenosis ($p = 0.009$). The model showed a significant interaction between vessel size and type of DES ($p = 0.008$). More specifically, there was a significant difference between the 2 DESs among patients grouped in the lower tertile regarding TLR (8.6% with SES vs. 16.4% with PES; $p = 0.002$), but not among those grouped in the middle and upper tertiles (Fig. 2). Notably, there were no significant differences between patients who received SESs and those who received PES with respect to known risk factors for restenosis such as diabetes and lesion length that could explain the different incidence of TLR in the lower tertile. The proportion of diabetic patients in the lower tertile was 35.4% among SES patients and 33.1% among PES patients ($p = 0.54$). Lesion length was 14.0 ± 7.6 mm among SES patients and 13.5 ± 7.8 mm among PES patients ($p = 0.20$). In addition, the proportion of patients of the lower tertile treated with SES was comparable between the 2 participating centers: 52.3% in the First Medizinische Klinik rechts der Isar and 55.8% in the Deutsches Herzzentrum ($p = 0.43$).

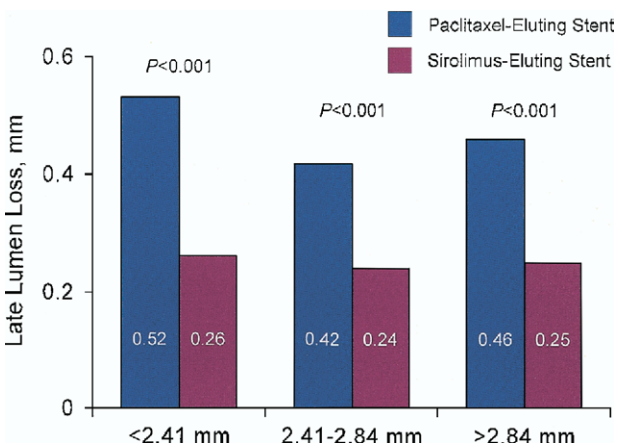

Figure 1. Late lumen loss in each vessel size tertile with sirolimus-eluting stents and paclitaxel-eluting stents.

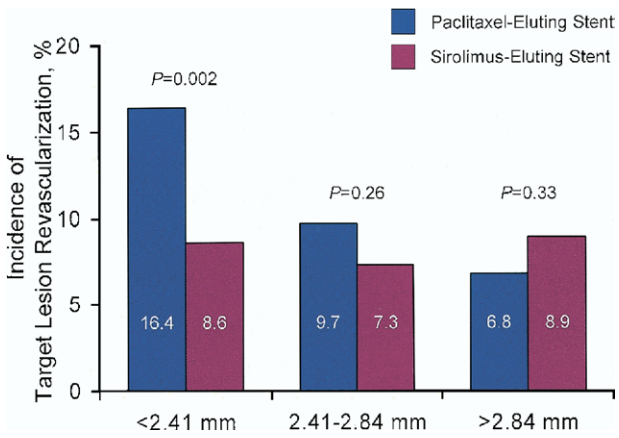

Figure 2. Target lesion revascularization rate in each vessel size tertile with sirolimus-eluting stents and paclitaxel-eluting stents. Note that a significant difference between the 2 drug-eluting stents is only seen among patients in the lower tertile.

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DISCUSSION

The results of the present study show that in patients undergoing SES or PES implantation vessel size does not influence the risk of death or myocardial infarction but it is an important determinant of the risk of restenosis. This impact of vessel size on the development of future clinical restenosis is closely related to the type of DES implanted, and patients treated with SES for lesions located in small vessels have a smaller risk of requiring repeat revascularization procedures compared with those treated with PES.

Patients with smaller vessels had several characteristics (e.g., a higher frequency of diabetes mellitus, multivessel disease, chronic occlusions) that have been often associated with a poorer outcome after stent implantation. Nevertheless, the findings from our large study population showed that patients with small vessels had a similar incidence of death and myocardial infarction compared with larger vessels, thus showing the safety of SES and PES implantation irrespective of vessel size. On the other hand, patients treated for lesions located in smaller vessels had a higher frequency of clinical and angiographic restenosis only when treated with PES. Multivariate analysis confirmed the independent influence of vessel size and its significant interaction with DES type regarding the risk of repeat revascularization procedures during the 9-month clinical follow-up.

Previous studies with BMS have shown a similar degree of late lumen loss across the whole range of vessel size (4). Drug-eluting stents have been shown to be an effective treatment strategy for attenuating intimal hyperplasia, the chief cause of restenosis and a major limitation of the long-term success of BMS (24,26). Indeed, in the early reports on the use of DES, which included small numbers of very carefully selected patients, there was an almost complete inhibition of neointimal hyperplasia, and therefore late loss was almost absent (23,27–29). Based on these results, investigators concluded that vessel size plays no role on the development restenosis after DES implantation (23). Meanwhile, other studies that included larger number of patients with less restrictive criteria treated with DES showed that late lumen loss occurs, albeit not to the same degree with various DES, and that restenosis rates were lower in vessels with bigger reference diameters (24,30). However, none of the aforementioned studies have specifically addressed the role of vessel size on clinical and angiographic outcome. Moreover, previous analyses have been based on patient populations that have received only a particular DES, either SES or PES, and small to moderate numbers of patients have been included. Instead, our analysis specifically focused on the impact of vessel size on the outcome of 2,058 patients treated with both U.S. Food and Drug Administration–approved DES, with follow-up angiography being performed in 1,666 of these patients.

The results of this study provide solid evidence that despite improved outcomes with DES compared with historical data of BMS in small vessels, the size of the reference diameter of the treated vessel has a major impact on the risk of restenosis even in the era of DES. Although clinical and angiographic restenosis rates were similar among patients with vessel diameters 2.41 to 2.84 mm and >2.84 mm, restenosis rates were markedly higher among patients with very small vessels (<2.41 mm). Considering the similar degree of in-stent late luminal loss regardless of the reference diameter of the target vessel (ranging from 0.32 to 0.36 mm), the reason for the difference in restenosis rates between patients in the upper and middle vessel size tertiles compared with those in the lower tertile is easily understandable. Thus, the same extent of late loss that was easily accommodated in larger vessels was great enough to lead to an increased incidence of restenosis and need of repeat revascularization procedures in smaller vessels.

Another important finding was the significant interaction between the 2 strongest predictors of clinical restenosis, namely vessel size and type of DES used. Although clinical restenosis rates were not significantly different between the 2 DES in patients grouped in the middle and upper tertiles, need of TLR was markedly lower with SES than PES in patients with vessel size <2.41 mm. Indeed, late lumen loss was significantly smaller with SES than with PES. Intuitively, in vessels with a similar size, a smaller late lumen loss is more easily accommodated compared with a larger late lumen loss. These findings highlight the importance of achieving maximal suppression of neointimal proliferation, and therefore, maximal reduction of late luminal loss with most effective DES (31,32) and echo the results of a recent randomized study that showed that the better efficacy of SES compared with PES was limited to the subset of very small vessels (33). On the other hand, these findings show that the use of PES was as effective as SES in about two-thirds of the present study population.

The present results add to the existing body of evidence on the impact of vessel size on outcomes after percutaneous coronary interventions. They show that for the treatment of vessels with a moderate to large reference diameter, the selection of a particular DES is not relevant. Recent comparative studies have also shown that differences between BMS and DES are markedly reduced in larger vessels (7,34).

Conclusions. The influence of vessel size on restenosis is related to the specific DES used. Small vessel size has a negative impact on the outcome of patients treated with PES. For lesions located in larger vessels, both SES and PES provide comparably favorable results.

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