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Drug-Eluting or Bare-Metal Stents for Coronary Artery Disease

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Abstract

BACKGROUND

Limited data are available on the long-term effects of contemporary drug-eluting stents versus contemporary bare-metal stents on rates of death, myocardial infarction, repeat revascularization, and

stent thrombosis and on quality of life.

METHODS

We randomly assigned 9013 patients who had stable or unstable coronary artery disease to undergo percutaneous coronary intervention (PCI) with the implantation of either contemporary drug-eluting stents or bare-metal stents. In the group receiving drug-eluting stents, 96% of the patients received either everolimus- or zotarolimus-eluting stents. The primary outcome was a composite of death from any cause and nonfatal spontaneous myocardial infarction after a median of 5 years of follow-up. Secondary outcomes included repeat revascularization, stent thrombosis, and quality of life.

RESULTS

At 6 years, the rates of the primary outcome were 16.6% in the group receiving drug-eluting stents and 17.1% in the group receiving bare-metal stents (hazard ratio, 0.98; 95% confidence interval [CI], 0.88 to 1.09; P=0.66). There were no significant between-group differences in the components of the primary outcome. The 6-year rates of any repeat revascularization were 16.5% in the group receiving drug-eluting stents and 19.8% in the group receiving bare-metal stents (hazard ratio, 0.76; 95% CI, 0.69 to 0.85; P<0.001); the rates of definite stent thrombosis were 0.8% and 1.2%, respectively (P=0.0498). Quality-of-life measures did not differ significantly between the two groups.

CONCLUSIONS

In patients undergoing PCI, there were no significant differences between those receiving drug-eluting stents and those receiving bare-metal stents in the composite outcome of death from any cause and nonfatal spontaneous myocardial infarction. Rates of repeat revascularization were lower in the group receiving drug-eluting stents. (Funded by the Norwegian Research Council and others; NORSTENT ClinicalTrials.gov number, NCT00811772.)

Introduction

Percutaneous coronary intervention (PCI) with implantation of drug-eluting or bare-metal stents has become one of the most frequently performed therapeutic procedures in medicine.[1] Each year, millions of patients are treated worldwide.[1,2] The use of drug-eluting stents has been shown to be more effective in the prevention of restenosis than the use of bare-metal stents,[1] and the use of newer-generation drug-eluting stents, as compared with first-generation devices,[3,4] may also reduce the rate of stent thrombosis.[5-8] It has been suggested that the benefits associated with the use of newer-generation drug-eluting stents may translate into reduced rates of death and myocardial infarction.[7-10]

Although newer-generation drug-eluting stents have been found to perform better than their first-generation predecessors,[5,11,12] the evidence in favor of the newer stents over contemporary bare-metal stents may not be as strong as has been thought. Randomized trials have had limited generalizability and

statistical power owing to patient-selection criteria and sample size.[7,8,13] Meta-analyses have used indirect evidence from trials that did not directly compare newer-generation drug-eluting stents with contemporary bare-metal stents,[9,14,15] and registry data may yield erroneous conclusions because of bias and residual confounding.[6,12,16,17]

We therefore evaluated the long-term risks and benefits of the use of contemporary drug-eluting stents versus bare-metal stents in a large, randomized trial.

Methods

TRIAL DESIGN AND OVERSIGHT

The Norwegian Coronary Stent Trial (NORSTENT) was a multicenter, randomized trial conducted at all eight centers in Norway that perform PCI. The trial **protocol** is available with the full text of this article at NEJM.org. The trial was funded by the Norwegian Research Council and other not-for-profit organizations. The steering committee designed the study, gathered the data, and made the decision to submit the manuscript for publication. The first and second-to-last author analyzed the data, and the first, third, and last two authors wrote the first draft of the manuscript. All the authors vouch for the accuracy and completeness of the data and the analyses, as well as for the fidelity of this report to the trial protocol. The sponsors had no role in the design of the study, the gathering or analysis of the data, the writing of the manuscript, or the decision to submit the manuscript for publication.

The trial was approved by the Norwegian Regional Committee for Medical and Health Research Ethics–Region North. All the patients provided written informed consent.

PATIENTS

Between September 15, 2008, and February 14, 2011, all the patients undergoing PCI in Norway were evaluated for enrollment. Eligible patients were men and women who were at least 18 years of age, presented with stable angina or an acute coronary syndrome, had lesions in native coronary arteries or coronary-artery grafts (all of which were amenable for implantation of either drug-eluting stents or bare-metal stents), had a Norwegian national identification number and were able to communicate in Norwegian, and provided informed consent. Patients were excluded if they had previously been treated with a coronary stent, had a bifurcation lesion requiring treatment with a two-stent technique, had a serious medical condition other than coronary artery disease with a life expectancy of less than 5 years, were participating in another randomized trial, had intolerable side effects to any drug in use during PCI or contraindications to long-term dual-antiplatelet therapy or had been prescribed warfarin, or were not able to follow the trial protocol, as judged by the investigator.

RANDOMIZATION AND PCI PROCEDURES

The patients were randomly assigned in a 1:1 ratio to receive drug-eluting stents or bare-metal stents after diagnostic angiography and before PCI. Each patient received as many stents as was judged to be clinically appropriate; the protocol specified that only stents of the randomly assigned type be placed in any patient. The assignment schedule was based on computer-generated random numbers. Randomization was performed in blocks of 8 to 20 patients, with stratification according to center.

Coronary stents for use in the trial were commercially available and in routine use in Norway during the trial period. All stents were purchased by the participating hospitals, and reimbursement was the same as for patients not enrolled in the trial. Patients, operators, and clinicians providing clinical care were aware of the types of stents that were being placed.

PCI was performed according to standard techniques at the discretion of each operator. The same type of stent (on the basis of the randomized assignment) was to be used in patients with multiple lesions and in staged procedures. All the patients in the two groups were prescribed aspirin at a daily dose of 75 mg indefinitely and clopidogrel at a daily dose of 75 mg for 9 months after the procedure regardless of the randomized assignment or the indication for PCI. Drugs for secondary prevention were prescribed according to current guidelines. Operators were encouraged to use the assigned type of stent if PCI was repeated during follow-up. Restenosis could be treated by means of balloon dilation, a cutting balloon, drug-eluting stents, or a combination of those methods at the discretion of the operator.

FOLLOW-UP AND OUTCOMES

Clinical follow-up of the patients was performed according to routine practice at the participating centers. There were no per-protocol follow-up visits, and no routine follow-up coronary angiography was performed. A quality-of-life questionnaire was administered to a representative sample of 941 patients (10%) at baseline and was mailed to all the patients at 6, 12, 24, 36, 48, and 60 months.

The primary outcome was a composite of death from any cause and nonfatal spontaneous myocardial infarction at a median follow-up of 5 years, as specified in an amendment to the protocol made by the steering committee in May 2012. Secondary outcomes were subcategories of death; fatal and non spontaneous and periprocedural myocardial infarction and stroke; hospitalization for unstable ar pectoris; revascularization of a target lesion, target vessel, or nontarget vessel with PCI or coronary-artery bypass grafting (CABG); definite stent thrombosis; major bleeding episodes; and health-related quality of life.

The manual for definitions and classifications of outcomes is provided in the Supplementary Appendix, available at NEJM.org. Definite stent thrombosis was defined according to the Academic Research Consortium criteria.[18] Bleeding was defined according to the Bleeding Academic Research Consortium (BARC) criteria.[19]

Outcome events were collected by means of electronic linkage to the Norwegian Patient Registry through December 31, 2014, with the use of a unique 11-digit Norwegian national identification number for each

patient. The patient registry includes the codes of the *International Classification of Diseases, 10th Revision* (ICD-10), with respect to all the main diagnoses and up to 20 secondary diagnoses and all procedure codes from all hospitalizations in Norway. A broad search was performed to identify any hospitalization for cardiovascular disease with or without coronary angiography, PCI, or CABG and any hospitalization for suspected bleeding. Search criteria are provided in the Supplementary Appendix. Copies of discharge letters and medical-record notes from all hospitalizations that were identified by the electronic search were then obtained from the hospitals. The date and cause of death were obtained by linkage to the Norwegian Causes of Death Registry.

All outcomes were adjudicated by members of an end-points committee of clinical and interventional cardiologists and an epidemiologist who were unaware of the patients' treatment assignments. The methods used for blinding are described in the Supplementary Appendix. All outcomes were assessed by at least two members of the end-points committee. In cases of disagreement, consensus was obtained. A few angiograms were reassessed by local investigators because the medical records were incomplete.

Disease-specific health status and quality of life were assessed by means of a validated Norwegian translation of the Seattle Angina Questionnaire, a 19-item survey that measures five domains of health status related to coronary artery disease: physical limitations, angina stability, angina frequency, treatment satisfaction, and quality of life.[20,21] Each domain produces a summary score ranging from 0 to 100, with higher scores indicating fewer symptoms and better health status.

STATISTICAL ANALYSIS

For the calculation of sample size, we assumed that the 5-year incidence of the primary outcome would be 17%. The planned enrollment of 8000 patients, with a median follow-up time of 5 years, was expected to provide a statistical power of 93% to detect an absolute between-group difference in the incidence rate of the primary outcome of 3 percentage points (rate ratio, 1.18) and a power of 65% to detect a difference of 2 percentage points (rate ratio, 1.12), given a two-sided alpha value of 0.05. An independent data and safety monitoring board reviewed the data after one interim analysis, with formal stopping rules, as described in the study protocol. Because mortality in the study group as a whole was lower than expected, in M the steering committee decided to increase enrollment to 9000 patients and to follow all the pati December 31, 2014.

Differences in baseline characteristics between the groups were tested with the independent-samples t-test for continuous variables, with the Pearson chi-square test for independent-observations binary variables, and with generalized estimating equations with the logit functions for binary variables that had repeated observations within some patients. Outcome analyses were performed according to the intention-to-treat principle with the use of time-to-event methods. In analyses of each outcome, follow-up continued until the occurrence of a trial outcome, emigration, or death or until December 31, 2014. Estimates of hazard ratios and 95% confidence intervals were obtained with the use of Cox proportional-hazards models and were adjusted for the trial center. Hazard ratios comparing drug-eluting stents with bare-metal stents were also assessed in subgroups. Possible differences in hazard ratios between subgroups were assessed by

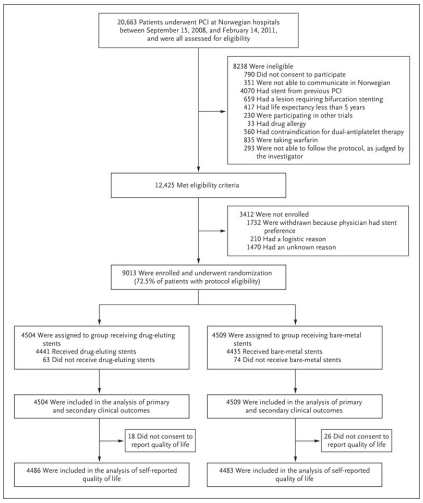
including cross-product terms between the intervention-group variable and indicator variables of subgroups and tested with likelihood-ratio tests. Kaplan–Meier survival analysis was used to compare the survival distributions between the two groups. The cumulative failure rate was estimated as one minus the Kaplan–Meier survivor function at 6 years of follow-up. Linear mixed models were used to estimate time-point–specific marginal mean scores on the Seattle Angina Questionnaire and to test for group differences. The reported P values are two-sided and have not been adjusted for multiple comparisons. P values of less than 0.05 were considered to indicate statistical significance.

The trial was registered at ClinicalTrials.gov on December 18, 2008. Owing to investigator oversight, 369 of the 9013 participating patients were enrolled between September 15, 2008, and the date of registration at ClinicalTrials.gov.

Results

PATIENTS AND FOLLOW-UP

Figure 1.



Enrollment, Randomization, and Follow-up.

Table 1.

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Drug-Eluting Stents (N=4504)	Bare-Metal Stents (N=4509)
Age — yr	62.6±10.8	62.6±10.9
Male sex — no. (%)	3377 (75.0)	3380 (75.0)
Body-mass index†	27.1±4.1	27.1±4.2
Current smoker — no. (%)	1538 (34.1)	1609 (35.7)
Medical history — no. (%)		
Diabetes mellitus	575 (12.8)	548 (12.2)
Hypertension	1934 (42.9)	1857 (41.2)
Hypercholesterolemia	2413 (53.6)	2455 (54.4)
Previous myocardial infarction	433 (9.6)	479 (10.6)
Previous stroke	177 (3.9)	169 (3.7)
Previous coronary-artery bypass grafting	293 (6.5)	300 (6.7)
Indication for percutaneous coronary intervention — no. (%)		
Angina		
Stable	1309 (29.1)	1327 (29.4)
Unstable	567 (12.6)	538 (11.9)
Myocardial infarction		
No ST-segment elevation	1404 (31.2)	1438 (31.9)
ST-segment elevation	1201 (26.7)	1171 (26.0)
Other clinical presentation	19 (0.4)	25 (0.6)
Multivessel disease — no. (%)	1813 (40.3)	1768 (39.2)
Lesion characteristic — no. (%)‡		
Lesion type B2 or C	2227 (49.4)	2118 (47.0)
Bifurcation lesion	688 (15.3)	664 (14.7)
Chronic total occlusion	180 (4.0)	177 (3.9)
Lesion in coronary-artery bypass graft	101 (2.2)	133 (2.9)
Ostial lesion	335 (7.4)	301 (6.7)
Calcified lesion	1042 (23.1)	1026 (22.8)
Thrombotic lesion	1041 (23.1)	1035 (23.0)
Index procedure characteristic		
Patients with more than one procedure — no. (%)	293 (6.5)	264 (5.9)
Procedures with radial approach only — no./total no. (%)	3991/4809 (83.0)	4011/4782 (83.9)
No. of treated lesions per patient	1.4±0.7	1.4±0.7
No. of stents implanted per patient	1.7±1.0	1.6±1.0
Total stent length per patient — mm	28.5±18.2	26.9±17.1
Receipt of allocated stent type — no. (%)	4441 (98.6)	4435 (98.4)
Segments with angiographic success — no./total no. (%)	6265/6422 (97.6)	6229/6350 (98.1)

* Plus–minus values are means ±SD. There were no significant differences between the groups except for lesion type B2 or C ($P=0.02$), lesion in coronary-artery bypass graft ($P=0.03$), and total stent length per patient ($P<0.001$).
† The body-mass index is the weight in kilograms divided by the square of the height in meters.
‡ Definitions of lesion characteristics are provided in the Supplementary Appendix.

Characteristics of the Patients at Baseline.

From September 15, 2008, to February 14, 2011, a total of 20,663 patients underwent PCI in Norway. Of the 12,425 patients who were eligible to participate in the trial, 9013 (72.5%) underwent randomization (Figure 1). The two study groups were well balanced for most clinical characteristics (Table 1), although there were imbalances in total stent length, lesion type (see the Supplementary Appendix), and the proportion of lesions in coronary-artery bypass grafts. In the group receiving drug-eluting stents, 82.9% of the patients received everolimus-eluting stents and 13.1% received zotarolimus-eluting stents. All the patients in the group receiving bare-metal stents underwent placement of contemporary devices with thin struts. The names and manufacturers of all types of stents that were placed at baseline are provided in Table S1 in the Supplementary Appendix.

The median follow-up time was 59 months (range, 1 day to 76 months). No patients were lost to follow-up with respect to death, but the completeness of clinical follow-up was uncertain for 5 patients. The response rate to the quality-of-life questionnaire was 91% at 6 months, 88% at 1 year, 84% at 2 years, 82% at 3 years, 80% at 4 years, and 78% at 5 years.

STUDY OUTCOMES

Table 2.

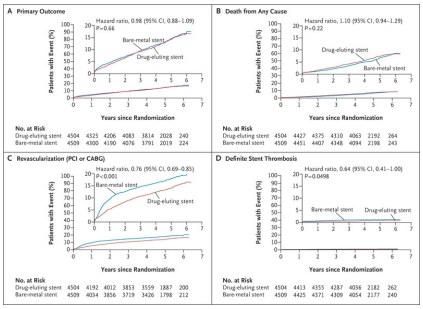
Table 2. Clinical Events during Follow-up and Cumulative Rates at 6 Years.[a]

Clinical Event	Drug-Eluting Stents (N=4504)	Bare-Metal Stents (N=4509)	Hazard Ratio (95% CI)	P Value
	no. of patients (cumulative rate)†			
Primary outcome	643 (16.6)	656 (17.1)	0.98 (0.88–1.09)	0.66
Nonfatal spontaneous myocardial infarction	356 (9.8)	399 (10.5)	0.89 (0.77–1.02)	0.10
Death from any cause	287 (7.5)	257 (7.4)	1.11 (0.94–1.32)	0.21
Death from any cause‡	331 (8.5)	302 (8.4)	1.10 (0.94–1.29)	0.22
Cardiac	103 (2.6)	98 (3.0)	1.06 (0.80–1.39)	0.70
Vascular	28 (0.7)	23 (0.6)	1.23 (0.71–2.13)	0.47
Noncardiovascular	183 (5.1)	170 (4.7)	1.08 (0.88–1.34)	0.45
Unknown cause	17 (0.4)	11 (0.3)	1.56 (0.73–3.32)	0.25
Total spontaneous acute myocardial infarction	428 (11.4)	470 (12.5)	0.91 (0.80–1.03)	0.14
Nonfatal	356 (9.8)	399 (10.5)	0.89 (0.77–1.02)	0.10
Fatal	72 (1.8)	71 (2.2)	1.01 (0.73–1.40)	0.95
Total periprocedural myocardial infarction	139 (3.4)	168 (3.8)	0.83 (0.66–1.04)	0.10
Nonfatal	137 (3.3)	167 (3.8)	0.82 (0.65–1.03)	0.09
Fatal	2 (<0.1)	1 (<0.1)	1.98 (0.18–21.8)	0.58
Death, nonfatal spontaneous myocardial infarction, or nonfatal periprocedural myocardial infarction related to repeat PCI during follow-up	660 (17.0)	675 (17.5)	0.97 (0.87–1.08)	0.61
Death, nonfatal spontaneous myocardial infarction, or nonfatal periprocedural myocardial infarction related to index PCI or repeat PCI during follow-up	751 (19.0)	785 (19.9)	0.95 (0.86–1.05)	0.30
Stroke	143 (3.4)	117 (3.0)	1.23 (0.97–1.57)	0.09
Nonfatal	122 (2.9)	99 (2.5)	1.24 (0.95–1.62)	0.11
Fatal	21 (0.5)	18 (0.5)	1.18 (0.63–2.21)	0.61
Hospitalization for unstable angina pectoris	216 (5.2)	243 (5.7)	0.89 (0.74–1.07)	0.21
Any revascularization	630 (16.5)	799 (19.8)	0.76 (0.69–0.85)	<0.001
Target-lesion	205 (5.3)	421 (10.3)	0.47 (0.40–0.56)	<0.001
With PCI	178 (4.6)	360 (8.9)	0.48 (0.40–0.58)	<0.001
With CABG	33 (0.8)	72 (1.7)	0.46 (0.30–0.69)	<0.001
Any PCI	567 (14.9)	709 (17.7)	0.78 (0.70–0.87)	<0.001
Any CABG	77 (2.0)	116 (2.8)	0.66 (0.50–0.88)	0.005
Definite stent thrombosis	32 (0.8)	50 (1.2)	0.64 (0.41–1.00)	0.0498
BARC 3, 4, or 5 bleeding	225 (5.5)	229 (5.6)	0.99 (0.82–1.18)	0.88

[a] Hazard ratios and P values were adjusted for the study center in the Cox proportional-hazards model. BARC denotes Bleeding Academic Research Consortium, CABG coronary-artery bypass grafting, and PCI percutaneous coronary intervention.
† The cumulative outcome rates (expressed as percentages) were calculated with the use of the Kaplan–Meier method.
‡ The total number of deaths from any cause is higher than the number of deaths in the composite primary outcome because some patients had a nonfatal spontaneous myocardial infarction before their subsequent death.

Clinical Events during Follow-up and Cumulative Rates at 6 Years.

Figure 2.



Clinical Outcomes.

At 6 years, the rate of the primary composite outcome of death from any cause and nonfatal spontaneous myocardial infarction was 16.6% in the group receiving drug-eluting stents and 17.1% in the group receiving bare-metal stents (hazard ratio, 0.98; 95% CI, 0.88 to 1.09, P=0.66) (Table 2 and Figure 2). There was also no significant between-group difference in the primary outcome after adjustment for baseline imbalances in smoking status, hypertension, history of myocardial infarction, target-lesion type, and total st
(data not shown). The results for the primary outcome were consistent in subgroups defined acc
demographic, clinical, lesion, and procedural characteristics (Fig. S1 in the Supplementary Appe

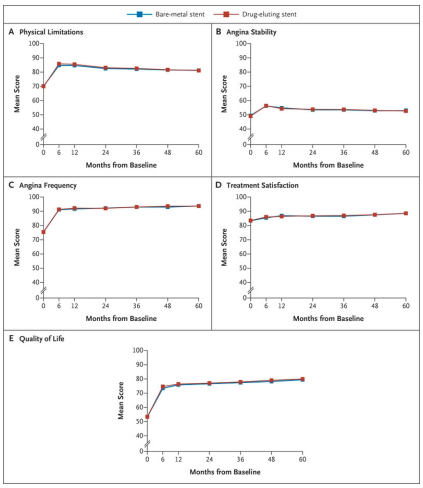
There were no significant between-group differences in the rates of the individual components of the primary outcome. There were no significant differences between the study groups in the rates of death from cardiac, vascular, or noncardiovascular causes, in the rates of stroke (Fig. S2 in the Supplementary Appendix), or in the rates of hospitalization for unstable angina.

At 6 years, the cumulative rate of spontaneous myocardial infarction was 11.4% in the group receiving drug-eluting stents and 12.5% in the group receiving bare-metal stents (hazard ratio, 0.91; 95% CI, 0.80 to 1.03; P=0.14) (Table 2, and Fig. S2 in the Supplementary Appendix). The corresponding event rates for periprocedural myocardial infarction were 3.4% and 3.8%, respectively (hazard ratio, 0.83; 95% CI, 0.66 to 1.04; P=0.10). There were no significant differences between groups in the composite outcomes that

included the primary outcome plus periprocedural myocardial infarction. The 28-day case fatality rate was 16% after spontaneous myocardial infarction, as compared with 1% after periprocedural myocardial infarction.

The 6-year rate of any revascularization was 16.5% in the group receiving drug-eluting stents and 19.8% in the group receiving bare-metal stents, an absolute risk reduction of 3.3 percentage points (hazard ratio, 0.76; 95% CI, 0.69 to 0.85; P<0.001) (Table 2 and Figure 2). On the basis of this result, 30 patients would need to be treated with drug-eluting stents rather than bare-metal stents to prevent one repeat revascularization. The difference in any revascularization between groups was driven by lower rates of target-lesion revascularization in the group receiving drug-eluting stents.

Figure 3.



Mean Scores for Disease-Specific Health Status.

At 6 years, the rates of definite stent thrombosis were low in both groups — 0.8% in the group receiving drug-eluting stents and 1.2% in the group receiving bare-metal stents (P=0.0498); the rates for BARC 3, 4, or 5 bleeding were 5.5% and 5.6%, respectively. Measures of disease-specific health status and qu did not differ significantly between the two groups during follow-up (Figure 3, and Table S2 in the Supplementary Appendix).

Discussion

In NORSTENT, we did not find a significant difference between contemporary drug-eluting stents and bare-metal stents in the rates of death from any cause or nonfatal spontaneous myocardial infarction during 6 years of follow-up. The rate of repeat revascularization was significantly lower in the group receiving drug-eluting stents, which showed the durability of this effect over 6 years. Rates of definitive stent thrombosis were low in both groups and appeared to be lower in the group receiving drug-eluting stents than in the group receiving bare-metal stents (P=0.0498). The type of stent had no significant effect

on quality of life, as assessed by means of the Seattle Angina Questionnaire. We compared the effectiveness of contemporary drug-eluting stents versus bare-metal stents in a broad group of patients that included more than 72% of those who were eligible, and the study was conducted in the setting of real-world patient care, which supports the generalizability of the results.

In the Basel Stent Kosten Effektivitäts–Prospective Validation Examination (BASKET-PROVE) trial[13] involving 2314 patients undergoing PCI, the investigators did not detect a difference between contemporary drug-eluting stents and bare-metal stents in rates of death or myocardial infarction at 2 years of follow-up, although they found a lower rate of target-vessel revascularization in the group receiving drug-eluting stents. Inclusion in that study was restricted to patients requiring larger coronary stents. In the Everolimus-Eluting Stent versus Bare-Metal Stent in ST-Segment Elevation Myocardial Infarction (EXAMINATION) trial[7] involving 1504 patients, second-generation everolimus-eluting stents did not reduce the primary end point of death from any cause, recurrent myocardial infarction, or revascularization at 1 year, but rates of stent thrombosis and target-lesion revascularization were significantly lower in the group receiving drug-eluting stents. At 5 years,[8] the primary end point was significantly lower in patients receiving drug-eluting stents than in those receiving bare-metal stents, a benefit that was driven mainly by a lower rate of noncardiac death, and there was a nonsignificantly lower occurrence of stent thrombosis.

A higher risk of stent thrombosis has been seen in patients receiving first-generation drug-eluting stents than in those receiving bare-metal stents,[4] and the long-term safety of drug-eluting stents has been a concern. NORSTENT contributes to the growing evidence that contemporary drug-eluting stents, as compared with first-generation drug-eluting stents,[4] may have a lower risk of stent thrombosis than bare-metal stents,[5-10] and demonstrates that this effect persists during long-term follow-up. However, the findings of fewer repeat revascularizations and a potentially lower rate of stent thrombosis with drug-eluting stents did not translate into any difference in the primary outcome or in quality of life, findings that may be explained by the low rates of restenosis and stent thrombosis in the two study groups.

Our trial has several limitations. NORSTENT was an open-label trial, although all outcomes were evaluated by an event committee whose members were unaware of study-group assignments. Patients were during the period from 2008 through 2011, but 95% of the patients in the group receiving drug-el stents underwent placement of everolimus-eluting or zotarolimus-eluting stents, which are still commonly used. The quality-of-life data should be interpreted with caution, since the Seattle Angina Questionnaire may not be sensitive enough for evaluation of stent performance. The primary outcome did not include periprocedural myocardial infarction. However, as has been shown in other studies,[2] we found that periprocedural myocardial infarction had less prognostic significance than spontaneous myocardial infarction.

In conclusion, in our evaluation of clinical outcomes in 9013 patients with stable or unstable coronary artery disease, we found no significant difference in the 6-year rates of death or spontaneous myocardial infarction between patients receiving contemporary drug-eluting stents and those receiving bare-metal

stents. There was also no significant between-group difference in quality of life. The rate of repeat revascularization was lower with the use of drug-eluting stents.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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Committees, study centers, and investigators participating in the Norwegian Coronary Stent Trial (NORSTENT) are listed in the Supplementary Appendix, available at NEJM.org.

Supplementary Material

Protocol	PDF	3572KB
Supplementary Appendix	PDF	532KB

Disclosure Forms PDF 356KB

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