Sirolimus-eluting stent treatment for unprotected versus protected left main coronary artery disease in widespread clinical routine: 6-month and 3-year clinical follow-up results from the prospective multicentre German Cypher Registry

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Background: Percutaneous coronary intervention (PCI) of left main coronary artery (LMCA) disease in the bare stent era was limited by high restenosis rates which eventually resulted in sudden death in unprotected cases. Clinical and angiographic restenosis has been substantially reduced by drug-eluting stents, reviving therefore this indication for PCI despite the absence of direct comparative studies with coronary artery bypass graft surgery.

Objective: To assess the acute, mid- and long-term outcomes of patients treated with sirolimus-eluting stents for unprotected LMCA stenoses and to compare them with those treated for protected LMCA disease in the same time period from the German Cypher Registry.

Setting and patients: The German Cypher Registry included 6755 patients. Eighty-two patients treated for unprotected LMCA disease were compared with 118 patients treated for protected LMCA stenoses. All patients were treated by sirolimus-eluting stents. The primary end point was death, myocardial infarction (MI) and target vessel revascularisation at 6 months' follow-up. Survival free of MI at the long term was considered as the safety end point.

Results: One-third of the patients in both groups were treated for the distal left main bifurcation. Angiographic success was 98.5% for both groups. The cumulative combined incidence of all-cause death, non-fatal MI and target vessel revascularisation at 6 months was 14.1% in the unprotected LMCA group and 13.1% in the protected group (hazard ratio=0.81 (95% CI 0.37 to 1.74), $p=0.8$). At long-term, death/MI were reported among 20.2% (95% CI 13.5% to 29.6%) of the protected group versus 11.8% (95% CI 6.3% to 21.4%) of the unprotected group ($p=0.2$).

Conclusion: Sirolimus-eluting stent treatment of unprotected and protected LMCA stenoses is technically feasible in widespread routine clinical use. Acceptable long-term clinical results can be achieved, with no particular safety concerns about treatment of unprotected LMCA disease.

The prevalence of significant involvement of the left main segment in patients with atherosclerotic coronary artery disease varies from 2.5% to 10%.¹ Numerous studies have shown that stenoses of the left main coronary artery (LMCA) are of critical prognostic importance; furthermore, they pose special management problems owing to the extensive myocardial territory at risk during revascularisation procedures.² The benefit of surgical treatment has been proved. This benefit has been shown in the Coronary Artery Surgery Study (CASS) to persist at long term, with a median survival in the surgical group of 13.3 years against 6.6 years in the medically treated group.^{2,3}

Since the introduction of percutaneous coronary intervention (PCI), interventions of the LMCA have been an attractive target. The initial acute emergencies of dissection with abrupt vessel closure have been overcome by the introduction of coronary stents, yet the high restenosis rates remain a major problem when bare metal stents (BMS) are used in this location, which may even result in sudden cardiac death, especially in unprotected cases.

Drug-eluting stents (DES) have reduced the incidence of restenosis in randomised trials and prospective registries to <10% across a wide spectrum of clinical and angiographic

subsets.⁴ Ever since, several studies started to examine their safety and effectiveness for LMCA disease. The limited patient numbers and the mixed results of these studies,^{5–9} however, have not allowed a conclusion to be reached.

No comparative studies of patients with unprotected and protected LMCA disease have been conducted; and no data from widespread clinical practice have been reported.

We therefore provide further insight into this crucial issue by comparing the results of sirolimus-eluting stent (SES) treatment of patients from the prospective multicentre German Cypher Registry with unprotected and protected LMCA disease.

METHODS

Design and population

The German Cypher Stent Registry is a project of the "Deutsche Gesellschaft für Kardiologie" (DGK, German Cardiac Society), the "Bund der Niedergelassenen Kardiologen" (BNK,

Abbreviations: BMS, bare metal stents; CABG, coronary artery bypass graft; DES, drug-eluting stents; HR, hazard ratio; LMCA, left main coronary artery; MI, myocardial infarction; PCI, percutaneous coronary intervention; SES, sirolimus-eluting stent; STEMI, ST-elevation myocardial infarction; TLR, target lesion revascularisation; TVR, target vessel revascularisation

Table 1 Baseline characteristics of patients treated for protected and unprotected LMCA disease using SES

Characteristics	Protected LMCA (n = 118)	Unprotected LMCA (n = 82)	p Value
Male (%)	76.3	72.8	0.6
Age (years), median	66.7	69.5	0.3
Diabetes mellitus (%)	34.7	22.8	0.07
Renal insufficiency (%)	15.4	13.8	0.8
BMI (kg/m ²), median	27	25	0.003
Hypertension (%)	86.2	84.6	0.8
Hypercholesterolaemia (%)	94	81.8	0.008
Current smoking (%)	15.6	23.9	0.2
Previous MI (%)	42.2	22.8	0.006
Left ventricular EF ≤ 40 (%)	25.6	29.4	0.6
STEMI (%)	4.2	8.6	0.2
NSTEMI (%)	10.2	18	0.09
Unstable angina pectoris (%)	22	21	0.9
Cardiogenic shock (%)	0.8	2.5	0.4

BMI, body mass index; EF, ejection fraction; LMCA, left main coronary artery; MI, myocardial infarction; NSTEMI, non-ST-elevation myocardial infarction; STEMI, ST-elevation myocardial infarction.

Association of out-of-hospital cardiologists) and the "Arbeitsgemeinschaft Leitende Kardiologische Krankenhausärzte" (ALKK, Working Group of hospital cardiologists). It is sponsored by Cordis Corporation, a Johnson & Johnson company. Details of the registry have been given elsewhere.^{10, 11}

In brief, the aim of this prospective multicentre registry was to monitor current use and outcome of the SES in daily clinical practice and to evaluate safety, effectiveness and socioeconomic data.

Inclusion started simultaneously with the launch of the Sirolimus-Eluting Cypher Stent (Cordis, Johnson & Johnson, Miami, Florida, USA) in Germany on 14 April 2002, and recruitment from the scientific database of the Cypher Registry was closed on 31 December 2004. Case report forms were collected through the internet, with description of the target lesion and interventional characteristics given by the implanting physician. Clinical and angiographic inclusion and exclusion criteria were not specified before enrolment. The

Table 2 Angiographic and procedural characteristics of lesions treated with a sirolimus-eluting stent for protected and unprotected left main coronary artery disease

Characteristics	Protected LMCA (n = 118)	Unprotected LMCA (n = 82)	p Value
Ostial (%)	54.2	38.8	0.03
Mid-stem (%)	12.7	27.4	0.01
Distal (%)	33.1	33.8	0.9
Distal stent technique (%):			
Two stents	30.7	18.5	0.4
Single stent	69.3	81.5	
In-stent restenosis (%)	15.3	0	0.01
Direct stenting (%)	27.1	45	0.009
Visual thrombi (%)	2.5	6.3	0.2
Percentage diameter stenosis, median	87.5 (75–90)	80 (75–90)	0.01
High pressure inflation ≥ 16 atm (%)	61.2	54.8	0.34
Stent diameter ≤ 2.75 mm (%)	18.6	9.3	0.06
Stent diameter = 3.0 mm (%)	49.6	41.9	0.2
Stent diameter = 3.5 mm (%)	31	48.8	0.008
Use of GP IIb/IIIa antagonists (%)	15.3	21.8	0.2
Angiographic success (%)	98.3	98.7	0.8

antithrombotic regimen, especially the use of glycoprotein IIb/IIIa antagonists, was left to the physician's discretion. All patients were advised to maintain a combined antiplatelet treatment of aspirin (100 mg) and clopidogrel (75 mg) daily for at least 2 months, and then to continue indefinitely with aspirin monotherapy.

The German Cypher Registry included 6755 patients in the above-mentioned time period. The study group comprised 200 patients treated for LMCA stenoses (82 unprotected vs 118 protected) using an SES and who had completed the follow-up. Protected LMCA was defined as LMCA disease bypassed by at least one functioning arterial or venous graft on one of its major branches. Long lesions starting within and extending beyond the LMCA were also included in the study. Angiographic success was defined as residual stenosis <20% by visual estimation in the presence of TIMI 3 flow.

Follow-up

Follow-up was carried out at a median of 6.6 (quartiles 6.1–8.1) months. A second follow-up was at a median of 32.2 (quartiles 27.5–41.1) months after implantation of the SES. The follow-up was performed either by the data centre in Ludwigshafen or by the treating hospital. All patients were contacted by telephone. All events were verified by hospital charts or by direct contact with the treating physician. If patients could not be reached, the "Einwohnermeldeamt" (local government registration office) was contacted to document deaths.

Monitoring and quality assurance

A query management system was established for missing or implausible data. Announced source data verification was performed at 15 hospitals selected randomly, with comparison of the documented data with the hospital charts.

An independent physician reviewed all adverse events observed during the inhospital and long-term follow-ups.

End points and definitions

Target vessel revascularisation (TVR) was defined as either PCI or coronary artery bypass graft (CABG) of the initially treated coronary vessel. Myocardial infarction (MI) was defined as either ST-elevation myocardial infarction (STEMI) or non-ST-elevation myocardial infarction (NSTEMI). The final diagnosis was left to the treating physician. Angiographic follow-up was optional.

The primary end point for this analysis was the occurrence of death (all cause), non-fatal MI or TVR (clinically and non-clinically driven) during the time frame from stent implantation until the 6-month follow-up. A safety end point, defined as the occurrence of death or MI, or both, up to the end of the second (long-term) follow-up, was set. Only patients treated with at least one SES were included in the current analysis.

Role of the funding source

The design of the German Cypher Stent Registry as well as the collection, analysis and interpretation of the data were all independent of Cordis Corporation, a Johnson & Johnson company, who supported the study by an unrestricted grant.

Statistics

Data collection

Data were collected through the internet by the "Institut für Klinische Kardiologische Forschung" (IKKF, Institute for Clinical Research of the German Cardiac Society). The registry was approved by the research and ethics committee at the institutions involved and the patients gave written informed consent for processing of their anonymous data at the "Institut für Herzinfarktforschung", Heart Centre Ludwigshafen.

Figure 1 Survival free of myocardial infarction and target vessel revascularisation at the 6-month follow-up in patients treated for protected (n = 118) and unprotected (n = 82) left main coronary artery disease using sirolimus-eluting stent.

Data analysis

Absolute numbers and percentages were computed to describe the patient group. Medians (with quartiles) or means (with standard deviation) were computed as appropriate. Categorical values were compared by χ^2 test and continuous variables were compared by two-tailed Wilcoxon rank sum test. Values of $p < 0.05$ were considered significant. All p values are results of two-tailed tests. Kaplan–Meier curves were calculated for death, MI or TVR during follow-up. A logistic regression model was used to analyse factors which were independently associated with the combined end point, death or TVR. Tests were performed using the SAS statistical package, version 8.2 (Cary, North Carolina, USA).

RESULTS

Tables 1 and 2 show the baseline clinical and procedural characteristics of the study group. The group of patients with protected LMCA had, in general, more advanced coronary artery disease than the unprotected group: there were significantly more obese patients (median body mass index 27 vs 25 kg/m² respectively, $p = 0.003$), more hyperlipidaemic patients (94% vs 82%, $p = 0.008$), more patients with previous MI (42% vs 23%, $p = 0.006$), more patients with additional multivessel disease (99.2% vs 93.8%, $p = 0.03$), 15.3% versus 0% ($p = 0.01$) were treated for in-stent restenosis and the stenoses were more severe (median percent diameter stenosis 87.5% vs 80%, $p = 0.01$). About 40% of patients in both groups presented with an acute coronary syndrome, 30% were diabetic and 27% of the patients had a left ventricular ejection fraction $\leq 40\%$. One-third of the lesions in both groups (n = 66) were located in

Table 3 Clinical adverse events at 6-month follow-up in patients treated with SES for protected and unprotected LMCA disease

Adverse events	Protected LMCA (n = 118)	Unprotected LMCA (n = 82)	p Value
All-cause death (%)	3.4	7.4	0.2
Myocardial infarction (%)	0.9	0	1.0
TVR (%)	8.8	6.7	0.6
All revascularisations (%)	12.2	10.7	0.8
PCI (%)	11.1	9.0	0.6
CABG (%)	0.9	1.3	0.8
Stroke (%)	1.8	0	0.8
Death/MI/stroke (%)	5.9	7.4	0.7
Death/MI/TVR (%)	13.1	14.1	0.8

CABG, coronary artery bypass graft; LMCA, left main coronary artery; MI, myocardial infarction; PCI, percutaneous coronary intervention; SES, sirolimus-eluting stent; TVR, target vessel revascularisation.

Table 4 Causes of death at 6-month follow-up among 200 patients treated for left main coronary artery disease using sirolimus-eluting stent

Deaths	Protected LMCA (n = 4/118)	Unprotected LMCA (n = 6/82)
In hospital	0	3*
After discharge		
Sudden cardiac death	2	2
Non-sudden cardiac death	2	0
Non-cardiac	0	0
Unknown	0	1

*All had ST-elevation myocardial infarction and two were in cardiogenic shock at presentation.

the distal bifurcation. Angiographic success was about 98.5% for both groups.

Three patients admitted with STEMI in the unprotected group died during initial hospitalisation, two of whom were in cardiogenic shock at presentation, a fourth patient was subjected to CABG for TVR, whereas in the protected group the only adverse event during initial hospitalisation was a new non-fatal MI (4.9% versus 0.8% respectively, $p = 0.07$).

Follow-up results

Six-month follow-up

Follow-up was complete for 99% of patients in both groups. The cumulative combined incidence of all-cause death, non-fatal MI and TVR (primary end point) was 14.1% in the unprotected LMCA group and 13.1% in the protected group (hazard ratio (HR) = 0.81 (95% CI 0.37 to 1.74), $p = 0.8$) as shown in the Kaplan–Meier curve (fig 1). TVR (clinically and non-clinically driven) was carried out in 6.7% of the unprotected group and 8.8% of the protected group (HR = 1.35 (95% CI 0.44 to 4.11), $p = 0.6$), while all-cause mortality was reported among 7.4% of the unprotected group and 3.4% of the protected group (HR = 0.44 (95% CI 0.12 to 1.61), $p = 0.2$). Table 3 shows the major adverse clinical events and table 4 lists the mortality causes at 6 months.

Table 5 shows clinical, angiographic, and procedural predictors of death, MI or TVR after SES among all patients with LMCA disease.

Long-term follow-up

Follow-up was done at a median of 32.2 (quartiles 27.5–41.1) months after the implantation of the SES. This was completed for 85% of patients in both groups. Cumulative all-cause mortality rate was 19% versus 14.5% ($p = 0.5$), while cumulative MI rate was 7.8% versus 0% ($p = 0.03$) in the protected and unprotected groups, respectively. Death/MI were reported

Table 5 Baseline clinical, angiographic and procedural univariate predictors of death, MI and TVR after SES among patients with LMCA disease (n = 200)

Predictors	OR (95% CI)	p Value
Female	2.44 (1.01 to 5.89)	0.044
Diabetes mellitus*	2.41 (0.99 to 5.82)	0.046
Renal insufficiency*	3.62 (1.38 to 9.49)	0.006
STEMI	6.35 (1.84 to 21.9)	0.001
Cardiogenic shock	15.91 (1.39 to 182.7)	0.003
LV ejection fraction $\leq 40\%$	3.33 (1.01 to 11.1)	0.038
No statin intake at initial discharge	3.57 (1.01 to 12.5)	0.037

LMCA, left main coronary artery; LV, left ventricular; MI, myocardial infarction; SES, sirolimus-eluting stent; ST-elevation myocardial infarction (STEMI), TVR, target vessel revascularisation.

*Independent predictors ($p < 0.05$) in the multiple logistic regression model.

Table 6 Cumulative clinical adverse events at long-term follow-up in patients treated with SES for protected and unprotected LMCA disease

Adverse events	Protected LMCA (n = 95)	Unprotected LMCA (n = 64)	p Value
All cause death (%)	19.0	14.5	0.5
Myocardial infarction (%)	7.8	0	0.03
All revascularisations (%)	20.8	18.6	0.8
PCI (%)	20.8	15.3	0.1
CABG (%)	1.3	5.1	0.2
Stroke (%)	7.8	3.4	0.3
Death/MI/stroke (%)	24.6	14.8	0.1
Death/MI/revasc (%)	33.9	25.9	0.2

CABG, coronary artery bypass graft; LMCA, left main coronary artery; MI, myocardial infarction; PCI, percutaneous coronary intervention; SES, sirolimus-eluting stent.

among 20.2% (95% CI 13.5% to 29.6%) of the protected group versus 11.8% (95% CI 6.3% to 21.4%) of the unprotected group ($p = 0.2$). Table 6 and fig 2 show the results of the long-term follow-up. Table 7 shows the drugs taken by the patients in both groups at the end of follow-up.

Antiplatelet treatment

In the protected group 94.1% were pretreated with aspirin compared with 100% in the unprotected group ($p = \text{NS}$). Clopidogrel pretreatment was received by 90.7% of the protected group versus 79.5% of the unprotected group ($p = 0.03$). Glycoprotein IIb/IIIa antagonists were administered in 15.3% of the protected group procedures and in 21.8% of the unprotected group procedures ($p = \text{NS}$). At the 6-month follow-up 32.4% were receiving dual antiplatelet treatment (aspirin and clopidogrel) in the protected group and 40.3% in the unprotected group ($p = \text{NS}$). The median duration for dual antiplatelet treatment was 26 (8–26) weeks and 24 (12–26) weeks in the protected and unprotected groups, respectively ($p = \text{NS}$). At long-term follow-up none of the unprotected group were receiving dual antiplatelet treatment while 13% of the protected group were continuing to receive it ($p = 0.02$).

DISCUSSION

A few single-centre registries conducted at highly experienced tertiary interventional sites have reported favourable acute and mid-term results for DES treatment of patients with unprotected LMCA disease as compared with historical controls using BMS.^{5–7} This was mainly owing to a significant reduction in the need for target lesion revascularisation (TLR) among patients treated with DES. Mortality rates between 0% and 11% were seen at 12 months' follow-up in the DES groups, without significant difference from the BMS controls, although Chieffo

Figure 2 Survival free of myocardial infarction at long-term follow-up in patients treated for protected (n = 95) and unprotected (n = 64) left main coronary artery disease using a sirolimus-eluting stent.**Table 7** Drugs used by patients treated for protected (n = 95) and unprotected (n = 64) left main coronary artery (LMCA) disease at the end of long-term follow-up

Drugs	Protected LMCA (n = 95)	Unprotected LMCA (n = 64)	p Value
Aspirin (%)	76	78	NS
Clopidogrel (%)	37	22	NS
Oral anticoagulants (%)	13	12	NS
β Blockers (%)	87	79	NS
ACE inhibitors (%)	73	62	NS
Statins (%)	84	78	NS
Calcium antagonists (%)	21	17	NS

et al reported fewer cardiac deaths among their DES group than among the BMS group (3.5% vs 9.3% respectively, $p = 0.17$).⁶ Unrecognised and therefore untreated restenosis of the LMCA may present as sudden cardiac death.

We present 3-year follow-up results of SES treatment for LMCA disease in a widespread everyday clinical practice from a multicentre all-comer registry analysis. We report similar favourable acute and mid-term results as in the published single-centre experiences. We did not compare our cohort with a historical control treated by BMS, because it has become obvious from previous studies^{5–7} that when PCI is undertaken at the left main stem, routine implantation of DES should currently be the preferred strategy. Instead, we compared two groups of patients treated for LMCA disease both using SES, one of which had at least one functioning graft on the left coronary artery (protected LMCA), which therefore reduces the amount of jeopardised myocardium in cases of acute or late stent failure as compared with the unprotected LMCA group. The protected group had several significantly different baseline clinical and angiographic characteristics, yet we found no statistically significant difference between the two groups for the primary end point (death, MI and TVR at 6 months). The initially higher death rate reported in the unprotected group after 6 months fell below that of the protected group at long term. Further, significantly more MIs developed in the protected group up to the long term follow-up despite the significantly longer duration of dual antiplatelet treatment in this group. Recent guidelines⁴ recommend elective coronary angiography at 3 and 9 months for patients subjected to stent treatment of unprotected LMCA disease to allow early detection and hence treatment of significant restenoses, a strategy which may reduce sudden deaths.

TLR rates after SES implantation for unprotected LMCA disease varied in previous studies between 2% and 38% at follow-up,^{5–9} with the vast majority of TLR procedures done for distal lesions. In comparison with these studies where at least 60% of the cases were treated for distal disease and mainly with a two-stent technique, in our series only 33.8% of the patients in the unprotected group were treated for distal disease and, of these, 81.5% were treated with a single-stent technique. This conservative approach makes it clear that distal lesions warranting a two-stent approach (dominant circumflex artery with significant ostial disease) are still considered a common indication for surgery by many interventional cardiologists in the everyday practice.

In the Unprotected Left Main Trunk Intervention Multicentre Assessment (ULTIMA) registry¹² conducted in the pre-DES era, the in-hospital and 1-year mortality were as high as 78% in patients with poor left ventricular function and acute coronary syndromes and as low as 3.4% in patients without such high risk markers. In our analysis we also found that STEMI,

cardiogenic shock and left ventricular ejection fraction $\leq 40\%$ (among other factors) are predictors of death, MI and TVR after SES treatment for patients with LMCA disease.

CONCLUSIONS AND LIMITATIONS

In our multicentre experience, SES treatment of unprotected and protected LMCA stenoses is technically feasible; it seems that many interventional cardiologists still avoid the broad elective use of DES in everyday practice for distal lesions, especially those necessitating a two-stent approach. Acceptable long-term clinical results can be achieved with no particular safety concerns about SES treatment for unprotected LMCA disease. Adverse events can be predicted, in part, by known clinical risk factors. This analysis has all the shortcomings of a registry, yet its value lies in its long-term follow-up. The results of a randomised trial with CABG are indispensable to clarify the equivalence of left main DES treatment.

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Conflict of interest: None. Mr Pfannebecker is an employee of Cordis, Germany.

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APPENDIX: ORGANISATION OF THE GERMAN CYPHER STENT REGISTRY

Members of the Steering Committee: Christian W Hamm (chairman), Tassilo Bonzel, Malte Kelm, Benny Levenson, Christoph A Nienaber, Gert Richardt, Georg Sabin, Jochen Senges, Ulrich Tebbe, Thomas Pfannebecker (Cordis), Wolfgang Witsch (Cordis).

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Study coordination: Thomas Fetsch.

The participating centres are reported elsewhere.⁶

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