Herz 2013 · 38:57–64
DOI 10.1007/s00059-012-3581-5
Received: 12 August 2011
Revised: 21 December 2011
Accepted: 24 December 2011
Published online: 2 February 2012

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Health economic evaluation of the use of drug-eluting stents

First results from the Drug-Eluting Stent Registry (DES.de)

Background

Drug-eluting stents (DES) have demonstrated efficacy in reducing reintervention rates following stent implantation in numerous randomised controlled trials [1, 2, 3, 4, 5, 6, 7, 8, 9, 10]. However, effectiveness in real world settings may differ from that in clinical trials, with a different case mix and protocol-driven follow-up procedures, leading to different reintervention rates compared to the clinical trial settings. Generalisability of findings observed within the context of controlled clinical settings and selected patient populations therefore requires close attention. Inevitably, differences between effectiveness in real world settings and efficacy in controlled clinical circumstances will also translate into different estimates regarding the economic consequences of DES. A recent health-technology assessment has suggested that DES might not be cost-effective based on real world evaluations conducted in some industrialised countries [11]. However, for many countries including Germany, no appropriate economic evaluations have been performed.

The German Drug-Eluting Stent registry (DES.de) was initiated to investigate the impact of DES in a real world setting within the German health care system. As part of phase I of this registry study, the economic evaluation of the DES.de registry was conducted to investigate whether the additional costs of DES may be offset by reduced follow-up burden due to fewer reinterventions for restenosis.

Specifically, the aim of this economic evaluation was to investigate the economic impact and the cost effectiveness of DES as compared to BMS within Germany. These first results compare demographic, procedural and in-hospital follow-up data between patients who received either DES or BMS, and among DES patients, between those receiving the paclitaxel-eluting (PES) Taxus or the sirolimus-eluting (SES) Cypher stents.

Methods

The present health economic evaluation was conducted as part of phase I of the DES.de registry, which enrolled participants from October 2005 to October 2006. Details of the clinical study design and methodology have been presented in detail elsewhere [12].

Briefly, eligible patients of this economic evaluation were recruited between December 2005 and October 2006 in 87 study centres across Germany. Patients receiving one of the FDA-approved DES, Taxus™ or Cypher™ or certified BMS were eligible. Procedural decisions and DES selection was at the discretion of the attending cardiologist. According to study protocol it was intended to include at least 1,000 Taxus, 1,000 Cypher and 500 BMS patients in participating German sites with access to both DES. According to the primary objective patients are here grouped as DES or BMS depending on the stents implanted. For the purpose of the present analyses, all patients with planned BMS implantation who received a BMS and no other stent were grouped as BMS. Patients with planned DES implantation were grouped as DES regardless of other stent types implanted. Patients who underwent the procedure without subsequent stent implantation were grouped as planned. To reduce baseline differences systematically favouring DES or BMS groups and reduce the risk of bias and confounding, BMS patients were allocated based on at least one of the following inclusion criteria: diabetes mellitus (DM), acute coronary syndrome (ACS), previous PCI or coronary artery bypass graft (CABG) and/or previously diagnosed coronary three-vessel disease.

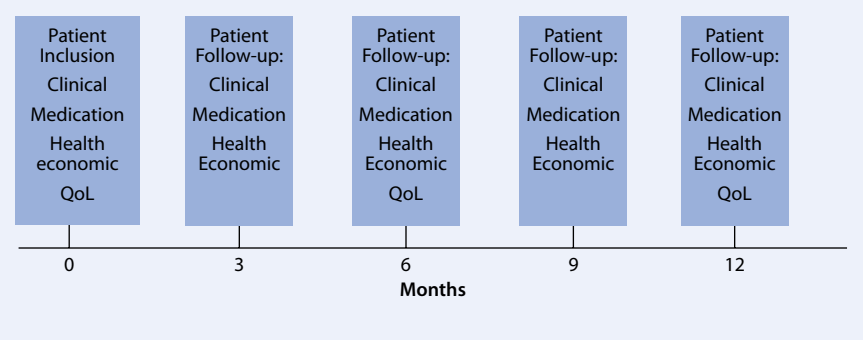

Fig. 1 ▲ Follow-up schedule and type of data collected at specific time points. *QoL* quality of life

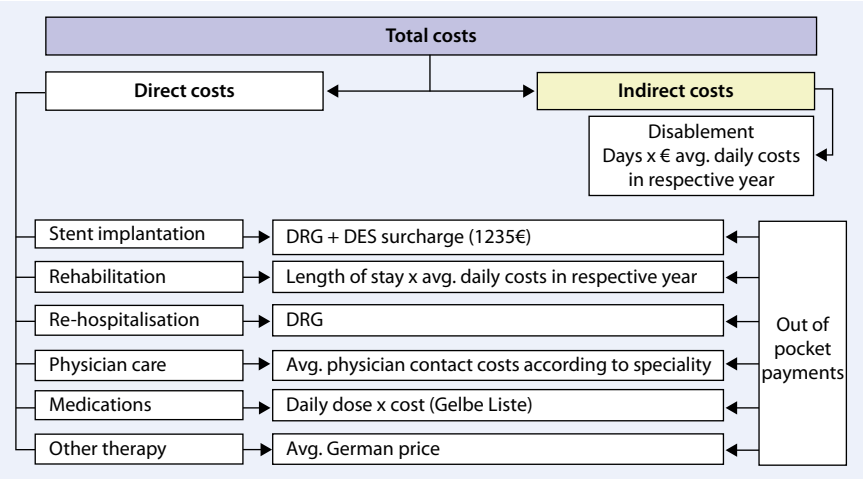

Fig. 2 ▲ Summary of cost determination and valuation of consumed resources according to type of investigated costs. *DRG* diagnosis-related groups, *DES* drug-eluting stent

Clinical assessments and follow-up

Baseline and in-hospital clinical and stenosis-related data were documented by the attending physician and collected through an internet platform. In addition, quality of life (QoL) data were collected from a subsample of patients prior to stent implantation using the SF-36 and the cardiac specific MacNew QoL questionnaire [13, 14, 15, 16]. Following index stent implantation, patients were followed by means of standardised questionnaires at 3, 6, 9 and 12 months to determine clinical events and clinical status, health economic parameters and QoL (**Fig. 1**). If questionnaires were not returned, patients were contacted by telephone to obtain essential clinical data. All possibly relevant events reported by patients through questionnaires or telephone contact were followed up further and adjudicated by independent Critical Event Committees (CEC) using hospital and angiography protocols. A query management system was implemented in order to ensure a high degree of data quality and completeness of patient questionnaires.

Major adverse cardiac and cerebrovascular events (MACCE) were defined as the composite of death, myocardial infarction (MI) and stroke. Target vessel revascularisation (TVR) was defined as repeat procedure, CABG or re-PCI of the target vessel. All re-interventions can be considered clinically driven as routine follow-up angiography was not intended. Stent thrombosis was classified as definitive, probable and possible according to definitions proposed by the Academic Research Consortium (ARC) [17]. Detailed descriptions of definitions used in the DES.de registry have been presented elsewhere [12].

Cost determination

The economic evaluation is primarily conducted from a societal perspective regarding cardiac specific costs. In patients treated in hospitals, costs of the index procedure and hospitalisation were determined according to diagnosis-related groups (DRGs) considering the year 2006 and the state in which the centre is located [18]. Costs of index procedures performed in private practices were determined according to the German reimbursement catalogue for physicians in private practice ("Einheitlicher Bewertungs-Massstab", EBM) of the year 2006 [19]. In addition, all DES implantations require a specific surcharge. Based on a sample of more than 100 German centres, estimated average 2006 surcharges were 1,235 € per implanted DES, which was considered on top of the DRG or EBM costs. In contrast, the costs for BMS are included in DRG and EBM reimbursement systems.

Information on resource consumption during follow-up was obtained through comprehensive patient questionnaires after 3, 6, 9 and 12 months. These questionnaires collected the amount of consumed resources related to direct and indirect costs. Direct costs included outpatient physician visits according to specialty, cardiac specific re-hospitalisations, repeat interventions, cardiac-related emergency physician contacts (e.g. emergency department, ambulance), cardiac procedures (e.g. echocardiograph, 24-h ECG), cardiac rehabilitations, cardiac medications, nursing, health remedies and adjuvants, physical therapy and out-of-pocket payments. To determine indirect costs the human capital approach for lost productivity due to cardiac-related illness or early retirement within the study period was applied. Patient questionnaires identified the type and number of relevant resources consumed. Costs for hospitalisations during follow-up and re-interventions will be allocated in the same way as baseline procedural costs. Other resources will be valued as presented in **Fig. 2**.

Because these first results relate to initial hospitalisation and index event main part of costs in this primary analysis are related to 2006 values and costs were not discounted.

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Health economic evaluation of the use of drug-eluting stents. First results from the Drug-Eluting Stent Registry (DES.de)

Abstract

Objective. The purpose of the economic evaluation of the German Drug-Eluting Stent (DES) registry includes the investigation of the economic impact and cost-effectiveness of DES compared to bare-metal stents (BMS) and between paclitaxel-eluting (PES) and sirolimus-eluting stents (SES). Here, methodology and initial results are presented.

Methods. Patients were recruited in 2005 and 2006 in 87 centres across Germany. Selection of PES, SES, or BMS was made at the discretion of the cardiologists in charge. Clinical, economic, and quality of life (QoL) data were collected at baseline and up to 12 months. Group comparisons were conducted using Fisher's exact and t test.

Results. Overall, 3,930 patients were enrolled: 3,471 (75% male, 65 ± 11 years) received DES and 458 (74% male, 67 ± 11 years) BMS. Among the DES patients, 1,821 received PES (75% male, 65 ± 10 years) and 1,600 SES (76% male, 65 ± 11 years). There were baseline differences in clinical and procedural characteristics but not in QoL. During the hospital stay, major adverse cardiac and cerebrovascular events occurred in 1.6% of DES (PES 1.9%, SES 1.1%) and 2.2% of BMS patients (BMS vs. DES, PES, and SES p = 0.327, 0.706, and 0.098, respectively). Hospital treatment costs were 4,989 ± 1,284 € and 3,609 ± 924 €, respectively, in DES and BMS patients (p < 0.001) with no significant difference between PES and SES.

Conclusion. The economic evaluation of the large DES registry demonstrates increased initial hospitalisation costs associated with DES compared to BMS. Further analysis of the economic impact and cost-effectiveness of DES will provide estimates on large "real world" patient populations for decision makers and aid in reimbursement decisions of DES within the German and other health care systems.

Keywords

Coronary disease · Stents · Economics, medical · Quality of life · Cost effectiveness

Gesundheitsökonomische Evalution von medikamentenfreisetzenden Stents. Baseline-Ergebnisse des deutschen Drug-Eluting-Stent-Registers (DES.de)

Zusammenfassung

Zielsetzung. Die gesundheitsökonomische Evaluation des deutschen Drug-Eluting-Stent (DES)-Registers untersucht die wirtschaftlichen Auswirkungen und die Kosteneffektivität von DES im Vergleich zu Bare-Metal-Stents (BMS) sowie von Paclitaxelfreisetzenden (PES) im Vergleich zu Sirolimusfreisetzenden Stents (SES). Ziel der vorliegenden Analyse ist die detaillierte Darstellung von Methoden und Baseline-Ergebnissen des gesundheitsökonomischen Teilprojekts von DES.de.

Methoden. Patienten wurden in den Jahren 2005 und 2006 in 87 Zentren in Deutschland rekrutiert. Die Wahl der Implantation von PES, SES oder BMS lag im Ermessen des verantwortlichen Kardiologen. Klinische, gesundheitsökonomische und Lebensqualitätsdaten wurden zu Studienbeginn sowie 3, 6, 9 und 12 Monate nach Stent-Implantation erhoben. Der Vergleich der Behandlungsgruppen bezüglich untersuchter Outcomes erfolgte unter Verwendung des Fisher-Exact- und des t-Tests.

Ergebnisse. Insgesamt wurden 3930 Patienten in die gesundheitsökonomische Evaluation von DES.de eingeschlossen. Bei 3471 Patienten (75% männlich, 65±11 Jahre) wurde ein DES und bei 458 Patienten (74% männlich, 67±11 Jahre) ein BMS implantiert. Bezogen auf DES-Patienten wurden 1821 mit PES (75% männlich, 65±10 Jahre) und 1600 mit SES (76% männlich, 65±11 Jahre) behandelt. Zu Studienbeginn wurden Unterschiede zwischen den Gruppen hinsichtlich klinischer und prozeduraler Eigenschaften, nicht aber hinsichtlich der Lebensqualität beobachtet. MACCE („major adverse cardiac and cerebrovascular events") traten im Verlauf des initialen Krankenhausaufenthalts bei 1,6% der DES- (PES: 1,9%, SES: 1,1%) bzw. 2,2% der BMS-Patienten auf. Die Unterschiede zwischen BMS und DES, PES und SES waren statistisch nicht signifikant (p=0,327/0,706/0,098). Die initialen Behandlungskosten betrugen 4989±1284 Euro und 3609±924 Euro für DES- bzw. BMS-Patienten (p<0,001), wobei kein signifikanter Unterschied zwischen PES- und SES-Patienten bestand.

Schlussfolgerungen. Die gesundheitsökonomische Evaluation von DES.de stellt eine der größten Untersuchungen der wirtschaftlichen Auswirkungen und der Kosteneffektivität von DES dar. Die bisherigen Ergebnisse machen die stark erhöhten anfänglichen Behandlungskosten durch DES deutlich. Follow-up-Ergebnisse werden für Entscheidungsträger wichtige Hinweise hinsichtlich der ökonomischen Auswirkungen und der Kosteneffektivität von DES im deutschen und in anderen Gesundheitssystemen liefern.

Schlüsselwörter

Koronare Herzkrankheit · Stent · Gesundheitsökonomie · Lebensqualität · Kosteneffektivität

Statistical analysis

The primary analysis includes all enrolled patients. Baseline characteristics of included patients are presented by group (DES or BMS, PES or SES) as mean and standard deviation (SD) (continuous variables) and percent (categorical variables). Between group differences of baseline characteristics were tested by the Fisher exact test (categorical variables) and t test (continuous variables). In-hospital follow-up, medication at discharge, as well as baseline health economic and QoL data and presented group comparisons are analysed and presented in the same way. A two-sided p value < 0.05 was considered statistically significant. Data analyses were conducted with PASW 18.0 for Windows.

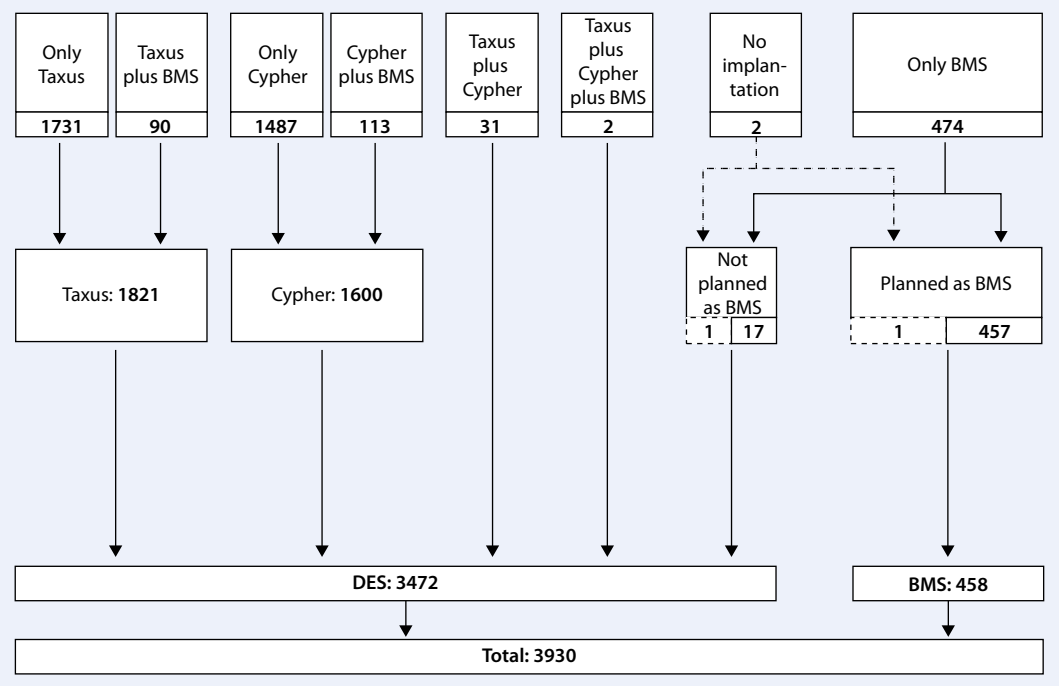

Fig. 3 ◀ Number of patients with implanted stent types or combinations of stent types and their group allocations

Results

Study participants

During the recruitment period between December 2005 and October 2006 a total of 3,930 patients were enrolled in the economic evaluation of DES.de. With 87 sites in different states across Germany enrolling patients, the average recruitment per site was 45 patients. Among all patients 3,472 and 458 were defined as DES or BMS, respectively. The distribution of stents in included patients and their group allocations in detail are illustrated in **Fig. 3**.

Baseline characteristics

The sociodemographic and cardiovascular characteristics of included patients separately for groups of DES and BMS, and within the DES group, for Taxus and Cypher patients are presented in **Tab. 1**. With regard to the comparison between DES and BMS patients, some significant baseline differences between both groups were observed as expected with a registry design. While patients in the BMS group were older than DES patients, they had a lower family history of coronary heart disease (CHD). Regarding modifiable cardiovascular risk factors DES patients indicated to have smoked more commonly in the past and had a higher prevalence of hypercholesterolaemia. In addition **Tab. 1** shows that previous MI and PCI were more frequently seen among DES patients. In contrast, MI, three-vessel disease, elevated cardiac markers and ejection fraction of less than 30% were more frequently reported in BMS patients. Stent- and stenosis-related characteristics were also not evenly distributed. TIMI 3 stenoses were observed more frequently in DES patients. While the average number of stents was identical in both groups, the average stent length was greater and stent diameter was smaller in DES patients (**Tab. 1**).

When comparing patients within the DES group according to implantation of Taxus or Cypher, less substantial differences were noted (**Tab. 1**). Nevertheless, statistically significant differences were observed concerning BMI, previous history of smoking, family history of coronary heart disease, diabetes, ejection fraction, STEMI, NSTEMI, IAP, elevated cardiac markers, in-stent restenosis and bifurcation lesions.

QoL prior to stent implantation was available on a subsample of patients (n = 1,617). No significant baseline differences with regard to the SF-36 or the MacNew QoL questionnaire were found when comparing DES to BMS or Taxus to Cypher patients (**Tab. 1**).

In-hospital follow-up

In-hospital events according to their assigned group are presented in **Tab. 2**. MACCE occurred in 1.6% of DES (Taxus 1.9%, Cypher 1.1%) and 2.2% of BMS patients, respectively. The difference in MACCE between BMS and DES, BMS and Taxus, or BMS and Cypher was not statistically significant (BMS vs. DES, Taxus, and Cypher: $p = 0.327$; $p = 0.706$, $p = 0.098$). Apart from these findings, univariate analyses indicated some significant differences between DES and BMS, as well as between Taxus and Cypher groups. In general, the number of events was low in all groups and no differences in renal failure and bleeding complications were noted between groups.

Medication at discharge

Medication at discharge included aspirin in 98%, clopidogrel in 99%, dual antiplatelet therapy in 98%, combination with oral anticoagulation in 3%, β-blocking agents in 90%, ACE inhibitors or AT-1 blocking agents in 86%, statins in 90% and calcium antagonists in 14% of the patients (**Tab. 3**). No significant differenc-

Tab. 1 **Main baseline characteristics of study participants according to groups of DES, BMS, Taxus, and Cypher**

	DES combined n = 3,472	BMS n = 458	p value (DES vs. BMS)	Taxus n = 1,821	Cypher n = 1,600	p value (Taxus vs. Cypher)
Male (%)	75.1	74.2	0.688	74.5	76.1	0.284
Age, years (mean ± SD)	65.1 ± 10.5	67.2 ± 11.1	< 0.001	65.2 ± 10.4	64.9 ± 10.6	0.407
BMI (mean ± SD)	28.0 ± 4.2	27.9 ± 4.3	0.658	28.2 ± 4.4	27.8 ± 4.0	0.008
Current smoking (%)	22.3	25.7	0.126	21.5	23.1	0.277
Family hx of CAD (%)	35.8	28.7	0.009	34.9	37.0	0.278
Diabetes (%)	32.0	33.0	0.670	33.9	29.9	0.012
Dyslipidaemia (%)	80.9	76.2	0.020	80.3	81.6	0.331
Hypertension (%)	84.8	83.7	0.534	84.6	85	0.810
Previous MI (%)	30.5	25.9	0.057	30.5	30.5	1.000
Previous PCI (%)	44.5	34.2	< 0.001	45.0	44.1	0.602
Previous CABG (%)	14.6	16.3	0.361	15.6	13.5	0.098
STEMI (%)	19.1	35.0	< 0.001	16.9	21.8	< 0.001
NSTEMI (%)	11.0	14.2	0.050	12.5	9.4	0.004
IAP (%)	11.0	12.0	0.527	13.7	7.9	< 0.001
3-vessel disease (%)	39.3	45.6	0.011	39.1	39.2	0.972
Left main disease (%)	0.8	0.4	0.572	1.1	0.6	0.095
In-stent restenosis (%)	15.7	2.0	< 0.001	14.4	17.2	0.026
Implanted stents						
Number (mean ± SD)	1.4 ± 0.7	1.4 ± 0.7	0.720	1.3 ± 0.6	1.4 ± 0.7	0.082
Length (mean ± SD)	19.3 ± 6.3	16.1 ± 5.3	< 0.001	18.7 ± 6.1	20.0 ± 6.5	< 0.001
Diameter (mean ± SD)	2.7 ± 0.5	2.7 ± 0.6	0.002	2.7 ± 0.5	2.7 ± 0.5	0.554
Quality of life prior to implantation						
SF-36 PSS (mean ± SD)	38.9 ± 10.6	38.2 ± 10.3	0.403	38.6 ± 10.5	39.1 ± 10.6	0.376
SF-36 MSS (mean ± SD)	45.8 ± 12.5	45.7 ± 12.6	0.899	45.5 ± 12.5	46.3 ± 12.5	0.251
MacNew GS (mean ± SD)	4.7 ± 1.2	4.7 ± 1.3	0.336	4.7 ± 1.2	4.8 ± 1.2	0.269

DES drug-eluting stent, BMS bare-metal stent, BMI body mass index, SD standard deviation, CAD coronary artery disease, MI myocardial infarction, PCI percutaneous coronary intervention, CABG coronary artery bypass graft, STEMI ST-elevation myocardial infarction, NSTEMI non-ST-elevation myocardial infarction, IAP instable angina pectoris, hx history, PSS physical summary scale, MSS mental summary scale, GS global scale.

Tab. 2 **In-hospital follow-up, proportion (%) of events according to groups of DES, BMS, Taxus and Cypher**

	DES n=3,472	BMS n=458	p value (DES vs. BMS)	Taxus n=1,821	Cypher n=1,600	p value (Taxus vs. Cypher)
Death	0	0.7	0.002	0	0	–
Myocardial infarction	1.0	1.5	0.334	1.2	0.8	0.307
Stroke	0.5	0.4	1.000	0.7	0.3	0.085
MACCE	1.6	2.2	0.326	1.9	1.1	0.049
Repeat urgent revascularisation						
CABG	0.1	0	1.000	0.1	0.1	1.000
PCI	0.7	1.1	0.366	0.6	0.8	0.405
Repeat elective revascularisation						
CABG	0.5	2.0	0.003	0.8	0.3	0.035
PCI	2.8	3.7	0.234	2.8	2.6	0.833
Renal failure	1.2	1.3	0.821	1.6	0.9	0.087
Severe bleeding complications	0.5	1.1	0.178	0.5	0.6	0.637

DES drug-eluting stent, BMS bare-metal stent, PCI percutaneous coronary intervention, CABG coronary artery bypass graft, MACCE major adverse cardiac and cerebrovascular event, ne not estimable.

es between DES and BMS were observed in the frequency of any of these medications. Between Taxus and Cypher patients some significant differences were noted at discharge as can be observed in **Tab. 3**. The average planned prescription length of clopidogrel was 31 (SD 12) and 15 (SD 15) weeks in DES and BMS patients, respectively ($p < 0.001$). Also, the planned duration of clopidogrel was significantly longer in Taxus compared to Cypher patients.

Health economic assessment

The majority (n = 3,852) of recruited patients was treated and reimbursed according to the DRG system (**Tab. 4**). Overall, there was a significant difference in procedural costs between DES and BMS patients of about 1,380 €, reflecting surcharges for implantation of DES. In contrast, no differences in costs between Taxus and Cypher patients were observed.

Mean initial procedural costs according to diagnosis-related groups (DRGs) for patients treated in hospitals and the private practice reimbursement catalogue EBM for patients treated in private practices are shown in **Tab. 4**. DES surcharges were considered in both instances.

Discussion

The present study is based on phase I of the large multicentre German Drug-Eluting Stent registry (DES.de). In total, 3,930 patients were enrolled, of whom 3,472 were treated with DES. Hence, the economic evaluation is based on more than 60% of the patient population of phase I of DES.de. Previous systematic reviews have identified only few economic evaluations of DES, none from Germany. Frequently these economic evaluations were based on Markov models and not primary studies [11]. To our knowledge only one previous economic evaluation of DES in Germany has been published so far and reported cost-effectiveness estimates of the Cypher stent in a considerably smaller population of about 900 patients [20]. Hence, the economic evaluation of the DES.de registry represents one of the largest economic evaluations investigating effective-

Tab. 3 **Medication at discharge according to groups of DES, BMS, Taxus and Cypher**

	DES n = 3,472	BMS n = 458	p value (BMS vs. DES)	Taxus n = 1,821	Cypher n = 1,600	p value (Taxus vs. Cypher)
Aspirin	98.5	97.8	0.314	98.6	98.4	0.574
Clopidogrel	99.5	99.1	0.315	99.5	99.5	1.000
Planned duration clopidogrel (days)	31.1	14.8	< 0.001	33.3	28.7	< 0.001
Marcumar	3.6	3.9	0.691	3.5	3.6	0.853
Aspirin + clopidogrel	97.4	98	0.384	98.1	97.9	0.712
Aspirin + clopidogrel + marcumar	2.7	2.8	0.761	2.7	2.6	0.751
Heparin	4.6	5.9	0.240	4.3	4.8	0.460
β-blocker	90.1	88.4	0.284	88.3	92.1	< 0.001
ACE inhibitor	76.4	75.5	0.726	73.9	79.2	< 0.001
AT1 antagonist	13	13.5	0.768	14.2	11.8	0.033
ACE inhibitor/AT1-antagonist	86.1	860	0.943	83.9	88.7	< 0.001
Statins	90.2	87.8	0.116	90.0	90.4	0.645
Calcium antagonist	13.8	15.9	0.224	14.2	13.6	0.62

DES drug-eluting stent, BMS bare-metal stent, ACE angiotensin-converting enzyme, AT1 angiotensin II receptor.

Tab. 4 **Mean initial procedural costs according to diagnosis-related groups (DRGs) for patients treated in hospitals and the private practice reimbursement catalogue "Einheitlicher Bewertungsmaßstab" (EBM) for patients treated in private practices. DES surcharges were considered in both instances**

Costs	DES	BMS	p value (DES vs. BMS)	Taxus	Cypher	p value (Taxus vs. Cypher)
Mean EBM ± SD (n = 78)	3,230 € ± 1,584 €	2,485 € ± 1,535 €	0.124	3,378 € ± 1,603 €	2,452 € ± 870 €	0.210
Mean DRG ± SD (n = 3,852)	5,022 € ± 1,253 €	3,641 € ± 881 €	< 0.001	5,034 € ± 1,233 €	4,988 € ± 1,253 €	0.285
Mean overall ± SD (n = 3,930)	4,988 € ± 1,283 €	3,608 € ± 923 €	< 0.001	4,983 € ± 1,278 €	4,981 € ± 1,260 €	0.947

DES drug-eluting stent, BMS bare-metal stent, EBM private practice reimbursement catalogue, DRG diagnosis-related groups, SD standard deviation.

ness, cost-effectiveness and economic impact of the use of DES in Europe.

Participants of this economic evaluation were not different from those of the entire cohort of phase I of DES.de [12], with baseline characteristics highlighting a high rate of "off-label" indication for stent implantation [21, 22]. In addition, due to the non-randomised nature of DES.de, reflecting real world practice, differences between DES, BMS, Taxus and Cypher participants were observed, similar to those previously reported for the entire DES.de registry [12]. These differences relate to sociodemographic, clinical and procedural characteristics of included participants and were found for both, DES vs. BMS and Taxus vs. Cypher.

Moreover, reported clinical events during follow-up were low and did not differ between groups. Also, medication prescriptions at discharge were similar in DES, BMS, Taxus and Cypher patients except for clopidogrel. The planned duration of clopidogrel was about twice as long with DES compared to BMS patients, which is compatible with standard clinical guidelines.

Results of our economic analysis indicate that costs of index stent implantation differed considerably between DES and BMS patients, but not between Taxus and Cypher. This is mainly due to DES surcharges that applied in 2006 and were estimated at 1,235 € per implanted DES. Although these surcharges have fallen substantially until 2010, reimbursement per implanted DES is comparable to reported differences in costs for DES and BMS used in other economic evaluations, e.g. in the Netherlands, Italy, Switzerland, Sweden and Austria [11]. Differences in implantation costs therefore seem realistic when considering 2006 prices. Hence, overall costs during the study will depend to a large degree on these implantation costs, which are in turn influenced by the number of implanted stents and their respective DES surcharges. With regard to the number of implanted stents, no differences occurred between investigated groups. In addition, the average number of stents is similar to that reported in DES.de and also to other economic evaluations of DES as summarised by Neyt et al. [11]. However, the observed higher upfront costs of DES could potentially be offset by lower follow-up costs due to reduced revascularisation rates, lower incidence of clinical events and lower re-hospitalisation rates. Previous studies have in part confirmed this assumption and reported lower follow-up costs of DES compared to BMS [11]. Moreover, when evaluating the cost-effectiveness of DES, not just overall costs but also the occurrence of clinical events, mortality and the impact on patient reported outcomes, such as QoL and patient satisfaction will be of importance. Thus, e.g. if DES resulted in an increase in QALYs gained compared to BMS, they might be considered cost-effective despite higher costs, if these costs are in a reasonable relation to incremental QALYs gained. As highlighted by Neyt et al. [11], some previous studies have indicated that DES can be considered cost-effective under certain circumstances while others did not find evidence of cost-effectiveness [23, 24, 25]. Future follow-up analyses of the presented economic evaluation of the DES.de registry will investigate clinical and quality of life outcomes over a longer follow-up period in order to investigate these issues. This economic evaluation will thereby provide data regarding the value of DES on a broad basis within the German health care system. Due to the inclusion of a large number of well distributed study centres in Germany, and liberal selection criteria in DES.de, findings will be able to provide extensive information likely to be more representa-

tive for routine care than that from smaller scale clinical trials, which are often also limited by restrictive selection criteria.

Another important strength of this economic evaluation is its comprehensiveness of data collection. While the quality of clinical data collection has been described elsewhere [12], the quantity and quality of relevant costing data collected is particularly important. A major advantage is that costing data is not based on secondary data provided by statutory health insurances or other agencies, but that the actual amount of resources consumed was detailed by the physician and patient. This approach will create excellent opportunities to compare findings with similar studies from other countries. In addition, the detailed information on resource consumption will enable the extrapolation of findings to the current or future situation beyond 2011. This is of special importance as health economic estimates are highly dependent on the structure of any given health care system, particularly reimbursement schemes and changes in cost estimates, which are highly relevant in light of DES surcharges. Furthermore, the present economic evaluation includes the two, at that time most frequently used types of DES, Taxus and Cypher. This allows the comparison of these two stent types in a real world setting not only with regard to clinical effectiveness but also cost-effectiveness.

Despite excellent recruitment and comprehensive data collection, the present economic evaluation has important limitations. Firstly, the comparison between BMS and DES groups is not a randomised comparison. Although we aimed to address this in the selection process to achieve high comparability and collected detailed data on confounding factors, bias and residual confounding cannot be excluded. Secondly, the present economic evaluation only consists of 12-month follow-up data. While this provides valid economic information, longer follow-ups would enable the evaluation of later events, such as late stent thrombosis. It should also be noted that the economic evaluation of the DES.de registry included only first generation DES. Since then second generation DES have been approved for implantation in Germany and other health care systems [18, 26]. Although there is currently no conclusive evidence, some studies suggest superior effectiveness of second generation DES [27, 28, 29, 30]. If confirmed, this could also result in improved cost-effectiveness of this new technology because reimbursement in Germany is currently the same for first and second generation DES. However, a recent systematic review concerned with second generation DES also highlighted the lack of economic evaluations targeting second generation DES and reported inconsistent evidence with regard to the cost-effectiveness compared to BMS or first generation DES [31].

The present economic evaluation is one of the largest studies investigating both the economic impact and the cost-effectiveness of DES in a real world setting. These early findings highlight markedly increased initial hospitalisation costs of DES compared to BMS. Although intervention groups differed in some confounding factors, future follow-up analyses will provide decision makers with economic estimates in unselected populations. In addition, they will aid decision makers with regard to the utilisation of DES in the context of the German health care system. Our findings can therefore be applied to support reimbursement decisions in the German and other health care systems.

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Conflict of interest. The corresponding author states the following: this study was funded by Boston Scientific and Cordis GmbH.

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Diabetes und Magen-Darm-OP: Studie bezweifelt Langzeiterfolg

Operationen am Magen-Darmtrakt dämmen einen Diabetes mellitus nicht so wirksam ein, wie bislang angenommen: Wie eine aktuelle US-amerikanische Studie zeigt, tritt der Diabetes bei einem Fünftel der Patienten nach drei bis fünf Jahren wieder auf.

Immer häufiger setzen Ärzte Methoden der bariatrischen Chirurgie ein, um bei stark übergewichtigen Menschen die Kalorienaufnahme zu reduzieren und einen Typ-2-Diabetes in Remission zu bringen. Aktuelle Kurzzeitstudien zeigen, dass sich die Blutzuckerwerte dadurch normalisieren und die Krankheit verschwindet, zumindest für ein bis zwei Jahre.

Eine Langzeitstudie ergab jetzt nach längeren Zeiträumen eine Rückfallrate von 21%. In einer rückblickenden Analyse untersuchten die Forscher dafür Daten von Patienten, die sich einer Magenbypassoperation unterzogen hatten. Von 66 Patienten mit Remission trat der Diabetes bei 14 wieder auf. Je länger dieser zuvor bestanden hatte, desto wahrscheinlicher war eine Rekurrenz.

Die Deutsche Gesellschaft für Endokrinologie weist darauf hin, dass sorgfältig abzuwägen sei, ob ein chirurgischer Eingriff tatsächlich zu vertreten ist. Parameter wie die Überlebensrate und die Langzeitfolgen der Operation müssen herangezogen werden.

Literatur: Ramos Y, Bersoux S, Roust LRet al (2012) Type 2 Diabetes Mellitus Re-Emergence Post Gastric Bypass Surgery Diabetes & Clinical Care Poster SAT-161

Quelle:
Deutsche Gesellschaft für Endokrinologie, www.endokrinologie.net

MRT ermöglicht Herzkatheteruntersuchungen ohne Strahlenbelastung

Dank einer am Max-Planck-Institut für biophysikalische Chemie in München entwickelten Technik (FLASH), konnte die Auflösung von MRT-Bildern so weit erhöht werden, dass sich beispielsweise die Herztätigkeit detailliert und in Echtzeit verfolgen lässt. Mit dieser Entwicklung können einzelne Aufnahmen zu einer flüssigen Bildserie aneinandergereiht werden. In einer Pilotstudie wurden, mit Unterstützung eines solchen Echtzeit-MRT, erstmals Untersuchungen des rechten Ventrikels durchgeführt. Die Methode erwies sich dabei als ebenso sicher und schnell wie unter der konventionellen Röntgendurchleuchtung. Untersucht wurden Kinder mit Herz- oder Klappenfehlern bei denen oft schon in den ersten Lebensmonaten ein Herzkatheter notwendig wird. Die Empfindlichkeit des Gewebes auf Röntgenstrahlen ist in diesem Alter deutlich höher als bei Erwachsenen.

Eine zu überwindende Hürde war die geringe Größe des Katheters. Um ihn im MRT-Film sichtbar zu machen, wurde die Spitze entweder mit Luft oder mit dem Kontrastmittel Gadolinium gefüllt. Vor allem die Markierung mit Gadolinium hat sich bei den ersten 16 untersuchten Kindern bewährt. Die Katheterspitze war ebenso gut sichtbar wie in der Röntgenkontrolle. Alle Kinder waren nacheinander mittels Röntgendurchleuchtung und im MRT-Film katheterisiert worden. In beiden Fällen dauerte die Untersuchung mit etwa 20 Minuten gleich lang. Die Sondierung der Pulmonalarterie war sogar leichter als unter Röntgenkontrolle.

Quelle:
National Heart Lung and Blood Institute, www.nhlbi.nih.gov