One-year mortality after surgical and non-surgical approaches to coronary revascularisation – results based on administrative data of a German health insurance

Ein-Jahres-Sterblichkeit nach koronarer Revaskularisation – Ergebnisse auf der Basis von administrativen Daten einer deutschen Krankenkasse

Abstract

Aims: In Germany, little is known about mortality of coronary revascularisation after discharge from hospital due to a lack of longitudinal population-based data. The availability of clinically relevant information in administrative health-insurance data increased during the last years. We determined the one-year mortality after surgical and non-surgical approaches to coronary revascularisation based on administrative data and explored the effectiveness of the available information for adjustment for confounders.

Methods/Results: We analysed the one-year mortality of all beneficiaries of a German health insurance who underwent coronary artery bypass grafting or percutaneous coronary interventions in the year 2005 with complete follow-up (n=3447). We report the observed and the confounder adjusted one-year mortality (logistic regression). Parameters for adjustment for confounders (i.e. age, sex, previous myocardial infarction) were derived from administrative claims data on outpatient physician contacts, prescriptions, and hospital claims data up to ten years before and one year after discharge from the index procedure. The observed (and the adjusted) 1-year mortality was: CABG: 7.7% (8.4%), PTCA only: 6.2% (4.6%), PTCA and bare-metal stent: 5.0% (4.3%), PTCA and drug-eluting stent: 3.5% (3.9%).

Conclusion: Adjustment for confounders based on administrative data accounted for the observed differences between the various percutaneous interventions, but the higher 1-year mortality after CABG remained unexplained.

Keywords: mortality, coronary revascularisation, coronary artery bypass grafting, percutaneous coronary intervention, bare-metal stents, drug-eluting stents

Zusammenfassung

Ziel: Für die Zeit nach der Entlassung aus dem Krankenhaus ist in Deutschland aufgrund fehlender längsschnittlicher bevölkerungsbezogener Daten gegenwärtig nur wenig über die Sterblichkeit nach koronarer Revaskularisation bekannt. In administrativen Daten der gesetzlichen Krankenkassen hat die Verfügbarkeit klinisch relevanter Informationen in den letzten Jahren zugenommen. Vor diesem Hintergrund haben wir auf der Basis von solchen Daten einer Krankenkasse die 1-Jahres-Sterblichkeit nach chirurgischen und interventionellen Interventionen zur koronaren Revaskularisation ermittelt und die Wirksamkeit einer auf administrativen Daten beruhenden Risikoadjustierung untersucht.

Methoden/Ergebnisse: Wie berechneten die 1-Jahres-Sterblichkeit der Versicherten einer deutschen gesetzlichen Krankenkasse, die sich im Jahr 2005 entweder einer koronaren Bypass-Operation (CABG) oder...
einem perkutanen Eingriff zur Revaskularisation der Herzkrankzugefälle unterzogen haben mit komplettem Follow-up (n=3447). Wir berichten die beobachtete sowie die mittels multipler logistischer Regression geschätzte adjustierte 1-Jahres-Sterblichkeit. Abrechnungsdaten zu ambulant ärztlichen Kontakten, Arzneimittelverordnungen und Krankenhausaufenthalten über einen Zeitraum von bis zu 10 Jahren vor und bis zu einem Jahr nach Entlassung aus dem Indexaufenthalt wurden für Ableitung der zur Adjustierung verwendeten Parameter (u.a. Alter, Geschlecht, früherer Myokardinfarkt) herangezogen. Die beobachtete (adjustierte) 1-Jahres-Sterblichkeit betrug: CABG: 7,7% (8,4%), ausschließlich PTCA: 6,2% (4,6%), PTCA und nicht-Medikamente-freisetzender Stent: 5,0% (4,3%), PTCA und Medikamente-freisetzender Stent: 3,5% (3,9%).

Schlussfolgerung: Mit Hilfe der auf administrativen Daten beruhenden Adjustierung für Confounder konnten die zwischen den unterschiedlichen perkutanen Interventionen bestehenden Unterschiede der beobachteten 1-Jahres-Sterblichkeit erklärt werden, nicht jedoch die höhere Sterblichkeit nach koronarer Bypass-Operation.

Schlüsselwörter: Sterblichkeit, koronare Revaskularisation, aortokoronare Bypass-Operation, perkutane koronare Interventionen, nicht-Medikamente-freisetzender Stent, Medikamente-freisetzender Stent

Introduction

Germany is one of the leading countries with regard to the frequency of surgical and non-surgical coronary revascularisations per million inhabitants: compared to the European average German rates of coronary artery bypass grafting (CABG) are twice as high and rates of percutaneous coronary interventions (PCI) are three times higher [1]. About 230,000 PCI (85% with implantation of at least one stent) and about 70,000 CABG-procedures (71% without concomitant heart surgery) were performed in German hospitals in the year 2005 [2], [3]. Due to a lack of longitudinal data, little is known about the mortality of revascularisation procedures after discharge from hospital. The mandatory clinical audit covers mortality but is limited to short-term mortality: in-hospital mortality is reported for PCI and CABG, and 30-day mortality is reported for CABG only. Apart from the mandatory clinical audit several voluntary registers exist that try to cover longer time frames. These registers are directed to certain medical conditions (e.g. acute coronary syndromes [4], [5]) or specific procedures (e.g. PCI, Sirolimus eluting stents, or CABG [6], [7], [8]), and may be confined to a single region. So far, in Germany no clinically derived database comprehensively covers longer term outcomes after common types of coronary revascularisation. The scarceness of clinically derived data on real-life or routine health care outcomes is not a particular German problem. To overcome this problem, other countries, especially the United States of America, have made substantial efforts to use the large amount of administrative data (e.g. from Medicare) to answer questions relevant for health services research [9], [10], [11], [12]. Administrative or billing data are widely available and rather cheap, but derived primarily to support reimbursement. Their usefulness with regards to answering clinical questions depends heavily on the extent to which they cover clinically relevant information. Until the 1990s the administrative data of most of the German statutory health insurances were not suitable for health services research or contained very little clinically relevant information [13]. Due to several health care reforms and legislative regulations the availability of clinically relevant information in administrative health insurance data increased during the last years. Now, German statutory health insurances have various person-specific databases containing administrative as well as billing information (for details see Table 1). Since the year 2000 the German version of the ICD-10 has been used to classify diagnostic information in outpatient and hospital claims. Procedures in hospitals are classified with the German Procedural Classification (GPC). Originally, this classification is based on the ICD-9 procedure code. However, to better accommodate national documentation needs the GPC has been and still is subject to modifications. I.e. different procedure codes for bare metal stents and drug eluting stents were introduced into the GPC in 2005, a further discrimination by type of drug eluting stent is available since 2006. Official versions of the GPC are launched every year by the German Institute for Medical Documentation and Information. Prescription data hold no ICD-coded diagnostic information, but a unique drug identifier that can be linked to the Anatomical Therapeutical Chemical Classification System (ATC) permitting the exact identification of each substance prescribed. Because the official German ATC-Classification contains information on daily defined doses, the calculation of prescribed daily defined doses (DDD) is possible, as well.

Neither of the administrative data sets contains information on laboratory or other non-invasive tests. Detailed characteristics of coronary artery disease (i.e. target vessel, diameter and length of stenosis, number of sten-
Person-specific linkage of administrative health insurance data offers options for longitudinal, denominator-based studies on large populations. We determined the mortality after surgical and non-surgical approaches to coronary revascularisation based on administrative hospital discharge data. Our main focus was the calculation of the one-year mortality after CABG, percutaneous transluminal coronary angioplasty without stenting (PTCA only) or with either bare metal stenting (BMS) or drug-eluting stenting (DES). However, since we used an oberservational database these comparisons may be biased due to prognostically important baseline differences among patients as a result of observed and unobserved treatment selection biases [14], demanding adequate adjustment methods. Therefore, we further aimed at exploring the effectiveness of adjustment for confounders based on information derived from various administrative databases, using descriptive and multivariable statistical approaches.

**Methods**

**Study design and patients**

We conducted a retrospective cohort-study on beneficiaries of a German statutory health insurance (Gmünder Ersatzkasse, GEK) undergoing coronary revascularisation in acute care hospitals in the year 2005 to assess crude and case-mix adjusted one-year mortality.

In 2006, the GEK offered benefits to approximately 1.5 million people all over Germany accounting to 1.9% of the German population. Historically, predominantly blue collar workers were insured with the GEK, with a focus on craftsmen and the metal-processing industry. Thus, a relatively high number of men of a working age are represented in the clientele of the GEK. Although the population represented here with the GEK cannot be considered representative of the German population in respect to its occupation mix, prior studies have found that results from analyses of data provided by the GEK can be transferred to the German population as a whole without major distortions. For example, an analysis of GEK data on hospital-made diagnoses corresponded well with the official data provided on diagnosis at the time of hospital discharge by the federal statistic bureau that covered the whole country [14].

To be eligible in our study a sickness fund beneficiary had to undergo at least one of the following procedures: CABG surgery (GPC-2005 5-361 or 5-362: Coronary artery bypass grafting), PTCA (GPC-2005 8-837.0: Balloon dilatation), implantation of bare metal stent(s) (GPC-2005 8-837.k: non-drug eluting stent implantation), or drug eluting stent(s) (GPC-2005 8-837-m: drug eluting stent implantation). Furthermore, eligibility criteria included known survival status 365 days after the index procedure. We used the first index procedure in 2005 to assign patients to one of four disjunctive groups:

1. CABG (regardless of other percutaneous procedures),
2. DES (Drug eluting stents regardless of concomitant bare metal stents or PTCA),
3. BMS (Bare metal stents, regardless of PTCA), and
4. PTCA (without additional stents).

We analysed two populations:

1. the complete eligible population and
2. a subgroup of patients that was characterised by a main diagnosis of coronary artery disease without acute myocardial infarction and without concomitant cardiac surgery (e.g. valve replacement).

**Data sources**

The datasets available for this study contained information on 1.5 million beneficiaries, and, per year, 22 millions physician contacts, 10 million prescriptions, and 280,000 hospital admissions. The time frames of data sets listed in Table 1 differed widely. In detail we used: basic information on beneficiaries up to ten years before and at least one year after the index-admission; outpatient physician’s claims up to one year prior to the index admission (at the time of analysis outpatient claims data after the index admission were not available); prescriptions one year before and one year after the index admission, general hospital claims data up to ten years before the index ad-

<table>
<thead>
<tr>
<th>Data source</th>
<th>Available electronically</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient physician’s claims</td>
<td>since 2004</td>
<td>i.e. date of contact, ICD-10 coded diagnosis</td>
</tr>
<tr>
<td>Prescriptions</td>
<td>since 1998</td>
<td>i.e. date of prescription, unique drug identifier</td>
</tr>
<tr>
<td>Hospital claims, general</td>
<td>since 1990</td>
<td>i.e. date of admission, date of discharge, up to eight ICD-9 (until 1999) or ICD-10 coded Diagnosis (since 2000)</td>
</tr>
<tr>
<td>Hospital claims, detailed</td>
<td>since 2003</td>
<td>additional information on procedures (German Procedural Classification, GPC), GM-DRGs, type of admission, ICD-10 coded main case diagnosis, reason of discharge</td>
</tr>
<tr>
<td>Basic information on beneficiaries</td>
<td>since 1990</td>
<td>i.e. age, sex, employment status, begin of insurance (date), end of insurance (date), reason for ending of insurance (i.e. change of insurance, death)</td>
</tr>
</tbody>
</table>
mission, and detailed hospital claims data from the year before to the year after index admission. For data protection within this research context, these data sets were linked by an insurance created “dumb” pseudonym that was used throughout the data sources instead of the actual insurance number.

Selection of confounders

We studied the following patient characteristics: age, sex, medical conditions known to adversely affect coronary artery revascularisation outcomes, including a history of depression, main diagnosis of index admission, and whether the patient was transferred from another hospital to the index admission.

We selected clinical characteristics known to be adverse risk factors for CABG and PCI mortality according to the EuroSCORE system [15], the Federal Office for Quality Assurance (that is responsible for mandatory clinical audit) [3], and some recent health technology assessment reports and meta-analyses [16], [17], [18]. The variable “main diagnosis of the index admission” was derived from the hospital claims data of the index-admission. For some of the selected risk factors, the available data sets allowed of different operationalisation: e.g., the presence of diabetes mellitus could be judged from diagnoses in outpatient physician data and/or from prescription files, looking for antidiabetics. Although, different operationalisations were tested, here we report the version used in the final calculations, only. We used outpatient physician’s diagnosis in the year prior to the index admission to derive indicators on myocardial infarction, peripheral vascular disease, and lipid disorders. Other indicators were derived from the prescription files in the year prior to the index admission: prescription of antidiabetics, vitamin K antagonists, antidepressants. Additionally, we constructed variables on known arterial hypertension, chronic obstructive pulmonary disease, stroke, and renal insufficiency based on ambulatory physician’s claims data.

As pointed out in the introduction, administrative data does neither contain detailed characteristics of coronary artery disease (i.e. number of affected vessels or length and diameter of stenosis) nor details of heart function (i.e. left ventricular ejection fraction). Such information could not be used to adjust for confounding.

Outcomes

The main outcome of interest was mortality until day 365 following the index procedure. Deaths during the index admission were identified by the detailed hospital claims data set, whereas deaths occurring following discharge were detected using the variable “reason for leaving insurance” from the basic information on beneficiaries data set.

Inpatient mortality for CABG patients without concomitant heart surgery was calculated and compared to the officially published data from the mandatory clinical audit.

Statistical analysis

Using the $\chi^2$ statistic and one-way analysis of variance, we examined differences among the four groups (CABG, PTCA, BMS, and DES) regarding age, sex, length of index-admission and transfer from another hospital, a physician diagnosis of myocardial infarction, peripheral vascular disease, or dyslipidaemia, and a prescription of antidiabetics, vitamin K antagonists, or antidepressants as well as known arterial hypertension, chronic obstructive pulmonary disease, renal insufficiency, and previous stroke.

Next, we calculated the one-year mortality. Further descriptive analysis included the calculation of the standardised mortality ratio (SMR) by type of coronary revascularisation. To attain the SMR, the observed one-year mortality was divided by the expected one-year mortality. Expected one-year mortality refers to the number of deaths that would have been expected in the study population (e.g. CABG patients) had they died at the same rate as the completely unselected insured population of the same age and sex. An SMR $>1$ indicates higher risk of dying compared to the average insured population, whereas an SMR $<1$ points to lower risk of dying. In case the confidence interval of SMR covers 1, the risk of dying in patients after coronary revascularisation is not statistically significant different to that of the general insured population. The standardised mortality ratios (SMRs) for the four groups by coronary revascularisation should not be compared by assessing overlapping confidence intervals, because the SMR applies only to the population it has been calculated for.

We evaluated the effect of the assumed case mix variables on the one-year mortality by stepwise entry of covariates in a logistic regression model in subsequent steps. First, we estimated the one-year mortality in a logistic regression model using only type of revascularisation as covariate. The one-year mortality rates estimated by this model resemble the unadjusted (observed) rates and serve as basic comparator for the three models fitted subsequently. In addition to type of revascularisation model 1 contained age and sex as exploratory variables. In model 2 we entered the main diagnosis of index admission as a further covariate, and in model 3 all other assumed covariates were added and checked for statistical significance. Other assumed covariates for our analysis included transfer from another hospital, a physician’s diagnosis of myocardial infarction, peripheral vascular disease, or dyslipidaemia, and a prescription of antidiabetics, vitamin K antagonists, or antidepressants. Further variables (previous stroke, arterial hypertension, COPD, renal insufficiency) were not included in the final model because they did not contribute statistically significantly to the prediction of one-year mortality.

Regression models were assessed for possible collinearity among covariates, appropriateness of model fit using the Hosmer-Lemeshow Goodness-of-Fit Test, and discriminatory capacity represented by the c-statistic or area under a receiver operating characteristic curve. Based on the
model prediction mean adjusted mortality rates and 95% confidence intervals were estimated. All statistical analyses were done for all eligible patients and for the subgroup of coronary artery disease patients without acute myocardial infarction, and performed with Statistical Applications Software (SAS) V.9.1.

## Results

### Patient characteristics

In the year 2005, a total 3461 beneficiaries underwent at least one surgical or percutaneous coronary revascularisation. Survival status at day 365 after the index-procedure was available for 3447 patients (99.6%) and unknown for 14 persons (5 CABG, 1 PTCA, 2 DES und 6 BMS). These 14 patients were excluded from further analysis.

There were 780 patients after CABG, 291 patients received percutaneous transluminal coronary angioplasty (PTCA) without stents, 1724 patients underwent PTCA and received at least one bare metal stent (BMS), and 652 patients were treated with PTCA and drug-eluting stent(s)(DES). As expected, patients varied in nearly all characteristics by type of revascularisation: CABG and PTCA patients were older, less often female, and suffered to a larger extend from peripheral artery disease when compared to DES or BMS patients (Table 2). Nearly half the BMS patients were hospitalised at the index admission with a main diagnosis of acute myocardial infarction, but only one third of the DES and PTCA patients and 12% of CABG patients (p<0.0001). CABG patients demonstrated more frequently a main diagnosis of other than ischaemic heart disease or other heart diseases compared to patients following percutaneous coronary interventions.

### One-year mortality in all eligible patients

The crude observed one-year mortality rate was highest in CABG patients (7.7%). In PTCA patients the observed one-year mortality was 6.2% and in BMS patients 5.0%. The lowest one-year mortality was observed in DES patients (3.5%). The observed differences between the four groups are statistically significant (p<0.01). Fitting a logistic regression model with type of revascularisation as the only exploratory variable yielded a c-statistic of 0.57 (Table 3). The low c-statistic indicates that prediction of one-year mortality of all eligible patients based solely on
Table 3: One-year mortality after coronary revascularisation by type of procedure – observed mortality, descriptive and multivariate approaches to risk adjustment

<table>
<thead>
<tr>
<th>One-year mortality</th>
<th>CABG</th>
<th>PTCA</th>
<th>DES</th>
<th>BMS</th>
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<tbody>
<tr>
<td>All eligible patients (n)</td>
<td>780</td>
<td>291</td>
<td>652</td>
<td>1724</td>
</tr>
<tr>
<td>Observed mortality (n)</td>
<td>60</td>
<td>18</td>
<td>23</td>
<td>86</td>
</tr>
<tr>
<td>Observed mortality rate (%)</td>
<td>7.7 (6.0–9.8)</td>
<td>6.2 (3.9–9.6)</td>
<td>3.5 (2.4–5.3)</td>
<td>5.0 (4.1–6.1)</td>
</tr>
<tr>
<td>Expected mortality rate (%)</td>
<td>1.9</td>
<td>2.1</td>
<td>1.5</td>
<td>1.8</td>
</tr>
<tr>
<td>Standardised mortality ratio (95%-CI)</td>
<td>SMR: 4.1 (1.1–5.1)</td>
<td>SMR: 3.0 (1.8–4.7)</td>
<td>SMR: 2.4 (1.5–3.5)</td>
<td>SMR: 2.7 (2.2–3.4)</td>
</tr>
<tr>
<td>Risk adjusted mortality rate (%)</td>
<td>Model 1* (95%-CI)</td>
<td>6.9 (5.0–9.5)</td>
<td>5.3 (3.2–8.6)</td>
<td>3.6 (2.3–5.6)</td>
</tr>
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<td>Model 2* (95%-CI)</td>
<td>9.9 (7.3–13.3)</td>
<td>5.8 (3.5–9.5)</td>
<td>4.7 (3.0–7.3)</td>
</tr>
<tr>
<td></td>
<td>Model 3** (95%-CI)</td>
<td>8.4 (6.0–11.6)</td>
<td>4.6 (2.7–7.7)</td>
<td>3.9 (2.4–6.2)</td>
</tr>
</tbody>
</table>

CAD-Patients without AMI§ (n) | 527 | 175 | 430 | 831
| Observed mortality (n) | 24 | 3 | 8 | 15 |
| Observed mortality rate (%) | 4.6 (3.1–6.7) | 1.7 (0.6–5.2) | 1.9 (0.9–3.7) | 1.8 (1.1–3.0) |
| Expected mortality rate (%) | 1.7 | 1.8 | 1.6 | 2.0 |
| Standardised mortality ratio (95%-CI) | SMR: 2.7 (1.7–4.0) | SMR: 0.9 (0.2–2.9) | SMR: 1.2 (0.5–2.3) | SMR: 0.9 (0.5–1.5) |
| Risk adjusted mortality rate (%) | Model 1* (95%-CI) | 4.4 (2.5–7.8) | 1.6 (0.5–5.2) | 1.9 (0.9–4.1) | 1.6 (0.8–2.9) |
| | Model 2* (95%-CI) | 4.5 (2.7–7.5) | 1.5 (0.5–4.8) | 1.8 (0.8–3.7) | 1.5 (0.8–2.7) |
| | Model 3** (95%-CI) | 4.1 (2.3–7.2) | 1.3 (0.4–4.2) | 1.6 (0.7–3.5) | 1.4 (0.8–2.6) |

§ CAD-Patients without AMI: Analysis confined to coronary artery disease patients without acute myocardial infarction and without concomitant cardiac surgery (e.g. valve replacement)
# Model 1: covariates: type of revascularisation, age, sex
+ Model 2: like model 1, additional covariates: main diagnosis of index admission
++ Model 3: like model 2, additional covariates: transferred to index-admission, known physician’s diagnosis of myocardial infarction, peripheral vascular disease, or dyslipidämia, prescription of antidiabetics, vitamin K antagonists, or antidepressants.
H-S: Hosmer-Lemeshow Goodness-of-Fit Test. This Test has to be non-significant to imply good model fit.

The type of revascularisation is slightly better than prediction by tossing a coin.
The expected one-year mortality in the four groups would have been 1.9% in CABG patients and 2.1%, 1.5% and 1.8% in PTCA, DES, or BMS patients, respectively (Table 3). The SMR is 4.1 in CABG patients, indicating that this group had a risk of dying four times higher than the general insured population. After PCI the SMR were between 2.4 (DES) and 3.0 (PTCA), and differed statistically from the general insured population.
After adjustment for age and sex (model 1) estimated one-year mortality decreased in CABG, PTCA and BMS patients and increased in DES patients, the c-statistic increased by 0.14 points to 0.71 indicating a better discriminative capacity, when compared to the model including only type of revascularisation. Adding the main diagnosis of index admission to the model further increased the c-statistic. Moreover, adjusted one-year mortality in DES and BMS patients did not differ any longer, and increased in CABG patients. In the fully adjusted model 3 (including further covariates) the c-statistic increased again, indicating very good discriminative power, now, and good calibration (Hosmer-Lemeshow p=0.8). The fully adjusted model accounted for the observed differences between the various percutaneous interventions, but the higher 1-year mortality after CABG remained unexplained.
One-year mortality in coronary artery disease patients without acute myocardial infarction

Confining the analysis to patients with a main diagnosis of “ischaemic heart disease without acute myocardial infarction” and without concomitant cardiac surgery results in a subgroup of patients with an a priori lower risk of dying within one year (see bottom part of Table 3). In this subgroup the observed one-year mortality did not vary statistically significantly by type of PCI, but was statistically significant lower compared to CABG patients. The expected mortality in the subgroup of patients with a lower risk of dying would have been slightly lower than the expected mortality in the total eligible population, signifying a more favourable distribution of age and sex in revascularized patients with neither myocardial infarction as main diagnosis nor concomitant heart surgery. In all three PCI groups the calculated SMRs are close to 1 and differ not statistically significantly from the general insured population (demonstrated by the 95% confidence intervals), whereas these CABG patients still have a statistically significant increased SMR compared to the general insured population.

Similar to the analysis based on all eligible patients, the predictive power of the multivariate model increased with successive entering of covariates, but differences in one-year mortality by type of revascularisation remained more or less unchanged: no statistically significant differences between PTCA, DES, and DES but higher mortality after CABG.

Discussion

One-year mortality compared to general insured population

The risk of dying within one year was increased compared to the general insured population, as indicated by the SMRs. In fact, because a part of the patients suffer from severe life threatening forms of coronary artery disease (e.g. myocardial infarction) one would expect them to be at a higher risk of dying within one year than the general insured population regardless of the type of revascularisation. When confining our population to coronary artery disease patients without acute myocardial infarction the observed one-year mortality of PCI patients is no longer different from that of the general population, as indicated by SMRs close to “1”. This is a reassuring message for patients scheduled for PCI for chronic CAD.

The case for CABG patients is a little more difficult: though the observed one-year mortality in CABG patients without concomitant heart surgery or acute myocardial infarction is lower compared to that of the total eligible population, still it is higher than that of the general insured population. This should not be attributed to CABG-surgery itself, it merely states that even the average “low risk” CABG patient is sicker than the average “low risk” PCI patient. This is not surprisingly, taking into consideration that only a small subset of patients scheduled for CABG could be treated effectively by PCI, as well [18].

One-year mortality by type of revascularisation

The observed differences in the crude one-year mortality rates by type of revascularisation in the total eligible population were large, but became smaller when looking at the low-risk population. The observed variation in crude one-year mortality by type of revascularisation is likely to result from bias due to baseline differences of prognostic factors among patients. In fact, age, sex, and the main diagnosis of the index admission explained the greater part of the observed variation in one-year mortality after percutaneous interventions, and including information about previous medication and diseases in the fully adjusted model reduced variation further. However, adjusting for confounders increased the difference in one-year mortality between CABG and other percutaneous interventions.

Discriminative power and calibration of the fully adjusted models was good and compared well to that of clinical prediction tools such as EuroSCORE [15] or GRACE [19]. These tools are intended to predict mortality in groups much more homogenous with regard to the underlying medical condition (e.g. EuroSCORE: CABG surgery, GRACE: acute myocardial infarction) than our study population, and rely to some extend on clinical information that can not be derived from German administrative health insurance data. From this point of view adjustment for confounders based on data of administrative data was reasonably good and accounted for much of the observed variation in one-year mortality after percutaneous coronary revascularisation, but it was unable to explain differences in mortality between CABG and PCI. It was more effective in the total eligible population than in the subgroup with lower risk, mainly because excluding patients with a main diagnosis of acute myocardial infarction and concomitant heart surgery from this subgroup attenuates the effect of the covariate “main diagnosis”.

Adjustment for confounders based on administrative database has been used for assessment of hospital performance and reimbursement decisions in the U.S. but also to compare outcomes of different therapies for scientific reasons [9], [10], [20]. In our case adjustment for confounding should allow a comparison of the outcomes of four common approaches to coronary revascularisation in unselected patients in daily clinical care. The information used for adjustment in this study was sufficient to explain observed differences in one-year mortality after PCI, but did not account for differences between in CABG and PCI patients. We tested some more variables commonly used in risk adjustment for mortality in coronary artery disease but neither a history of stroke, a physician diagnosis of hypertension, known renal insufficiency, nor COPD contributed statistically significant to the explana-
tion of differences in one-year mortality by type of revascularization. Instead, receiving antidepressants in the year prior to revascularization remained an independent predictor of one-year mortality after controlling for other confounders. This variable was superior to an ambulatory physician’s diagnoses of depression in predicting one-year mortality. This is difficult to explain, maybe it questions the validity of the physician’s diagnoses, or it is due to the fact that in some cases antidepressants may be prescribed for other than depressive disorders. There is contradictory evidence on the relationship between a history of depression prior to a cardiac event and subsequent cardiac mortality: In an early small study on patients presenting with myocardial infarction 8% reported antidepressant medication prior to myocardial infarction and these patients had a higher mortality [21]. This compares well to our findings. However, a recent study found a history of depression not to be related with cardiac mortality after myocardial infarction [22]. One has to keep in mind that we did not look on cardiac mortality but on all-cause mortality, and that our study population included all patients scheduled for coronary revascularisation, not only patients with myocardial infarction. We suggest that the higher adjusted one-year mortality in CABG patients in our study is a result of incomplete adjustment for confounders, e.g. we were unable to adjust for single- or multivessel disease, or ejection fraction, and we did not have information on the smoking status of the study population because such information was not available in the administrative data. The results from a recent observational register study seem to support this view: fully risk adjusted 18-months mortality in patients with multivessel disease after a CABG-procedure is lower than in patients having treated with DES [23].

Limitations and strengths of the study

Unfortunately, this study does not add to the ongoing discussion about long-term mortality by type of coronary stenting [24], because the time frame for analyses is too short, and, much more importantly, the study population is too small to detect differences in mortality by type of stent. Since the size of the population in a study based on health insurance data is a direct function of the size of the health insurance fund, it might be worth to replicate the work presented here with data of a larger health insurance fund in order to gain insight into longer term mortality after BMS and DES.

Because our analyses are based on administrative data from a medium sized health insurance fund, it has to be discussed whether these data can be regarded as representative for Germany in general or at least for the German population covered by the statutory health insurance. Due to a lack of corresponding information (i.e. representative data on one-year mortality for Germany) we are not able to compare our results directly. When looking at sources of potential biases two issues emerge:

1. bias due to selected hospitals (that would be the case, if beneficiaries from the health insurance were treated in hospitals that are not representative for all hospitals in Germany), and
2. bias due to selected beneficiaries (that would be the case, if a substantial part of the subpopulation is lost to follow-up or in case that beneficiaries from the health insurance are not representative for the German revascularisation population in general).

With regard to the first potential source of bias (selected hospitals) several points can be made: By law, the health insurance has contracted all hospitals offering surgical or percutaneous coronary revascularisation to patients from the statutory health insurance in Germany. Therefore, selection bias due to special contracting by the health insurance was not possible and beneficiaries from that specific health insurance could have been treated in any hospital. Furthermore, we looked to what extend the 77 cardiac surgery units and the 824 hospitals offering PCI in 2005 were represented in our eligible population. All cardiac surgery units and about 44% of the PCI performing hospitals were represented in our data (data not shown). Taking into account that our PCI-study sample it is too small to cover all German PCI-offering hospitals, and that even the mandatory clinical audit covered only 80% of the PCI performing hospitals in the year 2005 ([3], [25], we think a bias due to selected hospitals is unlikely to exist. In addition, the number of beneficiaries by index procedure and treating hospital was very low, ruling against a bias due to selected hospitals (and prohibiting hospital specific analysis).

With regard to a bias due to selective lost to follow, we think that a strength of our study is the completeness of the data: only 0.4% of the initial study population were lost to follow-up. The high completeness reflects the stability of the insured population in this health insurance, and might not be achieved with administrative data of other health insurances were more persons entering or leaving the insurance.

Is the reported mortality data representative for Germany? The surgical and percutaneous approaches analysed in this study accounted for about 1.1% of all CABG-surgery and PCIs performed in Germany during the year 2005. The CABG, DES, as well as the BMS group of patients comprised enough numbers of cases allowing for rather stable estimates of one-year mortality. We know from previous analyses that the population covered by the health insurance providing the data for this study differs from the general German health insured population insofar, that men and younger people are overrepresented [26]. To some extent this can be seen in our analysis: e.g. the mandatory clinical audit on isolated CABG surgery [3] reports an average age of 67.2 years and 22.7% females compared to 65.2 years and 13.7% females reported here. For PCI patients corresponding data on age and sex are not published by the mandatory clinical audit, but data from international and national PCI registers indicate a similar trend: in general PCI patients seem to be older...
and more often female than in our population [6], [27]. Therefore, our observed one-year mortality rates might be biased towards a better outcome. In fact, when we calculate in-hospital mortality, where officially published data on CAGB patients are available, and limit our the analysis to a subpopulation of CAGB patients without concomitant heart surgery (which resembles the target population of the clinical audit) our observed outcomes are slightly better than the official numbers, but the confidence interval around our observed in-hospital mortality includes the officially reported number, too (Table 4).

Table 4: Observed in-hospital in CAGB patients without concomitant heart surgery in the present study and the mandatory clinical audit [3]

<table>
<thead>
<tr>
<th>In-hospital mortality</th>
<th>Present study</th>
<th>Mandatory clinical audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (n)</td>
<td>629</td>
<td>49904</td>
</tr>
<tr>
<td>Mortality (n)</td>
<td>20</td>
<td>1650</td>
</tr>
<tr>
<td>Mortality rate (%)</td>
<td>3.2</td>
<td>3.3</td>
</tr>
<tr>
<td>(95%-CI)</td>
<td>(1.9-4.2)</td>
<td>(3.2-3.5)</td>
</tr>
</tbody>
</table>

We would like to conclude that analysing administrative data from a reasonably large German-wide operating health insurance is useful to gain valid information on one-year mortality following coronary revascularisation in unselected patients from routine German health care. Such information is currently unavailable from other sources. A draw back of these data is a lack of information on some (but not all) important confounders. That is, why adjustment for confounders based on administrative data did not account for the higher one-year mortality after CAGB, but explained observed differences between the various percutaneous interventions.

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Conflict of Interest
None declared.

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References


17. Bitzer et al.: One-year mortality after ...


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