ORIGINAL ARTICLE

Risk Factors and Event Rates in Patients With Atherothrombotic Disease in Germany

Results of the REACH Registry

Uwe Zeymer, Klaus G. Parhofer, Jochen Senges, Joachim Röther

SUMMARY

Introduction: The aim of the international Reduction of Atherothrombosis for Continued Health (REACH) registry was to identify prospectively characteristics, risk factors, treatments, and cardiovascular event rates in stable outpatients with atherothrombotic disease, as well as in asymptomatic patients with risk factors for atherothrombotic disease.

Methods: A total of 512 physicians in Germany enrolled 4986 outpatients with documented atherothrombotic disease, as well as 608 asymptomatic patients with at least three risk factors for atherothrombotic disease, in the REACH registry. Patients will be followed for up to four years, with assessments being performed at regular intervals; the results of the one-year follow-up are presented here.

Results: The documented risk factors were hypertension (58.2%), hypercholesterolemia (74.6%), diabetes (37.6%), and obesity (28.1%). A large percentage of patients did not reach the therapeutic target values specified in current German and European S1 guidelines. After 1 year, 2.1% of the patients with symptomatic atherothrombotic disease and 1.5% of the patients with at least three cardiovascular risk factors had died of a cardiovascular event, whereas 5.8% of the former and 2.5% of the latter patient group had reached a combined endpoint consisting of cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke.

Conclusion: The traditional risk factors are common in patients with coronary heart disease, cerebrovascular disease (stroke and/or transient ischemic attack), or peripheral arterial occlusive disease. Many patients with these conditions or associated risk factors are not treated according to current guidelines. This may explain, at least in part, the high rates of cardiovascular events observed after one year.

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Key words: cardiovascular risk factors, coronary heart disease, outpatient care, stroke, arterial occlusion

Although patients with acute coronary syndrome have been examined in a number of extensive registries or surveys (1–4), data on treatment patterns and risk in stable patients with atherothrombosis remain limited. The same applies to patients with established cardiovascular risk factors. Regional and national evaluations are especially important considering the degree to which patients may differ in terms of their characteristics, treatment patterns, and prognosis (5–7).

The Reduction of Atherothrombosis for Continued Health (REACH) registry is the first registry to characterize the entire spectrum of patients with atherothrombotic disease in one or more vascular beds (cerebral, coronary, peripheral). The aim of the registry is to collect data prospectively on the prevalence of risk factors, as well as on medication use and revascularization therapy. The registry is also designed to document the percentage of patients treated according to guidelines and the rate of cardiovascular events over time in patients with manifest atherothrombotic disease and in asymptomatic patients with ≥ 3 risk factors. In addition, the impact of different treatments and of meeting treatment targets on the clinical course of disease will be examined. The present study outlines the major findings pertaining to the German REACH population and the results of the one-year follow-up.

Methods

Design and representativeness

The REACH registry is an international, prospective, purely observational registry with an observation period of four years (8, 9). Participating physicians in Germany were selected based on market-research data from 2003 showing that the relative frequency of coronary artery disease (CAD), cerebrovascular disease (CVD), and peripheral arterial disease (PAD) among German patients was 45%, 30%, and 25%, respectively. The attempt was thus made to recruit general practitioners (GPs) and specialists in urban and rural areas, while taking into account the size of each state and the proportions of both categories of physician. For this purpose, private-practice physicians in all 16 German states were contacted by an independent clinical research organization (CRO). Three-fourths of the physicians' names were provided by field staff working for the CRO, and one fourth were obtained from physician registries. The proportion of

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FIGURE 1

Inclusion criteria for the REACH registry

participating physicians in each state was roughly equivalent to each state's proportion of the overall German population (*e-table*). Of the 650 physicians contacted, a total of 512 ultimately participated in the registry. Physicians received 150 euros for each included patient. Data on the participation rate among all patients approached by the physicians are not available.

The registry was funded by Bristol Myers Squibb GmbH & Co KGaA und Sanofi-Aventis GmbH. The sponsors were involved in planning the registry and developing the data entry forms, but had no influence on data analysis, data interpretation, or manuscript preparation. Although the manuscript was presented to the

sponsors before it was submitted for publication, they were not allowed to make or suggest changes.

Inclusion and exclusion criteria

Between January and June 2004, each participating physician enrolled up to 15 consecutive patients in the registry. To be eligible for the registry, patients had to be 45 years of age or older and have (a) a history of one or more of the three manifestations of atherothrombosis or (b) at least three established risk factors for atherothrombotic disease (*figure 1*).

CAD was defined as diagnostically confirmed stable or unstable angina, previous percutaneous coronary intervention (PCI), previous coronary artery bypass graft surgery, and/or previous myocardial infarction. CVD was defined as a transient ischemic attack or stroke documented by a hospital or neurologist. PAD was defined as intermittent claudication with an ankle-brachial index of less than 0.9 or a history of intermittent claudication in the context of PCI, atherectomy, peripheral revascularization, amputation, or other intervention involving the arteries of the legs or feet. Patients with no history of CAD, CVD, or PAD could only be included in the registry if they had at least three of the risk factors shown in *figure 1*. Exclusion criteria were participation in a clinical trial, hospitalization during the inclusion period, or foreseeable difficulty attending follow-up visits.

Ethics and quality assurance

The study protocol was centrally evaluated and approved by the Rhineland-Palatinate State Medical Association and the relevant local ethics committee. After all interested patients had received detailed information about the study, those who chose to participate provided written, informed consent. As a quality assurance measure, 10% of the study centers in each German state were audited on site (6% were chosen randomly, and 4% were chosen because the amount of missing data or the number of follow-up queries were greater than average). All patient data forms were checked for completeness and plausibility.

Definitions for baseline examination

Data were collected using standardized international case report forms, which were filled out at each study visit, and entered into a central database. The following parameters were evaluated: height, weight, and body mass index (BMI, kg/m²). Participants were classified as overweight if they had a BMI between 25 and 29.9, and as obese if they had a BMI of 30 or more. Moreover, patients with increased waist circumference (men >102 cm; women >88 cm) were also classified as obese. Current smoking was defined as consuming at least five cigarettes per day on average in the three months before entering the study; former smoking was defined as at least five cigarettes per day on average more than one month before entering the study. Guideline-consistent treatment goals (10–14) were defined as not smoking, blood pressure <140/90 mmHg, and total cholesterol <190 mg/dL. All of the guidelines were S1 guidelines,

FIGURE 2

Affected vascular beds among German patients included in the REACH registry (RF = risk factors; CAD = coronary artery disease; CVD = cerebrovascular disease; PAD = peripheral arterial disease)

TABLE 1

Demographic and clinical characteristics of the German REACH population

	Total	Asymptomatic patients with ≥ 3 risk factors	Symptomatic patients (total)	CAD	CVD	PAD
	(n = 5594)	(n = 608)	(n = 4986)	(n = 3510)	(n = 1706)	(n = 1354)
Age, mean (SD)	68.0 (9.1)	69.4 (9.1)	68.0 (9.1)	68.0 (9.0)	69.4 (9.1)	68.0 (8.9)
Men, %	67.7	51.0	69.7	73.6	62.4	71.5
Diabetes, %	37.6	67.1	34.0	35.0	36.4	39.0
Hypertension, %	58.2	79.3	55.6	55.4	63.5	57.9
Hypercholesterolemia, %	72.6	66.7	73.3	80.0	65.3	68.4
Overweight BMI 25.0–29.9 kg/m ² , %	48.4	41.9	48.6	49.5	47.9	44.2
Obesity BMI ≥ 30.0 kg/m ² , %	28.1	42.4	26.4	27.9	25.7	23.7
Abdominal obesity BMI ≥ 30 kg/m ² or abdominal obesity, %	50.2	60.5	49.4	49.2	51.1	48.5
Current smoker, %	17.3	22.2	16.7	13.7	16.3	28.7
Former smoker, %	45.6	26.2	47.9	51.1	44.0	49.1

SD = standard deviation, BMI = body mass index

and in cases where the target values differed, the higher, less strict value was used.

Follow-up assessments

The first two follow-up assessments took place at 12+3 months (results reported here) and at 21+3 months; additional follow-ups will be at 35+3 months and 45+3 months. Physicians were instructed to aim for high participation rates during this phase through active follow-up. During follow-up, data are collected on the following events: cardiovascular death, nonfatal stroke, nonfatal myocardial infarction, vascular procedures in any of the three vascular beds (PCI with or without stenting, bypass surgery, amputation due to ischemia), and hospitalization due to a cardiovascular event (including transient ischemic attack, unstable angina, and worsening of PAD). The primary combined endpoint of the analysis consisted of cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke. Another combined endpoint consisted of the primary combined endpoint together with hospitalization for a cardiovascular event.

Statistics

Continuous data were presented as mean, with standard deviation (SD) as the measure of spread; categorical data were presented as frequencies and percentages. All analyses were performed with SAS 8.0 (SAS Institute Inc., Cary, NC, USA). Data for the German cohort were analyzed by the Institute for Myocardial Infarction Research (Institut für Herzinfarktforschung Ludwigshafen) at the University of Heidelberg, Germany.

Results

In Germany, a total of 512 physicians participated in the study (46.8% family practitioners and GPs; 41.3% internists; 17.5% cardiologists; 8.9% neurologists; 5.2% endocrinologists; 9.9% angiologists; 10.5% physicians in other fields; some physicians may have been counted in more than one category). They recruited a total of 5594 patients, of whom 10.8% had cardiovascular risk factors only and 89.2% had one or more manifestations of atherothrombotic disease (i.e. 63.8% CAD; 31.1% CVD; 24.2% PAD; due to overlap between the locations of atherosclerotic disease, some patients were counted in more than one group). Almost one-third of the patients had two or three manifestations of atherothrombosis, as can be seen in *figure 2*.

Comorbidities and risk factors

Table 1 shows the baseline data and characteristics of the study participants at baseline. The majority of patients with symptomatic atherothrombosis were men. Among asymptomatic patients with cardiovascular risk factors only, gender distribution was equal. The average age in both groups was high (i.e. approximately 69 years). Comorbidities and cardiovascular risk factors were frequent, especially hypertension, hypercholesterolemia, and diabetes. In total, 26.4% of patients with symptomatic atherothrombosis and 42.4% of patients with only risk factors for atherothrombotic disease were obese. A sizable percentage of patients in both groups were current smokers (symptomatic atherothrombosis: 16.7%; risk factors only: 22.2%). The percentage of current smokers among patients with PAD was especially high (i.e. 28.7%).

TABLE 2

Pharmacotherapy

	Total	Asymptomatic patients with ≥ 3 risk factors	Symptomatic patients (total)	CAD	CVD	PAD
	(n = 5594)	(n = 608)	(n = 4986)	(n = 3510)	(n = 1706)	(n = 1354)
Platelet inhibitors						
• At least 1, %	79.0	45.2	84.0	84.7	81.6	81.6
• Acetylsalicylic acid, %	66.7	41.6	69.3	72.9	58.6	68.2
• Other, %	23.6	4.3	25.7	24.1	34.7	24.2
• Two, %	9.8	0.7	11.1	12.3	10.6	10.7
Oral anticoagulants, %	12.0	6.3	12.0	12.5	13.9	14.2
Nonsteroidal anti-inflammatory drugs, %	10.2	13.7	9.8	9.8	12.4	11.2
Lipid-lowering agents						
At least 1, %	74.1	64.1	75.4	82.5	66.2	71.5
Statins, %	69.9	57.8	71.4	79.1	62.0	66.9
Other, %	8.3	9.8	8.1	8.0	6.9	9.0
Number of patients with diabetes	(n = 2101)	(n = 408)	(n = 1693)	(n = 1227)	(n = 621)	(n = 528)
• At least 1 antidiabetic agent, %	97.8	97.3	97.9	97.5	97.7	97.9
• Sulfonylureas, %	35.8	32.8	36.6	36.5	38.3	34.5
• Biguanides, %	42.0	52.5	39.4	38.3	38.3	33.4
• Insulin, %	42.4	35.0	44.2	45.2	41.6	50.2
• Thiazolidinediones, %	4.5	8.0	3.6	3.8	2.8	3.1
• Other, %	11.0	16.0	9.8	9.7	10.0	7.7
Antihypertensive (AH) and antianginal (AA) therapy						
• At least 1 AH and/or AA, %	93.2	92.4	93.5	97.0	91.7	89.4
• 2 AHs and/or AAs, %	15.3	21.4	11.5	11.8	11.2	10.6
• 3 AHs and/or AAs, %	26.2	14.8	21.4	11.7	28.7	27.2
• > 3 AHs and/or AAs, %	39.4	40.3	35.9	45.8	38.7	39.2
• Beta-blockers, %	60.9	44.1	63.8	74.8	51.3	52.5
• Calcium antagonists, %	27.7	29.8	27.8	27.4	31.9	31.2
• Diuretics, %	47.1	49.2	47.4	50.1	48.9	48.7
• ACE inhibitors, %	55.8	50.0	57.1	60.9	54.2	55.2
• Angiotensin receptor blockers, %	19.8	28.8	18.9	19.4	19.3	18.2
• Other blood-pressure-lowering agent, %	9.6	13.7	9.2	9.4	7.9	9.2
• Nitrates, %	23.0	5.1	25.4	33.6	19.5	22.5

Medication use

Table 2 gives an overview of the medication used at baseline to treat important comorbidities. Platelet inhibitors were administered to 94% of patients with clinically manifest CAD, but less frequently to patients with CVD or PAD. In patients with only risk factors, approximately 50% received this treatment. Among symptomatic patients, statin treatment was administered, predominantly to patients with CAD; patients with only risk factors were less likely to receive statin treatment.

Meeting guideline-based treatment targets

Patients in the REACH registry frequently failed to meet the treatment targets specified in current German and European guidelines (10–14). Figure 3 shows the proportion of patients in different subsets of the cohort who had not reached specific treatment targets at baseline.

Cardiovascular events

One-year follow-up was available for 5267 (95%) of the German registry patients. Baseline data for this group did not differ from baseline data for patients for whom 1-year follow-up data were not available. All-cause mortality at one year was 2.5% for patients with symptomatic atherothrombosis and 2.6% for patients having risk factors only. Cerebrovascular mortality at one year was 1.8% for patients with symptomatic atherothrombosis (i.e. 72% of all mortalities in this subset) and 1.5% for patients having risk factors only (i.e. 57.7% of all mortalities in this subset). Figure 4 shows the cardiovascular event rates in the individual subgroups. Compared to patients with CAD or CVD, patients with PAD had the highest cardiovascular mortality. In contrast, the risk for the combined endpoint consisting of cardiovascular death, nonfatal myocardial infarction, and nonfatal

stroke was highest among patients with CVD. For the combined cardiovascular mortality and morbidity endpoint (i.e. including hospitalization for cardiovascular events), the risk was by far the highest among patients with PAD (i.e. 18.1%) compared to patients with CAD (15.0%) or CVD (14.9%). A clear increase in event rates was observed in patients with multiple symptomatic vascular beds (*figure 5*).

Discussion

The German data from the REACH Registry show that the established risk factors are distributed evenly among patients with atherothrombotic disease, and that the different manifestations of atherothrombotic disease appear frequently in combination. The data also show that rates of acute cardiovascular events were high even after only a short period of follow-up.

It is important to note that the REACH registry is not population based, and therefore its data set does not allow for conclusions to be drawn about the prevalence of different manifestations of atherothrombosis in the general community. Similarly, because participating physicians were not chosen randomly, the physician practices in the sample cannot be regarded as representative. Indeed, physicians who participate in registries and studies are generally a selected group with a disproportionately large percentage of patients treated in a guideline-consistent manner.

Nevertheless, the REACH registry provides a detailed overview of typical patients with atherothrombotic disease. Compared to most clinical trials, for example, the percentage of women in the registry is considerably higher, with female patients accounting for approximately half of asymptomatic patients and one-third of symptomatic patients. The large proportion of older patients in the registry is also noteworthy; because these patients are frequently underrepresented in clinical trials, formulating treatment recommendations for them has traditionally been a challenge (15).

Almost one-third of patients in the registry had symptomatic atherothrombosis simultaneously in two or even three vascular beds. In fact, in patients with PAD, polyvascular disease was observed in more than 60% of cases, compared to earlier epidemiological surveys and clinical trials, in which polyvascular disease was observed in 23% to 40% of patients (16, 17). The prevalence of such factors was consistent across the individual subgroups of symptomatic patients.

Earlier epidemiological studies in Germany have unanimously criticized the inadequacy of treatment, including pharmacological interventions, in patients with cardiovascular risk factors. This applies in particular to patients with cardiovascular disease or diabetes (18–20). Therapy among patients in the REACH registry who had risk factors for atherothrombotic disease was also in need of improvement: Lipid-lowering or antiplatelet agents, for example, were being administered to only three-fourths of the patients requiring these treatments. The inadequate use of pharmacological therapy may also explain the low percentages of patients

FIGURE 3

Percentage of smokers, hypertensive patients with blood pressure >140/90 mmHg, and patients with total cholesterol >190 mg/dL in various subsets of German cohort; RF = risk factors, CAD = coronary artery disease; CVD = cerebrovascular disease; PAD = peripheral arterial disease

meeting target goals for blood pressure or cholesterol. Indeed, 27% of patients with hypertension had blood pressure greater than 140/90 mmHg, and 66% of patients with hyperlipidemia had cholesterol values greater than 190 mg/dL. Here it should be noted that for some groups of patients (e.g. those with diabetes or nephropathy) even lower blood pressure and target lipid values are recommended, which means that the use of evidence-based preventive therapies in REACH may actually be overestimated. Looking at the patients with multiple treatable risk factors reveals that, in everyday clinical reality, there are hardly any patients whose condition or disease can be described as being managed perfectly (20, 21). In this context, defining cut-off values for managing risk factors in individual patient groups plays an important role. In the United Kingdom, for example, guidelines recommend treatment with statins, ACE inhibitors, and beta-blockers for all patients following myocardial infarction, but without defining target goals for blood pressure or cholesterol (22). It can be assumed, although it has not been investigated yet, that when different guidelines are used, the results vary as well.

The REACH registry is limited by the fact that it does not document the reasons for or against a particular pharmacological intervention, or for or against meeting a particular treatment goal. In addition, the extent to which a guideline-consistent treatment can reduce event rates is not something that can be measured precisely using this registry; to do so, randomized studies are necessary. Absolute risk reduction depends on a patient's baseline risk. Considering event rates of approximately 10% in primary prevention, the absolute benefit of guideline-consistent pharmacological treatment in preventing the combined endpoint consisting of death, nonfatal

FIGURE 4

Cardiovascular events within the first year of follow-up in patients with manifest atherothrombosis; CAD = coronary artery disease; CVD = cerebrovascular disease; PAD = peripheral arterial disease; CV = cardiovascular; MI = myocardial infarction; combined endpoint = CV death, nonfatal stroke, nonfatal MI, and hospitalization for CV event

myocardial infarction, and nonfatal stroke ranges from 2% to 3% for thrombocyte aggregation inhibitors, from 3% to 4% for statins, and from 2% to 3% for ACE inhibitors. These percentages are somewhat higher in secondary prevention. It should be pointed out, however, that there are currently no data on any additive benefit of these treatments. Naturally, even guideline-consistent

FIGURE 5

Cardiovascular events within the first year of follow-up and their relationship to the number of vascular beds affected by atherothrombotic disease; RF = risk factors; CV = cardiovascular; MI = myocardial infarction; combined endpoint = CV death, nonfatal stroke, nonfatal MI, and hospitalization for CV event

treatment cannot always prevent cardiovascular events, especially in patients with high overall risk (21). The foundation of any recommendation should consist, of course, of nonpharmacological interventions, such as smoking cessation, dietary adjustments, weight loss, and exercise training.

The high prevalence of overweight and obese patients in REACH is notable, as both increased BMI (23) and abdominal obesity (24) are established risk factors for cardiovascular mortality and morbidity.

In the follow-up period of the study, the high rate of cardiovascular events was especially apparent. Considering all fatal and nonfatal events, including hospitalization, shows that one out of five symptomatic patients, and one out of 15 asymptomatic patients, were affected. In other words, clinically manifest atherothrombosis is associated with an event rate roughly three times greater than that observed among asymptomatic patients at a clinically silent preliminary stage of disease. Patients with PAD were not only more likely to experience cardiovascular death, but were also much more likely than patients with CAD or CVD to reach the combined mortality/morbidity endpoint. PAD patients appeared to be at an especially high risk, even in cases where the ankle-brachial index was less than 0.9 but intermittent claudication had not yet occurred. This finding is due in particular to the high proportion of PAD patients with polyvascular disease (25).

The REACH registry will provide up to four years of follow-up data on morbidity and mortality (26). Evaluations of the cross-risk among patients with one manifestation of atherothrombosis for experiencing additional events in other vascular beds will contribute to a better understanding of atherothrombosis as a systemic vascular disease

Conflict of interest statement

The REACH registry was funded by Bristol Myers Squibb GmbH & Co KGaA and Sanofi-Aventis GmbH. All authors have received research support and lecture fees from both companies.

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E-TABLE

Distribution of physicians participating in the REACH registry

State	Total	GPs	Internists	Cardiologists	Angiologists	Vascular surgeons	Neurologists	Endocrinologists/ diabetologists	Others
Baden-Württemberg	49	26	16	11	4	0	4	2	3
Bavaria	85	43	39	10	8	0	7	3	8
Berlin	20	8	9	5	4	0	0	0	1
Brandenburg	18	8	8	0	1	0	2	2	4
Bremen	5	2	2	0	0	0	1	1	0
Hamburg	16	9	4	3	1	0	2	0	2
Hesse	43	22	19	5	6	0	2	3	6
Mecklenburg-West Pomerania	18	10	5	2	1	0	4	0	0
Lower Saxony	36	17	13	6	4	0	3	3	4
North Rhine-Westphalia	111	46	49	20	12	0	12	5	14
Rhineland-Palatinate	27	12	12	5	2	0	1	5	2
Saarland	8	5	5	2	1	0	1	0	2
Saxony	36	15	17	11	2	0	3	3	5
Saxony Anhalt	12	8	4	1	2	0	0	0	2
Schleswig-Holstein	16	6	5	4	0	1	2	0	0
Thuringia	12	3	4	5	2	0	1	0	0
Total	512	240	211	90	50	1	45	27	53