ORIGINAL ARTICLE

The Epidemiology of Osteoporosis—Bone Evaluation Study (BEST)

An Analysis of Routine Health Insurance Data

Peyman Hadji, Silvia Klein, Holger Gothe, Bertram Häussler, Thomas Kless, Torsten Schmidt, Thomas Steinle, Frank Verheyen, Roland Linder

SUMMARY

Background: Osteoporosis is a widespread disease of the skeleton that becomes more common with advancing age. Its prevalence is still inadequately documented. The goal of this study is to determine how common osteoporosis is in Germany.

Methods: The routine billing data of a large statutory health insurance carrier in Germany (the TK company) from the years 2006 to 2009 were anonymized and retrospectively analyzed. Insurees aged 50 and above with osteoporosis were identified either from their bearing the diagnosis of osteoporosis or of osteoporosis-related fractures, or from their having received prescription medication for osteoporosis. The prevalence and incidence of osteoporosis and the frequency of osteoporotic fractures were calculated for TK insurees and extrapolated to the overall German population.

Results: The prevalence of osteoporosis among persons aged 50 and above, as revealed by diagnoses of osteoporosis or osteoporotic fractures, or by the prescription of medication for osteoporosis, was found to be 14% (240 657 of 1.7 million insurees) in the year 2009; the sex-specific prevalence was 24% in women and 6% in men. An extrapolation of these figures implies that 6.3 million persons in Germany have osteoporosis. The incidence of osteoporosis in the same age group, as revealed by a diagnosis of osteoporosis or prescription of medication for osteoporosis, was found to be 2.1% per year, with 104 528 insurees having an index event for osteoporosis (initial diagnosis of osteoporosis or first prescription of a medication for osteoporosis). An extrapolation of this figure implies that 885 000 persons newly develop osteoporosis in Germany each year. Over the period of observation, 52% of the affected persons (total, 172 473 persons) sustained fractures, many of which were multiple.

Conclusion: Osteoporosis is still common in Germany. The large number of insurees with single and multiple fractures implies that the treatment of this disease in Germany needs to be improved.

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Osteoporosis is a systemic disease of the skeleton characterized by low bone density and abnormal microarchitecture of bone tissue. It becomes clinically evident through the occurrence of osteoporosis-related fractures (1). Low bone density, other risk factors, and the associated fractures are seen above all in the elderly. The prevalence of osteoporosis and of osteoporotic fractures can be expected to rise, because the population as a whole is growing older.

Osteoporotic fractures—particularly of the femoral neck and of the vertebral bodies—impair the quality of life (2, 3) and increase mortality (4, 5). They account for most of the burden of disease in patients with osteoporosis. Fractures also lead to greater utilization of medical services, with the associated high costs (4, 6).

The prevalence of osteoporosis in Germany has been assessed in a number of studies, yet these have been heterogeneous with regard to their methods, data sources as well as the age groups and populations studied (7–10) and have therefore yielded divergent findings. In the telephone health survey of the Robert Koch Institute (RKI), 11.9% of the persons aged 50 and above who were interviewed (5.2% of men and 17.6% of women) said that they had received a medical diagnosis of osteoporosis (8). On the other hand, the BoneEVA study, carried out in 2003, arrived at the conclusion that 25.8% of the insurees aged 50 and above who were studied (9.7% of men and 39.0% of women) were osteoporosis patients (9, 10). Meisinger et al., in 2002, arrived at prevalence figures of 1.2% for men and 7.0% for women between the ages of 25 and 74 (7).

The assessment of the MONICA cross-sectional study (Augsburg, Germany) revealed that, in 1994/1995, 31.0% of women and 45.1% of men aged 25 to 74 had at least one fracture, with markedly higher fracture rates in women over age 65 (7). Although the presence of osteoporosis and the circumstances of the fractures were also investigated in this study, it was not stated what percentage of the fractures were due to osteoporosis. Figures on the latter question were reported by Brecht and Schädlich (11).

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The S3 guideline of the German Osteology Group (*Dachverband Osteologie*, DVO) was initially issued in 2003 and updated in 2006 and 2009. On the basis of this guideline, we carried out the present study with the goal of analyzing the current epidemiological status of osteoporosis in Germany, and the state of care, by means of routine billing data of a large statutory health-insurance carrier (*Techniker Krankenkasse*, TK) for the years 2006 to 2009. This article focuses on the frequency of osteoporosis and of fractures; prescribing behavior, the frequency of bone-density measurement, and the costs due to osteoporosis are reported elsewhere. The Bone Evaluation Study (BEST) was conceived by the IGES Institute in cooperation with its project partners, the Scientific Institute of the TK (WINEG) and Prof. Dr. med. Peyman Hadji of Philipps-Universität Marburg (Germany). The study was supported by Amgen GmbH and Nycomed GmbH.

Methods

Anonymized billing data of TK were retrospectively analyzed. The patient population (*Figure 1*) consisted of insurees who were at least 50 years old during the period of the study (2006–2009) and who were identified as suffering from osteoporosis in that time (*Box 1*, *Figure 1*). For technical reasons relating to data acquisition, there were two subpopulations, A and B; the difference between them was that population A included insurees who exclusively had osteoporosis-related fractures without fulfilling any of the other inclusion criteria. The data collected on patients in population B were more complete; therefore, certain analyses were based only on population B. The methods of this study are presented in full detail in the *eBox*.

Results

Over the period of the study, 1.7 million persons aged 50 or over were insured by TK for at least one day. 331 468 insurees with a mean age of 66.6 years were identified as osteoporosis patients and included in the analysis (patient population A). 63% of them carried a diagnosis of osteoporosis, 21% were prescribed medication to treat osteoporosis, and 52% had osteoporotic fractures. 2% of the insurees received prescriptions for medications used to treat osteoporosis but were not diagnosed as having osteoporosis and did not have any osteoporotic fractures.

The group of patients who bore the diagnosis of osteoporosis and/or were treated with medications against osteoporosis consisted of 217 960 persons (patient population B). 96% bore the diagnosis of osteoporosis, 32% filled prescriptions for medications used to treat osteoporosis, and 28% met both criteria for inclusion in the group. 3.9% of all persons in patient population B received medications against osteoporosis without having received a diagnosis of osteoporosis (*Figure 1*).

Patient populations (Pat. pop.) broken down by inclusion criteria

The prevalence of osteoporosis among insurees aged 50 and above was found to be 14% in 2009 (240 657 cases), with a higher prevalence in women (24%) than in men (6%) (patient population A) (*Figure 2*). An extrapolation of these figures to all of Germany yields an estimated 6.3 million osteoporosis sufferers in the country in 2009, including 5.2 million women and 1.1 million men.

A total of 104 528 insurees in patient population B had an osteoporosis index event; the annual incidence of osteoporosis derived from this figure is 2.1% (3.6% for women and 0.9% for men). The new cases of osteoporosis displayed typical age and sex distributions: Among 50- to 54-year-olds, 2.1% of women and 0.4% of men newly developed osteoporosis, while the corresponding figures for persons over age 74 were 5.8% and 2.3%, respectively. An extrapolation of these figures to the entire German population yields an estimated 885 000 new cases of osteoporosis in the country per year.

A total of 172 437 insurees had at least one osteoporosis-related fracture within the period of observation (patient population A). The fracture rate was thus 52% (women, 45%; men, 67%) and rose with increasing age; *Table 2* shows the distribution of fracture sites. 40 553 (69%) of the 58 929 patients with fractures in population B actually had multiple fractures.

Discussion

The purpose of this study was to provide an epidemiological analysis of osteoporosis among persons aged 50 or above in Germany.

Current figures for the incidence of diagnosed or treated osteoporosis were calculated: The routine-data

BOX

Inclusion criteria for the identification of insureds as osteoporosis patients

- Diagnosis of osteoporosis with or without pathological fracture (ICD-10 code M80.* or M81.*) (patient populations A and B).
- At least one prescription for an osteoporosis-specific medication: bisphosphonates, raloxifen, strontium ranelate, parathormone, other (e.g., alfacalcidol, calcitonin, sodium fluoride) (patient populations A and B).
- At least one prescription of a hormone preparation (estrogens, including combined preparations) AND basic therapy (calcium, vitamin D) (patient populations A and B).
- Diagnosis of an osteoporotic fracture (S22.*–S82.*). Only some, not all, insureds with one or more fractures but no other fulfilled inclusion criteria were considered to be osteoporosis patients for the purpose of inclusion in the analysis. The percentage of insureds whose fractures were designated as due to osteoporosis (Table 1) was based on considerations of age, sex, and fracture site, analogously to the procedure previously used in the BoneEVA study (9–11) (patient population A only).

analysis revealed an annual incidence of 2.1 new cases per 100 TK insureds aged 50 or above. This can be extrapolated to an expected 885 000 new cases per year in all of Germany, not including undiagnosed and untreated cases.

Moreover, an annual prevalence of 14% was found among TK insureds aged 50 or above (women, 24%; men, 6%). This corresponds to an estimated nationwide figure of 6.3 million affected persons. This annual prevalence determined by BEST is markedly above the 11.9% lifetime prevalence figure calculated from information that patients gave about themselves in a previous study conducted by telephone survey (8). The difference becomes smaller when the prevalence is estimated from the group of insureds who received either a diagnosis of osteoporosis or medications for it (patient population B); when calculated in this way, the annual prevalence among insureds aged 50 or over is found to be 12%. Methodological differences—annual vs. lifetime prevalence, routine-data analysis vs. telephone survey—might account for the discrepancy. Differences between data sources might also account for the discrepancy between these prevalence figures and the much higher prevalence of 25.8% determined by the BoneEVA study in 2003 (9, 10): In the present study, lower prevalences were found in all age groups, most prominently in women. In the BoneEVA study, two different data sources were used, namely, billing data

FIGURE 2

The prevalence of osteoporosis within a single year, in percent, according to age and sex

from two different health-insurance carriers, the *Gmünder Ersatzkasse* and the *Zentralinstitut für die Kassenärztliche Versorgung*. Moreover, the criteria for a diagnosis of osteoporosis changed between 2003 and 2009, the years for which the data in the BoneEVA study and the BEST were obtained: The DVO-S-III guideline was issued in 2003 and its effect was not yet observable in data from that year. There were also more medications available to treat osteoporosis in 2009 (intravenous bisphosphonates, strontium ranelate, parathormone). On the other hand, a number of factors tending to limit the number of prescriptions for such medications in 2009 were not yet in effect in Germany in 2003 (e.g., positive and negative physician incentive programs, medication testing, restriction of prescribing to the active substance).

The reimbursement of inpatient treatment according to diagnosis-related groups (DRGs) was introduced in Germany in 2004. This led to hospitalized patients with osteoporosis being preferentially treated for osteoporosis-associated fractures, followed by routine clinical coding of the fracture, while osteoporosis was not necessarily coded as a secondary diagnosis; the additional coding of osteoporosis generally did not lead to any increased revenue for the hospital. Because of these and other differences in method and in the conditions of care, we think the apparent drop in prevalence from 2003 to 2009 is unlikely to be real. The figure determined for the year 2009 is the best possible estimate of the current prevalence of osteoporosis in Germany on the basis of the available data.

TABLE 1

Osteoporotic fractures as a percentage of all fractures, subdivided by ICD-10 code, age, and sex

	Fracture site	Age 50–64		Age 65–74		Age 75+	
		Men (%)	Women (%)	Men (%)	Women (%)	Men (%)	Women (%)
S22.*	Rib(s), sternum, thoracic spine	63	73	65	75	65	75
S32.*	Lumbar spine, pelvis	62	72	65	75	68	78
S42.*	Shoulder region, arm	34	44	40	50	60	70
S52.*	Forearm	63	73	68	78	74	84
S72.*	Femur	47	57	59	69	79	89
S82.*	Tibia, ankle	10	12	11	14	14	17

Source: modified from (11) in (9)

The estimated percentage of insurees who had a fracture during the period of observation seems very high, at first glance, in comparison to corresponding figures published in reports from other countries. For example, Chrischilles et al. (1991) estimated that nearly half of all postmenopausal women sustain at least one osteoporosis-related fracture at some time in their lives after menopause (13). In another American study, 50-year-old women were found to have a 40% probability of sustaining a proximal femoral fracture, a vertebral body fracture, or a distal arm fracture at some time in the remainder of their lives (corresponding figure for men, 13%) (14). Femoral fractures were the most common type of fracture in this study; in contrast, in BEST, forearm fractures were most common. In another American study, vertebral body fractures were most common, followed by fractures of the hand, the femur, and the pelvis (15). The MONICA cross-sectional study from Augsburg, like BEST, found that forearm fractures were the most common type in men and women aged 25 to 74 (7). When comparing BEST with other studies, one must bear in mind that BEST only determined fracture frequencies among persons with osteoporosis aged 50 or above, not in the overall population of persons with or without osteoporosis. Moreover, in the other studies, data were collected on a per fracture basis, rather than per insuree with at least one fracture.

Anonymized routine billing data of the TK health-insurance carrier were analyzed for the present study (BEST). Such data, by their nature, contain no clinical information. Bone-density values or x-rays were not available for inspection, and so the WHO definition of osteoporosis could not be operationalized on the basis of the information available. The insurees with osteoporosis thus had to be identified on the basis of physicians' diagnoses from all care sectors, and on the basis of outpatient prescriptions. The medications considered to be indicative of osteoporosis were chosen in accordance with the DVO-S-III guideline. The mere prescription of basis therapy

was not considered specific for osteoporosis, as this may be indicated in other diseases as well; therefore, insurees were classified as having osteoporosis only if they were receiving hormone therapy in addition. For osteoporosis diagnosis there was no further requirement for any particular diagnosis or treatment from other care sectors, as it was assumed that osteoporosis had been diagnosed for valid medical reasons.

Insurees who had only a single fracture, did not carry the diagnosis of osteoporosis, and were not receiving medications to treat osteoporosis were considered to have osteoporosis or not depending on the site of the fracture. By means of this procedure, the study was able to account for osteoporosis sufferers who had not (yet) been given a diagnosis of the disease but already had symptoms of it, i.e., an osteoporosis-related fracture. This procedure was justified by the fact that the diagnosis of osteoporosis is often missed in patients with fractures: If only diagnosed cases had been counted, the number of affected persons might have been seriously

TABLE 2

Insurees with at least one fracture, by fracture site (patient population A)

	Fracture site	Insurees with osteoporosis and fractures	Percentage of insurees with osteoporosis
S22.*	Rib(s), sternum, thoracic spine	42 025	12.7%
S32.*	Lumbar spine, pelvis	29 532	8.9%
S42.*	Shoulder region, arm	22 245	6.7%
S52.*	Forearm	45 590	13.8%
S62.*	Wrist, hand	9758	2.9%
S72.*	Femur	26 152	7.9%
S82.*	Tibia, ankle	14 800	4.5%
	Total	172 437	52.0%

underestimated. For technical reasons, only limited data were available on insurees who had osteoporosis-associated fractures but no further inclusion criteria. We cannot rule out the possibility that the number of persons with osteoporosis may have been overestimated.

The identification of fractures by way of the five-digit ICD-10 codes may have led to an overestimation of the prevalence of multiple fractures, because mild deviations in coding practices (e.g., differences between the outpatient and inpatient sectors) can lead to a variable assessment of the fractures. On the other hand, the ICD has no way to code the multiplicity of, for example, fractures of more than one thoracic vertebral body. It is also possible that cases of already existing fractures that needed further treatment (e.g., removal of previously implanted orthopedic hardware) may have been counted as new fractures. Even considering that the number of insurees with fractures (single or multiple) may have been overestimated, the very large figures that were obtained do indicate a need for improved care.

The TK health-insurance carrier has insurees all over Germany, but the population structure of its insurees is such that a direct extrapolation of the study findings to the overall German population might be misleading. Therefore, all epidemiological extrapolations were standardized for the age and sex structure of the population. Nonetheless, TK insurees still tended to enjoy better health and higher social status than the population at large; this may have led to an underestimation of the incidence and prevalence of osteoporosis, but also to an overestimation of the utilization of care (which generally rises with the educational level of the patients). In any case, the prevalence of diagnosed osteoporosis in this study did not differ much from that revealed by the GEDA study. It follows that the prevalence figures determined here, which also take account of yet undiagnosed osteoporosis, are likely to be a rather good approximation to the true value. Despite all of the known limitations to the representativeness of data from individual health-insurance carriers, the use of such data does not cause the classic errors that can arise when survey data are used. Regional differences can make the results of regional studies such as KORA difficult to extrapolate to the entire country. Differences between survey participants and non-responders are not an issue when the routine data of nationwide health-insurance carriers are analyzed (16).

In summary, this study has the following main limitations: The use of routine health-insurance data does not permit the direct identification of patients with osteoporosis according to the official definition of the WHO, and the number of fractures per patient was not known for certain and had to be estimated with an algorithm. The study population was unrepresentative of the overall German population in

some respects. Moreover, the cases in which the health insurance data indicated that osteoporosis had, indeed, been diagnosed could not be independently verified, and limited data were available for the portion of the study population who had fractures but had not received the diagnosis of osteoporosis.

The regional distribution of osteoporosis needs further study. Moreover, analytical standards are needed to judge the validity of comparisons between findings from data derived from different sources (not just with regard to osteoporosis), and for the proper interpretation of secular trends.

Despite these limitations, the BEST study arrived at what we consider to be a good estimate of the actual prevalence of osteoporosis in the German population aged 50 and over, on the basis of a single, large set of data. This study takes account of persons who have osteoporosis but have not yet received the diagnosis. The large number of persons with multiple fractures leads us to suspect that, in Germany at present, the available diagnostic and therapeutic resources for the avoidance of fractures and for the care of persons with osteoporosis are not yet being exploited as fully as they could be.

Conflict of interest statement

Peyman Hadji works at the Philipps-Universität in Marburg, Germany, and at the Universitätsklinikum Gießen und Marburg GmbH. He has received lecture honoraria and research support from Amgen, Eli Lilly, GSK, Novartis, Nycomed, Pfizer, Procter and Gamble, and Roche.

Silvia Klein, Torsten Schmidt, and Holger Gothe are employees of the IGES Institute, which is under the direction of Bertram Häussler.

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Thomas Kless is an employee of Nycomed GmbH, and Thomas Steinle is an employee of AMGEN GmbH.

The data were made available to the investigators free of charge by the Techniker Krankenkasse, a statutory health-insurance carrier in Germany.

Roland Linder and Frank Verheyen state that, as members of the Techniker Krankenkasse, they have a potential conflict of interest as defined by the guidelines of the International Committee of Medical Journal Editors.

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KEY MESSAGES

- 6.3 million persons with osteoporosis lived in Germany in 2009, including 5.2 million women and 1.1 million men.
- Every 4th woman and every 17th man over age 50 has osteoporosis.
- There are a total of 885 000 new cases of osteoporosis in Germany each year.
- More than half of the affected persons sustain at least one fracture within four years.

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eBOX

Methods

Anonymized routine billing data of the TK health-insurance carrier, obtained from about 7.3 million insurees, were retrospectively analyzed for this study (2009). The data included basic personal information (age, sex, etc.) on the insurees and further information on outpatient and inpatient treatments, prescriptions for medications and other medical/surgical aids, rehabilitative care (for example, after a hospitalization), nursing care, and occupational disability.

The patient population for the study (*Figure 1*) consisted of persons who were insured by the TK for at least one day in the period from 1 January 2006 to 31 December 2009, were at least 50 years old on the first day of this period (1.7 million people), and were identified as having osteoporosis. For technical reasons, the process of identifying persons as osteoporosis patients resulted in the creation of two subpopulations of patients, which were designated A and B. The difference between patient population A and patient population B was that the former included insurees who exclusively had osteoporosis-related fractures without fulfilling any of the other inclusion criteria. The data collected on patients in population B were more complete; therefore, certain analyses (see below) were based only on population B. For each insuree, the criteria listed in *Box 1* were used to determine whether osteoporosis was present. Diagnoses were obtained for evaluation from the data sectors that concerned occupational disability, in-hospital care (main diagnosis or secondary diagnosis), outpatient care (only definitive diagnoses), and post-hospital care. Persons with osteodystrophia deformans (M88.*), disturbances of calcium metabolism (E83.5*), and fractures due to neoplasia (M90.7*) were excluded.

The annual prevalence was calculated as the ratio of patient population A to the entire study population of the same age group the number of TK insurees in the same age group (age 50 or above) who were insured for at least one day over the same period of time. Only population B was used to calculate the incidence of diagnosed or treated osteoporosis, because the available data reflected the onset of the disease only for patients in population B: The index event for the onset of osteoporosis was taken to be the first prescription of an osteoporosis-specific medication from the defined medication list, and/or the first diagnosis of osteoporosis in the period of observation, after a preceding period of at least one year without any such events. The incidence was defined as the ratio of the number of patients with an index event in patient population B to the number of insurees who were insured continuously for at least one year over the period of the study (the study population for incidence).

The prevalence and incidence figures were first calculated for distinct groups classified by age and sex, then extrapolated to the general population by direct standardization. Population figures for 2009 were obtained from the German Federal Statistical Office: there were 32.7 million persons over age 50 in Germany at that time.

Insurees who were documented (in any sector of care) as having one or more fractures were analyzed in separate groups depending on the site of the fracture (5-digit ICD code). A counting algorithm was developed for the counting of multiple fractures that were cared for in either an inpatient or an outpatient setting (patient population B): To count as multiple fractures, an interval of at least 30 days was required between two identically coded fractures that were treated in an inpatient setting. Fractures treated in outpatient care were counted only if no identically coded fracture had been treated in either an inpatient or an outpatient setting in the preceding quarter-year, and if no identically coded fracture was treated in an inpatient setting in the same quarter-year or the following one.