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Prevalence and Regional Distribution of Lower Limb Amputations from 2006 to 2012 in Germany: A Population based Study

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WHAT THIS PAPER ADDS

Population based analyses are relevant for resource planning. Previously published amputation studies are based on event related amputation frequencies and on selected patient groups and thus do not allow population based statements. This study provides estimates of the frequency of amputations from a large and mostly unselected German population. From 2006 to 2012 the overall amputation rate in the population has remained unchanged, despite the 1989 St. Vincent Declaration. However, there is a small decrease in the amputation rate among patients with diabetes mellitus and arterial occlusive disease. In order to further reduce the number of lower limb amputations, more preventive action is needed in Germany.

Objective/Background: International studies show conflicting results regarding the frequency of lower limb amputations over time. However, published data are often based on event related amputation frequencies per year, on hospital statistics or on regional surveys. Thus, they do not allow population based statements. The present study assesses the population based epidemiology of amputations in Germany.

Methods: Secondary analyses of 80 German statutory health insurance companies with 4 million insurants nationwide in 2012 were performed. From 2006 to 2012, lower limb amputations were identified in the entire population and in persons with diabetes mellitus (DM) and arterial occlusive disease (AOD). Lower limb amputations and persons with DM and arterial occlusive diseases were extracted by specific operation procedure codes and International Classification of Diseases-10 codes. Descriptive standardized analyses by age, sex, and regional distribution were conducted.

Results: The proportion of patients with at least one lower limb amputation in the entire population stayed constant over time at 0.04% (95% confidence interval [CI] 0.04–0.04). Extrapolated to the German population in 2012 there were 49,150 cases and 32,767 persons with amputations. In 2012, about 70% of amputations were minor (0.03% [95% CI 0.03–0.03]) versus major amputations (0.01% [95% CI 0.01–0.01]). Related to DM and AOD, there was a small decrease in the amputation rate per patient, even though the DM prevalence increased by 10.4%.

Conclusion: The amputation rates per patient in Germany have remained stable in the overall population and show slight decline in patients with diabetes mellitus and with arterial occlusive disease between 2006 and 2012. In the future, intensified preventive measures are crucial to reduce the number of amputations of the lower extremities permanently.

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INTRODUCTION

Patients with arterial occlusive disease (AOD) or diabetes mellitus (DM) have a higher risk of amputation than patients without previous illnesses.[1–8] In Germany, the prevalence of AOD is estimated to be 3–10% for the entire population and 6–8% among diabetic patients. The prevalence of DM increased by 38% (5.2–7.2%) from 1998 to 2011.[9]

To improve diabetes care, in 1989 the St. Vincent Declaration defined major targets for the first time; for example, to reduce the rate of limb amputations among patients with diabetes by half within 5 years.[10] Patient organizations and diabetes experts from all European

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Table 1. Amputations in the overall population, and in individuals with diabetes mellitus and/or arterial occlusive disease in Germany (observation period 2006–12).

		All amputations[a]						Amputations with target diagnosis[b]					
		Cases[c]		Patients				Cases[c]		Patients			
		n	%	*n*	%	Rate	95% CI	*n*	%	*n*	%	Rate	95% CI
2006	Major	519	27.42	317	24.57	0.01	0.01–0.01	340	23.19	184	19.25	0.07	0.06–0.08
	Minor	1,374	72.58	854	66.20	0.03	0.03–0.03	1,126	76.81	671	70.19	0.27	0.25–0.29
	Both	–	–	119	9.22	[d]	[d]	–	–	101	10.56	0.04	0.03–0.05
	Total	**1,893**	**100.00**	**1,290**	**100.00**	**0.04**	**0.04–0.04**	**1,466**	**100.00**	**956**	**100.00**	**0.38**	**0.35–0.40**
2007	Major	918	36.72	398	28.92	0.01	0.01–0.01	450	28.75	246	23.88	0.09	0.08–0.11
	Minor	1,582	63.28	820	59.59	0.02	0.02–0.03	1,115	71.25	649	63.01	0.25	0.23–0.27
	Both	–	–	158	11.48	[d]	[d]	–	–	135	13.11	0.05	0.04–0.06
	Total	**2,500**	**100.00**	**1,376**	**100.00**	**0.04**	**0.04–0.04**	**1,565**	**100.00**	**1,030**	**100.00**	**0.40**	**0.37–0.42**
2008	Major	861	32.85	385	26.28	0.01	0.01–0.01	465	27.18	248	22.16	0.08	0.07–0.09
	Minor	1,760	67.15	930	63.48	0.02	0.02–0.03	1,246	72.82	746	66.67	0.25	0.23–0.27
	Both	–	–	150	10.24	[d]	[d]	–	–	125	11.17	0.04	0.03–0.05
	Total	**2,621**	**100.00**	**1,465**	**100.00**	**0.04**	**0.04–0.04**	**1,711**	**100.00**	**1,119**	**100.00**	**0.38**	**0.36–0.40**
2009	Major	809	31.19	358	25.00	0.01	0.01–0.01	424	24.72	235	21.48	0.08	0.07–0.09
	Minor	1,785	68.81	942	65.78	0.02	0.02–0.03	1,291	75.28	742	67.82	0.24	0.22–0.26
	Both	–	–	132	9.22	[d]	[d]	–	–	117	10.69	0.04	0.03–0.05
	Total	**2,594**	**100.00**	**1,432**	**100.00**	**0.04**	**0.04–0.04**	**1,715**	**100.00**	**1,094**	**100.00**	**0.35**	**0.33–0.37**
2010	Major	785	28.31	356	22.70	0.01	0.01–0.01	419	23.15	247	20.25	0.08	0.07–0.09
	Minor	1,988	71.69	1,090	69.52	0.03	0.03–0.03	1,391	76.85	870	71.31	0.27	0.25–0.28
	Both	–	–	122	7.78	[d]	[d]	–	–	103	8.44	0.03	0.03–0.04
	Total	**2,773**	**100.00**	**1,568**	**100.00**	**0.04**	**0.04–0.04**	**1,810**	**100.00**	**1,220**	**100.00**	**0.37**	**0.35–0.40**
2011	Major	931	31.52	406	24.59	0.01	0.01–0.01	466	24.13	251	20.13	0.07	0.06–0.08
	Minor	2,023	68.48	1,097	66.44	0.03	0.03–0.03	1,465	75.87	870	69.77	0.25	0.23–0.27
	Both	–	–	148	8.96	[d]	[d]	–	–	126	10.10	0.04	0.03–0.04
	Total	**2,954**	**100.00**	**1,651**	**100.00**	**0.04**	**0.04–0.04**	**1,931**	**100.00**	**1,247**	**100.00**	**0.36**	**0.34–0.38**
2012	Major	834	29.02	358	22.03	0.01	0.01–0.01	433	22.91	240	19.20	0.07	0.06–0.08
	Minor	2,040	70.98	1,131	69.60	0.03	0.03–0.03	1,457	77.09	891	71.28	0.25	0.24–0.27
	Both	–	–	136	8.37	[d]	[d]	–	–	119	9.52	0.03	0.03–0.04
	Total	**2,874**	**100.00**	**1,625**	**100.00**	**0.04**	**0.04–0.04**	**1,890**	**100.00**	**1,250**	**100.00**	**0.36**	**0.34–0.38**

Note. CI = confidence interval.

[a] All insurants standardized for age and sex (2006 = 3,119,869; 2007 = 3,281,073; 2008 = 3,749,668; 2009 = 3,832,490; 2010 = 4,021,701; 2011 = 4,036,280; 2012 = 4,010,870).

[b] All insurants with underlying disease standardized for age and sex (2006 = 253,064; 2007 = 260,578; 2008 = 296,720; 2009 = 309,875; 2010 = 325,992; 2011 = 346,339; 2012 = 351,873).

[c] Cases defined as occurrences of amputation within 1 year.

[d] Because of the small number of amputations per patient and the large sample size the rate is 0.00.

countries met in St. Vincent Declaration under the aegis of the Regional Offices of the World Health Organization and the International Diabetes Federation, and representatives of Government Health Departments. Furthermore, recommendations for medical care in diabetes exist and several disease management programs by statutory health insurance (SHI) in Germany have been implemented to reduce the risk of lower limb amputation.[11] In an international comparison of the amputation frequency, a heterogeneous trend can be detected. Specifically in Germany, data concerning the prevalence or incidence amputation rates are rare and show varying results. There are frequent reports on overall increasing amputation rates.[3] In the population of patients with DM or arterial vascular disease there is a decreasing number of major amputations and an increase of minor amputations.[12,13] However, other studies show a reduction of amputation rates.[14] At international level, amputation rates also vary considerably. For example, in the USA, there is a significant reduction of major and minor amputations.[15–17] Considering only patients with DM, some international studies report an increase in amputations; others do not identify any changes.[4,18–23]

So far, published data regarding amputation frequency in Germany mostly derive from regional surveys or from performance and cost statistics of hospital discharge registries and therefore they do not allow population based statements. Furthermore, official statistics are not patient based and do not count the frequency of amputations per patient but exclusively show case- related frequencies per year.[24] Therefore, the hospital changes or re-hospitalization cannot be identified as "double counting" of events. Considering the fact that the probability of multiple counting deviates significantly by age, sex, region, and change over time, it would lead to biased estimates.[25] Only data with a reference population allow patient based analyses and thus statements about the healthcare quality and social parameters.

Therefore, this paper is based on longitudinal SHI data with a time frame of 7 years. The accounting data of health insurance agencies can be used for research purposes.

These routine data allow statements on a large and mostly unselected German population. Additionally, it is possible to give estimates of prevalence or incidence rates as these data are highly population based. About 90% of the German population are members of a SHI; the rest of the population is privately insured.[26,27]

The present study examines the prevalence of lower limb amputations in patients with and without DM or arterial vascular disease, and analyses age and sex specific differences, as well as regional differences, over a long period of time.

METHODS

The analyses are based on anonymous routine data from the research database of the Health Risk Institute (HRI; Berlin, Germany), which were assessed from 2006 to 2012. The age and sex standardized research database contains data from 80 different health insurance companies of the company health insurance funds (BKK) and health insurances of guilds (IKK). As of 2012, the database includes nationwide data of 4,010,870 members. The age and sex standardization was performed according to the population structure of the general German population (as at 31 December 2011, as provided by the Federal Statistical Office).[28]

For historical reasons, the German healthcare system administration is based on quarters per year. The healthcare delivery system in Germany is institutionally separated between public health services, ambulatory primary care, and hospital based (inpatient) care.[26] Lower limb amputations were identified using specific operation procedure codes (OPS codes: 5-864.x major-amputations and 5-865.x minor amputations). Minor amputations are amputations where only a toe is removed; major amputations are amputations where part of the leg is removed. Insurants were included if they were insured for at least 1 day in every quarter of the observational years. All documented amputations were analyzed as case and patient specific.

Patients with DM or AOD were identified by using International Classification of Diseases (ICD)-10 Codes (DM: E10-E14; AOD: I70.2, I70.20-I70.24). Diagnoses were only included when at least two outpatient diagnoses were recorded in two quarters of the respective diagnosis group within 1 year. The point prevalence rates are given as percent values with their corresponding 95% confidence intervals (CIs).

Regional differences in Germany were determined by comparing north with south, and west with east. The classification of regional differences is based on the states of Germany and is defined as follows: east (Brandenburg, Mecklenburg-West Pomerania, Saxony, Saxony Anhalt, Thuringia); west (remaining states including Berlin); south (Hessen, Rhineland Palatinate, Baden Wurttemberg, Bavaria, Saarland, Saxony, Thuringia); north (remaining states).

The point prevalence is presented as percent values with corresponding 95% CIs. The point prevalence of lower limb amputations were analyzed firstly in the entire population and secondly in persons with DM and AOD. To verify statistical regional differences, binary logistic regression analyses, including adjustments for age and sex, were applied. Statistical analyses were conducted using SAS 9.3 (SAS Institute, Cary, NC, USA).

RESULTS

Frequency of amputations in the entire population

In 2012, 0.04% of all insurants had at least one amputation (95% CI 0.04—0.04). In total, 2,874 amputations were performed in 1,625 patients, which accounts for 41 persons with amputations per 100,000 insurants (Table 1). Considering all amputations from 2006 to 2012, the standardized amputation rate was stable at 0.04%. In comparison, the amputation frequency increased by 51%, from 1,893 in 2006 to 2,874 in 2012, considering only the amputation cases.

In total, 70% of the amputations were minor, almost 22% were major and about 8% of the patients underwent both forms of amputation. On average (± SD), there were 1.77 ± 1.42 (range 1—10) amputations per patient in 2012.

Frequency of DM and AOD

In 2006, the prevalence of DM in the observed population was 7.87% (95% CI 7.84—7.90; 245,610/3,119,869), and in 2012 it was 8.69% (95% CI 8.66—8.72; 333,050/4,010,870), which means an increase in the annual prevalence of DM of 10.4% within the observed period of time.

The prevalence of AOD increased, as coded by ICD codes, from 2006 to 2012 with an average difference of 0.12% (2006: 0.13% [95% CI 0.13—0.13; 4,044/3,119,869]; 2012: 0.24% [95% CI 0.23—0.40; 9,434/4,010,870]). Accordingly, the prevalence of AOD also increased by 84.6%.

Frequency of amputations among patients with DM or arterial vascular disease

The proportion of patients with DM or AOD among all patients with at least one amputation was between 74% and 78%. Related to the total number of patients with these diseases the amputation rate decreased from 2006 to 2012 by 5.3% (average difference of 0.02%) in patients with amputations and 6.9% (average difference of 0.04%) in cases of amputation. The proportion of patients with amputations was 0.38% (95% CI 0.35—0.40; 956/253,064) in 2006 and 0.36% (95% CI 0.34—0.38; 1,250/351,873) in 2012. Within the observed period, there were only slight variations of 0.05% from the lowest rate (0.35%) in 2009 to the highest rate (0.40%) in 2007. Major amputations per patient stayed constant compared with minor amputations per patient with a slight decrease from 2006 to 2012.

Extrapolated to the German population in 2012 there were 49,150 cases and 32,767 persons with amputations. Of 32,767 persons with a lower limb amputation 24,575 amputations (78%) were performed in patients with DM or AOD.

A regional comparison of patients with amputations and DM or AOD showed a declining trend in the amputation rate of 0.02% (0.38% to 0.36%) for western Germany and 0.05% (0.34% to 0.29%) for eastern Germany from 2006 to 2012. In a regional north—south comparison, there was a slight change in north Germany (0.01%; 0.36% to 0.35%). However, there was a reduction of 0.04% (0.40% to 0.36 %) in the south from 2006 to 2012.

Nevertheless, there were slight variations over time (Fig. 1). Eastern Germany show the highest variation over the years, from the highest amputation rate in 2009 (0.41%) to the lowest amputation rate in 2012 (0.29%). In 2009, eastern Germany showed significantly more amputations per patient than western Germany ($p = 0.01$). The overall mean amputation rate over the 7 years was between 0.37% in western and 0.35% in eastern Germany. Therefore, there was a difference between eastern and western Germany in 2009 but only a small variation in the overall mean amputation rate. The north of Germany differed only slightly from the south with 353 per 100,000 persons compared with 357 per 100,000 persons in 2012. Significantly fewer amputations in northern Germany than in southern Germany could only be found in 2011. The average regional distribution, adjusted for age and sex, was not a significantly relevant factor influencing the frequency of amputations.

DISCUSSION

Unlike other studies, the present study does not show any changes in the amputation rate in the entire population in Germany from 2006 to 2012. Regarding only the amputations among patients with DM or AOD, there is a slight decrease in the amputation rate of 5.3%. In contrast, considering only the absolute frequency of amputation cases, without taking the reference population into account, there is an increase of lower limb amputations among patients with DM or AOD in Germany. Accordingly, the absolute number of amputations has increased owing to demographic factors rather than the population based amputation rate. It can be concluded that the quality of healthcare of patients with DM or AOD has improved slightly in Germany.

Extrapolated to the German population, there were 32,767 persons with at least one amputation in 2012 in Germany. Additionally, this study detected that the majority of amputations (76%) were performed in patients with DM or AOD. Similar results were reported in other German studies, in which 75% had AOD or a neurovascular disease. Citation studies from the UK show comparable results, with a proportion of 50%.[6,29]

Compared with other studies, the trend of increasing minor amputations and decreasing major amputations,

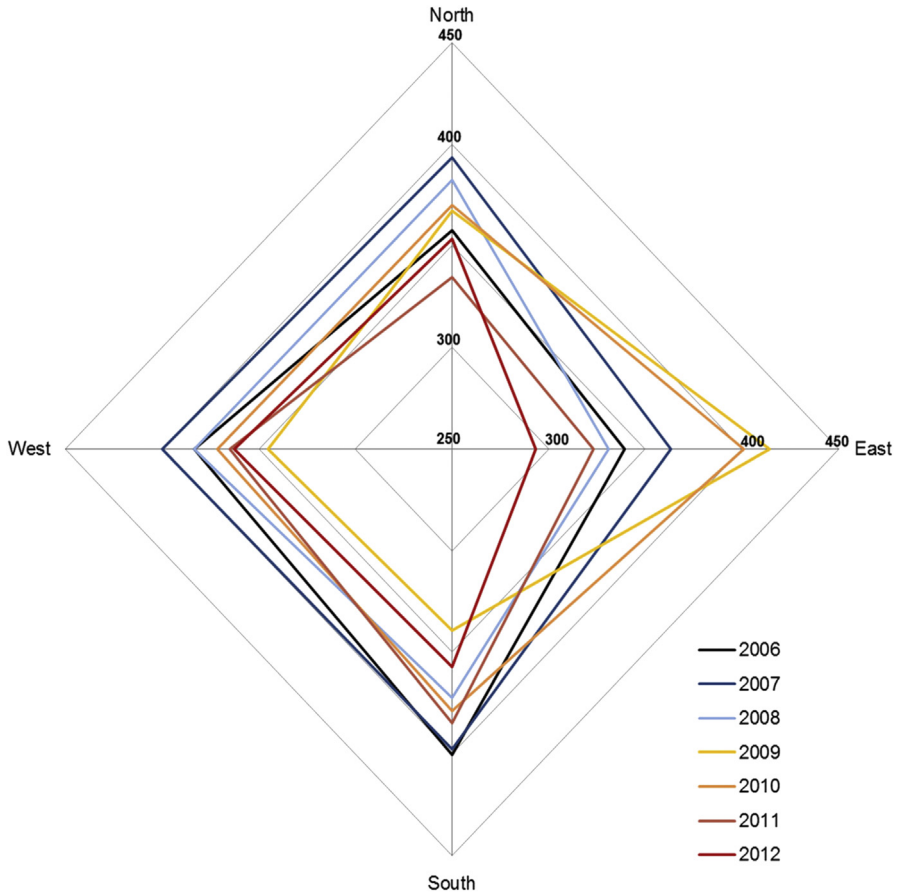

Figure 1. Regional and bilateral (north—south and east—west) comparison of amputation rate per 100,000 persons with arterial occlusive disease or diabetes mellitus in Germany (observation period 2006—12).

which was observed in previous German studies, could not be confirmed.[3,7,12–14] The prevalence of DM in the present study corresponds with estimates from 2004 of 6–8%, based on SHI data in Hessen.[30,31] Until now, it has not been possible to compare the analyzed prevalence rates, owing to the lack of availability of more recent SHI data.

Regarding the regional distribution (east–west and north–south) there were no significant differences in the overall mean amputation rate throughout the observed period of 7 years. Dividing the German states into west and east, especially ascribing Berlin to "western Germany", has historical reasons, as well as infrastructural reasons, owing to the fact that the healthcare system of Berlin still differs significantly compared with the other defined eastern states, for example Brandenburg, Mecklenburg-West Pomerania, Saxony, Saxony Anhalt, and Thuringia.

Strengths and limitations of the study

The present longitudinal study, based on SHI data over a period of 7 years, is the first to allow statements on the frequencies of amputations on a patient level in Germany. Owing to the close connection to the German population, these routine data permit analyses of a vast and widely unselected nationwide cohort. Unlike previous studies, cross sectorial estimates on prevalence rates could also be realized.

A number of limitations have to be considered. Owing to the selection of insurants from the research data base of HRI (consisting of SHI data from 80 different insurances of BKK and IKK from a total of 146 SHI in Germany in 2012[27]), a relativized external validity needs to be discussed. SHI data show marked differences between health insurance funds with regard to the structure of the people insured, not only for age and sex, but also for educational levels and morbidity, which cannot be eliminated completely by the standardization for age and sex, as done in this study.[32–34] This might limit extrapolations of the findings to the whole German population. Further limitations are potentially undiagnosed DM or AOD, which would result in underestimation of disease prevalence. In addition, misclassification of the relevant diseases could lead to an over or underestimation, which might affect the internal validity. The used case-selection algorithm for the identification of patients with lower limb amputations and with diabetes was based on an established procedure.[1] However, it can be assumed that SHI data procedures like amputations in inpatient care are coded with high validity as they are strongly controlled by the diagnosis-related group (DRG) system. Compared with other studies, which were not population based, the SHI data are an important source for health services research. However, owing to different data sources, comparison with previous studies on amputations is limited.

As patients with amputations have an impaired quality of life and an increased mortality, further preventive action is needed in Germany in order to decrease the number of amputations of lower limbs in the entire population and those with DM or AOD in the future. Additional studies on barriers to guideline adherence to treatment of patients at risk amputation are necessary to optimize the prevention of amputations.

CONFLICT OF INTEREST

None.

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