Incidence of Lower Limb Amputations and Diabetes

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OBJECTIVE — We collected data on the incidence rates of amputations and their relative risk in diabetic subjects compared with the nondiabetic population.

RESEARCH DESIGN AND METHODS — From all three hospitals in a city of approximately 160,000 inhabitants, we obtained complete lists of nontraumatic lower limb amputations. From each patient record, diabetic status was determined. We estimated age-specific and standardized incidence rates of amputations in the diabetic and nondiabetic populations and in the entire population, as well as the relative and attributable risks due to diabetes.

RESULTS — Nontraumatic lower limb amputations were performed on 106 residents of Leverkusen (Germany) in 1990 and 1991. Of them, 82 (77.4%) had diabetes. Mean age was 72.0 years. In the case of multiple amputations, only the highest level was counted for the analysis. The following results were standardized to the German population. Incidence rates ($100{,}000^{-1} \cdot year^{-1}$) were determined to be as follows: for all amputations per total population, 33.8; for amputations in diabetic individuals per diabetic population, 209.2; for amputations in nondiabetic individuals per nondiabetic population, 9.4. Relative risk was 22.2; attributable risk among exposed, 0.96; population attributable risk, 0.72. When the study is repeated to monitor the St. Vincent targets (50% reduction), a reduction in the amputation rate in the diabetic population by 46% will be detected with 90% power.

CONCLUSIONS — We found incidence rates similar to those in the non-Indian population of the U.S. Great relative and population-attributable risks indicate that improving foot care in diabetic individuals appears to be the main target for the reduction of amputations in the general population.

A reduction of diabetes-related amputations by at least one half within five years was declared a primary objective for Europe (St. Vincent Declaration) (1). However, even worldwide, data about the incidence of amputations and their relative risk in diabetic individuals compared with the general population are scarce. A recent overview of international studies of the incidence of lower limb amputations showed extreme variability between different areas and ethnic groups (2). Published data lack comparability (2–4). No data about the incidence of amputations are available in Germany. It was the purpose of this study to estimate age-specific and standardized incidence rates, as well as relative and attributable risks, to obtain baseline data in a limited area.

RESEARCH DESIGN AND METHODS

From all three hospitals with surgical departments in Leverkusen (Germany), we obtained complete lists of nontraumatic lower limb amputations performed in 1990 and 1991 by analyzing operation theater documentation. We then reviewed the hospital records of each patient thus identified. Only patients with residence in the city were included. We determined date of birth, address, sex, amputation level, date of operation, presence of diabetes, and—where applicable—diabetes duration. When more than one amputation was performed on one patient within the observation period, only the highest level was counted for the analysis. Population data were obtained from the city administration. As of 31 December 1990, the total population of the study area was 160,684. The population with diabetes in each stratum was estimated by multiplying the population of the study area in the stratum by the age- and sex-specific prevalence of diabetes in East Berlin obtained from the former East German diabetes registry (5), because these are the only age-specific and reliable prevalence data available for the German population. Stratum-specific incidence rates in the diabetic and nondiabetic populations and in the entire population were estimated. In addition, the rates were standardized, using the method of direct standardization, to the (West) German population of 1991. The rate in the diabetic population was also standardized to the estimated German diabetic population because such a rate is the only one given in some publications. We estimated relative risks of amputations for people with diabetes compared with people without diabetes, attributable risks among exposed, population attributable risks, and 95% confidence intervals of epidemiological measures (6). The significance level for all tests was 0.05. Calculations were carried out with the SAS Statistical Package (Version 6.09). The power of detecting a significant reduction of the amputation rate in the diabetic population was calculated (7) using the EGRET SIZ (Version 1) statistical package. The rates calculated on the basis of our data underestimate the true rates of amputations because of operations performed on residents of the study area in hospitals outside this region. A prior analysis undertaken by the city administration in cooperation with health insurance organizations showed that 89% of surgical patients who reside in Leverkusen underwent surgery at the local hospitals. Therefore, in addition to the

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Table 1—*Incidence of lower limb amputations in Leverkusen, both major and minor amputations*

Age (years)	Amputations: Total	Amputations: With diabetes	Incidence rates*: IRt	IRd	IRp	IRn	RR	ARE	PAR
Men†	49	36	31.2 (27.0–35.3)	213.6 (201.1–226.1)	22.9 (19.4–26.4)	9.6 (7.3–11.9)	22.3 (11.4–43.8)	0.955 (0.912–0.977)	0.693 (0.395–0.844)
<40	0	0	0.0	0.0	0.0	0.0			
40–59	10	7	21.5 (8.2–34.8)	353.7 (91.7–615.7)	15.0 (3.9–26.2)	6.7 (0–14.3)‖	52.6 (13.6–203.3)	0.981 (0.926–0.995)	0.687 (0.349–0.896)
60–79	31	23	136.1 (88.2–184.0)	648.0 (383.2–912.8)	101.0 (59.7–142.3)	41.6 (12.8–70.4)	15.6 (7.0–34.8)	0.936 (0.856–0.971)	0.694 (0.482–0.841)
80+	8	6	274.3 (84.2–464.5)	1110.7 (222.0–1999.4)	205.8 (41.1–370.4)	84.2 (0–200.9)‖	13.2 (2.7–65.4)	0.924 (0.624–0.985)	0.693 (0.236–0.923)
Women‡	57	46	36.3 (31.9–40.6)	205.0 (193.1–217.0)	29.0 (25.0–33.0)	9.3 (7.4–11.2)	22.1 (10.8–44.9)	0.955 (0.908–0.978)	0.744 (0.484–0.873)
<40	0	0	0.0	0.0	0.0	0.0			
40–59	4	4	8.7 (0.2–17.2)	277.8 (5.6–550.0)	8.7 (0.2–17.2)	0.0		1.000	1.000
60–79	30	26	92.6 (59.5–125.7)	442.7 (272.5–612.8)	80.2 (49.4–111.1)	15.1 (0.3–29.9)	29.4 (10.2–84.1)	0.966 (0.902–0.988)	0.837 (0.626–0.938)
80+	23	16	292.8 (173.2–412.5)	890.0 (453.9–1326.1)	203.7 (103.9–303.5)	115.6 (30.0–201.2)	7.7 (3.2–18.7)	0.870 (0.684–0.947)	0.605 (0.332–0.802)
All	106	82							
Standardized to the German population			33.8 (27.3–40.3)	209.2 (151.3–267.1)	26.0 (20.4–31.7)	9.4 (5.6–13.2)	22.2 (13.6–36.2)	0.955 (0.926–0.972)	0.721 (0.546–0.829)
Corrected for amputations in hospitals out of area§			38.0	235.0	29.3	10.6			
Standardized to the estimated German diabetic population				540.5 (423.0–657.9)					

Data are *n* or incidence rates (CI). *, Incidence rates per 100,000 person years; †, Standardized to the German male population; ‡, Standardized to the German female population; §, Rates divided by 0.89; ‖, Lower confidence limit set to 0 when the calculation yielded negative values. IRt, All amputations in total population; IRd, Amputations in individuals with diabetes in population with diabetes; IRp, Amputations in individuals with diabetes in total population; IRn, Amputations in individuals without diabetes in population without diabetes; RR, Relative risk of diabetic vs. nondiabetic population (IRd/IRn); ARE, Individual attributable risk of diabetes among exposed; PAR, Population attributable risk of diabetes.

Table 2—***Incidence of lower limb amputations in Leverkusen, major amputations only***

	Amputations		Incidence rates*						
Age (years)	Total	With diabetes	IRt	IRd	IRp	IRn	RR	ARE	PAR
Men†	32	24	20.6 (17.5–23.8)	136.1 (126.5–145.7)	15.6 (12.8–18.3)	5.9 (4.2–7.7)	22.9 (9.8–53.4)	0.956 (0.898–0.981)	0.713 (0.326–0.877)
<40	0	0	0.0	0.0	0.0	0.0			
40–59	5	4	10.7 (1.3–20.1)	202.1 (4.1–400.2)	8.6 (0.2–17.0)	2.2 (0–6.6)‖	90.1 (10.1–806.5)	0.989 (0.901–0.999)	0.791 (0.278–0.972)
60–79	20	14	87.8 (49.3–126.3)	394.4 (187.8–601.1)	61.5 (29.3–93.7)	31.2 (6.2–56.2)	12.6 (4.9–32.9)	0.921 (0.794–0.970)	0.645 (0.375–0.832)
80+	7	6	240.1 (62.2–417.9)	1110.7 (222.0–1999.4)	205.8 (41.1–370.4)	42.1 (0–124.6)‖	26.4 (3.2–219.2)	0.962 (0.685–0.995)	0.825 (0.287–0.976)
Women‡	38	28	24.2 (20.6–27.8)	118.8 (109.8–127.8)	17.6 (14.4–20.8)	8.4 (6.6–10.2)	14.2 (6.4–31.3)	0.929 (0.844–0.968)	0.654 (0.250–0.840)
<40	0	0	0.0	0.0	0.0	0.0			
40–59	2	2	4.3 (0–10.4)‖	138.9 (0–331.4)‖	4.3 (0–10.4)‖	0.0		1.000	1.000
60–79	21	17	64.8 (37.1–92.5)	289.4 (151.8–427.0)	52.5 (27.5–77.4)	15.1 (0.3–29.9)	19.2 (6.5–57.0)	0.948 (0.845–0.982)	0.767 (0.497–0.910)
80+	15	9	191.0 (94.3–287.6)	500.6 (173.6–827.7)	114.6 (39.7–189.5)	99.1 (19.8–178.3)	5.1 (1.8–14.2)	0.802 (0.444–0.930)	0.481 (0.154–0.751)
All	70	52							
Standardized to the German population			22.5 (17.2–27.8)	127.2 (83.6–170.8)	16.6 (12.1–21.2)	7.2 (3.8–10.6)	17.7 (9.9–31.5)	0.943 (0.899–0.968)	0.861 (0.432–0.820)
Corrected for amputations in hospitals out of area§			25.2	142.9	18.7	8.1			
Standardized to the estimated German diabetic population				345.0 (250.8–439.2)					

Data are *n* or incidence rates (CI). *, Incidence rates per 100,000 person years; †, Standardized to the German male population; ‡, Standardized to the German female population; §, Rates divided by 0.89; ‖, Lower confidence limit set to 0 when the calculation yielded negative values. IRt, All amputations in total population; IRd, Amputations in individuals with diabetes in population with diabetes; IRp, Amputations in individuals with diabetes in total population; IRn, Amputations in individuals without diabetes in population without diabetes; RR, Relative risk of diabetic vs. nondiabetic population (IRd/IRn); ARE, Individual attributable risk of diabetes among exposed; PAR, Population attributable risk of diabetes.

rates based on the actual data, we show standardized incidence rates corrected for patients being treated elsewhere by dividing the rates by 0.89. All analyses of epidemiological measures were repeated, including only amputations above the toe level (major amputations).

RESULTS — Nontraumatic lower limb amputations were performed on 106 residents of Leverkusen in 1990 and 1991. Mean age was 72.0 years (SD 10.4, median 73.5, range 46–90). Mean diabetes duration obtained for 77 subjects was 15.9 years (SD 10.1, median 15.0, range 0–55). Amputation levels were as follows: toe, 36; forefoot, 23; lower leg, 14; thigh, 33. Five patients had also amputations of the contralateral leg during the study period. Age-specific and standardized epidemiological measures, as well as the distribution with respect to age, sex, and diabetic status, are shown in Tables 1 and 2. As expected, incidence rates were much higher in the diabetic population than in the nondiabetic population. The relative risk of diabetic individuals compared with nondiabetic individuals decreased with increasing age. When standardized results are considered, the risk of having an amputation was 22.2-fold in the diabetic population compared with the nondiabetic population. Amputation rates were 205 per 100,000 person-years in diabetic women and 213.6 per 100,000 person-years in men with diabetes. More than 95% of the amputation risk in diabetic individuals and >72% of the amputation risk in the entire population were attributable to diabetes. When the study is repeated to monitor the St. Vincent targets, a reduction in the amputation rate in the diabetic population by 46% will be detected with 90% power.

CONCLUSIONS — We have obtained incidence rates of lower limb amputations, as well as relative and attributable risks due to diabetes, in one German city. The data source used here appears to be more reliable than hospital discharge data because diabetic status was ascertained from individual patients' records. Multiple amputations in the same patient could not bias the selection toward high risk groups because we counted patients, not operations. It is not surprising that, as in other studies (3,4), the risk of amputations attributable to diabetes decreased with increasing age, given the higher prevalence of vascular disease in older age. Diabetic rates standardized to the general population are lower than diabetic rates standardized to a much older estimated diabetic population. Our results are similar to those found in the non-Indian population of the U.S. (3), much lower than those found in Native American diabetic populations (2), and also lower than rates from a recent Finnish study (4).

Obviously, this study has some limitations. We studied the incidence of amputations in a restricted area because it is usually impossible to correlate amputations in certain hospitals with a well-defined population. However, correction for the underestimation of amputations due to operations performed outside the study area was possible. It was based on a former analysis showing that most residents of Leverkusen had surgery in the local hospitals, whereas both in that study and in our investigation one third of all patients came from outside the city. This indicates similar mechanisms guiding hospital selection for amputations and general surgery. Bias would result if individuals with diabetes were more or less prone to be treated outside the study area than individuals without diabetes. Although this cannot be excluded, there is no reason to assume that such mechanisms introduced large bias. The need to estimate the proportion who receive care in Leverkusen reduces precision in the estimation of rates. As in other epidemiological studies, confidence intervals consider only variability under a given statistical model, not possible sources of bias. An additional underestimation of toe amputations is possible if toe amputations were performed in surgeons' offices on an outpatient basis. Possible misclassification of a few diabetic subjects as nondiabetic would bias the relative risk toward 1. Another possible source of error is the estimation of the diabetic population from the registry of a different city.

Great population attributable risks indicate that improving foot care in people with diabetes appears to be the main target for the reduction of amputations in the general population. Repeating this study in the future will show with sufficient power whether the risk of amputations in diabetic individuals will have decreased according to the St. Vincent goals in the area studied here. (If the proportion seeking care in other cities differs over time, the estimated reduction would be over- or underestimated.) We do not claim that our results are representative of larger areas. However, with some additional effort, types of operations and diabetic status could be included in computer files that are mainly used for the purposes of the hospital administration. Such data could be collected in larger areas with reasonable effort and should be made available for monitoring complications of diabetes in the framework of routine quality control.

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