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Research Article

Time dependent impact of diabetes on mortality in patients with stroke: Survival up to 5 years in a health insurance population cohort in Germany

Zeitabhängiger Einfluss des Diabetes-Effekts auf die Mortalität in Patienten mit Schlaganfall: 5-Jahres-Überleben in einer bundesweiten Krankenkassen-Bevölkerung

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Abstract

Aims: To estimate the impact of diabetes on mortality in patients after first stroke event.
Methods: Using claims data of a nationwide statutory health insurance fund (Gmünder ErsatzKasse, GEK), we assessed all deaths in a cohort of all 5,757 patients with a first stroke between 2005 and 2007 (69.3% male, mean age 68.1 years, 32.2% diabetic) up to 2009. Using Cox regression, we estimated time dependent hazard ratios (HR) to compare patients with and without diabetes stratified by sex.
Results: The cumulative 5 year mortality was 40.0% and 54.2% in diabetic men and women, and 32.3% and 38.1% in their non-diabetic counterparts, respectively. In males, mortality was significantly lower in diabetic compared to non-diabetic patients in the first 30 days (multiple-adjusted HR 0.67; 95% confidence interval 0.53–0.84). In the following time, the diabetes risk increased yielding crossed survival curves after about a quarter year. Later on, mortality risk tended to be similar in diabetic and non-diabetic men (1–2 years HR 1.42; 1.09–1.85; 3–5 years HR 1.00; 0.67–1.41) (time-dependency of diabetes, p=0.008). In women, the pattern was similar, however, time dependency was not statistically significant (p=0.89). Increasing age, haemorrhagic stroke, renal failure (only in men), levels of care dependency, and the number of prescribed medications were significantly associated with mortality.
Conclusions: We found a time dependent mortality risk of diabetes following first stroke in men. Possible explanations may be type of stroke, or earlier and more intensive treatment of risk factors in diabetic patients.

Keywords: diabetes, stroke, mortality

Zusammenfassung

Ziel: Untersuchung des Einflusses von Diabetes auf die Mortalität in Patienten nach erstem Schlaganfall.
Methoden: Anhand von Routinedaten einer bundesweiten Krankenkasse (Gmünder ErsatzKasse, GEK) wurden alle Todesfälle in einer Kohorte von 5.757 Patienten mit erstem Schlaganfall zwischen 2005 und 2007 ermittelt (69,3% männlich, durchschnittliches Alter: 68,1 Jahre, 32,2% mit Diabetes).
Mit Hilfe der Cox-Regression wurden stratifiziert nach Geschlecht zeitabhängige Hazard Ratios (HR) geschätzt, um die Mortalität von Patienten mit und ohne Diabetes miteinander zu vergleichen.
Ergebnisse: Die kumulative 5-Jahres Mortalität nach Schlaganfall betrug für männliche und weibliche Personen mit Diabetes 40,0% und 54,2%, während sie bei entsprechenden Personen ohne Diabetes bei 32,3%

bzw. 38,1% lag. Innerhalb der ersten 30 Tage nach Schlaganfall war das Mortalitätsrisiko bei diabetischen Männern signifikant niedriger im Vergleich zu männlichen Patienten ohne Diabetes (multipel-adjustiertes HR: 0,67; 95% Konfidenzintervall 0,53–0,84). In der darauf folgenden Zeit erhöhte sich das Risiko der Personen mit Diabetes derart, dass sich nach etwa einem Vierteljahr die Überlebenskurven überkreuzten und das Risikoverhältnis sich signifikant umkehrte (1-2 Jahre HR: 1,42; 1,09–1,85). Am Ende des Beobachtungsraumes glichen sich die Überlebenskurven wieder an, so dass das Risiko für Männer mit und ohne Diabetes wieder auf einem ähnlichen Niveau lag (3-5 Jahre HR: 1,00; 0,67–1,41, Zeitabhängigkeit des Diabetes, p=0,008). Bei den Frauen war ein ähnliches Muster zu erkennen, wenngleich die Zeitabhängigkeit nicht statistisch signifikant war (p=0,89). Des Weiteren waren zunehmendes Alter, durch Blutung verursachter Schlaganfall, Nierenversagen (nur bei Männern), erhöhte Pflegestufe sowie die Anzahl verschriebener Medikationen signifikant assoziiert mit der Mortalität.

Schlussfolgerungen: Mögliche Erklärungen für das mit der Zeit variierende Mortalitätsrisiko des Diabetes könnten der Schlaganfalltyp oder die frühere und intensivere Behandlung potentieller Risikofaktoren bei Patienten mit Diabetes sein.

Introduction

Although the reduction of stroke in diabetes has frequently been cited as a primary objective by health systems and organizations [1], diabetic individuals still have an about twofold stroke risk compared to non-diabetic patients [2], [3], [4], [5], [6]. Diabetes has been considered as risk factor for higher mortality in patients after stroke [7], [8], [9]. However, to the best of our knowledge, there are only few population- or insurance-based studies which investigated mortality after stroke in the diabetic compared to the non-diabetic population [10], [11], [12], but they analysed only single subtypes of stroke or shorter periods of follow-up. The studies found a higher mortality in the diabetic population, for the 28-days fatality as well as for periods up to one year. The latter finding is in contrast to the short term mortality after beginning of renal replacement therapy and after amputation, where a time-dependent impact of diabetes for mortality has been found, with lower or virtually the same mortality in diabetic patients during the first period [13], [14], [15]. However, thereafter diabetes became a risk factor. For mortality after beginning of renal replacement therapy, differences between men and women have been observed.

Hence, aim of our study was to evaluate the mortality risk in diabetic and non-diabetic individuals after a first stroke up to 5 years of follow-up in Germany, using claims data of a nationwide statutory health insurance. We further focussed on differences between men and women.

Material and methods

Definition of the study population

We used data from a statutory health insurance company, the Gmünder ErsatzKasse (GEK), which insures about 1.6 million people located in all regions of Germany (1.9% of the German population). We included only first strokes between 2005 and 2007 in persons with a period free from stroke of at least 1 year (n=6,160). Persons younger than 30 years were excluded as well as all co-insured persons as a dependent and members who left the GEK for reasons other than death within the study period. Both criteria were applied to avoid informative censoring in the survival analysis (e.g., an insurance period ends due to death but this reason might not be documented in these cases). Our final cohort, therefore, consisted of 5,757 patients with a first stroke during 2005 to 2007 and was followed up until the end of 2009.

Strokes (cerebral ischemia, intracerebral hemorrhage, subarachnoid hemorrhage, and stroke of uncertain cause, but no transient ischemic attacks) were defined following WHO definition [16]. Diabetes status was assessed according to an established algorithm that has been used in several studies analyzing claims data of German statutory health insurance funds (e.g., [13], [17]). A person was identified as diabetic if at least one of the following characteristics was fulfilled within 12 months in the observation period between 2004 and 2007: (a) diabetes diagnosis (ICD E10-E14) in at least three of four consecutive quarters in outpatient care, (b) at least two prescriptions of antihyperglycemic medication (ATC code A10) within 12 months, or (c) at least one prescription of an antihyperglycemic medication and one diabetes diagnosis or one measurement of blood glucose or HbA1c within 12 months.

Statistical analysis

The main analyses were performed stratified for men and women. The outcome of interest was the time from the first stroke up to death or the end of the study period (December 31, 2009), whichever came first. We assessed crude survival with the Kaplan Meier estimator, stratified for diabetes as well as for sex. The appropriateness of the Cox proportional hazard assumption was further visualised using log-log survival plots (i.e. plotting log (-log(S(t)) against log(t)). If the assumption is fulfilled, the curves should be parallel to each other. Furthermore we tested the proportional hazards assumption via the test proposed by Grambsch and Therneau [18]. Because we expected that the interaction between diabetes and time was statistically significant, that means that the proportional hazard assumption was violated, we performed Cox regression using discrete time intervals to model the time dependency of diabetes [19]. We estimated time-dependent hazard ratios (HR) and 95% confidence intervals (95% CI) in multivariate analyses. As predictors, we included diabetes, interaction of diabetes with the discrete time intervals (30 days, 6, 12, 24, 36, and 60 months), and age (as continuous variable). We chose the time intervals in line with previous studies to be able to compare our results, and based on clinical experience. In a second model the type of stroke (ischemic, haemorrhagic, not specified), the number of prescribed medications (as continuous variable), the level of care dependency (4 categories) as well as the above given outpatient diagnoses for hypertension, coronary heart diseases and renal failure were added as further independent variables. The study was conducted according to the principles expressed in the Declaration of Helsinki. We considered the STROBE statement and the criteria of a national good practice guideline [20], [21]. The use of health insurance claims data for scientific research is regulated by the German Code of Social Law (SGB X). Because our study was based on pseudonymous data, we did not have to obtain informed consent. According to the Good Practice of Secondary Data Analysis, a national guideline for the use of administrative databases, no approval of an ethical committee is required [21].

Results

The 5,757 individuals with a first stroke between 2005 and 2007 were at average 68.1 years old, were predominantly male, while almost a third was classified as having diabetes (Table 1). Cerebral infarction was by far the most common type of stroke followed by cerebral haemorrhage and subarachnoid haemorrhage.

The mean observation time was 2.66 years (25% and 75% quartiles 1.98 and 3.83). Overall, 1.828 individuals died within the study period of up to 5 years, 470 and 698 men as well as 264 and 396 women with and without diabetes, respectively. The cumulative mortalities including the population at risk are presented in Table 2. Figure 1 shows the Kaplan Meier curves (a, b) as well as the log-log-survival plots (c, d). We present both, since in the log-log-plots, the early period after stroke event can be seen, whereas the Kaplan Meier curves give a better picture of the later period. In men, the crude relative mortality risk due to diabetes was significantly time dependent (p=0.002): in the first month after stroke, diabetic individuals had better survival. But thereafter, mortality risk in diabetic men increased, resulting in a higher survival in non-diabetic men. The curves cross each other after about a quarter year. After about 3 years, the curves seem to become more convergent again, that means that the difference between diabetic and non-diabetic men is no longer visible. A significant time dependency of diabetes on mortality could also be seen in multivariate analysis (p=0.008). Adjusted for age, it yields a significant decreased mortality risk in diabetes within the first month and an increased mortality risk in diabetes between 1 month and 3 years of follow-up which was no longer the case after 3 to 5 years (model 1 in Table 3). After further adjustment for comorbidities, level of care dependency, number of prescribed medications and subtype of stroke, relative risks decreased somewhat but remained significantly increased between 1 and 3 years (model 2 in Table 3).

In women, there is a quite similar pattern. However, time dependency was not statistically significant in crude (p=0.08) as well as in multivariate analysis (p=0.89). The curves do cross only slightly in the first week of follow-up, and the Cox model shows no significant decreased hazard ratio in the first months after stroke. Nevertheless, the relative risk of mortality in the fully adjusted model was significantly increased for diabetic women between 6 months and 1 year as well as between 2 and 3 years with an almost twofold increased risk of diabetic women for the first time interval. Again, we found no significant differences between 3 and 5 years of follow-up.

Increasing age, renal failure (only in men), levels of care dependency, number of prescribed medications and haemorrhage stroke, were positively associated with mortality in the fully adjusted model (model 2, Table 3).

Discussion

In this study based on data of a nationwide health insurance we could analyse survival in patients with incident stroke in Germany over up to 5 years (2005–2009), with a focus on diabetes as a predictor. As expected, we found a high mortality in this population. After 5 years follow up, more than one third of the patients in our cohort had died. Interestingly, the influence of diabetes in our study was significantly time-dependent in men: In the first 30 days after incident stroke, mortality was lower in diabetic than in non-diabetic individuals. Thereafter, there was an increasing trend of diabetes risk during observation time, and after about a quarter year, diabetic individuals had a higher mortality than non-diabetic individuals. After three years, the mortality risk tended to become equal. In women, the pattern was similar, however, there was no statistically significant time dependency. Age, renal failure (only in men), the level of care dependency, the number of prescribed drugs and haemorrhagic stroke were significantly associated with mortality, however, did not alter the association between diabetes and mortality. Our results remained almost unchanged in several

Table 1: Description of the study population: patients with first incident stroke during 2005 to 2007, GEK insurants, stratified for diabetes and sex (cited from Icks A et al. Diabetes Care 2012;35:1868-75 [26])

	Total	Diabetes		No Diabetes	
		Men	Women	Men	Women
	(n=5,757)	(n=1,304)	(n=550)	(n=2,683)	(n=1,220)
Mean age* (years (SD))	68.1 (13.0)	69.9 (9.8)	76.3 (10.0)	65.3 (12.8)	68.6 (15.5)
Median age* (years (Q1, Q3)	69.0 (60.0, 78.0)	70.0 (64.0, 77.0)	78.0 (70.0, 83.0)	66.0 (56.0, 75.0)	71.0 (57.0, 81.0)
Subtype of stroke (%)					
Cerabral infarct	73.7	79.8	79.6	72.5	67.1
Hemorrhage	17.9	12.7	9.8	20.1	22.0
– Cerebral hemorrhage	13.6	12.0	8.9	15.7	12.8
– Subararchnoid hemorrhage	4.2	0.7	0.9	4.4	9.2
– Other/unknown	8.4	7.4	10.6	7.4	10.9
Comorbidities (%)					
Hypertension	71.2	82.8	84.7	65.2	65.9
CHD**	28.5	40.7	36.4	24.5	20.7
renal failure	9.4	14.4	15.1	7.4	5.8
Level of care dependency*** (%)					
0	87.2	86.5	69.1	92.7	83.9
1	5.8	6.2	13.1	3.5	7.3
2	5.3	5.4	12.7	2.8	7.2
3	1.7	1.8	5.1	1.0	1.6
Mean number of prescribed medications (SD)	7.2 (5.8)	9.2 (5.9)	11.3 (6.5)	5.4 (4.8)	7.2 (5.5)
Median number of prescribed medications (Q1, Q3)	6.0 (3.0, 10.0)	8.0 (5.0, 12.0)	10.0 (7.0, 15.0)	4.0 (2.0, 8.0)	6.0 (3.0, 10.0)
Intake of specified medications (%)					
Beta Blocker	40.2	48.3	57.1	33.9	38.0
ACE inhibitor/sartans	47.1	64.0	68.7	37.9	39.3
Calcium antagonists	22.9	30.4	35.1	17.6	20.9
Insulin	9.5	28.6	32.0	0.0	0.0
oral Anti-diabetic drug	14.2	43.3	45.8	0.0	0.0

* Age at time of incident stroke, ** CHD coronary heart disease, *** 0 = none, 1 = considerable, 2 = severe, 3 = extreme

Table 2: Crude mortality estimates after first incident stroke, GEK insurants, Germany 2005–2007, stratified for sex and diabetes (cited from Icks A et al. Diabetes Care 2012;35:1868-75 [26])

male						
Cumulative time	1 month	6 months	1 year	2 years	3 years	5 years
No Diabetes						
Number at risk	2,431	2,323	2,260	2,140	1,306	50
mortality (%)	9.4	13.4	15.8	20.2	24.3	32.3
(95% CI)	(8.3–10.5)	(12.1–14.7)	(14.4–17.1)	(18.7–21.8)	(22.7–26.0)	(29.5–35.1)
Diabetes						
Number at risk	1,190	1,106	1,049	946	605	25
mortality (%)	8.7	15.2	19.6	27.5	33.7	40.0
(95% CI)	(7.2–10.3)	(13.2–17.1)	(17.4–21.7)	(25.0–29.9)	(31.1–36.4)	(37.0–43.1)
female						
Cumulative time	1 month	6 months	1 year	2 years	3 years	5 years
No Diabetes						
Number at risk	1,068	987	955	892	530	18
mortality (%)	12.5	19.1	21.7	26.9	31.2	38.1
(95% CI)	(10.6–14.3)	(16.9–21.3)	(19.4–21.3)	(24.4–29.4)	(28.5–33.8)	(34.4–41,7)
Diabetes						
Number at risk	462	403	369	333	190	6
mortality (%)	16.0	26.7	32.9	39.5	46.5	54.2
(95% CI)	(12.9–19.1)	(23.0–30.4)	(29.9–36.8)	(35.7–43.5)	(42.2–50.8)	(48.7–59.7)

CI: confidence interval

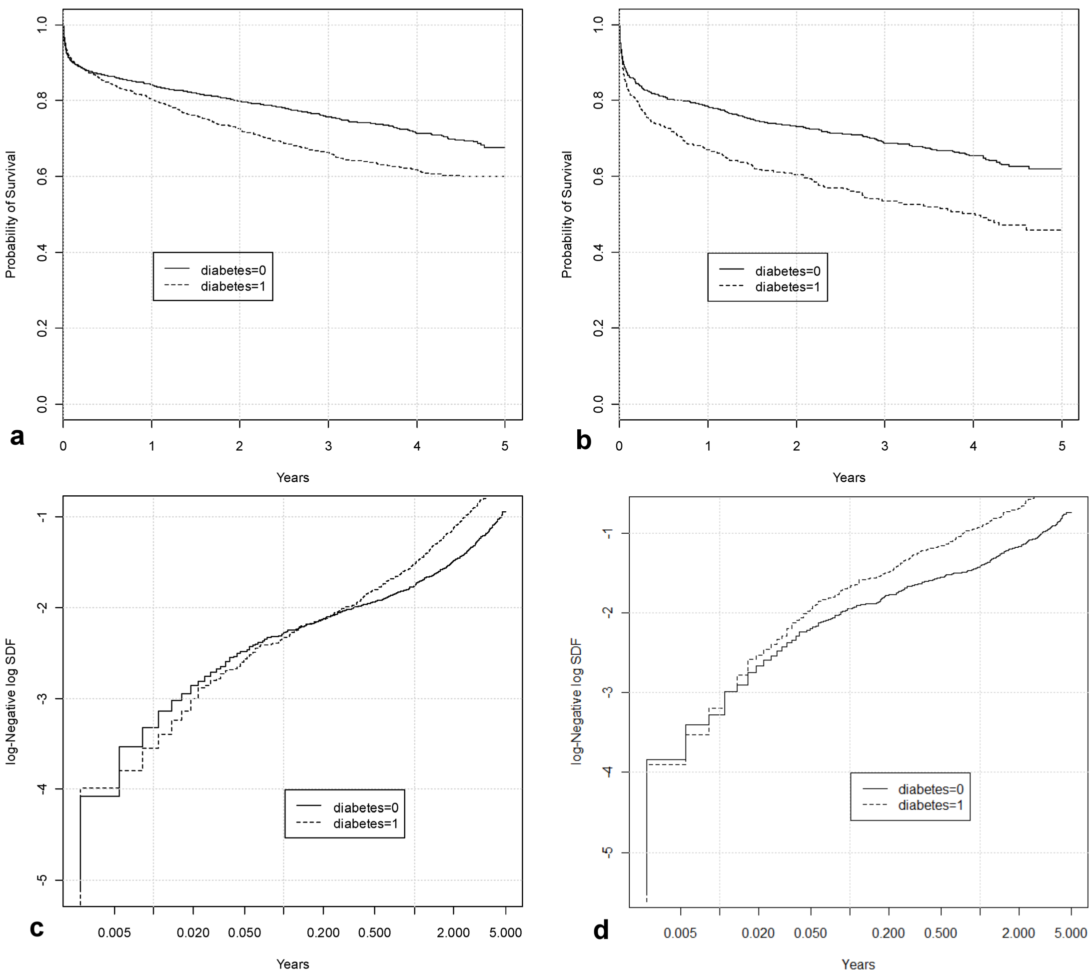

Figure 1a+b: Kaplan-Meier estimates of crude survival after first incident stroke, GEK insurants, Germany 2005–2007; a: male; b: female. c+d: Crude log-log survival curves after first incident stroke, GEK insurants, Germany 2005–2007; c: male; d: female.

Table 3: Predictors for mortality after first incident stroke, Cox regression GEK insurants, Germany 2005–2007, stratified for sex (cited from Icks A et al. Diabetes Care 2012;35:1868-75 [26])

	male population (n=3,987)		female population (n=1,770)	
	Hazard Ratios for death (95% CI) Model 1	**Hazard Ratios for death (95% CI) Model 2**	**Hazard Ratios for death (95% CI) Model 1**	**Hazard Ratios for death (95% CI) Model 2**
Diabetes vs. no diabetes within 0–30 days	0.78 (0.63–0.98)*	0.67 (0.53–0.84)*	1.00 (0.77–1.30)	0.94 (0.72–1.23)
Diabetes vs. no diabetes within 30 days to 6 months	1.35 (1.01–1.79)*	1.14 (0.86–1.52)	1.31 (0.94–1.84)	1.25 (0.89–1.75)
Diabetes vs. no diabetes within 6 months to 1 year	1.61 (1.12–2.30)*	1.40 (0.97–2.00)	2.04 (1.26–3.31)*	1.98 (1.22–3.23)*
Diabetes vs. no diabetes within 1 to 2 years	1.60 (1.23–2.08)*	1.42 (1.09–1.85)*	1.14 (0.76–1.72)	1.12 (0.74–1.70)
Diabetes vs. no diabetes within 2 to 3 years	1.54 (1.13–2.10)*	1.39 (1.02–1.90)*	1.62 (1.02–2.58)*	1.63 (1.02–2.59)*
Diabetes vs. no diabetes within 3 years to 5 years	1.06 (0.72–1.57)	1.00 (0.67–1.48)	1.08 (0.58–2.04)	1.10 (0.58–2.06)
Age (years) (continuously, per year)	1.06 (1.05–1.07)*	1.05 (1.04–1.05)*	1.06 (1.06–1.07)*	1.05 (1.04–1.06)*
Comorbidities				
Hypertension	–	0.83 (0.72–0.95)*	–	0.76 (0.64–0.92)*
CHD**	–	1.04 (0.91–1.18)	–	1.15 (0.97–1.37)
renal disease	–	1.31 (1.11–1.54)*	–	1.11 (0.88–1.40)
Level of care dependency (baseline: 0)				
1	–	2.06 (1.68–2.53)*	–	2.07 (1.65–2.59)*
2	–	2.32 (1.88–2.87)*	–	1.98 (1.57–2.49)*
3	–	3.36 (2.45–4.60)*	–	2.92 (2.08–4.10)*
Number of prescribed medications (continuously)	–	1.05 (1.04–1.06)*	–	1.02 (1.01–1.03)*
Subtype of stroke (baseline: cerebral infarct)				
Hemorrhage	–	2.40 (2.10–2.75)*	–	2.61 (2.15–3.16)*
Other/unknown	–	1.39 (1.14–1.69)*	–	1.31 (1.05–1.65)*

CI: confidence interval. * p<0.05; ** coronary heart disease; *** 0 = none, 1 = considerable, 2 = severe, 3 = extreme sensitivity analyses, e.g. using logistic regression models with the variable log(time) as well as time as a linear predictor (data not shown).

Several limitations have to be considered. (a) In particular over the last years of observation and especially in women, the case numbers are low, leading to a lack of power to detect statistically significant differences between patients with and without diabetes. (b) We cannot exclude misclassification when we define patients with diabetes, because our identification criteria had to be fulfilled within 12 months in the observation period between 2004 and 2007 and not solely before the first stroke. On the other hand, diabetes is often identified for the first time in hospital stays due to typical complications like strokes, and these patients would not be classified as diabetics if we used only the period before the event. However, we performed a sensitivity analysis, defining a person as diabetic when our criteria were fulfilled within the 12 months prior to the first stroke. We found that about 9 of 10 diabetes patients already fulfilled our criteria before their index stroke. Furthermore, results of the mortality analysis remained unchanged. (c) We studied stroke survivors, and the number of fatal strokes may differ among those with and without diabetes. This may be an explanation for the reduced mortality seen among patients with diabetes, within the first 30 days. However, based on data from the German stroke registry as well as from several other countries, it can be assumed that the number of fatal strokes and strokes which are treated outside the hospital are small. About 95% of strokes are hospitalised in clinics and thus identified by our data [22]. (d) Information about clinical variables (e.g. blood glucose, diabetes duration) and patients' lifestyle (e.g. smoking, physical activities) is not available in the database. However, we included the number of prescribed drugs as well as outpatient diagnoses of relevant comorbidities and the level of care dependency. (e) A translation of our results to other populations should be performed with caution since it is known that differences in morbidity as well as demographic and socioeconomic variables exist between health insurance funds [23], [24]. However, the incidence of stroke in our population was well in line with the incidence of stroke in a well-designed regional register-based study [2], [22], [25]. Further, the population has been used for several analyses regarding comorbidities in diabetes [2], [13], [14].

The main strength of our study is that we were able to analyze a large dataset without selection with respect to diabetic complications that could be followed up to 5 years.

Conclusions

In conclusion, in our German study, based on data of a nationwide health insurance, we found a high mortality in patients with a first stroke. Interestingly, the influence of diabetes was time-dependent in men: In the first about a quarter year after incident stroke, mortality was lower in diabetic than in nondiabetic individuals. Only thereafter, diabetic patients had a higher mortality than non-diabetic patients; after about three years, there was a convergence. In women, the pattern seems to be similar, no significant time-dependency was found. Our observation is in line with findings for mortality in diabetic compared to non-diabetic patients after beginning of renal replacement therapy and amputation. Possible explanations may be differences in the type of stroke, or in earlier and more intensive treatment of distinct cardiovascular risk factors in diabetic patients, in particular men. Patients that survive up to three years after stroke might be healthier, independent of their diabetes status. However, results remain conflicting, and further studies are warranted to confirm and explain the results.

Notes

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Contributions

Heiner Claessen is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

AI initiated the study. AI and FH developed the study protocol. SM provides clinical expertise. FH and HC coordinated the data analysis. HC performed the statistical analysis and wrote the paper. All authors commented on paper drafts.

Competing interests

The authors declare that they have no competing interests.

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