Heart Failure Prevalence, Incidence, and Mortality in the Elderly With Diabetes

Alain G. Bertoni, md, mph[1,2]
W. Gregory Hundley, md[2]
Mark W. Massing, md, phd[3]
Denise E. Bonds, md, mph[1,2]
Gregory L. Burke, md, ms[1]
David C. Goff, Jr., md, phd[1,2]

OBJECTIVE — The goal of this study was to determine heart failure prevalence and incidence rates, subsequent mortality, and risk factors for heart failure among older populations in Medicare with diabetes.

RESEARCH DESIGN AND METHODS — We used a national 5% sample of Medicare claims from 1994 to 1999 to perform a population-based, nonconcurrent cohort study in 151,738 beneficiaries with diabetes who were age ≥65 years, not in managed care, and were alive on 1 January 1995. Prevalent heart failure was defined as a diagnosis of heart failure in 1994; incident heart failure was defined as a new diagnosis in 1995–1999 among those without prevalent heart failure. Mortality was assessed through 31 December 1999.

RESULTS — Heart failure was prevalent in 22.3% in 1994. Among individuals without heart failure in 1994, the heart failure incidence rate was 12.6 per 100 person-years (95% CI 12.5–12.7 per 100 person-years). Incidence was similar by sex and race and increased significantly with age and diabetes-related comorbidities. The adjusted hazard of incident heart failure increased for individuals with the following: metabolic complications of diabetes (a proxy for poor control and/or severity) (hazards ratio 1.23, 95% CI 1.18–1.29), ischemic heart disease (1.74, 1.70–1.79), nephropathy (1.55, 1.45–1.67), and peripheral vascular disease (1.35, 1.31–1.39). Over 60 months, incident heart failure among older adults with diabetes was associated with high mortality—32.7 per 100 person-years compared with 3.7 per 100 person-years among those with diabetes who remained heart failure free.

CONCLUSIONS — These data demonstrate alarmingly high prevalence, incidence, and mortality for heart failure in individuals with diabetes. Prevention of heart failure should be a research and clinical priority.

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Diabetes is widely recognized as a significant risk factor for the development of heart failure and is an independent risk factor for increased mortality among individuals with heart failure (1–4). It is also established that the incidence of heart failure rises sharply with age (5,6). Diabetes prevalence has been increasing among the elderly, and it is estimated that the 3.5 million individuals aged ≥65 years with diabetes in 2000 will increase to 5 million individuals by 2010 (7). One may expect, therefore, that elderly individuals with diabetes will contribute substantially to the overall burden of heart failure in the U.S. and especially to the Medicare program. However, there are limited data on heart failure prevalence, incidence, or prognosis among older individuals with diabetes, as cohort studies and heart failure randomized trials have enrolled few individuals ≥75 years of age with diabetes. Prior reports regarding heart failure among individuals with diabetes have been in health maintenance organizations that typically serve younger and healthier populations (8,9) or have been limited to a nursing home population (10); we are not aware of similar data in the Medicare fee-for-service population. Given the expected relationship between diabetes and heart failure, we undertook this study to more precisely quantify heart failure prevalence, incidence, and mortality among elderly Medicare beneficiaries with diabetes and to determine if demographics or comorbidity identify specific individuals at higher risk for heart failure.

RESEARCH DESIGN AND METHODS

Study sample

We conducted a national, nonconcurrent cohort study of U.S. elders with diabetes by using data from the 5% standard analytical file, which contained Medicare claims for 1,941,453 individuals in 1994. Details regarding inclusion/exclusion criteria and data collection have been published (11). The standard analytical file allows for linkage of claims records through time. We excluded 312,460 beneficiaries aged <65 years, 77,407 who died in 1994, 142,964 enrolled in managed care, 31,151 who were not U.S. residents, and 92,818 who were not in Medicare part A (inpatient) and part B (outpatient) for the entire calendar year (1994). Managed care enrollees were excluded because individual claims for disease episodes are not generated. Among the remaining 1,284,653 beneficiaries, individuals were classified as having diabetes if there were at least two outpatient claims with a diabetes-related International Classification of Diseases (ICD)-9 diagnosis code (250.xx) or at least one hospitalization claim with a diabetes-related diagnosis code, which yielded 151,738 elders with diabetes alive as of 1 January 1995. For comparison purposes, we compared our study population with

From the [1]Department of Public Health Science, Wake Forest University School of Medicine, Winston-Salem, North Carolina; the [2]Department of Internal Medicine, Wake Forest University School of Medicine, Winston-Salem, North Carolina; and the [3]Medical Review of North Carolina, Cary, North Carolina.
Address correspondence and reprint requests to Dr. Alain Bertoni, Public Health Sciences, Medical Center Boulevard, Winston-Salem, NC 27157. E-mail: abertoni@wfubmc.edu.
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Abbreviations: ICD, International Classification of Diseases.
A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

the U.S. Census 1990 population aged ≥65 years (12).

Covariates and outcomes classification

We defined prevalent heart failure as one or more inpatient or outpatient claims with an ICD-9 code (428.x) indicating heart failure in 1994. We also examined additional ICD-9 codes suggestive of heart failure (see online appendix available at http://care.diabetesjournals.org); however, as these have a lower specificity for heart failure, our primary heart failure definition was ICD-9 code 428.x (13). For incidence analyses, we first excluded beneficiaries with any 1994 heart failure diagnosis. Claims were analyzed in quarterly intervals. For our primary definition of heart failure, we identified the first heart failure claim (428.x) occurring after 1 January 1995. Alternatively, we identified the first heart failure claim after 1 January 1995 with any ICD-9 code suggestive of heart failure. The date of heart failure was the first day of the quarter in which the claim was filed. Participants were censored if they joined a managed care plan (assessed annually) or died. Follow-up extended until 31 December 1999. Deaths were ascertained using the Medicare denominator file, which includes data on mortality, including date of death (14). We identified beneficiaries who were dual-eligible for Medicaid in 1994 as a marker for lower socioeconomic status. Race classification was as reported in the Medicare denominator file. Comorbidities were defined as the presence in 1994 of at least one claim containing diagnosis codes for ischemic heart disease, hypertension, peripheral vascular disease, stroke, nephropathy, neuropathy, metabolic decompensation (including diabetic ketoacidosis and hyperosmola coma), or hypoglycemia (see online appendix for ICD-9 codes). We identified beneficiaries receiving dialysis in 1994 through the Medicare enrollment file, which indicates whether individuals are also enrolled in the end-stage renal disease program.

Analysis

Heart failure prevalence was calculated as the proportion of the study sample with heart failure in 1994 and determined by 5-year age strata from age 65–84 and ≥85 years. Cross-sectional associations between prevalent heart failure and selected covariates were evaluated in logistic regression analyses. An incident heart failure event was defined as the first diagnosis of heart failure from 1995 through 1999 (by the above criteria) among those without heart failure in 1994. Follow-up time was determined from 1 January 1995 to the date of the incident heart failure event (the first day of the quarter in which the first heart failure claim was recorded) or censoring (enrollment in managed care or death). For those without incident heart failure or not censored, follow-up time was the time interval from 1 January 1995 through 31 December 1999 (15). Total person-time of follow-up was calculated as the sum of individual follow-up times. Heart failure incidence rates were calculated as the number of individuals with an incident heart failure event divided by total person-time of follow-up among those without prevalent heart failure and were calculated by sex, race, and age strata. Proportional hazards regression was used to assess the relative hazard of incident Heart failure (expressed as the hazards ratio [HR]) associated with selected covariates. For mortality analyses, deaths were identified from 1995 through 1999 for those without heart failure in 1994. Heart failure status was analyzed as a time-dependent covariate. Individuals were considered to be heart failure free until the first day of the quarter in which the first heart failure claim was recorded. Heart failure free follow-up time was determined from 1 January 1995 to the date of death or 31 December 1999 for those remaining heart failure free or to the last day of the quarter preceding the incidence of heart failure. The mortality rate in those heart failure free was the number of deaths divided by the sum of the heart failure free follow-up time. Incident heart failure follow-up time accrued from the date of heart failure incidence to the date of death or 31 December 1999. The incident heart failure mortality rate was the number of deaths divided by the sum of the follow-up time following heart failure incidence. Five-year survival was estimated from Kaplan-Meier survival plots for individuals with and without incident heart failure. Log rank tests were used to test equality of survival. Proportional hazards regression was used to assess the relative hazard of death associated with incident heart failure controlling for selected covariates. All significance tests were two tailed. Analyses were performed using Stata 7.0 (Stata, College Station, TX).

Table 1—*Baseline characteristics of study population with diabetes in Medicare in 1994 by heart failure status*

Cohort in 1994	No heart failure	Prevalent heart failure
n	117,933	33,805
Age (years)	73.8 ± 6.4	76.3 ± 7.1
Woman	59.4	61.8
White race*	84.0	83.7
Black race*	11.8	12.0
Other/missing race*	4.2	4.3
Dual eligible	15.3	23.7
Hypertension	59.8	68.1
Ischemic heart disease	30.4	67.4
Peripheral vascular disease	17.8	30.1
Stroke/transient ischemic attack	15.3	28.6
Nephropathy	4.0	16.4
End-stage renal disease	0.4	2.2
Retinopathy	14.6	17.3
Neuropathy	14.0	19.6
Metabolic acidosis/coma	4.0	6.1
Hypoglycemia	2.3	4.6

Data are % and mean ± SD. Dual eligible persons qualify for Medicaid coverage. All comparisons are significant at $P < 0.001$ except for *those that are not significant.

RESULTS

Cohort characteristics and heart failure prevalence

The selection criteria resulted in a population with diabetes that was 84% white, 12% black, and 4% other race. This differed from the racial distribution of the U.S. population aged ≥65 years in the 1990 census (89% white, 8% black, and 3% other) in that the cohort had proportionately more black participants. The age distribution was slightly older than the corresponding U.S. population, with fewer elderly between age 65 and 74 years (cohort 56 vs. 58%), more aged 75–84 years (cohort 36 vs. 33%), and fewer aged ≥85 years (cohort 9 vs. 10%).

There were 33,805 individuals with a diagnosis of heart failure in 1994. In comparison with those without heart failure, individuals with prevalent heart failure were somewhat older, more likely to be of lower socioeconomic status, and to have cardiovascular and diabetes-related comorbidities diagnosed (Table 1). The prev-

Table 2—*Prevalence of heart failure in 1994 among adults with diabetes aged ≥65 years in Medicare and incidence of heart failure during 1995–1999 among those free of heart failure in 1994*

Demographic group	Prevalent heart failure in 1994	Incident heart failure during 1995–1999
n	151,738	115,803
All	22.3	12.6
Men	21.2	12.5
Women	23.0	12.7
Whites	22.4	12.8
Blacks	22.6	12.8
Age 65–69 years	15.7	8.4
Age 70–74 years	19.6	9.8
Age 75–79 years	23.8	12.2
Age 80–84 years	29.6	15.8
Age ≥85 years	37.4	20.5

Data are % (prevalence) or rate per 100 person-years (incidence) by demographic group.

alence of heart failure increased substantially with age but was similar by sex and race (Table 2). In a multivariable-adjusted logistic regression analysis (Table 3), ischemic heart disease and nephropathy were most strongly correlated with prevalent heart failure. Other vascular diagnoses and metabolic complications of diabetes were modestly associated with heart failure. The findings were similar when reclassifying 2,130 individuals with heart failure identified only via the alternate heart failure definition. Our prevalence estimate increased slightly to 23.7%. Including these individuals in the logistic regression model did not appreciably change any estimates (data not shown).

Incidence of congestive heart failure

Among 115,803 individuals without any heart failure–related claim in 1994, 45,542 had at least one new claim for heart failure over 60 months of follow-up. Incidence of heart failure increased with age and was similar in men and women as well as in whites and blacks (Table 2). Hazard ratios for demographic variables and prevalent (1994) comorbid conditions are presented in Table 3. Individuals dual-eligible for Medicaid in 1994 were at higher risk. Ischemic heart disease and renal disease were associated with higher risk than other comorbidities. Although individual diabetes-related complications (renal, metabolic, hypoglycemia, retinopathy, amputation, neuropathy) were variably related to incident heart failure, individuals with none, one, two, three, and four or more of these complications had an increasing rate of heart failure (11.5, 14.3, 18.5, 24.2, and 28.8 per 100 person-years, respectively). Inclusion of alternate heart failure diagnoses in our definition of incident heart failure did not significantly change the incidence rate nor were there any significant differences in the coefficient estimates from the prior proportional hazards model (data not shown).

Mortality

The survival of the cohort free of heart failure in 1994 was significantly lower in those with incident heart failure compared with those remaining heart failure free (log rank $P < 0.001$, Fig. 1). Among the 46,720 who developed heart failure through 1999, 20,962 (44.9%) had died by the end of 1999. Among the 69,083 who remained heart failure free during these 5 years, 16,604 (24.0%) died by the end of 1999. The mortality rate among individuals free of heart failure in 1994, with incident heart failure in 1995–1999, was 32.7 per 100 person-years. In comparison, the mortality rate for those remaining free of heart failure was 3.7 per 100 person-years (HR 10.6, 95% CI 10.4–10.9). This increased risk of death for individuals developing heart failure was only slightly attenuated by adjustment for age, sex, and race (9.5, 9.3–9.7). The median survival was 1.1 year; the 5-year survival rate was 12.5%. In contrast, the 5-year survival of individuals free of heart failure exceeded 80%. Mortality rates were higher for diabetic men with heart failure (37 per 100 person-years) compared with women (30 per 100 person-years) and for whites (34 per 100 person-years) compared with blacks (27 per 100 person-years). When including the alternate diagnosis for heart failure in our definition of incident heart failure, the mortality rates among individuals with and without incident heart failure were not substantially different.

CONCLUSIONS— These data demonstrate that heart failure is very common among elders with diabetes in Medicare,

Table 3—*Association between selected baseline demographic characteristics and comorbidities with prevalent and incident heart failure among adults with diabetes aged ≥65 years*

Characteristics	Prevalent heart failure in 1994		Incident heart failure during 1995–1999	
	OR	95% CI	HR	95% CI
n	151,738		115,803	
Women	1.10	1.07–1.13	0.96	0.94–0.98
5-year age interval	1.28	1.27–1.29	1.23	1.22–1.24
Black (vs. white)	0.94	0.90–0.98	0.95	0.92–0.98
Other race (vs. white)	0.84	0.79–0.89	0.80	0.76–0.84
Dual eligible	1.51	1.45–1.56	1.30	1.26–1.33
South (vs. Northeast)	1.06	1.02–1.1	0.97*	0.94–0.99
Midwest (vs. Northeast)	1.14	1.10–1.19	1.03*	1.01–1.06
West (vs. Northeast)	1.15	1.10–1.20	0.95	0.92–0.98
Ischemic heart disease	4.14	4.03–4.26	1.62	1.59–1.66
Hypertension	1.21	1.18–1.25	1.10	1.07–1.12
Stroke/TIA	1.40	1.35–1.44	1.24	1.20–1.27
Peripheral vascular disease	1.36	1.32–1.41	1.25	1.22–1.28
Nephropathy	3.51	3.34–3.68	1.53	1.46–1.59
End-stage renal disease	1.43	1.25–1.63	1.99	1.77–2.24
Metabolic acidosis/coma	1.17	1.1–1.24	1.11	1.06–1.16
Hypoglycemia	1.37	1.28–1.48	1.15	1.08–1.21
Amputation	1.37	1.22–1.55	0.99†	0.89–1.10
Retinopathy	1.11	1.07–1.16	1.25	1.22–1.29
Neuropathy	1.12	1.08–1.16	1.16	1.13–1.19

Results presented are from multivariate logistic (prevalence) and proportional hazards (incidence) models including all characteristics listed in the table. TIA, transient ischemic attack. All *P* values are <0.001, except *$P < 0.05$ and †not significant.

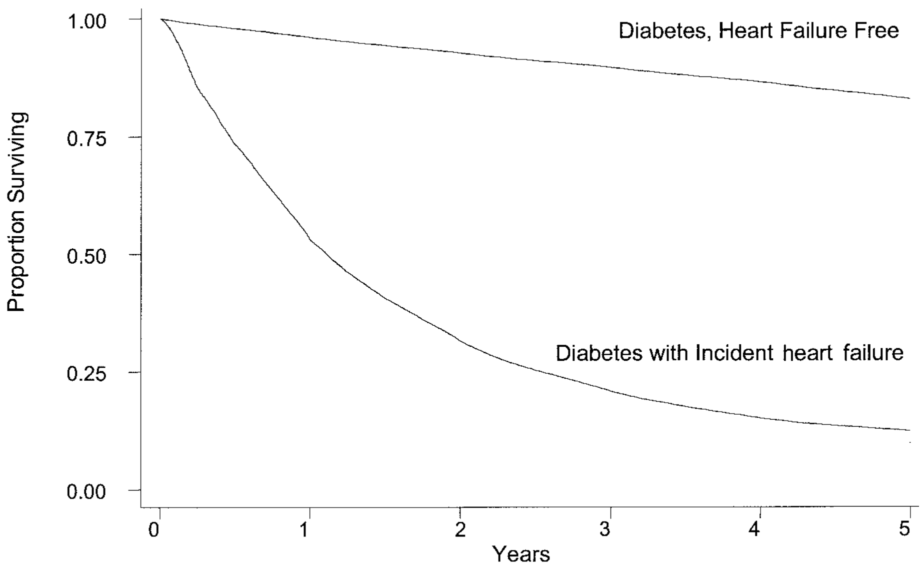

Figure 1—*Five-year Kaplan-Meier survival estimates for 115,803 adults age ≥65 years in fee-for-service Medicare with diabetes by incident heart failure status.*

perhaps more so than previously suspected. For every 100 elderly individuals with diabetes free of heart failure at the beginning of a year, on average 12 will develop heart failure and 6 will die by the end of the year. Prevalence and incidence of heart failure both increased with age and diabetes-related comorbidities, in particular ischemic heart disease and renal insufficiency. The detrimental effect of heart failure on individuals with diabetes is highlighted by the dramatically higher mortality rates among individuals with heart failure compared with those who remain heart failure free.

Strengths of this study include a large, nationally representative sample of older people with diabetes in the Medicare program, inclusion of all older age-groups, investigation of a variety of diabetes-related comorbidities as risk factors, examination of all-cause mortality, and use of survival analysis to calculate incidence and mortality rates. We also investigated a variety of heart failure–related ICD-9 codes.

The main limitation is reliance on claims data for all aspects of this work, which could lead to misclassification bias. We are confident that our cohort had diabetes, as our criteria for defining diabetes has been reported to have a specificity of 98% (16). Incomplete diabetes ascertainment could have biased heart failure rates upward. We did not use stringent clinical criteria to define heart failure, but for inpatient heart failure, ICD-9 code 428 had a sensitivity of 63% and specificity of 95% when compared with clinical criteria using the medical record (13). High specificity but poor sensitivity for many diagnoses including ischemic heart disease and stroke has been reported when comparing claims databases to clinical records (17). There may be financial incentives for hospitals to more frequently use heart failure diagnoses, although it is unclear if "upcoded" claims represent people without heart failure or rather are for people with heart failure whose hospitalization are primarily for another diagnosis (18). The most likely effect of these limitations is to obscure the ability to detect associations between demographic and comorbidity variables and the outcomes, which would cause us to underestimate the true effects of these variables and diminish the precision of the prevalence and incidence data.

Our prevalence and incidence estimates are higher than most previous reports despite the concerns regarding poor sensitivity (19,20). One prospective study demonstrated slightly higher incidence rates of heart failure among individuals with diabetes; however, that was in the setting of a long-term health care facility (10). In contrast to two prior studies with incidence data (one of which only investigated hospitalization or death from heart failure), our study population is older and not in managed care (8,9). Individuals who choose to enroll in Medicare managed care plans are likely to be healthier than those choosing fee-for-service Medicare (21). There is also evidence that diabetes care may be better in managed care organizations with diabetes registries compared with fee-for-service Medicare (19,20). Thus, it is plausible that the risk of heart failure in fee-for-service Medicare is higher than in the managed Medicare population. Given the small proportion of Medicare beneficiaries enrolled in managed care in 1994, 7.4% in this data source, our estimates are likely generalizable to the elderly population with diabetes in the U.S.

We could not determine duration of diabetes, glycosylated hemoglobin level, blood pressure, or which medications were prescribed to these patients. However, we found higher rates of heart failure with a greater number of complications related to poor glycemic and blood pressure control. This is consistent with the limited clinical trial data, which suggest that blood pressure control and treatment with ACE inhibitors may reduce the risk of heart failure among individuals with diabetes, whereas observational data suggest glycemic control may reduce the risk of heart failure (8,22–24). Our data do not inform about the specific subtypes of heart failure (such as ischemic or idiopathic), and we cannot differentiate between heart failure with preserved versus decreased left ventricular function. Our findings of an increased risk of heart failure in individuals with ischemic heart disease and renal impairment is consistent with prior work (9,25), as is our finding of a similar incidence of heart failure in blacks with diabetes compared with whites (26).

It is well recognized that diabetes is a risk factor for mortality among individuals with heart failure (4). Diabetes was associated with an 11% (blacks) to 24% (whites) increased mortality risk in a cohort of Medicare beneficiaries with a first hospitalization for heart failure in 1986 (27). We are not aware of studies that have demonstrated the differential mortality impact heart failure has in a population with diabetes. The 5-year survival after the diagnosis of heart failure is lower in this study than the 21% 5-year survival reported for elderly white men with heart failure (27) and is comparable with the 5-year survival rate (13%) of elderly lung cancer patients (28).

Despite the high mortality observed, heart failure has a high prevalence in populations with diabetes due to a high incidence rate. This underscores the need to focus on the prevention of heart failure in individuals with diabetes. There have been no clinical trials enrolling exclusively diabetic individuals for testing either specific drugs or different glycemic or blood pressure control strategies to prevent or treat heart failure, although subgroup analyses of heart failure clinical trials suggest similar treatment benefits from ACE inhibitors and β-blockers regardless of diabetes status (4). Ramipril decreased the risk of heart failure by 20% among individuals with diabetes at high risk for cardiovascular disease in the Heart Outcomes Prevention Evaluation study (23). However, the heart failure incidence rate (11%) among those taking ramipril was still quite high. New efforts for the prevention and treatment of heart failure among individuals with diabetes are urgently needed, especially among older populations with the highest burden of both diabetes and heart failure.

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