ORIGINAL RESEARCH

Who Enrolls in the Medicare Part D Prescription Drug Benefit Program? Medication Use Among Patients With Heart Failure

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***Background*—**Dispensing data from Medicare Part D standalone prescription drug plans are now available, but characteristics of enrollees with heart failure have not been well described.

***Methods and Results*—**We identified 81 874 patients with prevalent heart failure as of January 1, 2010, in a nationally representative 5% sample of Medicare beneficiaries. We classified patients according to enrollment in a Medicare Part D plan as of January 1, 2010. Demographic characteristics, comorbid conditions, and prescriptions were compared by enrollment status. A total of 49 252 (60.2%) were enrolled in a Medicare Part D plan as of January 1. Enrollees were more often women, black, and of lower socioeconomic status. Enrollees with heart failure more often filled prescriptions for loop diuretics than angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, β-blockers, or aldosterone antagonists. During the first 4 months of 2010, 5444 (12.3%) reached the coverage gap, and 566 (1.3%) required catastrophic coverage beyond the gap.

***Conclusions*—**Medicare beneficiaries with heart failure differ significantly according to enrollment in Part D prescription drug plans and represent a population underrepresented in clinical efficacy trials. Many face the coverage gap, and few select Medicare Part D plans that provide coverage during the gap. Linking Medicare Part D event data with clinical registries could help to determine whether eligible enrollees are undertreated for heart failure. **(*J Am Heart Assoc.* 2013;2:e000242 doi: 10.1161/JAHA.113.000242)**

Key Words: heart failure • Medicare Part D • outcome assessment (health care)

Heart failure is highly prevalent in the Medicare population and is responsible for a substantial portion of annual Medicare spending. An estimated 1 in 10 Medicare beneficiaries with heart failure accounts for 33 cents of every Medicare dollar spent.[1] Medical therapy is the mainstay of care for older patients with heart failure, yet these patients often are underrepresented in the clinical trials that form the evidentiary base for their care.[2] Narrowly defined eligibility criteria ensure the feasibility and validity of trials of treatment efficacy, but the generalizability of the results to broader, real-world populations may be limited. As a result, there is a paucity of data to support the effectiveness of treatments in elderly patients with multiple comorbid conditions.[3]

With the introduction of the Medicare Part D prescription drug benefit in 2006, the Centers for Medicare & Medicaid Services began to collect outpatient prescription drug information on millions of enrollees. To date, the characteristics of Medicare Part D enrollees with heart failure have not been well described. In this study, we sought to identify a cohort of older patients whose prescription drug event data could be used to investigate the comparative effectiveness of pharmacotherapies for heart failure. We describe a population of Medicare beneficiaries with heart failure enrolled in Part D and the medications they received.

Methods

Data Sources

We accessed research-identifiable administrative claims data from the Centers for Medicare & Medicaid Services for a 5% nationally representative, random sample of Medicare beneficiaries. The data included inpatient, outpatient, carrier, and prescription drug event claim files and the corresponding denominator files from January 1, 2010, through December

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31, 2010. The inpatient files contain institutional claims for facility costs covered under Medicare Part A, and the outpatient files contain claims from institutional outpatient providers (eg, hospital outpatient departments, ambulatory surgery centers) covered under Medicare Part B. The carrier files contain noninstitutional provider claims for services covered under Medicare Part B. The denominator files contain beneficiary demographic data and information about program eligibility and enrollment.

The prescription drug event data contain information from pharmacies about prescriptions covered by multiple Medicare Part D insurance plans. These data include descriptors of prescription drugs and the benefit phases under which the prescriptions were submitted for coverage. The standard benefit phases include (1) the deductible phase, during which the beneficiary assumes 100% of drug costs; (2) the preinitial coverage limit phase, during which the beneficiary assumes 25% of costs; (3) the coverage gap, during which the beneficiary assumes 100% of costs; and (4) the catastrophic coverage phase, during which the beneficiary assumes 5% of drug costs. Although beneficiaries may enter the phases at different times depending on the prescription drug plan in which they are enrolled, Medicare Part D event data describe the current phase associated with a prescription for a beneficiary. The plan characteristics file provides information about the Medicare Part D plan, including whether the plan provided coverage during the coverage gap.

Study Cohort

We constructed a cohort of fee-for-service Medicare beneficiaries aged ≥65 years who had prevalent heart failure on January 1, 2010. To establish a diagnosis of heart failure, we required 1 year of prior claims, which necessitated that beneficiaries in the final study group were enrolled in fee-for-service Medicare for all of 2009. As a result, all beneficiaries were ≥66 years in 2010. As described in detail elsewhere,[4] we identified beneficiaries for whom a diagnosis of heart failure (*International Classification of Diseases*, *Ninth Revision*, *Clinical Modification* code 428.x, 402.x1, 404.x1, or 404.x3)[5] was reported on a single inpatient claim or ≥3 carrier or outpatient claims for services provided during the previous year. We classified patients as either enrolled or not enrolled in a Medicare Part D plan as of January 1 using indicators found in the denominator files. To describe medication use in the cohort of beneficiaries who were enrolled in a Medicare Part D plan, we analyzed prescriptions from the first 4 months of 2010, which allowed us to capture at least one 30-day or 90-day prescription refill. This approach allowed us to define a sufficient assessment period for identifying dispensing activities for Medicare beneficiaries with heart failure on January 1, 2010. We excluded beneficiaries in this subgroup who died or discontinued enrollment in the Medicare Part D plan during the first 4 months of 2010.

Beneficiary Characteristics

Using the denominator files, we gathered demographic data and information about program eligibility and enrollment for all beneficiaries in the study cohorts. We identified comorbid conditions using previously validated coding algorithms.[6,7] Specifically, we searched the inpatient, outpatient, and carrier claims from the year before the cohort year for evidence of atrial fibrillation, cancer, cerebrovascular disease, chronic obstructive pulmonary disease, coronary heart disease, dementia, diabetes mellitus, hypertension, myocardial infarction, peptic ulcer disease, and peripheral vascular disease.

Medication Use

For beneficiaries with heart failure who were enrolled in a Medicare Part D plan, we identified prescriptions filled for medications of interest using the National Drug Code numbers for individual drug formulations. Specifically, we were interested in potentially indicated medications for patients with left ventricular systolic dysfunction (ie, aldosterone antagonists, angiotensin-converting enzyme [ACE] inhibitors, angiotensin receptor blockers, β-blockers, and hydralazine–nitrate combinations), commonly used medications (ie, digoxin and loop diuretics), potentially contraindicated medications (ie, selected medications including antiarrhythmic agents, cilostazol, corticosteroids, metformin, terazosin, and thiazolidinediones), and the most frequently prescribed nonrelevant medications for patients with heart failure. To capture at least 1 outpatient prescription refill (either a 30-day or a 90-day refill), the ascertainment period for all medications was the first 4 months of each cohort year. During this period, we used the prescription drug event data to determine the number of beneficiaries who entered the coverage gap and whether the plan in which they were enrolled provided coverage during the gap.

Statistical Analysis

We used descriptive statistics to describe the characteristics of the study population by enrollment in a Medicare Part D plan. We present categorical variables as frequencies and percentages and continuous variables as means with standard deviations. We tested for differences between groups using χ^2 tests for categorical variables and Wilcoxon rank sum tests for continuous variables.

Among beneficiaries enrolled in a Medicare Part D plan, we used descriptive statistics to describe how many

beneficiaries had any prescription for the medications of interest and how many entered each phase of Part D coverage. We considered a 2-sided $P<0.05$ to be statistically significant for all tests. We used SAS software version 9.3 (SAS Institute Inc, Cary, NC) for analyses. The institutional review board of the Duke University Health System approved the study.

Results

We identified 81 874 eligible beneficiaries with prevalent heart failure as of January 1, 2010. Among eligible beneficiaries, 49 252 (60.2%) were enrolled in a Medicare Part D plan as of January 1, 2010, and 44 218 were alive and enrolled as of April 30, 2010. Table 1 shows the baseline characteristics of the study population by Medicare Part D enrollment status. Mean age was 80 years among both enrollees and nonenrollees. Nearly 2 of every 3 enrollees were women. Enrollees were more frequently black than nonenrollees. They also more frequently had a portion of their Medicare Part A and Part B premiums paid by the state (ie, state buy-in), an indication of low socioeconomic status.

Like nonenrollees, enrollees tended to have multiple comorbid conditions (Table 2). Hypertension was the most frequently documented comorbid condition (>90% of beneficiaries, regardless of Medicare Part D enrollment status). More than two-thirds of enrollees had a history of coronary heart disease, more than half had chronic obstructive pulmonary disease, and more than half had diabetes mellitus. Nearly half had prevalent atrial fibrillation. A considerable number of beneficiaries had other noncardiovascular comorbid conditions, including cancer and dementia.

Table 1. Baseline Characteristics of Medicare Beneficiaries With Heart Failure by Part D Enrollment Status*

Characteristic	Not Enrolled in Medicare Part D (n=32 622)	Enrolled in Medicare Part D (n=49 252)	*P* Value
Age (y), mean (SD)	80.6 (7.7)	80.7 (8.2)	0.03
Male, n (%)	17 300 (53.0)	17 334 (35.2)	<0.001
Race, n (%)			<0.001
Black	2344 (7.2)	5417 (11.0)	
White	29 634 (90.8)	40 934 (83.1)	
Other/unknown	644 (2.0)	2901 (5.9)	
Medicare state buy-in, n (%)	279 (0.9)	18 542 (37.6)	<0.001

Table 2. Comorbid Conditions Among Medicare Beneficiaries With Heart Failure by Part D Enrollment Status*

Comorbid Condition	Not Enrolled in Medicare Part D (n=32 622)	Enrolled in Medicare Part D (n=49 252)	*P* Value
Atrial fibrillation	16 701 (51.2)	22 835 (46.4)	<0.001
Cancer	6374 (19.5)	7805 (15.8)	<0.001
Cerebrovascular disease	10 961 (33.6)	17 589 (35.7)	<0.001
Chronic obstructive pulmonary disease	16 910 (51.8)	26 515 (53.8)	<0.001
Coronary heart disease	24 255 (74.4)	35 151 (71.4)	<0.001
Dementia	3229 (9.9)	8520 (17.3)	<0.001
Diabetes mellitus	15 489 (47.5)	25 422 (51.6)	<0.001
Hypertension	30 475 (93.4)	46 224 (93.9)	0.01
Myocardial infarction	7636 (23.4)	10 538 (21.4)	<0.001
Peptic ulcer disease	1237 (3.8)	2105 (4.3)	<0.001
Peripheral vascular disease	12 904 (39.6)	21 433 (43.5)	<0.001

*Values are expressed as n (%).

Table 3 shows the percentage of Medicare Part D enrollees with heart failure who filled prescriptions for medications potentially indicated or contraindicated for patients with heart failure. Enrollees more frequently filled prescriptions for loop diuretics than for ACE inhibitors or angiotensin receptor blockers. Approximately 1 in 10 enrollees with heart failure filled prescriptions for aldosterone antagonists; nearly one-third of enrollees filled a prescription for potentially contraindicated diabetic medications, such as thiazolidinediones and metformin. In addition to potassium supplements, enrollees were frequently prescribed antibiotics and medications indicated as treatment for chronic pain, hypothyroidism, and gastroesophageal reflux disease (Table 4).

By the end of the first 4 months of 2010, 5444 beneficiaries (12.3%) reached the coverage gap, and 566 (1.3%) required catastrophic coverage beyond the gap. Overall, 49.5% of this cohort did not enroll in plans that provided coverage during the gap. Of the 40 649 beneficiaries without coverage during the gap, 5065 (12.5%) reached the initial coverage limit. Among 3569 beneficiaries enrolled in a plan with gap coverage, 379 (10.6%) reached the coverage gap.

Discussion

In this study, Medicare beneficiaries with heart failure who were enrolled in a Medicare Part D plan were more often

Table 3. Medication Classes of Interest Among Medicare Beneficiaries With Heart Failure Enrolled in a Part D, January to April 2010

Medication	Patients, n (%)*
Indicated or potentially indicated	
Loop diuretic	27 115 (61.3)
Angiotensin-converting enzyme inhibitor or angiotensin receptor blocker	23 477 (53.1)
β-Blocker	27 136 (61.4)
Angiotensin-converting enzyme inhibitor	16 700 (37.8)
Digoxin	7475 (16.9)
Angiotensin receptor blocker	7674 (17.4)
Aldosterone antagonist	4825 (10.9)
Hydralazine-nitrate combinations (ie, BiDil, hydralazine and isosorbide mononitrate, or hydralazine and isosorbide dinitrate)	906 (2.0)
Potentially contraindicated	
Diabetes medication (ie, thiazolidinediones, metformin)	14 245 (32.2)
Corticosteroids	6318 (14.3)
Contraindicated antiarrhythmics (ie, sotalol, disopyramide, mexiletine, flecainide, propafenone, or quinidine)	1105 (2.5)
Terazosin	650 (1.5)
Cilostazol	449 (1.0)

*The denominator for this analysis is the 44 218 beneficiaries who were alive and enrolled in a Medicare Part D plan as of April 30, 2010.

Table 4. Other Prescription Medications Filled by Medicare Beneficiaries With Heart Failure and Enrolled in a Part D Plan, January to April 2010

Medication	Patients, n (%)*
Azithromycin	4472 (10.1)
Ciprofloxacin	3956 (8.9)
Hydrocodone–acetaminophen combination	8049 (18.2)
Levofloxacin	3677 (8.3)
Levothyroxine sodium	10 722 (24.2)
Omeprazole	9419 (21.3)
Pantoprazole sodium	2741 (6.2)
Potassium chloride	14 812 (33.5)
Propoxyphene–acetaminophen combination	2540 (5.7)

*The denominator for this analysis is the 44 218 beneficiaries who were alive and enrolled in a Medicare Part D plan as of April 30, 2010.

women and black than were nonenrollees. In addition, enrollees more often had a portion of their Medicare Part A and Part B premiums paid by the state, an indication of low socioeconomic status. Medicare Part D enrollees and nonenrollees had multiple comorbid conditions, often with higher rates of prevalence than those previously documented among Medicare beneficiaries. For example, nearly half had prevalent atrial fibrillation, a substantially higher prevalence than the previously observed rates of 3.2% in 1992 and 6.0% in 2002.[8] The prevalence of diabetes among Part D enrollees in this study was 51.6%, compared with a previously reported rate of 24.3% among Medicare beneficiaries in 2005.[9] The prevalence of chronic obstructive pulmonary disease was 53.8% in this study population, compared with 10.9% in 2005.[9]

Using a nationally representative sample of Medicare beneficiaries with heart failure enrolled in the Part D program, this study describes a real-world population often underrepresented in clinical trials. Compared with patients enrolled in landmark trials in heart failure, this population was older, included more women and nonwhite patients, and had greater comorbidity. For example, the mean age of patients in the control arm of the Survival and Ventricular Enlargement trial was 59.5 years, compared with 80.7 years in our cohort of Medicare Part D beneficiaries.[10] Similarly, 74% of patients in the Carvedilol Post-Infarct Survival Control in Left Ventricular Dysfunction study were men, compared with 35.2% in the Medicare Part D cohort.[11] Participants in the Valsartan in Acute Myocardial Infarction Trial was 93.5% white, compared with 83.1% in the Medicare Part D cohort.[12] Previous studies have raised concerns about the exclusion of populations from the trials that provide a foundation of evidence for their care.[13] These oft-excluded populations are at higher risk for adverse outcomes in actual practice[14–18]; thus, the need for studies of pharmacotherapies in these patients is great.[19]

In the first 4 months of 2010, 61.4% of Medicare Part D enrollees with heart failure filled a prescription for a β-blocker. In contrast, an earlier analysis of the 2004 Medicare Current Beneficiary Survey found that 40% of Medicare beneficiaries with heart failure reported using a β-blocker.[20] The use of ACE inhibitors or angiotensin receptor blockers among surveyed Medicare beneficiaries was 58%, compared with the 53.1% we observed among Part D enrollees. Whether the higher use of β-blocker therapy among Medicare Part D enrollees reflects a continuation of temporal trends described previously[20,21] or differences between the study cohorts is unclear. Evaluation of temporal trends in the use of guideline-recommended therapies among Medicare Part D enrollees will be critical as additional years of data become available. The use of evidence-based therapies such as aldosterone antagonists has been historically low among Part D enrollees with heart failure, especially compared with other medications that are either unrelated to heart failure or potentially contraindicated.

This cohort represents all Medicare Part D enrollees with inpatient or outpatient diagnoses of heart failure. It includes patients with varying degrees of left ventricular systolic dysfunction, as well as patients with preserved ejection fraction. Medicare Part D enrollees tended to be older and female. Hypertension was the most prevalent comorbid condition, and a considerable percentage of patients also had atrial fibrillation. As a result, a substantial number of enrollees resembled patients likely to have heart failure with preserved ejection fraction.[22] Evidence-based therapies for heart failure with preserved ejection fraction are lacking, and guidelines emphasize the management of comorbid conditions.[23,24] This can explain the low frequency of prescriptions of many therapies, including ACE inhibitors, β-blockers, hydralazine-nitrate combinations, and aldosterone antagonists. Therefore, future efforts to link Medicare Part D prescription event data with clinical registries represent an opportunity not only to characterize the effectiveness of drug therapy in patients with heart failure, who are underrepresented in clinical trials, but also to generate hypotheses about its effectiveness in patients with various forms of heart failure. For example, Medicare data have been used to investigate the comparative effectiveness of and adherence to aldosterone antagonist therapy among older patients with heart failure.[25,26]

Our study used the Medicare 5% nationally representative sample, which includes (1) beneficiaries who are self-enrolled and receive no subsidies, (2) beneficiaries who are dually eligible for Medicare and Medicaid, and (3) beneficiaries who receive partial low-income subsidies. In our analysis, roughly 1 in 8 enrollees in Medicare Part D reached the coverage gap within 4 months. We found that half of Medicare Part D enrollees were responsible for 100% of the total cost of their medications during this period. A greater proportion of beneficiaries with chronic diseases like hypertension and diabetes reach the coverage gap.[27] Previous studies have indicated that the lack of coverage affects prescription fulfillment decisions and adherence to medication regimens.[28–30] Comparative effectiveness studies using Medicare Part D data should consider the lack of prescription drug coverage in analyses of adherence to recommended pharmacotherapies for chronic diseases like heart failure. Through Medicare subsidies, the Patient Protection and Affordable Care Act is gradually phasing out the coverage gap so that enrollees will be responsible for only 25% of out-of-pocket expenses by 2020. Although this change will eliminate a prominent cost-shifting mechanism, the rising cost of Medicare can still affect Part D enrollees through cost-sharing mechanisms, such as increasing deductibles and coinsurance, which may similarly affect drug adherence. In 2010, cost sharing for Medicare Part B and Part D together accounted for 27% of the average Social Security benefit. By 2030, this share is expected to increase to 36%.[31]

Our study has some limitations. Medicare Part D enrollees may fill prescriptions for generic medications (eg, β-blockers, ACE inhibitors, digoxin, furosemide, spironolactone) at "$4 formularies" without generating a prescription drug event. As a result, the observed prescription rates may underestimate true prescription rates in this study population. However, previous analyses have found little evidence of nonadjudicated out–of-plan use of discount generic drugs among Medicare Part D enrollees.[32] Over-the-counter medications (eg, nonsteroidal anti-inflammatory drugs) do not require a prescription and are not captured in Part D event data. The exclusion of beneficiaries who died or discontinued enrollment in the Medicare Part D plan during the ascertainment period may limit the generalizability of the results. The prescription rates we observed should be interpreted with caution given the lack of clinical data and our inability to identify patients with clinical contraindications to evidence-based therapies. Similarly, administrative data sets do not allow for clinical characterization of disease severity or differentiation among patients with left ventricular systolic dysfunction and those with preserved ejection fraction. Linking Medicare Part D event data with clinical registries has enabled the clinical characterization of enrollees and helped to generate hypotheses about the effectiveness of therapies for various forms of heart failure.

In conclusion, Medicare beneficiaries with heart failure who are enrolled in Medicare Part D prescription drug plans differ significantly from those who are not enrolled and represent a population underrepresented in clinical efficacy trials. Linking Medicare Part D event data with clinical data from registries will help to confirm whether enrollees are undertreated for heart failure. Many enrollees face the coverage gap, and few are enrolled in plans that provide coverage during the gap.

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