Association of Medicare's Bundled Payment Reform With Changes in Use of Vitamin D Among Patients Receiving Maintenance Hemodialysis: An Interrupted Time-Series Analysis

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Background & Rationale: Medicare's 2011 prospective payment system (PPS) was introduced to curb overuse of separately billable injectable drugs. After epoietin, intravenous (IV) vitamin D analogues are the biggest drug cost drivers in hemodialysis (HD) patients, but the association between PPS introduction and vitamin D therapy has been scarcely investigated.

Study Design: Interrupted time-series analyses.

Setting & Participants: Adult US HD patients represented in the US Renal Data System between 2008 and 2013.

Exposures: PPS implementation.

Outcomes: The cumulative dose of IV vitamin D analogues (paricalcitol equivalents) per patient per calendar quarter in prevalent HD patients. The average starting dose of IV vitamin D analogues and quarterly rates of new vitamin D use (initiations/100 person-months) in incident HD patients within 90 days of beginning HD therapy.

Analytical Approach: Segmented linear regression models of the immediate change and slope change over time of vitamin D use after PPS implementation.

Results: Among 359,600 prevalent HD patients, IV vitamin D analogues accounted for 99% of the total use, and this trend was unchanged over time. PPS resulted in an immediate 7% decline in the average dose of IV vitamin D analogues (average baseline dose = 186.5 μg per quarter; immediate change = −13.5 μg [$P < 0.001$]; slope change = 0.43 per quarter [$P = 0.3$]) and in the starting dose of IV vitamin D analogues in incident HD patients (average baseline starting dose = 5.22 μg; immediate change = −0.40 μg [$P < 0.001$]; slope change = −0.03 per quarter [$P = 0.03$]). The baseline rate of vitamin D therapy initiation among 99,970 incident HD patients was 44.9/100 person-months and decreased over time, even before PPS implementation (pre-PPS β = −0.46/100 person-months [$P < 0.001$]; slope change = −0.19/100 person-months [$P = 0.2$]). PPS implementation was associated with an immediate change in initiation levels (by −4.5/100 person-months; $P < 0.001$).

Limitations: Incident HD patients were restricted to those 65 years or older.

Conclusion: PPS implementation was associated with a 7% reduction in the average dose and starting dose of IV vitamin D analogues and a 10% reduction in the rate of vitamin D therapy initiation.

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In 1972, Medicare eligibility was expanded to all patients with end-stage renal disease (ESRD) in the United States. Since then, the number of patients requiring maintenance hemodialysis (HD) increased from 16,000 to more than 400,000,[1,2] accounting for 7.4% of all Medicare expenditures in 2010, although these patients represent <1% of the Medicare population.[1-3] Use of injectable drugs in patients with ESRD has soared over time because historically, Medicare reimbursed these drugs separately from HD services, a practice that created financial incentives for providers to aggressively prescribe them. Between 2007 and 2010, vitamin D therapy in patients with ESRD was largely based on the intravenous (IV) vitamin D analogue paricalcitol (Zemplar [Abbott Laboratories]), which embodied the second largest cost driver, accounting for 4.3% of the reimbursed cost per HD session, only preceded by erythropoiesis-stimulating agents (23% of the reimbursed cost).[4-7]

In consequence, Congress implemented a bundled prospective payment system (PPS) for ESRD in January 2011, with the aim to reduce incentives for overuse of profitable ESRD drugs. Under this PPS, 11 injectable drugs, including erythropoiesis-stimulating agents and vitamin D analogues and their oral equivalents, are included into a capitated payment per in-center HD session.[5,7,8] Evidence on the effect of the PPS on overall vitamin D therapy in ESRD remains equivocal, and incident vitamin D therapy following PPS has not been studied.[9]

Given the lack of evidence suggesting superior clinical outcomes with IV vitamin D analogues compared with the much less expensive oral equivalents or active vitamin D (calcitriol [Rocaltrol {Validus Pharamceuticals} and generics]),[10-15] we hypothesized that PPS introduction would lead to a reduction in the use of IV vitamin D analogues in favor of their oral equivalents or calcitriol or in favor of cinacalcet, which has not yet been included into the bundle.[6] Furthermore we hypothesized that PPS would lead to a shift from IV paricalcitol to the less expensive IV vitamin D analogue doxercalciferol (Hectorol [Sanofi]; for

comparative Medicare-allowable payment amounts from 2007, see Table S1). Using nationally representative data from the US Renal Data System (USRDS), we aimed to evaluate the association between the PPS and overall use patterns and new use patterns of vitamin D therapy in patients with ESRD. We used phosphate-binder use patterns as a negative control outcome to account for temporal changes in prescribing practices for patients with ESRD because they have not been included into the bundle yet.

Methods

Data Source

We used the USRDS database from 2008 through 2013, which collects data for patients with ESRD in the United States. Information that is collected at HD therapy initiation describes demographics, primary cause of ESRD, preexisting comorbid conditions, and certain laboratory values, as well as longitudinal data for death and transplantations. Additionally, the USRDS contains all Medicare Part A and B claims, including information for diagnoses and procedures from hospitalizations and outpatient visits and, since 2006, also all Medicare Part D claims containing information on claims for prescription drugs.[16]

The investigators obtained data use agreements by the USRDS, and this study was approved by the Brigham and Women's Hospital Institutional Review Board. Informed consent was waived due to exclusive use of deidentified observational data.

Study Design

We established 2 mutually exclusive study populations of: (1) prevalent and (2) incident HD patients. In population 1, we assessed overall use of vitamin D before and after PPS implementation (ie, average number of dispensations of IV vitamin D analogues vs oral vitamin D analogues or calcitriol), as well as the average dose of IV vitamin D analogues per patient over time. In population 2, we quantified the treatment initiation rate with different vitamin D products, cinacalcet, and phosphate binders (negative control) within 90 days after starting HD therapy, as well as the average starting dose of IV vitamin D analogues over time. A maximum follow-up of 90 days was chosen because most patients initiate vitamin D and phosphate-binder treatment shortly after the HD therapy start, and patients who start treatment later may not be comparable.

Prevalent HD Patients (Study Population 1)

We established yearly cohorts between 2008 and 2013, each including all patients aged 18 to 99 years on January 1 of the respective year. Eligible patients were required to be undergoing prevalent in-center HD from 90 days before January 1 of the respective year until death or December 31 of the respective year and to have continuous Medicare Parts A (inpatient claims), B (outpatient claims), and D (prescription drug claims) coverage (primary payer) from January 1 until death or December 31. We excluded all patients with a history of kidney transplantation before or during the year of interest. The yearly cohorts were not mutually exclusive; patients contributed data to multiple yearly cohorts if they met inclusion criteria (Fig S1).

Variable Measurement

Within these yearly cohorts, we captured the following patient demographics and characteristics at the beginning of each year or during the 90 days before cohort entry: age, sex, race, ethnicity, primary cause of ESRD, low-income subsidy status, age at first ESRD treatment, HD provider chain, and provider profit status. We further quantified the use of phosphate binders (calcium acetate, lanthanum carbonate, sevelamer carbonate, and sevelamer hydrochloride), vitamin D products (oral and IV calcitriol, paricalcitol, or doxercalciferol), and cinacalcet during each year. Drug exposure was captured as 1 or more dispensation, including prescription fills and outpatient drug administration claims for IV applications, for the drug of interest during the respective year. Calcium carbonate could not be assessed because it is an over-the-counter product, which is not covered by Medicare Part D. We tabulated absolute numbers and proportions to display demographics and absolute drug use within each yearly cohort.

Dispensations of Vitamin D Therapy and Dose of IV Vitamin D Analogues

Based on the yearly cohorts, we calculated the total number of dispensations of IV vitamin D analogues and of alternative vitamin D products (oral vitamin D analogues or calcitriol) per calendar-quarter per patient. We further quantified the average cumulative IV vitamin D dose per patient during each quarter-year as the total number of billed micrograms of IV paricalcitol equivalents divided by the number of patients who had at least one application of an IV vitamin D analogue during this quarter. Units of 1 μg of paricalcitol and doxercalciferol were captured by means of 2 J-codes; J2501 and J1270. Each microgram of doxercalciferol was multiplied by 1.48 to obtain paricalcitol equivalents.[17]

Incident HD Patients (Study Population 2)

We created 3 study cohorts including all patients aged 18 to 99 years with 90 or more days of available pre-HD Medicare data who had not received a transplant before HD treatment start. We excluded patients with use of any vitamin D therapy (cohort 1), cinacalcet (cohort 2), or phosphate binder (cohort 3) within 90 days before the first prescription of the respective drug post-HD (prevalent users; flow chart of patient enrollment in Fig S2).

Average Vitamin D Starting Dose and Rates of Treatment Initiation

Patients were followed up from day 1 after HD therapy start for 90 days to evaluate their first dispensation of either vitamin D (in cohort 1), cinacalcet (cohort 2), or a