Hemoglobin Stability and Patient Compliance With Darbepoetin Alfa in Peritoneal Dialysis Patients After the Implementation of the Prospective Payment System

James L. Pirkle Jr., MD[1]; Carly J. Paoli, PharmD[2]; Greg Russell, MS[3]; Jeffrey Petersen, MD[2]; and John Burkart, MD[1]

[1]Department of Internal Medicine, Section on Nephrology, Wake Forest School of Medicine, Winston-Salem, North Carolina; [2]Amgen Inc, Thousand Oaks, California; and [3]Department of Biostatistical Sciences, Wake Forest School of Medicine, Winston-Salem, North Carolina

ABSTRACT

Purpose: Since the Centers for Medicare & Medicaid Services implemented the End-Stage Renal Disease Prospective Payment System, dialysis providers have increasingly focused on balancing resource utilization and quality outcomes for the treatment of anemia in patients undergoing peritoneal dialysis. Limited data exist regarding anemia management outcomes for these patients in US-based dialysis centers after the implementation of the new payment system.

Methods: This was a retrospective, observational, cohort study of stable PD patients with end-stage renal disease who received darbepoetin alfa for anemia management over a 15-month period (April 1, 2011–June 29, 2012). The medication was administered by staff in the home-training unit instead of being self-administered at home. The primary end point was mean quarterly hemoglobin (Hb) levels. Variability in Hb levels was assessed over the 5 quarters by using repeated measures ANOVA to test for differences in the observed mean SDs.

Findings: In the 139 adult patients on stable peritoneal dialysis and meeting the eligibility criteria, mean (SD) Hb level by quarter was 10.8 (1.2) g/dL in quarters 2 and 3 of 2011, 10.5 (1.1) g/dL in quarter 4 of 2011, and 10.4 (1.1) g/dL in quarters 1 and 2 of 2012. Hb levels were stable (mean SDs, 0.58–0.72) over the 5 quarters of the study. Patient compliance with attendance for all scheduled home training unit visits was 84%.

Implications: PD patients who underwent darbepoetin alfa administration and twice-monthly laboratory testing in the home-training unit had stable Hb levels. Despite more frequent center visits compared with a home-administered approach, patient compliance was high. (*Clin Ther*. 2014;36:1665–1674)

Key words: anemia, darbepoetin alfa, erythropoiesis-stimulating agent, hemoglobin, peritoneal dialysis.

INTRODUCTION

In January 2011, the Centers for Medicare & Medicaid Services implemented the End-Stage Renal Disease Prospective Payment System (PPS), a "bundled" case payment method establishing financial incentives to reduce the costs of outpatient dialysis care.[1] The new bundled PPS created a financial incentive for increased use of peritoneal dialysis (PD) for both incident and established patients.[2,3]

Intravenous and subcutaneous medications, previously paid for on a fee-for-service basis, were included in the bundle, affecting use of erythropoiesis-stimulating agents (ESAs). The Quality Incentive Program was concurrently introduced to prevent any potentially deleterious consequences of the PPS on the quality of patient care.[4] Facility-level metrics during the first year of the Quality Incentive Program included reporting the percentage of patients with a mean annual hemoglobin (Hb) level <10 g/dL and >12 g/dL. In July 2011, the lower Hb metric was retired. There have been further changes to the Quality Incentive Program which will be implemented in 2016, including a clinical measure and a reporting measure for anemia of percentage of patients with an

Accepted for publication August 20, 2014.
http://dx.doi.org/10.1016/j.clinthera.2014.08.011
0149-2918/$ - see front matter

Hb level >12 g/dL and a facility reporting Hb/hematocrit and ESA dose, respectively.[5]

These policy changes have created challenges for dialysis providers who must try to balance resource utilization and quality outcomes in the treatment of anemia in PD patients. Anemia treatment for patients undergoing PD is commonly achieved by using self-administration or caregiver administration of ESAs subcutaneously in the home. However, noncompliance with ESA administration reportedly occurs in 35% to 55% of patients undergoing PD.[6,7] According to experiences at Wake Forest Outpatient Dialysis (WFOPD), Wake Forest, North Carolina, further challenges to anemia management in this population (compared with the in-center hemodialysis [HD] population) can include patient noncompliance with scheduled laboratory studies and intravenous iron administration as well as having to use a single Hb level to determine an entire month's dosing of ESA. Dialysis Facility Report data from 2013 show that PD patients are more likely to have Hb levels >12 g/dL and <10 g/dL compared with in-center HD patients (13% vs 10.8% and 8.3% vs 3.2%, respectively),[8] which may reflect some of the consequences of these challenges.

Barriers to successful anemia management in PD patients may be overcome by more frequent Hb assessments and in-center administration of ESAs. Indeed, some centers have moved away from home dosing of ESAs and have begun administering them to PD patients during home training center visits to ensure that the ESA is administered appropriately; this prevents potential drug wastage if the drug is supplied and not administered (the latter would have financial implications to the provider). However, limited data exist regarding anemia management in PD patients who receive ESAs at US-based dialysis centers, especially in centers with this type of anemia practice. WFOPD began an anemia management protocol in January 2011 by which laboratory studies are obtained twice monthly and darbepoetin alfa is administered subcutaneously by WFOPD home-training staff on a twice-monthly schedule (or more/less frequently depending on patient need). This method allows delivery of a known dose and frequency of ESA, and the frequent monitoring of anemia parameters enables timely dose adjustments with the goal of maintaining Hb levels in an optimum range. The objective of the present study was to describe mean Hb levels and Hb variability in PD patients treated with a protocol created for the new reimbursement environment.

PATIENTS AND METHODS

Study Design

This was a retrospective, observational, cohort study of PD patients at WFOPD who received darbepoetin alfa for anemia management. It was approved by the Wake Forest Health Sciences institutional review board. WFOPD is an academic-based dialysis organization servicing the Piedmont Triad of North Carolina. Patients with end-stage renal disease included in the study were ≥18 years of age, were stable on PD (defined as undergoing PD for ≥3 months) as of April 1, 2011, and had received at least 1 dose of darbepoetin alfa for chronic anemia management from April 1, 2011, to June 29, 2012.

The cohort was treated by using an anemia management protocol that had been developed separately from this study by WFOPD. Before January 1, 2011, WFOPD used epoetin alfa for anemia management of PD patients in which they were instructed to inject the medication subcutaneously at home. On January 1, 2011, a new anemia management protocol was instituted, converting patients from epoetin alfa to darbepoetin alfa. Patients were required to attend twice-monthly visits to the home training center for their anemia management and administration of darbepoetin alfa. The first visit of the month was a standard monthly PD evaluation, during which laboratory studies and a physician visit were conducted. The second visit consisted of a brief interaction (usually no more than 10 minutes) between patient and nurse and another phlebotomy to obtain an Hb level. Based on Hb levels from the previous visit, darbepoetin alfa was administered subcutaneously in the clinic by dialysis staff using SingleJect pens (Amgen, INC, Thousand Oaks, CA) (25, 40, 60, 100, 150, 200 μg) at each of these twice-monthly visits. Subsequent to the introduction of this initial protocol, some patients' schedules could vary from 1 to 4 visits per month depending on patient needs for anemia management based on the twice-monthly laboratory values, which included Hb levels and iron biomarkers. In most cases, patients required only once- or twice-monthly dosing administered in the home training center.