CLINICAL INVESTIGATION

Administer but Do Not Dispense: Effect of Change in Medication Handling by Nurses on Outcomes of Home Dialysis Patients

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ABSTRACT

Background: To come into compliance with South Carolina statute, we changed how nurses handle medications (antibiotics, erythropoietin [EPO], calcitriol and heparin) in our outpatient home dialysis clinic. Nurses continued to administer medications in the clinic but no longer dispensed medications for patients to take home; instead, medications were dispensed from pharmacies to the patients by mail. We hypothesized that the abovementioned change in medication handling worsened clinical outcomes. There is very little medical literature on this topic.

Materials and Methods: A retrospective case series of quality and safety in 31 patients in a community-based, medical center–affiliated home dialysis program was performed. We compared laboratory values and adverse clinical events relevant to the medications mentioned above during 4-8 months before and during 5 months after September 1, 2014 (the day when medication handling was changed).

Results: We observed no changes in the incidences of dialysis access dysfunction, access infections, antibiotic inaccessibility to patients for access-related infections, infection outcomes, parathyroid hormone concentrations, hemoglobin concentrations, monthly EPO dose and missed monthly clinic visits after September 1, 2014. However, we noted significantly fewer subcutaneous EPO administrations per month and less time between phlebotomy and laboratory review with patients by their nephrologists at monthly clinic visits after September 1, 2014.

Conclusions: The change in handling of medications by nurses in our outpatient home dialysis program to comply with the state statute did not worsen patient outcomes relevant to the affected medications and in fact caused several unexpected improvements.

Key Indexing Terms: Medication dispensing; Peritoneal dialysis; Hemoglobin; Erythropoietin. [Am J Med Sci 2016;▮(▮):▮▮▮–▮▮▮.]

BACKGROUND

Approximately 10% of patients with end-stage renal disease in the United States are maintained on home dialysis.[1] Most patients who are on home dialysis are patients on peritoneal dialysis (PD). The PD has distinct advantages over in-center hemodialysis (HD)—dialysis at home, continuous nature of dialysis, less hemodynamic instability, lack of post-HD syndrome and patient independence. Patients on in-center HD are seen by nurses, nurse practitioners or physician assistants or nephrologists 3 times weekly, but patients on home dialysis are seen only once or twice monthly. This difference has distinct implications for administrating and dispensing of medications.

For many years, our home dialysis program (HDP) nurses had been dispensing certain medicines (heparin, gentamicin cream, antibiotics, erythropoietin (EPO) and calcitriol) to HDP patients. However, it came to our attention recently that our practice violated a South Carolina statute (South Carolina Pharmacy Practice Act, Title 40, Chapter 43), which states that HDP nurses are allowed to administer medications in the clinic but are not allowed to dispense them to the patients for self-administration at their homes. Therefore, starting on September 1, 2014, we changed our handling of medications in HDP to come into compliance with the abovementioned statute. However, we were concerned that this change in medication handling might make it more difficult for patients to obtain their medications in a timely fashion. Therefore, we examined clinical outcomes that might be influenced by this change in medication handling over a period of time before (control) and after (experimental) September 1, 2014. We tested the hypothesis that change of medication handling so that the HDP came into compliance with the South Carolina Pharmacy Practice Act worsened quality of HDP care.

MATERIALS AND METHODS

Study Site, Study Period and Patient Selection

Our HDP, located at a single site 22.53 km from the Medical University of South Carolina in Charleston, is a collaboration between Dialysis Clinic Incorporated (the largest nonprofit dialysis provider in the United States) and the Division of Nephrology of the Medical University

of South Carolina. One of us (M.E.U.), the HDP medical director and a faculty member in the Division of Nephrology of the Medical University of South Carolina, cares for approximately 75% of patients. All patients undergoing renal replacement therapy at home (HD or PD) continuously from May 1, 2014 or earlier through January 31, 2015 were evaluated retrospectively in February 2015 for inclusion in this quality and safety assessment. At least 4 months before September 1, 2014 was defined as the control period, and the 5 months after September 1, 2014 was defined as the experimental period. A minimum of 4 months before September 1, 2014 was chosen so that we could discern a stable pattern of health and laboratory values before change in medication handling. The 5-month period after September 1, 2014 was deemed long enough for us to observe changes in patterns of laboratory values and clinical events. Although the shortest period of data accumulation before September 1, 2014 was 4 months (i.e., starting May 1, 2014), we accumulated data back through January 1, 2014 if available. The control period averaged 7.4 months, and the experimental period was 5.0 months in every patient. Patients were excluded if any of the following occurred during the study period: age < 18 years, dialysis modality change, renal transplantation, prolonged hospitalizations, medical instability or bleeding. Patient characteristics are detailed in Table 1. This study was evaluated by the human research review boards of the Medical University of South Carolina and Dialysis Clinic Incorporated and was considered by both to be a quality assessment and thus to be outside of their purviews.

TABLE 1. Causes of exclusions and characteristics of eligible patients on February 1, 2015.

Causes	Number
Number of home patients excluded/eligible	17/31
Causes of 17 exclusions (Number of patients [%])	
Not HDP patient for entire study period	10/17 (59)
Age < 18 years	4/17 (24)
Medically unstable[a]	3/17 (17)
Characteristics of 31 eligible patients	
Causes of ESRD (Number of patients [%])	
Hypertension	11 (36)
Diabetes	8 (26)
Drug toxicity	4 (13)
Nondiabetic glomerular disease	3 (10)
Others[b]	5 (15)
Sex (Number of patients [%])	
F	18 (58)
M	13 (42)
Home dialysis modality (Number of patients [%])	
PD	28 (90)
HD	3 (10)
Race (Number of patients [%])	
African-American	21 (68)
White	9 (30)
Other (Hispanic, Native American)	1 (2)
Age (years, median with range)	55 (31–74)
Dialysis vintage (months, median with range)	
Since first dialysis	19 (1–300)
Since start of current home dialysis period	13 (1–59)

ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis.
[a] Coronary artery disease or endocarditis, automobile accident and anemia induced by mycophenolate mofetil.
[b] Nephritis caused by systemic lupus erythematosus, human immunodeficiency virus infection, obstructive nephropathy and renal cystic disease.

Medication Handling Before September 1, 2014

The EPO was administered subcutaneously at the lowest dose (to reduce cost) and the longest interval (to minimize pain caused by the injections) that would maintain plasma hemoglobin concentration (Hgb) in the target range of 10.0-12.0 g/dL. According to a protocol created by the HDP nephrologists, EPO dosing was changed by the HDP nurses in response to the most recent Hgb. If Hgb decreased toward the bottom of the target range or below target, EPO dose was increased. If Hgb increased toward the top of the target range, EPO dose was decreased. If Hgb exceeded 12.0 g/dL, EPO was temporarily discontinued and restarted at a lower dose when Hgb decreased back to 11.2 g/dL or less. This protocol of altering EPO dose in response to the most recent Hgb was used in both control and experimental periods of the study. The EPO dosing interval varied between patients: once weekly, twice monthly or rarely once monthly. Blood for Hgb was obtained monthly or twice monthly if EPO was temporarily discontinued or if Hgb was particularly unstable. Even before September 1, 2014, some patients did not self-administer EPO at home but rather came to the HDP for nurses to administer it, either because of patients' choices not to self-administer or because HDP nurses had decided that these patients were not capable of or were not reliable in self-administering EPO. Frequency of patient visits to the HDP was once monthly at the minimum, for the required monthly phlebotomy and review of care including laboratory values with the nephrologist. Monthly laboratory values were reviewed by the nephrologist and an HDP nurse within 1 week of phlebotomy, and changes to medications and PD prescriptions were made as necessary at that time. A subset of patients visited the HDP more than once monthly, some because they lived in close proximity to the HDP and desired laboratory values to be obtained closer in time to their clinic visit with their nephrologist and others because they did not self-administer EPO at home. Oral calcitriol dosing was determined by nephrologists to maintain plasma parathyroid hormone (PTH) concentrations between 150 and 600 pg/mL; PTH levels were measured quarterly, or occasionally more frequently if levels were unstable or out of range. Gentamicin cream was administered daily by patients