



FDA CRDAC Meeting

Testimony of Dr. Myra Kleinpeter

On behalf of

The American Kidney Fund

Introduction

Good Afternoon,

Thank you for convening this hearing today to re-examine the use of erythropoiesis-stimulating agents (ESAs) in patients with kidney disease in light of additional clinical information from recent clinical trials. The American Kidney Fund appreciates the opportunity to submit testimony to the panel on ensuring patients with kidney disease and anemia, receive ESAs appropriately, in the setting of chronic kidney disease as part of the chronic care management strategy.

My name is Dr. Myra Kleinpeter, and I currently serve on the Medical Advisory Committee for the American Kidney Fund. I work full time as Director of the Peritoneal Dialysis program and Associate Professor of Medicine, at Tulane University School of Medicine. My clinical practice includes urban and suburban dialysis units and clinical lead for the Chronic Kidney Disease program at the Medical Center of Louisiana.

The American Kidney Fund is the nation's #1 patient financial assistance organization. Last year, AKF provided over \$155 million in financial assistance to patients on dialysis to help pay for health insurance and dialysis treatment related expenses. Along with providing financial services, AKF works to ensure that kidney patients have access to the quality health care that they need.

Safe and Appropriate Anemia Management

Anemia is a serious, life-threatening problem affecting many dialysis patients. It causes fatigue, weakness, increased risk of hospitalization and death. It is also a complication for patients with chronic kidney disease who are not on dialysis. According to an article published in the Clinical Journal of the American Society of Nephrology, the transfusion burden among patients with chronic kidney disease and anemia remains significant despite the use of ESAs in this study of 97,636 patients with CKD and chronic anemia from 2002 through 2007 in the Veterans Administration Healthcare System. Among those patients studied with CKD and anemia, 68,556 transfusion events were observed.

Prior to the introduction of ESA's patients suffering from anemia relied heavily on blood transfusions to maintain an adequate red blood cell count. Kidney disease patients are a fragile population and they often have a significant disease burden and co-morbid conditions such as diabetes, hypertension, cardiovascular disease, vitamin D deficiency. Coupled with kidney failure and anemia, these conditions can severely debilitate patients and have a severe impact on their ability to live a quality and productive life.

With the introduction and appropriate dosing of erythropoietin stimulating agents (ESAs), many patients no longer require blood transfusions, require fewer hospitalizations and are better able to lead productive, quality lives.

While there has been controversy over dosage administrative practices, it is important to understand that each patient receiving dialysis responds differently to the drugs used to treat anemia. It is not possible to determine a single dosing regimen that works for all patients at all times. I feel that it is important that the physician and patient be permitted to decide an anemia care plan that is best suited for that patient from a clinical perspective.

Quality of Life Measurements

All dialysis patients have the right to live normal and productive lives. Patients should have access to the best quality of care that allows them to have careers, raise children, and enjoy life.

There have been advances and achievements in anemia management brought about by ESA's. An observational study conducted by the Clinical Evaluation of the Dose of Erythropoietins Study Group at the Department of Clinical Pharmacology and Epidemiology, Mario Negri Sud Consortium, found that higher hemoglobin levels (around 11-13 g/dL) are associated with improved survival and quality of life compared to hemoglobin levels around 9-10 g/dL.

Receiving the proper dosing of ESA's has greatly made living a higher quality and more productive life possible for many patients. ESA's have reduced the rate of transfusion in the dialysis population. As you know, there are many health risks of transfusions including disease, infection, and iron overload.

However, the risk outweigh the benefit of therapy in normalizing the hemoglobin in chronic kidney disease patients as demonstrated in the CREATE study. As a result of this study, many primary care physicians and advance practice nurses are reluctant to use ESAs in patients with chronic kidney disease. In Network 13, there has been a trend of decreasing hemoglobin levels in incident and prevalent patients over the past 3 years since the CREATE study appeared in the New England Journal of Medicine in November 2006.

As a nephrology fellow, the doses of ESAs used were miniscule in comparison to the doses used today, and the route of administration has changed from subcutaneous dosing in all patients to

subcutaneous dosing in CKD patients and intravenous dosing in hemodialysis patients. During that era, most dialysis patients received transfusions frequently and often required hospitalization for prolonged periods of time if blood suitable for transfusion was not readily available due to multiple antibodies. These multiple transfusions with the development of antibodies may impact on future kidney transplants as a result of these pre-formed antibodies.

Accessibility for CKD Patients

The Medicare Benefit has provided great new advances and successes in fighting kidney disease over the past 10 years. AKF believes that any change in policy should take into consideration its impact on quality patient care and not be centered on incentives.

Patients with CKD, but not yet on dialysis, should have access to ESAs when their physicians and their chronic management team determine that there is a need. The AKF believes that addressing anemia issues prior to dialysis should result in better outcomes and healthier patients for those who later require dialysis and are kidney transplant candidates.

Consequently, healthier patients at the onset of dialysis are likely to help drive down first year mortality rates among dialysis patients. According to an article “Comparative mortality risk of anemia management practices in incident hemodialysis patients” in the Journal of American Medical Association, greater ESA and iron use among patients with CKD were associated with decreased mortality risk at the onset of dialysis.

The initial evaluation and management of anemia in chronic kidney disease is similar to the management strategy in other patients, however, ESA use is more likely due to erythropoietin deficiency in patients with chronic kidney disease. The hemoglobin target should be individualized for patients but generally likely be between 10 and 12 g hemoglobin using the lowest possible ESA dose to maintain this target.

Conclusion

In closing, AKF is committed to the goals of safe, appropriate, and high-quality care for ESRD patients. AKF recently submitted comments on the Quality Incentive Program proposed rule expressing our support for an anemia management measure as an indicator of quality dialysis care.

We encourage continuing efforts to ensure that physicians and other health care providers have the flexibility to adjust medications based on patient needs and that patients have access to the medications that provide the best health outcomes.

Thank you for the opportunity to express our comments on this issue.

CITATIONS

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