6-4-2020

Effect of epoetin alfa-epbx versus epoetin alfa on hemoglobin levels in myelodysplastic syndromes, chemotherapy induced anemia, and chronic kidney disease

Gabrielle DuBruille
Boca Raton Regional Hospital, GDubruille@brrh.com

Sigal Nadulek
Boca Raton Regional Hospital, SNadulek@baptisthealth.net

Anderson Mabour
Boca Raton Regional Hospital, AMabour@baptisthealth.net

Effect of epoetin alfa-epbx versus epoetin alfa on hemoglobin levels in myelodysplastic syndromes, chemotherapy induced anemia, and chronic kidney disease

Gabrielle DuBruille, PharmD
PGY1 Resident Pharmacist
Boca Raton Regional Hospital, Baptist Health South Florida
GDubruille@brrh.com

Disclosure Statement

The listed individuals have the following to disclose regarding financial or personal relationships with commercial entities (or their competitors) that may be referenced in this presentation:

- Gabrielle DuBruille, PharmD: Nothing to disclose
- Sigal Nadulek, BSPharm: Nothing to disclose
- Anderson Mabour, PharmD, BCPS: Nothing to disclose

Boca Raton Regional Hospital

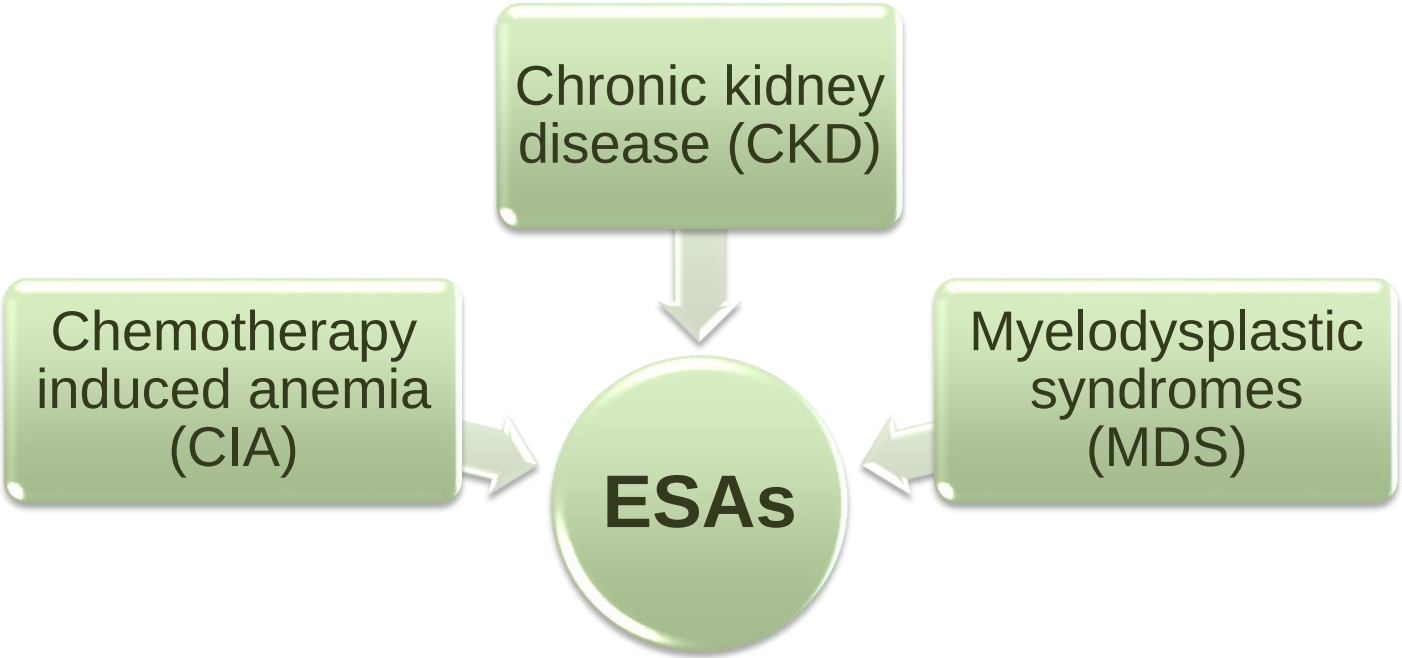
- Not-for-profit 400 bed advanced academic tertiary medical center
- **Recognized leader in:**
  - Cardiovascular Care
  - Oncology
  - Women's Health
  - Orthopedics
  - Emergency Medicine
  - Neurosciences

- Predominantly elderly patient population
- Highest ranked hospital in Palm Beach County
  - Listed by U.S. News & World Report 2019-2020
- **Lynn Cancer Institute** is one of the largest cancer programs in the state of Florida and accredited by the American College of Surgeons

Presentation Objective

- Identify the benefits of utilizing a biosimilar compared to a reference product in patients at the Lynn Cancer Institute

Erythropoietin-Stimulating Agents (ESAs)



Epoetin alfa [package insert]. Thousand Oaks, CA: Amgen; 2000.
Epoetin alfa-epbx [package insert]. Lake Forest, IL: Hospira; 2018.

Introduction

A biosimilar is a biological product that is:

- Highly similar to a reference product
- Contains no clinically meaningful differences in safety, purity, and potency compared to it’s reference product

The approval process does not require independent safety and efficacy analyses of the biosimilar

Declerck P, Danesi R, Petersel D, Jacobs I. The Language of Biosimilars: Clarification, Definitions, and Regulatory Aspects. *Drugs*. 2017;77(6):671–677.

Introduction

Epoetin alfa-epbx was FDA approved in May 2018

Therapeutic substitution between epoetin alfa and epoetin alfa-epbx has not been established

In the Lynn Cancer Institute, patients were transitioned from epoetin alfa to epoetin alfa-epbx due to a cost savings initiative

Epoetin alfa-epbx [package insert]. Lake Forest, IL: Hospira; 2018.

Previous Studies

EPOE 10-13 (SC), EPOE 10-01 (IV)

- **Objective**: Compare the safety and efficacy of epoetin alfa-epbx with epoetin alfa in patients with CKD on hemodialysis
- **Methods**: Phase 3, randomized, double-blind controlled trials
- **Patients**: N=932
- **1º outcome**: Difference between mean weekly hemoglobin levels and mean weekly dose
- **Results**: Epoetin alfa-epbx demonstrated no clinically meaningful differences in efficacy compared to epoetin alfa

Fishbane S, Singh B, Kumbhat S, Wisemandle WA, et al. Intravenous epoetin alfa-epbx versus epoetin alfa for treatment of end-stage kidney disease. *Am Soc Nephrol.* 2018;13:1204-1214.
Fishbane S, Spinwitz B, Wisemandle WA, et al. Randomized controlled trial of subcutaneous epoetin alfa-epbx versus epoetin alfa in end-stage kidney disease. *Kidney Int Reports.* 2019;4:1235-1247.

Purpose

To analyze the effectiveness of epoetin alfa-epbx in maintaining hemoglobin levels in conditions that typically require ESAs

Study Design

Methods: Observational, retrospective, crossover study conducted at the Lynn Cancer Institute from January 2019 through May 2019

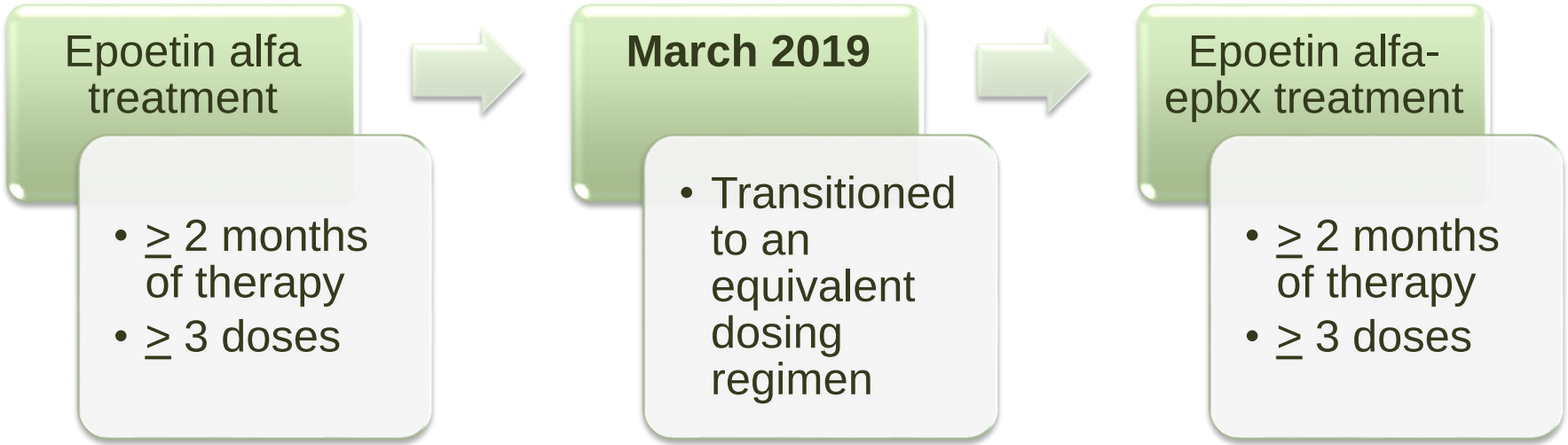
Inclusion Criteria

- Diagnosed with CIA, CKD, or MDS
- First dose and frequency of epoetin alfa-epbx matched epoetin alfa dose and frequency
- Received a minimum of 5 months of therapy

Exclusion Criteria

- Packed red blood cells or IV iron administration during the study period

Transitioning Period



Data Collection

Study Outcomes

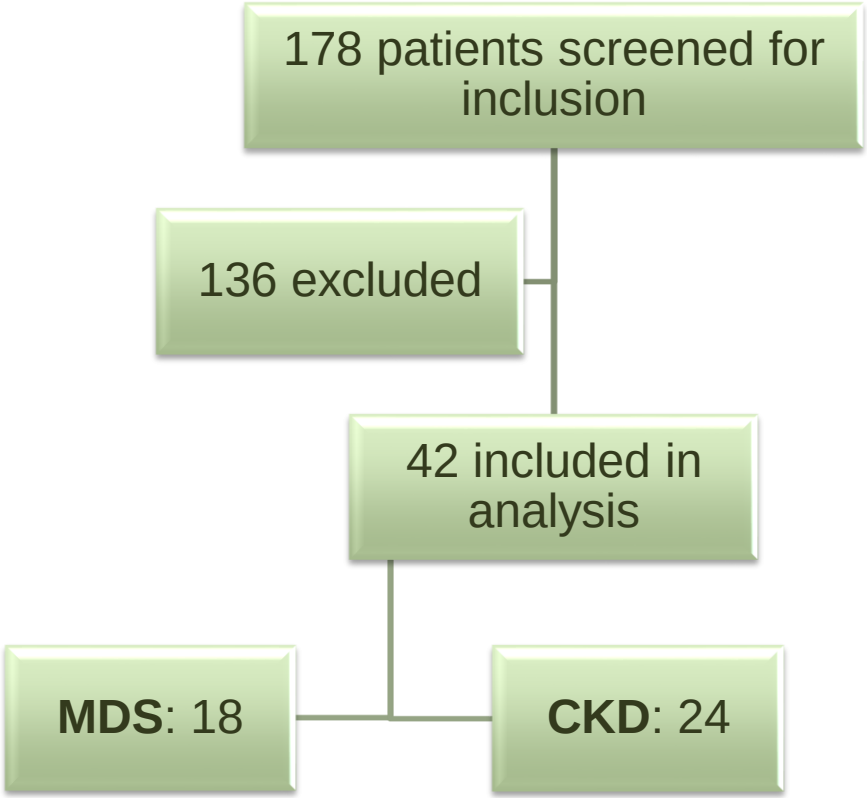
Primary Outcome

- The mean difference between hemoglobin levels collected during epoetin alfa treatment and epoetin alfa-epbx treatment

Secondary Outcome

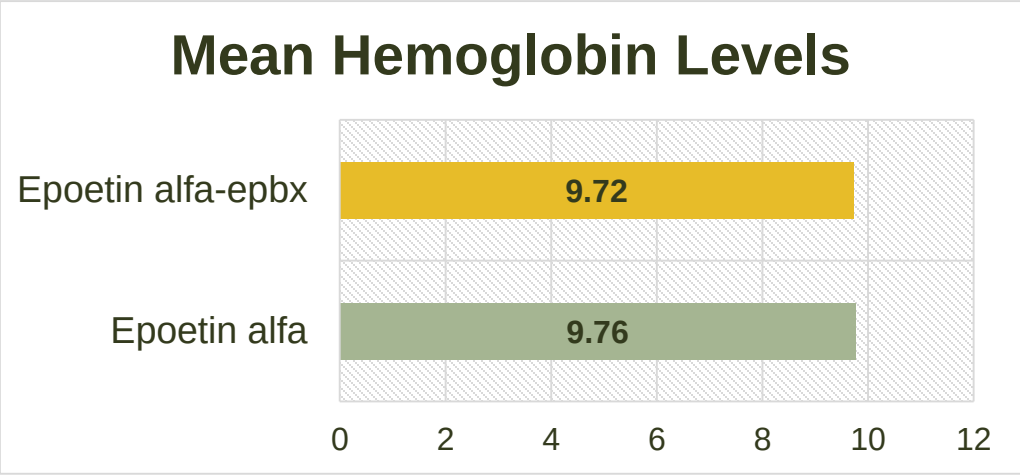
- The rate of hemoglobin levels not maintained after transitioning from epoetin alfa to epoetin alfa-epbx, defined by an absolute difference of 1 g/dL

Results


178 patients screened for inclusion
136 excluded
42 included in analysis
MDS: 18
CKD: 24

Results

Primary outcome: The mean difference between hemoglobin levels collected during epoetin alfa treatment and epoetin alfa-epbx treatment

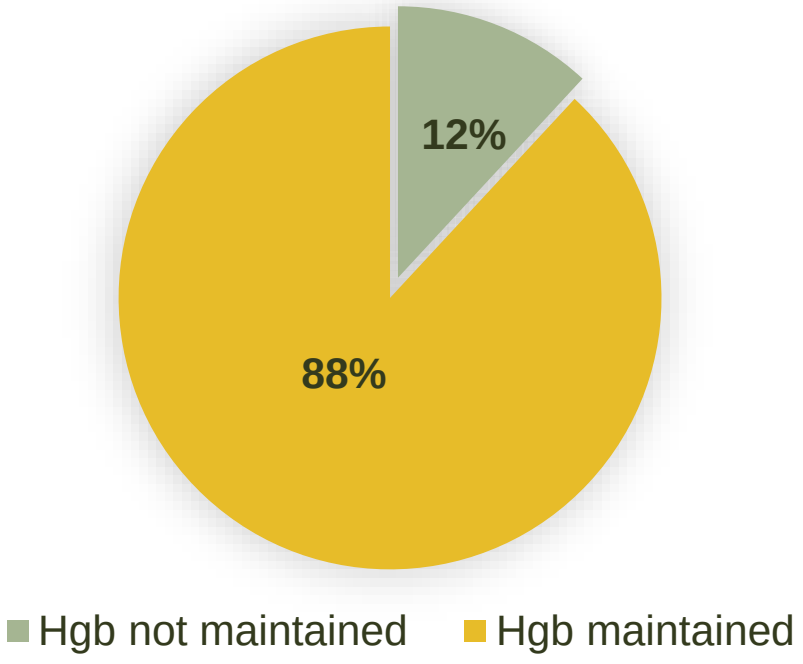


Mean difference: 0.04 g/dL

T-test p value: 0.5999

Results

Secondary outcome: The rate of hemoglobin levels not maintained after transitioning from epoetin alfa to epoetin alfa-epbx, defined by an absolute difference of 1 g/dL



Conclusion

There was no statistically significant difference between hemoglobin levels after transitioning to epoetin alfa-epbx

Hemoglobin levels were not maintained in 5 out of 42 (12%) patients after transitioning products

- 4 patients experienced a decrease in Hg levels
- 1 patient experienced an increase in Hg levels

Discussion

This trial demonstrates that transitioning to epoetin alfa-epbx is associated with similar hemoglobin levels in patients with CKD and MDS

- In 3 out of 5 patients where hemoglobin levels were not maintained, disease progression was noted

Epoetin alfa-epbx is an efficacious agent for patients diagnosed with CKD or MDS

Limitations

- The disease states assessed are progressive conditions that require dose alteration and produce inconsistent laboratory values
- The data collection time frame limited the size of the study population increasing the variability of the results
- Results cannot be generalized to all patients receiving ESAs due to the specific patient population studied

Limitations

The inclusion and exclusion criteria did not successfully capture patients diagnosed with CIA

- Results would be predicted to be similar for this patient population

The average rate of patients that do not normally maintain hemoglobin levels is unknown

Self Assessment

Which of the following is not a benefit of utilizing a biosimilar? Select all that apply.

- ❑ Results in cost savings for both the institution and patient
- ❑ Are interchangeable with their prior reference product due to similar efficacy and safety
- ❑ Retain the same approval indications as their prior reference product
- ❑ Expand treatment options

Self Assessment

Which of the following is not a benefit of utilizing a biosimilar? Select all that apply.

- ❑ Results in cost savings for both the institution and patient
- ☑ Are interchangeable with their prior reference product due to similar efficacy and safety
- ☑ Retain the same approval indications as their prior reference product
- ❑ Expand treatment options

Acknowledgement

- Sigal Nadulek, BSPharm
- Anderson Mabour, PharmD, BCPS

Effect of epoetin alfa-epbx versus epoetin alfa on hemoglobin levels in myelodysplastic syndromes, chemotherapy induced anemia, and chronic kidney disease

Gabrielle DuBruille, PharmD
PGY1 Resident Pharmacist
Boca Raton Regional Hospital, Baptist Health South Florida
GDubruille@brrh.com