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

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

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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
- **Lynn Cancer Institute** is one of the largest cancer programs in the state of Florida and accredited by the American College of Surgeons
• Identify the benefits of utilizing a biosimilar compared to a reference product in patients at the Lynn Cancer Institute
Erythropoietin-Stimulating Agents (ESAs)

Chemotherapy-induced anemia (CIA)

Chronic kidney disease (CKD)

Myelodysplastic syndromes (MDS)

ESAs

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 its reference product

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

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
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

Purpose

To analyze the effectiveness of epoetin alfa-epbx in maintaining hemoglobin levels in conditions that typically require ESAs
**Methods**: Observational, retrospective, crossover study conducted at the Lynn Cancer Institute from January 2019 through May 2019

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
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<tr>
<td>• Diagnosed with CIA, CKD, or MDS</td>
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<td>• First dose and frequency of epoetin alfa-epbx matched epoetin alfa dose and frequency</td>
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<tr>
<td>• Received a minimum of 5 months of therapy</td>
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<table>
<thead>
<tr>
<th>Exclusion Criteria</th>
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</thead>
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<tr>
<td>• Packed red blood cells or IV iron administration during the study period</td>
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</tbody>
</table>
Transitioning Period

Epoetin alfa treatment

- ≥ 2 months of therapy
- ≥ 3 doses

March 2019

- Transitioned to an equivalent dosing regimen

Epoetin alfa-epbx treatment

- ≥ 2 months of therapy
- ≥ 3 doses
Data Collection

ICD-10 code generated report

Retrospective chart review

Data recorded on Excel spreadsheet
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
178 patients screened for inclusion

136 excluded

42 included in analysis

MDS: 18

CKD: 24
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
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
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
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
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
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Acknowledgement

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