DRUG COST CONSIDERATIONS FOR ERYTHROPOIETIC STIMULATING AGENTS (ESAs) IN PATIENTS INITIATED AT FDA-APPROVED DOSING: RESULTS FROM PRACTICE PATTERNS IN A PROSPECTIVE OBSERVATIONAL STUDY

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Abstract

**Background:** Two ESAs have received FDA-approval for fixed initial dosing in cancer patients with chemotherapy-induced anemia: 40,000 Units for epoetin alfa (EPO) and 500 mcg for darbepoetin alfa (DARB). To understand cost considerations, data were analyzed from the Dosing and Outcomes Study of Erythropoiesis-Stimulating Therapies (D.O.S.E.) Registry, an ongoing, prospective registry collecting data on real-world practice patterns.

**Methods:** Data from 18 U.S. hospital and community-based outpatient practices from were assessed from 1/06–12/06. Chemotherapy-treated adult patients initiated on either EPO 40,000 Units or DARB 500 mcg were evaluated. Outcomes assessed included: administered dose, treatment duration, dosing patterns, and cumulative administered dose. EST cost was based on dose and 9/2006 wholesale acquisition cost (EPO $12.17/1000 Units; DARB $4.446/mcg) with sensitivity analysis based on 4Q06 Average Sales Price +6%.

**Results:** 168 patients (145 EPO, 23 DARB) were eligible for analysis. Patient groups were similar with regard to baseline age, gender, tumor type, and Karnofsky score. The predominant dosing pattern was QW for EPO and Q3W for DARB. The mean administered dose was EPO 42,879 Units and 497 mcg in DARB group, corresponding to an EST cost of $522 and $2,210 per injection. Treatment duration and number of office visits was similar between groups. Mean cumulative administered dose was 305,241 Units for EPO and 1665 mcg for DARB. The corresponding EST costs were $3,715 for EPO and $7,404 for DARB (p < 0.0001) with similar findings based on sensitivity analysis.

**Conclusion:** Practice pattern data from this observational study of cancer patients initiated at FDA-approved fixed dosing reported significantly lower costs in the EPO group compared to the DARB group. Mean cumulative drug cost was $3,689 less (50% less) in the EPO group compared to the DARB group. These findings provide further understanding of anemia management costs for health care professionals, hospital systems, and patients. Note: Data on poster presentation based on updated analyses.
Patients with cancer undergoing treatment often experience chemotherapy-induced anemia (CIA)\(^1\)

Epoetin alfa (EPO) and darbepoetin alfa (DARB) are two erythropoiesis-stimulating agents (ESAs) that have received FDA approval for the treatment of CIA in patients with non-myeloid malignancies\(^2,3\)

Fixed dosing is FDA-approved for both agents

- EPO: 40,000 Units weekly (QW)
- DARB: 500 mcg every three weeks (Q3W)

Outcomes data from practice settings investigating ESAs initiated at fixed doses have not been reported
Objectives

- The purpose of this analysis is to understand dosing patterns and economic outcomes in chemotherapy-treated oncology patients initiated at FDA-approved fixed ESA doses
Data Source

- Data come from the Dosing and Outcomes Study of Erythropoiesis-Stimulating Therapies (D.O.S.E.) Registry, which is an ongoing prospective, observational study that aims to understand dosing patterns, hematologic outcomes, costs and patient-reported outcomes of cancer patients treated in U.S. oncology clinics⁴
Methods

OVERALL STUDY
• Study Design
  – Prospective observational study
• Study Population
  – Inclusion Criteria
    • Adult oncology patients (age ≥ 18 years) receiving an ESA
    • EPO or DARB naïve (no prior ESA for at least 90 days prior to study entry)
  – Exclusion Criteria
    • Dialysis for end-stage renal disease
    • Myelodysplasia or any myelodysplastic syndrome
    • Planned stem cell transplant

CURRENT ANALYSIS
• Analysis Population
  – Additional Inclusion Criteria
    • Received chemotherapy
    • ESA initiated with EPO 40,000 Units or DARB 500 mcg
    • Received ≥ 2 doses of either EPO or DARB initiated between January 2006 and February 2007 and no more than 35 days apart
  – Additional Exclusion Criteria
    • Receipt of both EPO and DARB during the data collection period
Methods

DOSING ANALYSES
• EPO/DARB dosing patterns assessed included:
  • Mean administered dose
  • Mean cumulative administered dose
  • Mean treatment duration

CONSIDERATIONS FOR DOSING ANALYSES
• Dosing after a treatment gap of >35 days was excluded
• Mean cumulative administered dose was calculated as the sum of all ESA doses
Methods

DOSE RATIO
• Dose ratio (Units EPO: mcg DAR) was calculated based on the mean cumulative ESA dose (mean cumulative EPO dose/mean cumulative DAR dose)

COST ANALYSIS
• EPO/DAR drug costs were calculated based on the mean cumulative EPO or DAR dose and September 2006 and January 2007 wholesale acquisition cost (WAC) and 4Q06 and 2Q07 average sales price (ASP) + 6%

<table>
<thead>
<tr>
<th>Cost Consideration</th>
<th>Cost per 1000 Units EPO</th>
<th>Cost per 1 mcg DAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2006 WAC</td>
<td>$12.17</td>
<td>$4.446</td>
</tr>
<tr>
<td>January 2007 WAC</td>
<td>$12.52</td>
<td>$4.576</td>
</tr>
<tr>
<td>4Q06 ASP+6%</td>
<td>$9.362</td>
<td>$2.991</td>
</tr>
<tr>
<td>2Q07 ASP+6%</td>
<td>$9.452</td>
<td>$3.143</td>
</tr>
</tbody>
</table>

STATISTICAL ANALYSES
• Descriptive statistics (means, standard deviations, frequencies, and percentages) were used to summarize variables
• Statistical tests included $\chi^2$ and Kruskal-Wallis test for categorical and continuous variables, respectively
Results

• 201 patients from 21 sites were identified (169 EPO and 32 DARB)
• Baseline characteristics were similar between groups

Table 1: Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>EPO n=169</th>
<th>DARB n=32</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean (SD)</td>
<td>63 (12)</td>
<td>66 (12)</td>
<td>0.15</td>
</tr>
<tr>
<td>Women, n (%)</td>
<td>97 (57)</td>
<td>19 (59)</td>
<td>0.84</td>
</tr>
<tr>
<td>Weight, kg, mean (SD)</td>
<td>74.7 (17.1)</td>
<td>83.1 (26.0)</td>
<td>0.22</td>
</tr>
<tr>
<td>Hemoglobin, g/dL, mean (SD)</td>
<td>10.7 (0.8)</td>
<td>10.8 (0.7)</td>
<td>0.57</td>
</tr>
<tr>
<td>Tumor Type, n (%)*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>37 (22)</td>
<td>7 (23)</td>
<td>0.47</td>
</tr>
<tr>
<td>Lung</td>
<td>41 (25)</td>
<td>8 (26)</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>34 (20)</td>
<td>4 (13)</td>
<td></td>
</tr>
<tr>
<td>Hematologic</td>
<td>16 (10)</td>
<td>1 (3)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>39 (23)</td>
<td>11 (34)</td>
<td></td>
</tr>
<tr>
<td>Not Specified</td>
<td>2 (1)</td>
<td>1 (3)</td>
<td></td>
</tr>
</tbody>
</table>

* Percentages may not add to 100 due to rounding
Results

• Treatment duration was similar between groups.
• Mean number of office visits during ESA treatment was significantly greater for the DARB-treated group.
• Comparison of mean cumulative dose produced a dose ratio of 188:1 (Units EPO: mcg DARB)

Table 2. Patterns of anemia care

<table>
<thead>
<tr>
<th></th>
<th>EPO n=169</th>
<th>DARB n=32</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Duration, days, mean (SD)</td>
<td>58 (34)</td>
<td>55 (33)</td>
<td>0.63</td>
</tr>
<tr>
<td>Mean administered dose (SD)</td>
<td>42,844 (6465) Units</td>
<td>490 (29) mcg</td>
<td>NA</td>
</tr>
<tr>
<td>Cumulative dose, mean (SD)</td>
<td>310,533 (189,834) Units</td>
<td>1656 (756) mcg</td>
<td>NA</td>
</tr>
<tr>
<td>Number of office visits, mean (SD)</td>
<td>5.5 (5.5)</td>
<td>7.8 (6.3)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

NA – not applicable
Figure 1. Total ESA drug cost was lower in the EPO group by $3,584 and $3,690, based on September 2006 and January 2007 WAC, respectively.
Figure 2. Total ESA drug cost was lower in the EPO group by $2,046 and $2,270 based on 4Q06 and 2Q07 ASP+6%, respectively.
Conclusions

In chemotherapy-treated oncology patients initiated at FDA-approved fixed ESA doses (EPO 40,000 U, DARB 500 mcg), the following was observed:

- Baseline characteristics and mean treatment duration were similar
- Dose ratio was 188:1 (Units EPO: mcg DARB)
- EPO drug cost was 49% lower than DARB drug cost based on WAC pricing
  - Similar findings were observed in a sensitivity analysis using ASP + 6%
- Such findings are consistent with previous studies\(^8\text{-}^{10}\) and provide greater understanding of ESA treatment for health care professionals, hospital systems, and policy decision makers
References

4. Grad O et al. Poster presented at the Multinational Association of Supportive Care in Cancer Meeting June 24-27, 2004 Miami, FL
5. List price for Procrit and Aranesp from September 2006 Medi-Span Master Drug Data Base (MDDB)
6. List price for Procrit and Aranesp from January 2007 Medi-Span Master Drug Data Base (MDDB)
9. Harley C et al. Poster presented at the 41st American Society of Health-System Pharmacy (ASHP) Midyear Clinical Meeting and Exhibition December 3-7, 2006; Orange County, CA
10. Chen E et al. Poster presented at the American Society of Hematology (ASH) 48th Annual Meeting and Exposition; December 9-12, 2006; Orlando, FL.

Poster presentation at the 12th Annual International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 2007, May 19-23, Arlington VA

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