DaVita® Pilot Program Evaluation of Darbepoetin Alfa in Peritoneal Dialysis (PD) Patients

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INTRODUCTION

Home administration of erythropoiesis stimulating agents (ESAs) renders assessment of adherence difficult among PD patients. Some degree of nonadherence to ESA prescription occurs in 35-55% of PD patients. Nonadherence increases with increasing frequency of ESA administration, with unsupervised ESA self-administration, and with subcutaneous administration. 

Objective: To determine whether supervised twice-monthly in-center administration of darbepoetin alfa is effective in maintaining hemoglobin (Hb) within ±1 g/dL of the mean baseline value in PD patients previously receiving epoetin alfa.

METHODOLOGY

- 1-year pilot program with patients in 13 PD programs.
- Patients converted from epoetin alfa (administered subcutaneously, according to program practice) to darbepoetin alfa administered subcutaneously at twice-monthly intervals (Figure 1) under direct supervision by a PD nurse.
- Darbepoetin alfa doses were recorded and anemia and iron status was assessed monthly.

Figure 1. Pilot program design

RESULTS

Table 1. Summary of pilot program

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>Baseline</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>All patients</td>
<td>Pts w/ Hb within ±1 g/dL of mean baseline</td>
</tr>
<tr>
<td>Mean Hb (g/dL)</td>
<td>11.7</td>
<td>11.7</td>
</tr>
<tr>
<td>Lower quartile dose (per mo)</td>
<td>20,000 U</td>
<td>80 µg</td>
</tr>
<tr>
<td>Median quartile dose (per mo)</td>
<td>44,000 U</td>
<td>140 µg</td>
</tr>
<tr>
<td>Upper quartile dose (per mo)</td>
<td>100,000 U</td>
<td>300 µg</td>
</tr>
<tr>
<td>Mean dosing interval (wks)</td>
<td>1.84</td>
<td>2.93</td>
</tr>
<tr>
<td>Pts achieving therapeutic Hb</td>
<td>46%</td>
<td></td>
</tr>
</tbody>
</table>

Figure 2. Baseline epoetin alfa and 6 month darbepoetin alfa doses. Medians of each decile are shown. (A) n=128, (B) n=63.

Table 2. Percent of patients within Hb category

<table>
<thead>
<tr>
<th>Hemoglobin (g/dL)</th>
<th>&lt;10</th>
<th>10-11</th>
<th>11-12</th>
<th>&gt;12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (128)</td>
<td>5%</td>
<td>17%</td>
<td>39%</td>
<td>38%</td>
</tr>
<tr>
<td>6 months (63)</td>
<td>14%</td>
<td>10%</td>
<td>35%</td>
<td>41%</td>
</tr>
<tr>
<td>6 mo ±1 g/dL Hb</td>
<td>3%</td>
<td>14%</td>
<td>55%</td>
<td>28%</td>
</tr>
<tr>
<td>from baseline (29)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

LIMITATIONS

- Fairly small initial sample size
- 82% early termination rate due to death, patient transfer to hemodialysis, injection painful, bi-monthly dosing difficult to calibrate, and dose adjustment tools needed for physicians.
- 15% of patients were withdrawn from pilot at the request of their physicians.

CONCLUSIONS

- During the 4 weeks prior to ESA conversion, mean hemoglobin was 11.7 g/dL, median epoetin alfa dose was 44,000 units per month, and mean dosing interval was every 1.84 weeks.
- A preliminary analysis showed that at six months after initiating darbepoetin alfa, mean hemoglobin level was 11.8 g/dL and median dose was 140 µg per month; 46% of patients evidenced hemoglobin within ±1 g/dL difference from mean baseline hemoglobin.
- The median monthly darbepoetin alfa dose among patients with a hemoglobin within ±1 g/dL of mean baseline was 120 µg; mean darbepoetin alfa dosing interval was every 2.93 weeks.

KEY LEARNINGS

- Supervised darbepoetin alfa administration is effective in managing anemia in the majority of patients.
- Highly variable sensitivity to ESA makes a single Epoetin alfa:Darbepoetin alfa conversion ratio misleading.

REFERENCES

3. Lo WK. PDI 2008; 28 Suppl. 3: S76-80