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

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INTRODUCTION

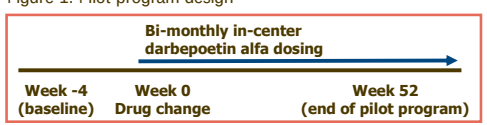
Home administration of erythropoiesis stimulating agents (ESAs) renders assessment of adherence difficult among PD patients. Some degree of nonadherence to ESA prescription occurs in 35-55% of PD patients.[1,2] Nonadherence increases with increasing frequency of ESA administration, with unsupervised ESA self administration, and with subcutaneous administration.[3]

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



References
1. Wazny et al AJKD 2002; 22:1462-4
2. Nicoletta et al. Adv Perit Dial 2000; 16:90-92
3. Lo WK. PDI 2008; 28 Suppl. 3: S76-80

RESULTS

Table 1. Summary of pilot program

	Baseline	6 months	
	All patients	All patients	Pts w/ Hb within ±1 g/dL of mean baseline
n	128	63	29
Mean Hb (g/dL)	11.7	11.8	11.7
Lower quartile dose (per mo)	20,000 U	80 µg	50 µg
Median quartile dose (per mo)	44,000 U	140 µg	120 µg
Upper quartile dose (per mo)	100,000 U	300 µg	250 µg
Mean dosing interval (wks)	1.84		2.93
Pts achieving therapeutic Hb			46%

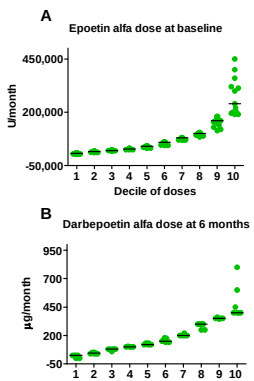


Figure 2. Baseline epoetin alfa and 6 month darbepoetin alfa doses. Medians of each decile are shown. (A) n=128, (B) n=63.

Table 2. Percent of patients within Hb category

	Hemoglobin (g/dl)				
Timepoint (n)	**<10**	**10-11**	**11-12**	**>12**	**10≥ Hb ≤12**
Baseline (128)	5%	17%	39%	38%	56%
6 months (63)	14%	10%	35%	41%	44%
6 mo ±1 g/dl Hb from baseline (29)	3%	14%	55%	28%	69%

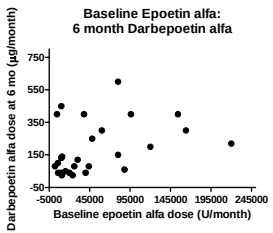


Figure 3. Scattergram of baseline epoetin alfa dose and darbepoetin alfa dose at 6 months for patients who maintained Hb within ± 1 g/dL of mean baseline does not reveal a correlation, n=29.

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.

We thank the patients who participated in this pilot program and DaVita Clinical Research® for support in preparing this poster. DCR is committed to advancing the knowledge and practice of kidney care.

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