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Efficacy and cost-effectiveness of darbepoetin alfa once every 4 weeks for the correction of anemia in patients with chronic kidney disease not on dialysis in Korea

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Objectives: No previous randomized controlled trial (RCT) have been reported examining once every 4 weeks (Q4W) administration of darbepoetin alfa in patients with chronic kidney disease. We report results from a RCT that compared darbepoetin alfa Q4W with continuous erythropoietin receptor activator (C.E.R.A.) Q4W for the correction of anemia and total cost of erythropoiesis-stimulating agents (ESAs) in patients with CKD not on dialysis nor receiving treatment with ESAs in Korea.

Methods: Forty-four patients were randomized (1:1) to receive either darbepoetin alfa Q4W or C.E.R.A. Q4W during a 12-week correction period and a 24-week evaluation period. Dosage was adjusted to maintain hemoglobin (Hb) between 10 and 11 g/dL. Two primary end points were assessed: changes in Hb concentration over time during evaluation period and total cost of erythropoiesis-stimulating agents by subject during study period.

Results: Patient baseline characteristics and risk factors were well balanced across both treatment groups. Changes in Hb concentration over time during evaluation period were not different between two groups ($p = 0.577$). Total cost of ESAs by subject during study period were lower in darbepoetin alfa group than C.E.R.A. group (₩ 257,108 ± 118,586 vs ₩ 728,383 ± 409,987, respectively, $p < 0.001$). The Hb response rate and mean Hb changes from baseline were not different between darbepoetin alfa and C.E.R.A group (100.0 vs 90.0%, $p = 0.487$ and 1.24 ± 0.82 vs 1.13 ± 1.09 g/dL, $p = 0.748$, respectively). Adverse event rates were comparable between the treatment groups.

Conclusions: Darbepoetin alfa Q4W was comparable in the correction of anemia and superior in terms of cost effectiveness compared with C.E.R.A. Q4W in Korea.

Baseline characteristic of the two groups

Table. Baseline characteristics of the two groups

Variable	Mircera (n = 22)	Nesp (n = 22)	p Value
Age (years)	68.3 ± 11.9	67.2 ± 12.7	0.779
Sex (male)	8 (36.4%)	8 (36.4%)	>0.999
Body mass index (kg/m^2)	23.7 ± 3.3	23.7 ± 5.4	0.984
Diabetes mellitus	12 (54.5%)	15 (68.2%)	0.353
Hypertension	21 (95.5%)	22 (100.0%)	>0.999
Stroke	6 (27.3%)	6 (27.3%)	>0.999
Smoking	3 (13.6%)	6 (27.3%)	0.457
Systolic blood pressure (mmHg)	131.0 ± 23.9	136.6 ± 14.9	0.361
Diastolic blood pressure (mmHg)	65.6 ± 15.3	69.8 ± 13.6	0.343
Baseline eGFR (mL/min/1.73 m^2)	18.1 ± 7.0	22.0 ± 9.0	0.113
Hemoglobin (g/dL)	9.3 ± 0.4	9.2 ± 0.6	0.515
Transferrin saturation (%)	32.9 ± 13.0	33.3 ± 15.7	0.930
Ferritin (ng/mL)	479.8 ± 576.0	266.0 ± 166.9	0.115

Data are expressed as the mean ± standard deviation for continuous variables and n (%) for categorical variables. eGFR, estimated glomerular filtration rate.

Comparison of Micera and Nesp