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Health-Related Quality of Life (HRQL) Following Transplantation with Omidubicel Versus Umbilical Cord Blood (UCB) in Patients with Hematologic Malignancies: Results from a Phase III Randomized, Multicenter Study

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Introduction: Omidubicel, an advanced cell therapy used for allogeneic hematopoietic stem cell transplant has demonstrated faster hematopoietic recovery, shorter hospitalization, and lower rates of bacterial, viral, and invasive fungal infections compared with umbilical cord blood (UCB) in a phase III randomized trial (NCT02730299; *Blood* 2021;138:1429).

Objective: The objective was to compare changes in health-related quality of life (HRQL) between treatment groups in the phase III trial.

Methods: Patients who received protocol-defined treatment and provided HRQL evaluations at baseline and ≥ 1 follow-up visit were analyzed. Outcomes included Functional Assessment of Cancer Therapy General (FACT-G) domain scores for physical, social/family, functional and emotional well-being, and EQ-5D-3L index scores, at days 42, 100, 180, and 365 post-transplant. HRQL changes from baseline were compared using mixed effect models with repeated measures, adjusting for age, sex, race, region, primary diagnosis, HCT comorbidity index, and baseline HRQL score. Average HRQL over time was compared using the area under the curve (AUC) of mean HRQL trajectories in each treatment group.

Results: Seventy-five patients (omidubicel $n = 37$, UCB $n = 38$) provided HRQL data for inclusion and were representative of the full randomized population ($N = 125$) at baseline. Median age was 38 years, and 41% were female. During the first year post-transplant, patients receiving omidubicel had numerically superior average FACT-G domain and EQ-5D-3L index scores compared with UCB, with mean differences across time points ranging from 1.4 to 3.1 for physical well-being, 0 to 1.3 for social/family well-being, 0.5 to 1.4 for emotional well-being, 1.6 to 3.2 for functional well-being, and 0.03 to 0.09 for the EQ-5D-3L index score. Minimal clinically important differences (MCIDs) were exceeded at ≥ 1 time point for mean physical and functional well-being (MCIDs = 2 units) and for the EQ-5D-3L (MCID = 0.07 units). Initial mean declines in HRQL occurred for all measures at day 42 and were consistently numerically smaller in the omidubicel group than in the UCB group. Averaging across the first year post-transplant, patients receiving omidubicel had significantly improved HRQL for physical and functional well-being domains ($P < .05$ for comparison of AUCs).

Discussion: Along with faster time to engraftment, lower infection risk, and shorter hospitalization, omidubicel was associated with meaningfully greater preservation or improvement of important HRQL domains compared with UCB.