Effect of a single autologous cord blood infusion on beta-cell and immune function in children with new onset type 1 diabetes: a non-randomized, controlled trial.

The application of autologous cord blood in children with type 1 diabetes has been found to be safe, but not to preserve beta-cell function in a previous study, which, however, had not included a control group. To compare the changes of metabolic and immune function over time between cord blood infused children and natural controls. Seven children with newly diagnosed type 1 diabetes underwent a single autologous cord blood infusion and 10 children were enrolled as natural controls in a non-randomized, controlled, open label intervention trial. Primary analyses were performed 1 year following cord blood infusion. Cases and controls were compared regarding metabolic [area under the curve (AUC) and peak C-peptide, insulin use, and HbA1c] and immune outcome (islet autoantibody titer and T-cell response), adjusted for age, gender, diabetes duration, and baseline levels. There were no significant adverse events related to the infusion. Metabolic and immune outcomes were not significantly different at 12 months follow-up between infused children and controls (e.g., adjusted \( p = 0.244 \) for AUC C-peptide, adjusted \( p = 0.820 \) for insulin use, adjusted \( p = 0.772 \) for peripheral regulatory T cells). Six-month change of AUC C-peptide
correlated significantly with the number of infused CD34+ cells ($r = 0.931, p = 0.002$). An autologous cord blood infusion does not change the natural course of metabolic and immune parameters after disease onset. However, the content of CD34+ cells in the stored blood sample might offer potential for improvement of future cell therapies.