

## Combined Treatment of Intrapancreatic Autologous Bone Marrow Stem Cells and Hyperbaric Oxygen in Type 2 Diabetes Mellitus

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The objective of this study was to determine whether the combination therapy of intrapancreatic autologous stem cell infusion (ASC) and hyperbaric oxygen treatment (HBO) before and after ASC can improve islet function and metabolic control in patients with type 2 diabetes mellitus (T2DM). This prospective phase 1 study enrolled 25 patients with T2DM who received a combination therapy of intrapancreatic ASC and peri-infusion HBO between March 2004 and October 2006 at Stem Cells Argentina Medical Center Buenos Aires, Argentina. Clinical variables (body mass index, oral hypoglycemic drugs, insulin requirement) and metabolic variables (fasting plasma glucose, C-peptide, HbA1c, and calculation of C-peptide/glucose ratio) were assessed over quartile periods starting at baseline and up to 1 year follow-up after intervention. Means were calculated in each quartile period and compared to baseline. Seventeen male and eight female patients were enrolled. Baseline variables expressed as means  $\pm$  SEs were: age  $55 \pm 2.14$  years, diabetes duration  $13.2 \pm 1.62$  years, insulin dose  $34.8 \pm 2.96$  U/day, and BMI  $27.11 \pm 0.51$ . All metabolic variables showed significant improvement when comparing baseline to 12 months follow-up, respectively: fasting glucose  $205.6 \pm 5.9$  versus  $105.2 \pm 14.2$  mg/dl, HbA1c  $8.8 \pm 0.2$  versus  $6.0 \pm 0.4\%$ , fasting C-peptide  $1.5 \pm 0.2$  versus  $3.3 \pm 0.3$  ng/ml, C-peptide/glucose ratio  $0.7 \pm 0.2$  versus  $3.5 \pm 0.3$ , and insulin requirements  $34.8 \pm 2.9$  versus  $2.5 \pm 6.7$  U/day. BMI remained constant over the 1-year follow-up. Combined therapy of intrapancreatic ASC infusion and HBO can improve metabolic control and reduce insulin requirements in patients with T2DM. Further randomized controlled clinical trials will be required to confirm these findings.

**Key words:** Stem cell; Hyperbaric oxygen; Type 2 diabetes; Autologous transplant

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