EMBRYONIC STEM CELL TRANSPLANTATION IN DIABETES MELLITUS

Developed was method of Embryonic Stem Cell Transplantation (without pancreas β-cells) for treatment of diabetes mellitus (DM) that proved to be effective in DM types I and II and is protected by a number of patents and is pending patent in the U.S.

**Embryonic Stem Cell Transplantation (TESC) is indicated at all stages of diabetes, being the most effective in the following cases:**
- new-onset insulin-dependent DM (IDDM);
- DM complicated by diabetic nephropathy, chronic renal insufficiency (stages I and II), and anemia;
- brittle DM;
- DM complicated by infections and impaired immunity;
- non-healing trophic ulcers of soft tissues;
- secondary sulfamamide resistance and necessity of insulin-therapy for type II DM patients.

**Major Effects of Embryonic Stem Cell Transplantation**

- **Decrease of glycemia in new-onset IDDM**
  - In all cases, noted was gradual decrease of insulin dosages (ID) in 2-3 months after TESC. The average initial ID was 0.76±0.96 U/kg/day. Maximum decrease amounted to 90-100% of the initial dosage (mean 41%), the term ranging from 1 to 90 days (mean 59.0±3.3). In 65% of cases, achieved was clinical remission (daily ID < 0.4 U/kg/day or discontinuation) lasting 5-14 months.

- **Increase of endogenous insulin production**
  - 50-200% increase of serum C-peptide within one year after TESC.

- **Early Post-Transplantation Improvements of General State**
  - Syndrome of Early Post-Transplantation Improvements - decreased weakness, improved workability, appetite, and sleep - was reported in 63% of cases on the first day after TESC. It was very vivid for a period of 1 month, after which its slightly reduced manifestations were maintained for 2-4 months.

- **Improvement of Psycho-Physiological State**
  - Syndrome of Psycho-Physiological Changes - improvement of physical and mental activity, decreased manifestations of depression - was observed in 48% of cases and lasted for 6-8 months.

- **Restoration of Hematopoiesis**
  - Restoration of hematopoiesis in diabetic nephropathy complicated by chronic renal insufficiency (stages I-II), and anemia. Reliable increase of erythrocyte count and hemoglobin in 1-1.5 months after TESC. The above effects were maintained for 2-11 months.

- **Restoration of Immunity**
  - Increased counts of lymphocytes, T-lymphocytes, and sub-populations of T-lymphocytes and decreased (by mean 30-60%) B-lymphocyte count were maintained for 3-8 months.

- **Dystrophic Disorders and Lesions**
  - Disappearance of trophic ulcers, decreased manifestations of skin lipidosis, diabetic foot, infectious and mycotic dermatopathies, cutaneous lichenification, and lipoprotein lesions.

Strong effects were achieved in new-onset diabetes mellitus where Embryonic Stem Cell Transplantation proves to stop autoimmune aggression against pancreatic β-cells.

Embryonic Stem Cell Transplantation is effective in diabetes mellitus, and, as we believe, will soon become as important as insulin-therapy.