

EFFICACY AND SAFETY OF THE MESENCHYMAL STEM CELLS APPLICATION FOR INDUCTION OF IMMUNOSUPPRESSION IN KIDNEY TRANSPLANT PATIENTS: RESULTS OF PILOT STUDY.

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The aim of the study was to evaluate the efficacy and safety of the mesenchymal stem cells (MSC) application for induction of immunosuppressive therapy (IIT) in patients after kidney transplantation (KT) in the early postoperative period.

Methods. This is a report of pilot, prospective, single center, open label, randomized study of the superiority MSC induction of immunosuppression over standard IIT in regard of immunological dysfunction development and kidney transplant function improvement. Inclusion criteria: adult kidney transplant recipients who received first kidney transplant. Exclusion criteria were high immunological risks at the time of surgery (HLA mismatching, PRA>0%). In the first group MSCs introduction was performed on 0 and 4 days after surgery in total dose of 4 million cells / kg in 2 infusions (2 million cells / kg at a time). In the second group patients received basiliximab 20 mg on 0 and 4 days after transplantation. Third group hadn't any induction therapy. Maintenance therapy includes calcineurine inhibitor, mycophenolic acid, steroids and don't difference among groups. The protocol kidney transplant biopsies were performed on the 7th day.

Results of our research showed that the frequency of graft dysfunction which were associated with rejection, was approximately identical among groups – 40%. At the same time, level of serum creatinin decreased more intensively in 2nd group (basiliximab) and was assessed as $265 \pm 125 \mu\text{mol/l}$ at the 7 day after operation. In the 1st (MSC) and 3rd groups it was respectively $313 \pm 201 \mu\text{mol/l}$ and $548 \pm 317 \mu\text{mol/l}$ ($p > 0,05$). Dynamics of GRF level restoration didn't differ in groups and reached $31,72 \pm 10,34 \text{ ml/min}$, $34,7 \pm 12,4 \text{ ml/min}$, $35,7 \pm 11,97 \text{ ml/min}$ respectively on 7 day after transplantation. We didn't observed any significant difference in frequency and strength of side effects in study groups.

Conclusion. Application of allogeneic MSC as induction immunosuppressive therapy in kidney transplantation is effective and safely.