

Comparison of two different methods of stem cell therapy with conservative treatment in diabetic patients with critical limb ischemia

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Background and Aims: Patients with no-option critical limb ischemia (CLI) are in high risk of major amputation, autologous stem cell therapy is a new promising alternative for those patients. There is lack of studies comparing long-term results of different methods of stem cell therapy with conservative treatment. The aim of our study was to compare the therapeutic effect of two different stem cell therapy techniques - bone marrow mononuclear cells (BMMNC) and peripheral blood progenitor cells (PBPC) with conservative treatment in diabetic patients with no-option CLI. **Methods:** Twenty-eight diabetic patients with CLI treated by stem cells (active groups - 17 treated by BMMNC and 11 by PBPC) and 22 patients treated conservatively (control group) in our foot clinic were included into the study over 5 years. Patients were assessed per protocol, 27 patients finished follow-up in active group and 20 patients in control group (3 patients died during follow-up). Patients in active groups did not significantly differ from control group in severity of limb ischemia and in other demographic characteristics (cell therapy in control group was not possible to perform due to temporary transient changes of medicines agencies recommendations during inclusion period). Rate of major amputation and changes of transcutaneous oxygen pressure (TcPO₂) were compared between BMMNC, PBPC and control groups. Both cell therapy methods were also compared by the analyses of cell suspensions by number of injected mononuclear and precursor (CD34+) cells. **Results:** The rate of major amputation till 6 months follow-up was significantly lower in whole active cell therapy group compared to control group - 3/27 (11.1%) vs. 10/20 (50%), p=0.0032), there was no difference between BMMNC and PBPC groups. TcPO₂ increased significantly (p<0.05) compared to baseline in both active cell therapy groups after 6 months, with no significant differences between BMMNC and PBPC groups; however no significant change of TcPO₂ in control group was observed (from 14.6 ± 9.6 to 17.7 ± 8.1 mm Hg). Number of injected CD34+ cells did not significantly differ between BMMNC and PBPC methods. **Conclusion:** Our study showed superior benefit of both cell therapy methods (BMMNC or PBPC) in diabetic patients with no-option CLI when compared to conservative treatment. No significant difference between both cell therapy methods in clinical effect and number of injected precursor cells was observed.

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