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Efficacy and Safety of Autologous Cell-based Therapy in Patients with No-option Critical Limb Ischaemia: A Meta-Analysis

(E-pub Ahead of Print)

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Abstract:

Background: Revascularisation therapy is the current gold standard of care for critical limb ischemia (CLI), although a significant proportion of patients with CLI either are not fit for or do not respond well to this procedure. Recently, novel angiogenic therapies such as the use of autologous cellbased therapy (CBT) have been examined, but the results of individual trials were inconsistent.

Objective: To pool all published studies that compared the safety and efficacy of autologous CBT derived from different sources and phenotypes with non cell-based therapy (NCT) in CLI patients.

Methods: We searched Medline, Embase, Cochrane Library and ClinicalTrials.gov from 1974-2017. Sixteen randomised clinical trials (RCTs) involving 775 patients receiving the following interventions: mobilised peripheral blood stem cells(m-PBSC), bone marrow mononuclear cells(BM-MNC), bone marrow mesenchymal stem cells(BM-MSC), cultured BM-MNC(Ixmyelocel-T), cultured PB cells(VesCell) and CD34+ cells were included in the meta-analysis.

Results: High-quality evidence (QoE) showed similar all-cause mortality rates between CBT and NCT. AR reduction by approximately 60% were observed in patients receiving CBT compared to NCT (moderate QoE). CBT patients experienced improvement in ulcer healing, ABI, TcO₂, pain free walking capacity and collateral vessel formation (moderate QoE). Low-to-moderate QoE showed that compared to NCT, intramuscular BM-MNC and m-PBSC may reduce amputation rate, rest pain, and improve ulcer healing and ankle-brachial pressure index, while intramuscular BM-MSc appeared to improve rest pain, ulcer healing and pain-free walking distance but not AR. Efficacy of other types of CBT could not be confirmed due to limited data. Cell harvesting and implantation appeared safe and well-tolerated with similar rates of adverse-events between groups.

Conclusion: Implantation of autologous CBT may be an effective therapeutic strategy for no-option CLI patients. BM-MNC and m-PSBC appear more effective than NCT in improving AR and other limb perfusion parameters. BM-MSc may be beneficial in improving perfusion parameters but not AR, however, this observation needs to be confirmed in a larger population of patients. Generally, treatment using various sources and phenotypes of cell products appeared safe and well tolerated. Large-size RCTs with long follow-up are warranted to determine the superiority and durability of angiogenic potential of a particular CBT and the optimal treatment regimen for CLI.

Keywords: critical limb ischaemia, autologous cell-based therapy, peripheral blood stem cells, bone marrow mononuclear cells, mesenchymal stem cells meta-analysis

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