Clinical Trial of Osteochondral Lesion of Talus Treated with Human Mesenchymal Stem Cell

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**Introduction/Purpose:** The aim of surgery for osteochondral lesion of talus is to restore the damaged articular surface with a nearly normal cartilage and supporting subchondral bone. The operative treatment paradigms are still controversial. Though arthroscopic bone-marrow stimulation, autologous osteochondral transplantation and chondrocyte implantation have been performed, but the limitations of these techniques necessitate innovative methods such as cell-based treatment. We investigated the safety and efficacy of human umbilical cord-blood derived mesenchymal stem cell product (CartistemTM) in the treatment of symptomatic osteochondral lesion of the talus.

**Methods:** Between Feb 2014 and March 2015, 25 symptomatic OLT patients were enrolled and randomized into 2 groups with informed consents. They have all suffered from ankle pain more than 6 months despite of conservative treatment. The control group(12 patients) underwent the standard arthroscopic curettage and microfracture, and the study group(13 patients) had additional application of Cartistem on the defect after the same procedure. We measured and analyzed AOFAS ankle-hindfoot scale and MRI features of T2mapping, dGEMRIC, and MOCART scale as well as arthroscopic gross finding with ICRS(international cartilage repair society) scale at 48th week after the index surgery. Also any adverse reactions or complications were recorded. We acquired IRB approval and registered this study at clinicalTrial.gov as NCT02338375.
Results: There was no adverse effect or complication related to procedures and test drug. Clinically AOFAS ankle-hindfoot score was improved significantly after surgery in both groups, but there was no difference between them. Radiologically both groups showed significant improvement of MRI features without any differences. However on second look arthroscopic exam there was a tendency of better regenerative pattern(ICRS gross finding) in study group.

Conclusion: There was no adverse reaction and additional benefit of human mesenchymal stem cell product in treatment of symptomatic OLT. However in terms of arthroscopic findings, it might help better histologic regeneration. Further investigation with longer term follow-up can guarantee its usefulness in treatment of OLT.