Safety of autologous bone marrow aspiration concentrate transplantation: initial experiences in 101 patients. Hendrich C1, Franz E, Waertel G, Krebs R, Jäger M. *Orthop Rev (Pavia). 2009 Oct 10;1(2):e32*

Abstract

The clinical application of cellular based therapies with ex vivo cultivation for the treatment of diseases of the musculoskeletal system has until now been limited. In particular, the advanced laboratory and technical effort necessary, regulatory issues as well as high costs are major obstacles. On the other hand, newly developed cell therapy systems permit intra-operative enrichment and application of mesenchymal and progenitor stem cells from bone marrow aspirate concentrate (BMAC) in one single operative session. The objective of the present clinical surveillance study was to evaluate new bone formation after the application of BMAC as well as to record any possible therapy-specific complicationsFor this purpose, the clinical-radiological progress of a total of 101 patients with various bone healing disturbances was documented (surveillance study). The study included 37 necrosis of the head of the femur, 32 avascular necroses/bone marrow edema of other localization, 12 non-unions, 20 other defects. The application of BMAC was performed in the presence of osteonecrosis via a local injection as part of a core decompression (n=72) or by the local adsorption of intra-operative cellular bone substitution material (scaffold) incubated with BMAC during osteosynthesis (n=17) or in further surgery (n=12).After an average of 14 months (2-24 months), the patients were re-examined clinically and radiologically and interviewed. Further surgery was necessary in 2 patients within the follow-up period. These were due to a progression of a collapsed head of the femur with initial necrosis in ARCO Stage III, as well as inadequate new bone formation with secondary loss of correction after periprosthetic femoral fracture. The latter healed after repeated osteosynthesis plus BMAC application without any consequences. Other than these 2 patients, no further complications were observed. In particular, no infections, no excessive new bone formation, no induction of tumor formation, as well as no morbidity due to the bone marrow aspiration from the iliac crest were seen.There were no specific complications within the short follow-up period and a simple intra-operative use of the system for different forms of bone loss could be demonstrated. In the authors' opinion, the on-site preparation of the bone marrow cells within the operating theater eliminates the specific risk of ex vivo cell proliferation and has a safety advantage in the use of autologous cell therapy for bone regeneration. Additional studies should be completed to determine efficacy.