AB1012  

**CLINICAL TRIAL OF INTRAVENOUS INFUSION OF FUCOSYLATED BONE MARROW MESENCHYMAL STEM CELLS IN PATIENTS WITH OSTEOPOROSIS**

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**Background:** Osteoporosis (OP) is a systemic bone disease characterised by decreased bone mass and deterioration of bone microarchitecture with increased brittleness and fragility, which lead to risk of fractures and associated higher morbidity and mortality for patients, and has a high impact on health expenditure. Bone marrow stromal mesenchymal stem cells (BM-MSC) give rise to osteoprogenitor cells and osteoblasts and influence bone homeostasis. However after their intravenous (i/v) infusion their osteotropism is limited. Our group has demonstrated that the exofucosylation of the CD44 membrane antigen in MSC improves their homing to bone tissue and that its tropism is limited. Our group has demonstrated that the exofucosylation of the CD44 membrane antigen in MSC improves their homing to bone tissue and that this process is mediated by increased cell proliferation and appearance of a complex form in karyotype during the cell division. We hypothesised that fucosylated BM-MSC infusions would improve bone quality in osteoporotic patients. We aimed to evaluate the safety of i/v infusion of fucosylated BM-MSC in OP patients, and to secondarily assess their ability to improve the course of the disease.

**Methods:** 10 women between 50 and 75 years old diagnosed with osteoporosis and having a normal bone mineral density were included. They were treated with a dose of 2 × 106 cells/kg in 4 doses at 4-week intervals. The first 4 patients were treated with a dose of 2 x 10^6 cells/kg body weight and the other 6 with 5 x 10^6 cells/kg body weight. A 24 month follow-up will be conducted to evaluate the rate of severe and non-serious adverse events and secondary endpoints (decreased fracture rate, pain scores, functional status and quality of life, biochemical indexes of bone metabolism, quantitative computed tomography for morphometric and mechanical analysis of bone quality, densitometry, and histomorphometry).

**Results:** Seven patients have been recruited to date. Two left the study for lack of cell proliferation and appearance of a complex form in karyotype during the cell cycle, respectively. The first 4 patients were successfully infused, and after a median follow-up of 3 months no related adverse effects have been observed, no new osteoporotic fractures have appeared, and the analogue pain scale score (EVA) shows a tendency to decrease of pain in 3 of the 4 patients.

**Conclusions:** Our preliminary data indicate that clinical and GMP-grade production of BM-MSC is feasible. We have not observed any short-term adverse effects associated with treatment in infused patients.

**Disclosure of Interest:** None declared

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AB1013  

**PREDICTION OF BONE MINERAL DENSITY CHANGES IN PATIENTS WITH RHEUMATOID ARTHRITIS**

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**Background:** Osteoporosis and its related fractures is one of the most dominant, troublesome complications in rheumatoid arthritis (RA). Newly-introduced drugs such as methotrexate and biological and targeted synthetic disease modifying anti-arthritic drugs have decreased disease activity drastically, but the improvement of osteoporosis remains to be investigated.

**Objectives:** To find useful factors for bone mineral density (BMD) management of RA patients under the current treatment.

**Methods:** We consecutively recruited 370 RA patients treated at Kyoto University Hospital in 2012. We prospecively collected the BMD values of the lumbar spine and the distal forearm measured by dual-energy X-ray absorptiometry (DXA) blood sampling test, urinalysis including bone metabolic biomarkers and clinical parameters of the RA patients in 2012 and 2014. Multivariate regression analysis was performed after adjustment by age, sex, body mass index (BMI), steroid use, anti-osteooporosis medication. We set the annualised BMD change as an outcome variable and allotted the other parameters as explanatory variables by a stepwise procedure.

**Results:** The average values (minimum-maximum value) of age and BMI were 63.3 (32.8–85) and 22.1 (12.3–30.0), respectively. Female patients and steroid users accounted for 91.1%, and 41.0%, respectively. Coincidentally, anti-osteooporosis drug-user also reached 41.0%. User of biological accounted for 30.8% of RA patients. Under the current treatment. The averages of disease activity score (DAS) 28-erythrocyte sedimentation rate, Health Assessment Questionnaire was 2.6 (0.1–5.9) and 0.8 (–2.9), respectively. The average of total Sharp score was 122.6 ± 443. Laboratory data showed serum trarate-resistant acid phosphatase (TRACP)–5b, serum homocysteine, serum undercarboxylated osteocalcin, bone specific alkaline phosphatase, and urinary pentosidine were 320.0 (68–877) mU/dl, 9.7 (3.2– 25.8) ng/mg creatinine, 4.8 (0–23) ng/mg creatinine, and 0.8 (0.001–3.9) mmol/mmol creatinine, respectively. Next, we describe by the result of multiple regression analysis.

The levels of serum homocysteine (β = 0.19; 95%CI: 0.24 to 1.75; p < 0.001) and anti-osteooporosis drug (β = –0.19; 95%CI: 0.26 to –0.04; p = 0.009) were consistently significant predictive variables of annualised BMD change of the lumbar-spine. On the other hand, serum TRACP-5b (β = –0.28; 95%CI: –0.05 to –0.001; p = 0.002) was significant predictive one for the distal forearm.

**Conclusions:** Anti-osteooporosis medication may be particularly important for lumbar spine BMD for RA patients, regardless of steroid-use. Specific biomarkers would be useful such as homocysteine as lumbar spine BMD and TRACP-5b as.
background, the forearm BMD. These findings would be helpful for osteoporosis management in RA patients.

REFERENCES:


Disclosure of Interest: None declared


AB1014

EPIDEMIOLOGICAL FEATURES OF PERIPHERAL OSTEOINTEGRATED IMPLANTS FOR LOWER LIMB

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Objective: To document the outcomes of osseointegrated per-1ipheral implants in lower limb amputees and to address stress distribution issues associated with socket prostheses and to encourage bone growth and restore BMD levels for amputees within a short period of time post-surgery.

Conclusions: These results suggest that osseointegrated implants are effective at encouraging bone growth and restoring BMD levels for amputees within a short period of time post-surgery.

Disclosure of Interest: None declared


AB1016

OSSEOINTEGRATED IMPLANTS FOR LOWER LIMB AMPUTEES: EVALUATION OF BONE MINERAL DENSITY

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Background: The use of dual-energy X-ray absorptiometry (DXA) is a standard clinical procedure for the evaluation of bone mineral density (BMD). Amputee patients are known to have decreased BMD and an increased risk of osteoporosis in the affected proximal femur and hip region. The major cause of these issues in these patients is the absence of adequate loading leading to bone resorption in accordance with Wolff’s law.

Objectives: In this paper, we present a prospective study reporting changes in BMD among amputees who received osseointegrated implants to determine if the loading through the Osseointegrated implant can overcome the bone resorption issues.

Methods: This is a prospective study of 33 patients, consisting of 24 males and 9 females, aged 22–77 (mean=51.0 ± 20) years with one and two-year follow-up.

Results: Mean BMD and Z-scores of spine, and operative and contralateral sides were generated. DXA was used in the amputated limb. BMD was assessed using DXA in the femoral neck (operative and contralateral) and lumbar spine (L2-L4) regions, and corresponding Z-scores were generated. DXA scans were taken preoperatively as well as one-year and two-years following osseointegration surgery.

Conclusions: These results suggest that osseointegrated implants are effective at encouraging bone growth and restoring BMD levels for amputees within a short period of time post-surgery.

Disclosure of Interest: None declared