Paper - Annual Meeting

Paper Session: Program Highlights

Vitamin D3 Supplementation Does Not Improve Fracture Healing: A Double-Blinded Randomized Controlled Trial

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Purpose: Nearly half of adult fracture patients are vitamin D deficient (serum 25(OH)D levels <20 ng/mL). In response, many surgeons advocate prescribing vitamin D supplements to improve fracture healing outcomes. To date, there are no definitive trials that have demonstrated the effectiveness of vitamin D supplements to improve fracture healing. The purpose of this randomized controlled trial was to test the preliminary effectiveness of 3 potential vitamin D3 supplementation strategies for improving tibia and femur fracture outcomes. We hypothesized that larger doses of vitamin D3 supplements would improve early fracture healing.

Methods: A phase II screening randomized controlled trial was performed to select the vitamin D3 supplementation dose most likely to improve fracture healing, and ultimately be used in a future 2-arm definitive clinical trial. Adult patients aged 18-55 years receiving an intramedullary nail for a tibia or femoral shaft fracture were randomized to 4 treatment groups. Treatment allocation was double-blinded and all participants received active or placebo loading doses and daily supplements for 3 months: (1) 150,000 IU at injury and 6 weeks, (2) 4000 IU daily, (3) 600 IU daily, or (4) placebo only. The primary outcomes were radiographic (RUST [Radiographic Union Scale in Tibial Fractures]) and clinical (FIX-IT [Function Index for Trauma]) healing scores at 3 months. Statistical significance was a priori defined as $P < 0.20$.

Results: 101 participants were enrolled and 99 participants were analyzed at 3 months. The mean age was 27 years (SD [standard deviation] 8) and 25% of participants had a type I or II open fracture. 56% of participants were vitamin D deficient at baseline, with no differences between treatment groups ($P = 0.45$). At 3 months, there was no difference in RUST or FIX-IT scores between treatment groups ($P > 0.50$). Similar results were seen for comparisons between high loading dose versus high daily dose ($P > 0.62$), all high dose groups versus low dose groups ($P > 0.40$), or low dose versus placebo ($P > 0.51$). The largest between-group mean difference at 3 months in RUST scores was 0.9 (95% confidence interval [CI] -0.72, 2.33) and 1.1 (95% CI -0.34, 2.56) for FIX-IT scores. Additional subgroup analyses within vitamin D deficient patients also showed no difference in RUST or FIX-IT scores between groups ($P > 0.40$).

Conclusion: This study was designed to identify potential evidence to support the effectiveness of vitamin D3 supplementation to improve acute fracture healing. Based on the results of this screening trial, and other mounting evidence, it appears unlikely that vitamin D supplementation improves fracture healing in nonosteoporotic patients.

OTA Grant