

The Treatment of Atrophic, Recalcitrant Long-Bone Nonunion with Human Recombinant Bone Morphogenetic Protein-7 (rhBMP-7):**A Retrospective Cohort Review***Zachary Morison, MSc; Milena Vicente, RN; Emil H. Schemitsch, MD, FRCS(C);**Michael D. McKee, MD, FRCS(C);**St. Michael's Hospital, University of Toronto, Toronto, Ontario, Canada*

Purpose: Recombinant human bone morphogenetic protein-7 (rhBMP-7) has been shown to enhance bone formation and promote fracture healing in a number of clinical and basic science settings. However, there is little information from large-scale studies of its use for human nonunion. We sought to determine the safety and efficacy of rhBMP-7 in the treatment of atrophic human long-bone nonunions.

Methods: This was a single-center, retrospective, longitudinal cohort study of patients treated with the application of rhBMP-7 to a nonunion of the femur, tibia, fibula, clavicle, humerus, radius, or ulna. Patients were identified through a prospectively gathered clinical database. Patients were followed at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year post surgical procedure. Data from each of these clinical visits was collected for this study. To be considered eligible for inclusion in this study, patients were required to be over 16 years old and present with an atrophic, aseptic nonunion of a long-bone or clavicle. The rhBMP-7 must have been used in isolation when performing the open reduction internal fixation of the nonunion, although the use of available local autogenous bone graft was acceptable.

Results: We identified 95 eligible patients who were treated with rhBMP-7 for a long-bone nonunion between July 1997 and April 2012. The mean age of the patients at the time of treatment with rhBMP-7 was 50.5 years (range, 20-92). 47 of the patients had a history of smoking for a mean of 17.9 pack-years and 64 of the patients had significant comorbidities. 22 patients had received at least one failed surgical treatment for their nonunion with a mean of 1.8 procedures per person. Of these 22 patients, 14 had received a bone graft or an osteobiologic as a part of their treatment prior to receiving rhBMP-7. The primary mechanisms of injury for this cohort were falls (n = 37) and motor vehicle accidents (n = 21). During the 1-year postoperative period, 78 patients had achieved union as a result of their treatment. Five patients were lost to follow-up prior to definitive clinical or radiographic union, three patients had early hardware failure not related to the rhBMP-7 treatment, two patients developed a stable fibrous union, and seven patients went on to nonunion. Six of the seven nonunion patients went on to heal following revision ORIF (open reduction and internal fixation).

Conclusion: To our knowledge this is the largest report of rhBMP-7 used for the treatment of long-bone nonunions in North America. We found that the application of rhBMP-7 to long-bone nonunions was an effective way (86% union rate) of treating this challenging pathology and not associated with any increase in adverse events.