**Romosozumab prevents fracture in women with Osteoporosis**  
16th November 2020  
Mayoni Ranasinghe, MBBS, MPH

Post-menopausal women with osteoporosis treated with romosozumab followed by alendronate had a 48% lower chance of fracture compared with those who received only alendronate treatment according to the results of a new study.   
  
Kenneth G. Saag MD, MSc, with the University of Alabama in Birmingham and colleagues reported their findings in the September 11th 2017 issue of the New England Journal of Medicine.   
  
Alendronate, a bisphosphonate which helps inhibit bone resorption, is a recommended treatment for osteoporosis as described in the National Osteoporosis Foundation guidelines. Romosozumab, as stated by the authors, is a monoclonal antibody that binds to and inhibits sclerostin - a glycoprotein with anti-anabolic effects on bone.   
  
The current study included 4093 postmenopausal women with osteoporosis and a history of fragility fracture who were randomized to receive a blinded study treatment of either subcutaneous romosozumab monthly or oral alendronate weekly for a duration of 12 months, followed by open-label alendronate for both groups for another 12 months. The cumulative incidence of vertebral fracture at 24 months and the cumulative incidence of clinical fracture (nonvertebral and symptomatic vertebral fracture) at primary analysis (carried out after clinical fractures had been confirmed in at least 330 patients) were the primary endpoints. Incidences of nonvertebral and hip fractures were included as second endpoints.

Results showed that subjects who received both romosozumab and alendronate had a 48% lower risk of new vertebral fractures as compared to their alendronate-to-alendronate counterparts (6.2% vs 11.9%; P<0.001) in a 24 month period. The romosozumab-to-alendronate group also showed a 27% lower risk of clinical fractures as compared to the alendronate-to-alendronate group (9.7% vs 13%; P<0.001)  
  
In addition, the romosozumab-to-alendronate group reported lower risks of the secondary endpoints when compared to the alendronate-to-alendronate group (nonvertebral fractures: 8.7% vs 10.6%; P=0.04)( hip fractures: 2.0% vs 3.2%; P=0.02).

The most common adverse events observed were adjudicated cardiovascular episodes during the 1st year, with the romosozumab patients experiencing more events than their alendronate counterparts (2.5% vs 1.9%). In the 2nd year, adjudicated events of atypical femoral fracture were observed (0.1% vs 0.2% respectively).  
  
The authors conclude that initial treatment with romosozumab followed by alendronate could significantly lower the risk of fracture in postmenopausal women with osteoporosis who have a high risk of fracture.  
  
The study was funded by Amgen and others. A full list of disclosures is provided in the journal article.   
  
Saag KG, Petersen J, Brandi ML, et al. Romosozumab or Alendronate for Fracture Prevention in Women with Osteoporosis. *N Engl J Med*. 2017;377(15):1417-1427. doi:10.1056/NEJMoa1708322