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Reply:

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REPLY:

We thank Braillon and Bewley for their interest in our article, "Vertebroplasty and Kyphoplasty for Osteoporotic Vertebral Fractures: What Are the Latest Data?" The stated aim of this article was to provide an update to clinicians on the evolution of evidence for reduction in pain and disability from vertebroplasty and kyphoplasty for osteoporotic vertebral fractures and, in particular, highlight the limitations of the various prospective randomized controlled trials (RCTs). The most recent trial, A Randomised Sham-Controlled Trial of Vertebroplasty for Painful Acute Osteoporotic Vertebral Fractures (VERTOS IV)[1] had not been published at the time this review was conducted. Notably, there are important differences in the enrolled patient cohorts between A Controlled Trial of Vertebroplasty for Acute Painful Osteoporotic Fractures (VAPOUR) and VERTOS IV, which again highlight the challenge in the interpretation of outcomes from these procedures.[2]

Apart from the RCTs, there are also strong signals of benefit from large national or insurance-based-claims datasets from Germany, Sweden, France, Taiwan, and the United States.[3-9] In one of the largest analyses of more than 2 million patients during 10 years from the US Medicare dataset, there was a strong signal of reduced mortality after vertebral augmentation compared with medical management.[8] This signal of survival benefit has been replicated in further analysis of German[5] and Taiwanese[7] health insurance datasets. In addition, various national and medical societies have varied in their interpretation of the evidence, depending on when they examined the literature.[10-12] Most notably, the National Institute for Health and Care Excellence, which provides evidence-based guidance and advice to the National Health Service in the United Kingdom, recommends vertebroplasty and kyphoplasty as treatment options for patients with severe pain after a recent osteoporotic vertebral compression fracture and concluded that it was reasonable to assume that the procedures reduce mortality.[13]

Akin to many other areas in medicine, clinicians must integrate their clinical expertise with patient values and interpretation of the research evidence to provide optimized and meaningful care. For years, the results from the various RCTs have shown that vertebroplasty and kyphoplasty are best considered for patients with severe pain and disability and only after rigorous clinical and advanced imaging selection. Moreover, earlier treatment (potentially <3 weeks from fracture onset) may provide the best chance of benefit. Important questions remain unanswered; for example, what are the implications of the progressive height loss evident in untreated-versus-cemented levels in VERTOS IV and VAPOUR? Does this prevention of height loss help explain the mortality benefit observed in almost all claims-based studies? We concur with Braillon and Bewley that new patients should be included in further RCTs to clarify the role of these procedures or included in large registries in which data can be pooled and additional meaningful conclusions reached.

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