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New global task force report questions effectiveness of spinal fusion procedures, provides recommendations

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There is little to no evidence that two surgical procedures used to fuse crumbled vertebrae following a spinal fracture caused by osteoporosis reduce pain for patients any better than non-surgical or placebo procedures, according to a new report from a global task force of bone health experts published today in the *Journal of Bone and Mineral Research* (JBMR).

The task force was charged by the American Society for Bone and Mineral Research (ASBMR) to assess the relative efficacy and safety of the most commonly used procedures to treat osteoporotic spinal fractures: vertebroplasty, where medical grade cement is injected into the broken vertebrae to fuse the fragments of bone together; and, balloon kyphoplasty, where a balloon is inserted into the compressed area of spine to lift it and allow cement to be inserted before the balloon removal.

The task force's report, the most comprehensive to date, comes amid aggressive and often misleading marketing by device makers touting the procedures to doctors and patients as a "non-invasive" way to get immediate relief from the pain caused by vertebral compression fractures and a way to avoid potential opioid addiction.

"The message for doctors and their patients suffering from painful spinal fractures is that procedures to stabilize spinal fractures should not be a

first choice for treatment," said task force member and lead author Peter Ebeling, M.D., Head of the Department of Medicine in the School of Clinical Sciences at Monash University in Australia. "While patients who had these surgeries may have had a short-term reduction in pain, we found that there was no significant benefit over the long-term in improving pain, back-related disability, and quality of life when compared with those who did not have the procedures."

Key findings from the task force report include:

- Vertebroplasty (cement injection into the vertebrae) provides no clearly significant benefit in pain control over placebo or sham procedures based on five randomized placebo-controlled trials.
- For balloon kyphoplasty, the lack of placebo-controlled trials of this procedure, along with the absence of any benefits of kyphoplasty over vertebroplasty when compared in a small number of head-to-head trials, argues against the use of this procedure.

An estimated 750,000 people each year in the U.S. suffer from vertebral compression fractures caused by osteoporosis which result in acute and chronic back pain, impaired mobility, and disability. With an increasingly aging population, that number is expected to rise. Some 300,000 patients underwent vertebral augmentation procedures between 2006-2014, according to Medicare data. During that time-period, a majority of patients (73%) underwent the more expensive balloon cement injection procedure (kyphoplasty). The task force reported that both augmentation procedures were introduced into practice "prior to high quality evidence establishing its efficacy and safety and remains in some settings part of a standard routine of care."

While the procedures are minimally invasive, risks include infection at the site of the injection, cement leakage, and complications associated

with elderly patients undergoing anesthesia. There have also been concerns about the increased risk of fractures in vertebrae surrounding the fused area, but the task force concluded that more research is needed to assess this risk.

"This report makes it clear that these procedures are not a magic bullet," said Bart Clarke, M.D., President of the American Society for Bone and Mineral Health, and a practicing endocrinologist, Professor of Medicine at the Mayo Clinic and co-author of an accompanying perspective piece published in the JBMR. "Until now, doctors have been left to sift through the data on their own to determine whether these procedures can benefit their patients. This report coalesces all that information concisely and provides recommendations to guide them."

Dr. Clarke added that at his center at the Mayo Clinic, they do not normally perform vertebral augmentation procedures unless a patient's pain is unmanageable for more than 4-6 weeks. "We've seen that with analgesics and other pain relief, our patients often get better within about 6 weeks."

The task force also focused on the critical need for prevention. Patients who have experienced a first fracture of the hip or spine likely have osteoporosis are likely to experience a second fracture. Approximately 25% of older men and women who have a hip fracture will have a second fracture within one year, as will around 20% of older patients who have a vertebral fracture. But research shows that treatment rates for hip fracture patients are low and are actually decreasing over time.

"Overall, prevention is critical. and we need to get these high-risk patients on anti-osteoporosis drugs that have proven to reduce future fractures by as much as 70 percent," Clarke said.

The ASBMR task force offered the following guidance for healthcare

professionals and their patients for managing fractures to the spine:

- Fully inform their patients of the available evidence: there is little to no evidence that the use of vertebral augmentation works any better than a placebo.
- Anti-osteoporosis medications should be started or continued. A change in treatment may also need to be considered if the fracture occurred after 12 months from starting anti-osteoporosis treatment.

"This is a painful condition that for most people spontaneously gets better with time and can be managed with analgesic medications over the short-term," Ebeling said. "From our experiences with patients, we know that non-pharmacologic approaches may be effective, but we need more trials to explore these approaches."

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