

Vertebroplasty may see continued use in patient subset despite NEJM studies, AAOS guidelines; reimbursement risk remains

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Vertebroplasty may see continued use in a subset of patients, despite recent guidelines from the American Academy of Orthopedic Surgeons (AAOS) that recommend against the procedure, orthopedic spine surgeons said.

However, reimbursement may suffer in the future due to these guidelines, which surgeons noted will greatly limit their ability to perform this procedure.

AAOS released a guidance and evidence report about two weeks ago concerning the treatment of symptomatic osteoporotic spinal compression fractures.

The recommendations in the guideline were based on two Level I studies comparing vertebroplasty to a sham procedure, and three Level II studies comparing vertebroplasty to conservative treatment. The report stated a recommendation "against vertebroplasty for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact." The guidelines consider kyphoplasty to be an option on the basis of a weak recommendation.

The New England Journal of Medicine also published two negative studies last year, which concluded that vertebroplasty was not better when compared to a "sham" procedure.

However, Vertos II trial data published on 9 August in the Lancet served to restore confidence in vertebroplasty since the trial demonstrated that vertebroplasty is both safe and effective and provided greater pain relief than conservative treatment for patients with acute osteoporotic vertebral fractures.

Compression fractures have been treated with a polymethylmethacrylate filling that has been used in the vertebroplasty procedure for many decades and most of the recent innovation has been in the delivery system, said Dr Ralph Rashbaum, an orthopedic spine surgeon and a co-founder of the Texas Back Institute.

However, the issue is identifying the right patient for treatment and determining the right time to intervene, he said. Rashbaum noted that some patients heal naturally within four to six weeks of injury without any intervention. Since vertebroplasty is unnecessary in many situations, the creation of guidelines for the appropriate use of this procedure would be useful, Rashbaum said.

The recently issued AAOS guidelines may reduce the liberal use of vertebroplasty, said Dr Purnendu Gupta, director of the University of Chicago Spine Center, section of orthopedic surgery. He said that payers are likely to consider limiting or terminating reimbursement, but added that he hopes that does not happen because there is a narrow group of patients who do benefit significantly from vertebroplasty. For example, patients with severe pain who are unable to perform any kind of activity and are bed-ridden are good candidates for vertebroplasty, Gupta explained.

The procedure is often done without first confirming that the pain is being generated due to the compression fracture, noted Dr Rayshad Oshtory, an orthopedic surgeon from Post Street Surgery Center in San Francisco. In these cases the utility of vertebroplasty may be limited; however, the procedure does work great in patients who are experiencing pain because of the fracture.

Many patients with vertebral compression fractures do not show any symptoms at all, said Dr Michael Hisey, an orthopedic surgeon and a medical director at Texas Back Institute. Of the patients who do show symptoms, about 15-20% of them would be in the subgroup that would be good candidates for vertebroplasty, he added. The procedure is great for patients who progressively get worse due to their compression fracture or ones who cannot get out of bed due to their symptoms, Hisey noted.

"We hope that there are guidelines that help identify the right patients for vertebroplasty," said Jeffrey Marx, VP of corporate development at OrthoVita (NASDAQ:VITA), which sells Cortoss for compression fractures. He noted that the Vertos II data clearly indicates that vertebroplasty helps patients, adding that it may have been better if AAOS considered the Vertos II data prior to releasing the guidelines.

David Veino, national director of sales and marketing at Stryker (NYSE:SYK), said the company offers both kyphoplasty and vertebroplasty procedures. "We leave the decision up to the physicians," he said, adding that there is a large opportunity for the compression fracture market in the future.

It is difficult to tell how much of this debate is financial or scientific, said Dr Rick Delamarter, medical director of the Spine Institute at Saint John's Health Center. He noted that in addition to spine surgeons, interventional radiologists also perform a number of vertebroplasty procedures and it will be interesting to see how they respond to the guidelines.

Dr William Watters, chair of the Guidelines and Technology Oversight Committee at AAOS, noted that it is important to identify the subgroup of patients who would benefit from vertebroplasty. However, the AAOS is currently not working on guidelines to accurately identify this subgroup, he added.

The impact of these guidelines from a payer perspective may be greater than intended, Watters noted.

by Viral Gandhi in Orlando

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