

Medicare Vertebroplasty Coverage: No Time Soon

An advisory panel listened to a day of mostly favorable testimony on vertebral augmentation.

BY JOYCE FRIEDEN

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BALTIMORE — Although some local carriers already cover vertebral augmentation through vertebroplasty or kyphoplasty, the Centers for Medicare and Medicaid Services does not intend to consider a national coverage policy for the procedures, especially given the lack of solid data available, Stephen Phurrough, M.D., said at a meeting of the Medicare Coverage Advisory Committee.

"We have no open national coverage determination, and we have no plans to open a national coverage determination," said Dr. Phurrough, who is head of Medicare's coverage and analysis group.

The group does plan to "produce some type of guidance document that may distill what we think about this particular field of spinal disease," he said. That document will then be made available for comment.

Dr. Phurrough's remarks came after a day of mostly favorable testimony on vertebral augmentation. "We are showing that these patients are better, and we're making a difference in their pain," said Isador H. Lieberman, M.D., a surgeon at the Cleveland Clinic Foundation.

Dr. Lieberman and colleagues performed a prospective controlled trial on 329 vertebral augmentation patients, 70% of whom had osteoporosis. Duration of symptoms prior to the procedure was 1 week to 5 years, mean follow-up was 55 weeks, and the average hospital stay was 1.1 days.

The researchers found that the vertebral

augmentation patients showed a "statistically significant improvement in bodily pain, mental health, physical function, social function, and vitality," compared with the controls, said Dr. Lieberman, who serves as a consultant to several companies that make surgical equipment for vertebral augmentation. "Overall, these patients do well with this intervention."

Dr. Lieberman gave several reasons why no randomized controlled trials had been done on the benefits of one procedure vs. the other. "I've been involved in five attempts. To sum it up, it's lack of collaboration—we have not been able to get various factions to decide on how to do the study or whether to participate," he said.

There are also study design and institutional review board (IRB) issues. "One study I was potentially involved in demanded a sham procedure; my IRB would not let me do a sham procedure," he said. Getting funding for the study also is a problem.

But probably the most important problem is recruitment. "We're dealing with an elderly population who don't have time or patience to come back for all these follow-ups or fill out all this paperwork," Dr. Lieberman said.

Kevin McGraw, M.D., a Columbus, Ohio radiologist, testified that conservative treatment of vertebral fractures—usu-

ally bed rest—is not without its risks.

"During bed rest, virtually every organ system is adversely affected," said Dr. McGraw, who testified on behalf of the Society of Interventional Radiology. "Bone density declines about 2% per week, and muscle strength declines about 10%-15% per week. Nearly half of normal strength is lost during the first 3-4 weeks of bed rest."

Other serious consequences of bed rest include pressure sores, deep vein thrombosis, and pulmonary emboli, he continued. "If we subject patients to 6 weeks of bed rest, they've lost 12% of bone density

and half of their muscle strength, they have developed a decubitus ulcer, and they have a 10% chance of a pulmonary embolism. The Society of Interventional Radiology believes that since vertebroplasty results in early mobilization, it is

superior to conservative treatment."

Fergus McKiernan, M.D., of the Center for Bone Diseases at the Marshfield (Wisc.) Clinic, sounded a note of caution about the available data on vertebral augmentation.

First, he noted that one common method of reporting vertebral height restoration following vertebral augmentation invariably favored smaller restorations. For example, "if a 4-mm regression of the superior endplate is followed by a 3-mm restoration, one could say this 3 mm constituted a 75% vertebral height restoration," he said. "Using this same method, if a 25-mm regression of the superior endplate is followed by a 5-mm elevation, this reporting method would as-

sign a 20% vertebral height restoration."

Journal editors should require disclosure of anterior, middle, and posterior heights, "as the vertebrae may fail in the middle portion, and yet there may be no change in anterior height," said Dr. McKiernan. "Without knowledge of all vertebral heights, claims of vertebral height restoration based [solely] on middle height may not be clinically relevant."

He also said that one recent article touting the benefits of kyphoplasty cited two papers from his own research group. This citation was problematic because his group does not perform kyphoplasties, only vertebroplasties. In addition, the authors used his group's papers to make a point about vertebral compression fractures less than 4 weeks old, "and our average fracture age is 4 months," Dr. McKiernan said. "The notion of less-than-4-week-old fractures appears nowhere in the text of either article."

Panel members appeared to agree with some of Dr. McKiernan's points when it came to voting on the questions put before them. When asked to rate how well the evidence addresses vertebroplasty's effectiveness on a scale of 1-5—with 1 being "poor" and 5 being "very well"—the panel's average vote was 2.0. When asked about mortality data, the panel was particularly skeptical, giving it an average score of 1.5. Results of a vote on the evidence for kyphoplasty were similar.

"As patients expect this, a whole group of patients you wouldn't think of doing this on will receive it," said panel member Alexander Krist, M.D., a family physician in Fairfax, Va. "There is [an unsystematic] process for figuring out who gets it and who doesn't. That would be my fear." ■

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Surgeons Wax Skeptical on Mobile-Bearing Knee Implants

BY CHRISTINE KILGORE

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WASHINGTON — Mobile-bearing knee implants are hyped in advertisements and demanded by patients, but the jury is still out on whether the devices deliver what's promised.

During a panel discussion on "controversial issues and hot topics" in primary total knee replacement at the annual meeting of the American Academy of Orthopaedic Surgeons, several panelists objected to the idea that rotating platform knee implants are superior in many ways to fixed-bearing designs.

"There's certainly some skepticism here about whether mobile-bearing designs are really more forgiving [of rotational misalignment of the femoral and tibial components] and whether there truly is less wear," said William J. Maloney, M.D., professor of orthopedic surgery at Stanford (Calif.) University, who moderated the discussion.

Rotating platform, or mobile-bearing, knee replacements are designed for potentially longer performance with less wear to parts of the prosthesis. The devices have been marketed and are recommended by some physicians, particularly for younger, active, or overweight patients.

The mobile-bearing knees use three components—just like fixed-bearing replacements—but have a different bearing surface. The metallic femoral component and the metallic tibial tray both move across a mobile polyethylene insert. The insert creates a dual-surface articulation, absorbing force across a greater contact surface and en-

suring congruent contact between the femoral and tibial components.

These implants, said panelist Douglas A. Dennis, M.D., "allow increased conformity in both planes without dramatically increasing fixation stresses and the risk of component loosening."

This, he said, reduces polyethylene wear—which should be the focus of "any total knee design." Polyethylene wear has been the major mode of total knee replacement failure, said Dr. Dennis, of the Rocky Mountain Musculoskeletal Research Laboratory in Denver.

"We have seen in our laboratory better kinematics in gait with mobile bearings. They're more tolerant of condylar lift-off, which should reduce the potential for polyethylene wear, and I think they're more forgiving of component rotational mal-alignment—the bearing has the potential to self-correct," he said.

In a 10-year study of total knee replacements, Dr. Dennis and his colleagues found that mobile-bearing knees allow for a wider range of axial rotation without creating excessive polyethylene stresses. "A fairly large number [of mobile-bearing knees] rotated greater than 20 degrees, which is beyond the rotational boundaries of most fixed-bearing designs," he said.

Arlen D. Hanssen, M.D., argued that several studies have shown no difference in motion and no difference in patello-femoral mechanics between fixed and mobile-bearing knees. Early dislocation and instability continue to be a problem with the rotating-platform knee, and recently there have been reports of late dislocation.

"Late dislocation occurs in this knee because of advanced wear," said Dr. Hanssen, of the Mayo Clinic in Rochester, Minn.

"One of the reasons to use the rotating-platform knee has been to avoid osteolysis wear ... but osteolysis seems to be significantly higher [in patients with the mobile-bearing knee]," he said.

The rigid tibial trays that are required in the rotating platform design also contribute to stress shielding of the proximal tibia, he said.

"Why would you take a knee that [has only been studied] in the elderly, has no better motion, no better patello-femoral mechanics, has the unique complication of dislocation and instability, and now appears to have some wear and osteolysis problems and stress shielding problems?" Dr. Hanssen asked. "My answer is no thanks."

Other panelists agreed. "The advertisements say [the mobile-bearing knee] is the best thing, that it's going to give us 20 years," said Merrill A. Ritter, M.D., of the Center for Hip and Knee Surgery in Mooresville, Ind. "There [are] no data to support this, and there are too many things that do work."

Leo A. Whiteside, M.D., of the Missouri Bone and Joint Center in St. Louis, said that theoretically, the mobile-bearing design should perform better. "What worries me [are] the multiple reports of higher wear," he said.

Bearing surface is just one of several choices surgeons make when performing total knee arthroplasty. The type of fixation, the modularity of implants, and surgical technique are also controversial, Dr. Maloney added. ■