Position Statement on Percutaneous Vertebral Augmentation: A Consensus Statement Developed by the American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and American Society of Spine Radiology

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Abbreviation: PMMA = polymethylmethacrylate

IT is the position of the American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and American Society of Spine Radiology "the Societies") that percutaneous vertebral augmentation with vertebroplasty and kyphoplasty is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures when performed in a manner in accordance with published standards (1,2). These procedures are offered only when traditional medical therapy has not provided pain relief or pain is substantially altering the patient's lifestyle. With regard to vertebroplasty, multiple case series (3-17) and retrospective (18,19) and prospective (20–23) nonrandomized studies have shown a statistically significant improvement in pain and function—particularly with regard to ambulation—and these results have been confirmed in a prospective study with use of a control group (24) and in a prospective randomized control study (25). The benefits of vertebroplasty far outweigh its risks and the risks of conservative therapy, and the success rate is consistently high. This procedure is cost-effective because it produces immediate improvement in a patient's quality of life, primarily by means of the alleviation of pain and rapid return to ambulation. In addition to reducing the need for costly skilled care, expensive drugs, or orthopedic devices, a return to ambulation is known to reduce adverse outcomes in elderly patients confined to bed (26).

Kyphoplasty has been introduced as an alternative approach (27). It is similar to vertebroplasty and has been referred to as "balloon-assisted vertebroplasty." Kyphoplasty entails the inflation of a percutaneously delivered balloon in the vertebral body followed by the percutaneous injection of bone cement into the cavity created by the balloon. The balloon is intended to restore the vertebral body height in addition to creating the cavity (27).

After reviewing the published literature on kyphoplasty, the Societies have determined that the clinical response rate in individuals treated with kyphoplasty is equivalent to that seen in patients treated with vertebroplasty. There is no proved advantage of kyphoplasty relative to vertebroplasty with regard to pain relief, vertebral height restoration, or complication rate (27–44).

It is the position of the Societies that vertebral augmentation with vertebroplasty or kyphoplasty is a medically ap-

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propriate therapy for the treatment of painful vertebral compression fractures refractory to medical therapy when performed for the medical indications outlined in the published standards (1,2). We believe vertebral augmentation with vertebroplasty or kyphoplasty is established therapy and should be reimbursed by payors as a safe and effective treatment for painful compression fractures.

RATIONALE

Vertebral Augmentation versus Traditional Conservative Management

Although "conservative" implies "safe," conservative therapy of vertebral compression fractures is neither benign nor risk-free and its complications are well documented (46–48). Conservative treatment of painful vertebral compression fractures usually consists of bed rest, bracing, and narcotic analgesia. In a recent prospective study of 498 hospitalized patients aged 70 years or older, low mobility (defined as bed rest or ability to transfer to chair) or intermediate mobility (defined as ambulation one to two times with total assistance) were independent predictors of the following poor hospital outcomes at discharge: (a) decrease in activities of daily living, (b) new institutionalization, and (c) death when compared to patients with high mobility (defined as ambulation at least twice with partial or no assistance) (26). The contribution of low mobility to these outcomes remained statistically significant in multivariate analyses, even after controlling for multiple variables including age, sex, severity of illness, and co-morbidities. In short, conservative treatment leads to adverse outcomes associated with low mobility and bed rest, which may be viewed as iatrogenic events leading to complications such as functional decline.

As previously mentioned, conservative treatment often includes immobilization with bed rest. During bed rest, virtually every organ system is adversely affected. These effects tend to be more pronounced in older patients, who have less reserve than younger patients. Bone density decreases approximately 2% per week, a serious concern in patients with osteoporosis, and these patients are unlikely to ever regain the lost bone mass (49). Bone loss tends to occur in stages, with the most dramatic changes occurring in the first 12 weeks of immobilization.

Muscle strength decreases 1%–3% per day or 10%–15% per week (46). Almost half of normal strength is lost within 3–5 weeks of immobilization, and the rate of recovery from disuse weakness is slower than the rate of loss. Complete rest results in decreased endurance and this leads to a sense of fatigue and reduced patient motivation, setting up a vicious circle of greater inactivity. Ligament complexes are also affected by immobilization, leading to contractures, which are more prone to occur in frail, elderly individuals. Muscles that cross two joints, such as the back muscles, are particularly at risk of shortening during immobilization. There is abundant evidence that shows early active mobilization after initial stabilization—a benefit of vertebral augmentation—is the key to the prevention of contracture.

Early mobilization also leads to the prevention of pressure sores, the prevalence of which tends to increase substantially with age. Patients older than 70 years have more than 70% of all pressure sores and get them within 2 weeks of admission to the hospital. Once decubitus ulcers occur, nursing costs can increase by as much as 50%, with the total cost of treatment per ulcer estimated to be between $15,000 and $20,000. Complications often develop with pressure sores. Infection is the most common complication and leads to septicemia, osteomyelitis, anemia, and protein loss by means of chronic discharge.

Cardiovascular effects include increased heart rate, shorter diastolic times, and reduced coronary blood flow. In addition, patients have an overall decrease in cardiac output, stroke volume, and left ventricular function. In the elderly, orthostatic hypotension occurs within the first 3 weeks of bed rest. This, along with the elevated heart rate, leads to diminished diastolic ventricular filling and a decrease in cerebral perfusion. Depending on the length of bed rest, it may take 20–72 days to restore pre–bed rest cardiac function (46).

In patients at bed rest, the frequency of deep vein thrombosis is 61%, with proximal deep vein thrombosis occurring in 29%. Pulmonary embolism is seen in 2%–12% of patients and is fatal in 0.5%–10% (49). A restrictive impairment, an overall decrease in muscle strength, deconditioning of respiratory muscles, and failure to fully expand the chest wall results in a 25%–50% decrease in respiratory capacity (47). In addition, the lungs have decreased ciliary clearance, less effective coughing, atelectasis, and a predilection for pneumonia. Gastrointestinal effects include reduced appetite, constipation, and fecal impaction, all of which are exacerbated by the concomitant use of narcotics. Glucose intolerance is a frequent but often overlooked complication of bed rest and can mimic brittle diabetes (47). Patients are at increased risk of genitourinary calculus formation, incontinence, urinary tract infection, and urosepsis. Even the central nervous system is not immune; patients at bed rest exhibit higher levels of anxiety, depression, insomnia, pain intolerance, sensory deprivation, and balance problems.

Narcotic analgesia is commonly used in conjunction with bed rest in the treatment of acute and chronic nonmalignant musculoskeletal pain (48,50). Adverse drug reactions have been seen in more than 70% of individuals treated with opioids (48), and although most side effects are minor the elderly are more likely to have a severe adverse drug reaction such as confusion. In one study (48), severe adverse drug reactions occurred in more than 10% of patients. A multivariate analysis of the findings showed that the only factor associated with severe adverse drug reactions was advancing age.

Patients who undergo vertebroplasty have consistently shown immediate and considerable improvement in pain and mobility after treatment (3–25). In a recent study of 79 consecutive patients with osteoporotic compression fractures (24), 55 (70%) of whom were treated with vertebroplasty and 24 (30%) of whom were treated with conservative therapy, the vertebroplasty group showed a statistically significant reduction in pain and an improvement in physical functioning at 24 hours compared with the conservative treatment group. In addition, 24% of the patients who underwent vertebroplasty were able to cease all analgesia after 24 hours; none of the patients in the conservative treatment group were able to stop analgesia. These markedly different clinical outcomes at 24 hours to 1 week represent