AAOS Clinical Practice Guideline Summary

The Treatment of Symptomatic Osteoporotic Spinal Compression Fractures

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Abstract

This clinical practice guideline is based on a series of systematic reviews of published studies on the treatment of symptomatic osteoporotic spinal compression fractures. Of 11 recommendations, one is strong; one, moderate; three, weak; and six, inconclusive. The strong recommendation is against the use of vertebroplasty to treat the fractures; the moderate recommendation is for the use of calcitonin for 4 weeks following the onset of fracture. The weak recommendations address the use of ibandronate and strontium ranelate to prevent additional symptomatic fractures, the use of L2 nerve root blocks to treat the pain associated with L3 or L4 fractures, and the use of kyphoplasty to treat symptomatic fractures in patients who are neurologically intact.

Overview and Rationale

This clinical practice guideline was approved by the American Academy of Orthopaedic Surgeons (AAOS) on September 24, 2010. It is based on a systematic review of published studies on the treatment of symptomatic osteoporotic spinal compression fractures in adults (aged ≥18 years). In addition to providing practice recommendations, this guideline highlights gaps in the literature and areas that require future research.

The purpose of this guideline is to help improve treatment based on the current best evidence. Current evidence-based practice standards demand that physicians use the best available evidence in their clinical decision making. To assist in this, this clinical practice guideline consists of a series of systematic reviews of the available literature regarding the treatment of osteoporotic spinal compression fractures. These systematic reviews were conducted between January 1996 and December 31, 2009; they show where good evidence exists, where evidence is lacking, and which topics future researchers must target to improve the treatment of patients with symptomatic osteoporotic spinal compression fractures. AAOS staff and the work group systematically reviewed the available literature and subsequently wrote the following recommendations based on a rigorous, standardized process.

Musculoskeletal care is provided in many different settings by many different providers. In an effort to improve the quality and efficiency of care, we created this guideline as an educational tool to guide qualified physicians through a series of treatment decisions. This guideline should not be construed as including all proper methods of care or as excluding methods of care reasonably directed to obtaining the same re-

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The complete guideline, which includes all tables, figures, and appendices, is available at http://www.aaos.org/research/guidelines/SCFguideline.pdf

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sults. The ultimate judgment regarding any specific procedure or treatment must be made in light of all circumstances presented by the patient as well as the needs and resources particular to the locality or institution.

This guideline represents a cross-sectional view of current treatment and/or diagnosis and may become outdated as new evidence becomes available. It will be revised in accordance with new evidence, changing practice, rapidly emerging treatment options, and new technology. This guideline will be updated or withdrawn in 5 years in accordance with the standards of the National Guideline Clearinghouse.

Potential Harms and Contraindications

Most treatments are associated with some known risks; this is especially true of invasive and surgical treatments. In addition, contraindications vary widely based on the treatment administered. Therefore, discussion of available treatments and procedures applicable to the individual patient rely on mutual communication between the patient and physician.

Methods

The methods used to develop this clinical practice guideline were designed to combat bias, enhance transparency, and promote reproducibility. The purpose is to allow interested readers the ability to inspect all of the information the work group used to reach all of its decisions and to verify that these decisions are in accord with the best available evidence. The draft of this guideline was subject to peer review and public commentary, and it was approved by the AAOS Evidence-Based Practice Committee; Guidelines and Technology Oversight Committee; Council on Research, Quality Assessment, and Technology; and the Board of Directors.

All tables, figures, and appendices, as well as details of the methods used to prepare this guideline, are detailed in the full clinical practice guideline, which is available at **http://www.aaos.org/research/guidelines/SCFguideline.pdf**.

Recommendations

Recommendation 1

We suggest that patients who present with an osteoporotic spinal compression fracture on imaging, with correlating clinical signs and symptoms suggesting an acute injury (0 to 5 days after an identifiable event or onset of symptoms), and who are neurologically intact, be treated with calcitonin for 4 weeks.

Quality of Evidence: Level II

Quantity of Evidence: Four studies

Applicability Downgrade: No

Critical Outcome or Outcomes: Pain

Strength of Recommendation: Moderate

Rationale: This recommendation is based on two level II studies that showed benefit in reducing pain at 4 weeks using salmon calcitonin administered within 5 days of a fracture event.[1,2] In one study, 100 patients were treated with 200 IU nasal calcitonin or placebo. Calcitonin reduced pain in four positions (bed rest, sitting, standing, and walking) as well as the number of bedridden

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patients at 1, 2, 3, and 4 weeks, in a clinically important manner. In a second study with 36 patients, similar results were found with calcitonin suppositories 200 IU. Side effects of calcitonin include mild dizziness.[2]

Two additional level II studies with calcitonin showed benefit at longer periods (3 to 12) months but were not as well designed.[3,4] In one, possibly clinically important benefit was shown in pain reduction using nasal calcitonin in a 2-month-on and 2-month-off fashion for 12 months, compared with calcium 500 mg with vitamin D 200 IU.[3]

In another study, 200 IU nasal calcitonin led to possibly clinically important improvement in pain at 3 months when compared with 1,000 mg calcium.[4] The effect of subcutaneous administration of calcitonin is undetermined in a rigorous scientific manner.

Recommendation 2

Ibandronate and strontium ranelate are options to prevent additional symptomatic fractures in patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms.

Quality of Evidence: Level I

Quantity of Evidence: Four studies

Applicability Downgrade: No

Critical Outcome or Outcomes: Symptomatic fracture

Strength of Recommendation: Weak

Rationale: Numerous studies have examined the effects of medical therapies for the treatment of osteoporosis to prevent fractures. The focus of this recommendation is not the use of medical therapies for treatment of osteoporosis (ie, prevention of fragility fracture) but rather their use in patients with an existing fracture, as well as prevention in patients experiencing symptomatic fractures (ie, the critical outcome for this recommendation). Three studies of osteoporosis drugs exclusively enrolled symptomatic patients, but none reported the critical outcome of a symptomatic fracture.

Thirty-four additional studies were included that enrolled patients with symptomatic fractures or asymptomatic fractures (ie, incident fracture determined by radiograph). Three of these studies reported the critical outcome of symptomatic fracture.

One level II study investigated daily (2.5 mg) and intermittent (20 mg every other day for 12 doses every 3 months) administration of ibandronate for symptomatic vertebral fractures compared with placebo.[5] Daily and intermittent ibandronate treatment regimens reduced new symptomatic vertebral fractures in a statistically significant manner at 3 years. There were no statistically significant differences in adverse events between ibandronate and placebo groups, including those in the upper gastrointestinal tract.

One level II study investigated daily strontium ranelate (2 g) for vertebral fractures compared with placebo.[6] Strontium ranelate reduced new symptomatic vertebral fractures in a statistically significant manner at 1 and 3 years. The occurrence of adverse events was similar between patients assigned to placebo and those assigned strontium ranelate. The only statistically significant differences were diarrhea, which occurred more frequently in patients receiving strontium ranelate, and incidence of gastritis, which occurred more frequently in patients receiving placebo. Effective July 15, 2010, strontium ranelate is not approved for marketing or for the treatment of any medical condition in the United States. The United States Food and Drug Administration's (FDA) current policy regarding disclosure of marketing applications can be found in "Current Disclosure Policies for Marketing Applications" on the FDA Web site.

One level II study investigated daily oral pamidronate (150 mg) for vertebral fractures compared with placebo.[7] Oral pamidronate did not reduce new symptomatic vertebral fractures in a statistically significant manner at 3 years, and adverse events were similar between patients who received placebo and those who received oral pamidronate.

No recommendation is made for or against the use of any of the treatments that are considered not applicable to the reduction of future symptomatic vertebral fractures, despite the large body of evidence for their use in osteoporosis.

Recommendation 3

We are unable to recommend for or against bed rest, complementary and alternative medicine, or the use of opioids/analgesics for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.

Strength of Recommendation: Inconclusive

Rationale: No existing adequate data exist to address the use of the following potential conservative, nonsurgical therapies for a spinal compression fracture in patients who are neurologically intact: bed rest or complementary, alternative medicines and use of opioids/analgesics.

Recommendation 4

An L2 nerve root block is an option in treating patients who present with an osteoporotic spinal compression fracture at L3 or L4 on imaging with correlating clinical signs and symptoms suggesting an acute injury and who are neurologically intact.

Quality of Evidence: Level II

Quantity of Evidence: One study

Applicability Downgrade: No

Critical Outcome or Outcomes: Pain, function

Strength of Recommendation: Weak

Rationale: The role of L2 selective nerve root blocks as a nonsurgical treatment of back pain associated with midlumbar compression fracture has been studied.[8] In this trial, two groups of 30 acute fracture patients received either unilateral L2 root block or subcutaneous injection as a control. A possibly clinically important benefit was seen with the treatment at 2 weeks but became nonsignificant at 1 month. The effect of bilateral L2 injection was not addressed in this study or the literature. Based on this single study, support for L2 root injection for treating new-onset back pain associated with L3 or L4 compression fractures is weak and is, therefore, an option only for temporary pain relief.

Recommendation 5

We are unable to recommend for or against treatment with a brace for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.

Quality of Evidence: Level II

Quantity of Evidence: One study

Applicability Downgrade: Yes

Critical Outcome or Outcomes: Pain, function

Strength of Recommendation: Inconclusive

Rationale: Only one level II article studies the effect of bracing.[9] This recommendation was downgraded to Inconclusive because neither the age nor the level of the fracture being treated was reported. Additionally, this study investigated only a single, specific type of brace for all fractures, which calls into question the generalizability of these results to all braces. Although the results were statistically significant, we do not know if they were clinically important (ie, minimal clinically important difference unknown). Based on this single study, insufficient evidence exists to recommend for or against the use of bracing.

Recommendation 6

We are unable to recommend for or against a supervised or unsupervised exercise program for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.

Quality of Evidence: Level II

Quantity of Evidence: One study

Applicability Downgrade: Yes

Critical Outcome or Outcomes: Pain, function

Strength of Recommendation: Inconclusive

Rationale: Using the Osteoporosis Quality of Life Questionnaire, which evaluates five domains, a single level II study evaluated fractures in patients with low back pain of >3 months' duration who used a home-based exercise program compared with a control group who continued their usual activities.[10] We downgraded this recommendation to Inconclusive because the low back pain experienced by patients in this study may not be the direct result of a specific spinal compression fracture. Results did favor exercise to improve the symptom domain at 6 and 12 months and the emotion domain at 6 months, but not at 12 months. There was no difference in the physical function domain at 6 or 12 months. Evaluation of the domain of activities of daily living showed no difference at 6 months, but there was evidence favoring exercise at 12 months. Evaluation of the leisure/social domain revealed evidence to support exercise at the 6-month level but showed no difference at the 12-month level. The clinical importance of these outcomes is unknown. There was no documentation that the back pain measured was a direct result of the fracture.

Recommendation 7

We are unable to recommend for or against electrical stimulation for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.

Quality of Evidence: Level I

Quantity of Evidence: One study

Applicability Downgrade: Yes

Critical Outcome or Outcomes: Pain, function

Strength of Recommendation: Inconclusive

Rationale: One level I study addressed the use of electrical stimulation limited to symptomatic patients with chronic vertebral compression fractures, with short-term follow-up of 3 months.[11] This study had insufficient power to find a difference in this treatment compared with a control group for the critical outcome measure of pain relief, as well as for quality of life. A surrogate outcome measure of change in the use of nonsteroidal anti-inflammatory drugs (NSAIDs) was reported, but the change in use was based on percentage of patients using fewer NSAIDs with electrical stimulation rather than on the actual amount of NSAIDs used by individual patients. This outcome measure has little clinical significance and no quantitative measure to gauge pretreatment versus posttreatment effect. Because of the inability to detect a difference in pain (an outcome that is critical to understand treatment effectiveness) or quality of life, the evidence is in-

conclusive, and we are unable to recommend for or against this treatment.

Recommendation 8

We recommend 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.

Quality of Evidence: Levels I and II

Quantity of Evidence: Two studies (I) and three studies (II)

Applicability Downgrade: No

Critical Outcome or Outcomes: Pain, function

Strength of Recommendation: Strong

Rationale: Two level I studies compare vertebroplasty with a sham procedure.[12,13] These studies report no statistically significant difference between the two procedures in pain, using the visual analog scale, and function, using the Roland Morris Disability Questionnaire (up to 1 month and 6 months, respectively).

These studies have been criticized for a variety of reasons. It has been argued that one of the trials[12] was underpowered. However, this study did have sufficient power to detect the minimal clinically important difference in pain (see Supporting Evidence section for details, available at http://www.aaos.org/research/guidelines/SCFguideline.pdf). Although crossover of patients after 1 month may have influenced the results in one of these studies,[13] there was no crossover in the other study,[12] which also found no statistically significant or clinically important differences. Furthermore, crossover does not affect the lack of benefit for pain and function that the authors measured at 1 month.

Another concern was the low participation rate of eligible patients. This is an issue of external validity (generalizability) and not of internal validity. The work group discussed this flaw but chose not to downgrade this study for applicability because the trial authors noted that the enrolled patients were comparable to patients seen in routine care.

Furthermore, it has been proposed that vertebroplasty works better with certain fracture types than with others. There are no prospective studies that report significant differences in outcomes based on fracture type.

It has also been proposed that vertebroplasty works better in patients who have more pain than those who were included in these trials. The baseline pain in both of these trials was approximately 7 on a scale from 0 to 10. Other comparative studies had a baseline pain of approximately 8 and also had mainly negative outcomes.[14-16]

We recognize that a sham procedure may still introduce bias in the results (eg, surgeons who know they are performing a sham procedure can unintentionally convey expectations to their patients), but there are also three other level II studies that do not use a sham procedure as a control, and the authors of these studies report similar results. One of these studies found clinically important pain relief at 24 hours.[16] At 6 weeks, pain relief was still statistically significant but not clinically important. After 6 weeks, the effect was not statistically or clinically important (observations to 2 years). One study reported results for pain that were statistically significant and possibly clinically important at 1 day but inconclusive at 2 weeks.[15] Another study found inconclusive results at 3 months.[14]

By making a strong recommendation against the use of vertebroplasty, we are expressing our confidence that future evidence is unlikely to overturn the results of these trials.

Recommendation 9

Kyphoplasty is an option for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.

Quality of Evidence: Level II

Quantity of Evidence: Five studies

Applicability Downgrade: Yes

Critical Outcome or Outcomes: Pain, function

Strength of Recommendation: Weak

Rationale: Two level II studies examined the use of kyphoplasty compared with conservative treatment.[17,18] One study examined subacute fractures;[17] the other examined chronic fractures.[18] In the study of patients with subacute fractures, clinically important benefits in pain were found at 1 week and 1 month, with possibly important effects at 3 and 6 months. There was no clinically important benefit in pain management at 12 months. The study also found possibly clinically important benefits in physical function (at 1 and 3 months only) and in the Medical Outcomes Study 36-Item Short Form physical component score (at 1, 3, and 6 months only). Clinically important improvement in quality of life was present at 1 month, and it was possibly clinically important at 3, 6, and 12 months.

In the chronic fractures study, all patients had fractures that were >1 year old, raising the question as to whether the fracture was responsible for all of the pain. There was a statistically significant and possibly clinically important improvement in pain at 3, 6, and 12 months.

Three level II studies compared kyphoplasty with vertebroplasty.[19-21] These studies were inconsistent in design and outcome. In the first study, patients were treated at a median of 8 weeks after fracture.[19] No

conservative treatment control group was included. Kyphoplasty was favored over vertebroplasty when pain was measured out to 2 years. Repeat kyphoplasty in this study was a confounding factor. In the second study, 21 patients were treated.[21] Both groups experienced similar pain relief at 6 months, although there was insufficient power to find a difference. In the third and most recent study, 100 patients received either kyphoplasty or vertebroplasty within 43 days of fracture.[20] There was no difference in pain outcomes between the treatment groups at 3 days and 6 months.

When considering the technical similarities between kyphoplasty and vertebroplasty and the unique recommendations for their use within this guideline, several points deserve mention. The comparison of vertebroplasty to a sham procedure confirms the lack of benefit from vertebroplasty for critical outcomes. Both procedures were compared with similar control groups. In the case of kyphoplasty, the comparison to conservative treatment resulted in possibly clinically important differences for critical outcomes up to 12 months, whereas vertebroplasty compared with conservative treatment showed possibly clinically important differences for critical outcomes only at 1 day.

The direct comparison between vertebroplasty and kyphoplasty is logically consistent with the previous two points inasmuch as it shows a possibly clinically important advantage in critical outcomes for kyphoplasty at durations up to 2 years.

These points alone merit a Moderate strength recommendation for kyphoplasty due to the two level II studies, which compared kyphoplasty with conservative treatment. However, the comparisons between vertebroplasty and kyphoplasty are important. The results of the direct comparisons between kyphoplasty and vertebroplasty are not repeated across all studies, which lowers our confidence that future studies will confirm the results of the current evidence. Thus, the recommendation is downgraded from Moderate to Weak, and kyphoplasty is an option for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.

Recommendation 10

We are unable to recommend for or against improvement of kyphosis angle in the treatment of patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms.

Strength of Recommendation: Inconclusive

Rationale: We found no study that addressed sagittal balance correction and properly correlated kyphosis angle with any patient-oriented outcome. All studies retrieved for this recommendation either examined only a single vertebra as opposed to regional kyphosis or did not report the correlation between a change in kyphosis angle and a change in any patient-oriented outcome.

Recommendation 11

We are unable to recommend for or against any specific treatment of patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are not neurologically intact.

Strength of Recommendation: Inconclusive

Rationale: Patients who present with neurologic symptoms and osteoporotic spinal compression fractures clearly require treatment because they face pain, diminished function, and increased mortality.[10] However, despite the need to treat such patients, there is an absence of studies that examine which treatments are most effective for these patients. Therefore, we are unable to recommend for or against any specific treatment.

Future Research

The paucity of good quality research studies has limited the strength of the recommendations. This underscores the necessity for further work in this area. In particular, we hope that level I studies are performed to determine the effectiveness of modalities such as bracing, physical therapy/exercise, and kyphoplasty in the treatment of these fractures.

Our review suggests that radiographic fracture assessment is not a reliable surrogate measure of symptomatic fracture. In many of the studies we reviewed, the presence of a fracture on radiograph, even if chronic, was postulated to be the source of back pain symptoms with no clear rationale for that determination. This emphasizes the need for long-term prospective studies on the natural history of osteoporotic spinal insufficiency fractures. There are comments in the literature about various fracture parameters, such as type, location, and degree of kyphosis, as being clinically important. Unfortunately, this has not been adequately studied.

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