

Voting Questions

For each voting question, please use the following scale identifying your level of confidence - with a score of 1 being low or no confidence and 5 representing high confidence.

1 — 2 — 3 — 4 — 5
Low Intermediate High
Confidence Confidence

1. How confident are you that there is adequate published evidence percutaneous vertebroplasty improves health outcomes (symptom status, functional abilities, health related QOL) over nonsurgical management in select cases of osteoporotic vertebral compression fracture?
2. If less than intermediate confidence (< 3) is noted in question #1, how confident are you that each of the following concerns regarding percutaneous vertebroplasty has inadequate evidence?
 - a. Efficacy
 - b. Safety
3. If less than intermediate confidence (< 3) is noted in question #1, how confident are you that percutaneous vertebroplasty should only be performed within a clinical trial?
4. If less than intermediate confidence (< 3) is noted in question #1, how confident are you that each of the following additional percutaneous vertebroplasty evidence is needed?
 - a. Blinded randomized trials
 - b. Non-blinded randomized trials
 - c. Observational trials
 - d. Propensity-adjusted claims-based mortality data
 - e. Systematic reviews and meta-analyses
 - f. Registries
5. How confident are you that there is adequate published evidence percutaneous kyphoplasty improves health outcomes (symptom status, functional abilities, health related QOL) over nonsurgical management in select cases of osteoporotic vertebral compression fracture?

Discussion:

If the result of questions #1 and #5 was at least intermediate confidence (≥ 3), please discuss clinical parameters that would impact the choice of kyphoplasty or vertebroplasty.

6. If less than intermediate confidence (< 3) is noted in question #5, how confident are you that each of the following concerns regarding percutaneous kyphoplasty has inadequate evidence?
 - a. Efficacy
 - b. Safety
7. If less than intermediate confidence (< 3) is noted in question #5, how confident are you that percutaneous kyphoplasty should only be performed within a clinical trial?
8. If less than intermediate confidence (< 3) is noted in question #5, how confident are you that each of the following additional percutaneous kyphoplasty evidence is needed?
 - a. Blinded randomized trials
 - b. Non-blinded randomized trials
 - c. Observational trials

- d. Propensity-adjusted claims-based mortality data
 - e. Systematic reviews and meta-analyses
 - f. Registries
9. If at least intermediate confidence (≥ 3) is noted in question #1 or #5, how confident are you that there is sufficient published evidence that use of percutaneous vertebral augmentation (PVA) should be limited to each of the following fracture duration?
- a. Acute (< 6 wks.)
 - b. Subacute (6-12 wks.)
 - c. Chronic (> 12 wks.)
 - d. Timing is secondary to radiographic features and clinical presentation
10. If at least intermediate confidence (≥ 3) is noted in question #1 or #5, how confident are you that there is adequate published evidence each of the following nonsurgical management intervals be attempted, without success, before PVA?
- a. 0 days
 - b. 1-7 days
 - c. 1-3 weeks
 - d. 3-6 weeks
 - e. > 6 weeks

Discussion:

For each interval above that receives intermediate confidence (≥ 3), please discuss clinical parameters that would impact length of nonsurgical management.

11. How confident are you that there is adequate published evidence that each of the following nonsurgical managements should be attempted?
- a. Bed rest
 - b. Non-opioid analgesics
 - c. Opioid analgesics
 - d. Bracing
 - e. Physical therapy
 - f. Periosteal infiltration of local anesthetic on the pedicle
 - g. Anti-osteoporosis therapy
12. How confident are you that there is sufficient published evidence that each of the below is a reliable, valid and meaningful indicator of failed nonsurgical management?
- a. Pain precluding ambulation
 - b. Pain precluding physical therapy
 - c. Unacceptable side effects from nonsurgical management
 - d. Progression of vertebral height loss
 - e. Persistence of at least moderate pain (VAS ≥ 5)
 - f. Worsening kyphosis
13. How confident are you that each of the below specialists should be involved in the decision to use vertebral augmentation?
- a. Radiologist
 - b. Neurologist
 - c. Spine surgeon
 - d. Referring physician
 - e. Treating physician only
14. How confident are you that there is adequate published evidence these conclusions are generalizable to the Medicare patient population?

Additional Discussion Topics

1. What significant evidence gaps exist regarding the clinical criteria of individuals who should receive vertebral augmentation?
2. How important do you consider the claims-based data which suggests that kyphoplasty and vertebroplasty have a mortality advantage over non-surgical management?
3. Is vertebral augmentation indicated for patients requiring hospitalization for pain management?
4. Are more trials on exercise or rehabilitation interventions needed and will they be done?