Medical Policy Manual Surgery, Policy No. 107

Percutaneous Vertebroplasty, Kyphoplasty, Sacroplasty, and Coccygeoplasty

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

These procedures involve the injection of a polymethylmethacrylate (PMMA), a cement, into a fractured or weakened vertebral body to provide stabilization as an alternative to spinal fusion.

MEDICAL POLICY CRITERIA

I. Percutaneous vertebroplasty, balloon kyphoplasty, or mechanical vertebral augmentation using Kiva® may be considered **medically necessary** when either of the following criteria (A. or B.) are met:

   A. Treatment of *no more than* three symptomatic vertebral fractures of the T5-L5 spine, on any single date of service, when **all** of the following (1 – 5) criteria are met:

      1. Appropriate imaging (plain film x-ray, MRI, CT, or bone scan) has been performed preoperatively and the findings of such imaging correlate with the patient's pain; and

      2. Patient's pain is more likely than not, related to the demonstrated fracture(s); and

3. Functional impairment attributed to vertebral fracture is documented in the clinical record as limiting performance of instrumental activities of daily living (ADLs). Instrumental ADLs are defined as feeding, bathing, dressing, grooming, meal preparation, household chores, and occupational tasks that are required as a daily part of job functioning.

   Clinical records must specifically document the following:

   a. The specific instrumental ADL(s) that is(are) impaired; and

   b. A description of how performance of the instrumental ADL is limited.

4. The patient has failed to respond to conservative treatment (e.g., analgesics, physical therapy, rest) for at least six weeks; and

5. A pre-procedure assessment has documented the absence of the following contraindications:

   a. Untreated symptomatic foraminal or canal stenosis, facet arthropathy, or other significant coexistent spinal or bony pain generators at the planned treatment level

   b. Bone fragment retropulsion

   c. Symptoms that cannot be related to a fracture

   d. Unstable fracture or requirement for stabilization procedure in same or adjacent spinal region

   e. Active osteomyelitis whether fungal, bacterial or mycobacterial, or any other active infection, including urinary tract infection (UTI)

   f. Presence of painful metastases to areas other than the spine, spinal cord compression, primary bone and osteoblastic tumors, solitary plasmacytomas

   g. Uncorrected coagulation disorders

   h. Known allergy to any of the materials used in these procedures

   i. Chronic fracture at the same vertebral level (defined as greater than six months)

B. Treatment of symptomatic osteoporotic vertebral fractures that are less than 6 weeks in duration that have led to hospitalization or symptoms documented to persist at a level that prevents ambulation or transfers without assistance.

II. Percutaneous vertebroplasty, balloon kyphoplasty, or mechanical vertebral augmentation using Kiva® is considered **investigational** for all other indications, including but not limited to the following:

A. Vertebral hemangioma

B. Acute vertebral fractures due to trauma

C. Vertebrae of the cervical spine and thoracic levels T1-5

D. Stabilization of insufficiency fractures or lesions of the sacrum (sacroplasty) or coccyx (coccygeoplasty)

E. Prophylactic treatment for osteoporosis of the spine or for chronic back pain of long-standing duration, even if associated with old compression fracture(s).

III. Percutaneous mechanical vertebral augmentation using any device other than a balloon device is considered **investigational**, including but not limited to the following:

A. Radiofrequency-assisted vertebral augmentation with ultrahigh viscosity cement, including but not limited to Radiofrequency-Targeted Vertebral Augmentation™ (RF-TVA™) with the StabiliT® System

B. Vertebral body stenting

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Current Symptomology
- Imaging completed (plain film x-ray, MRI, CT or bone scan)
- Description of functional impairment and how it limits instrumental ADLs
- Conservative treatments (e.g., analgesics, physical therapy, rest) attempted for at least six weeks and documented response
- Pre-procedure Assessment documenting absence of contraindications outlined in criteria I.A.5. a-i

CROSS REFERENCES

1. Sacroiliac Joint Fusion, Surgery, Policy No. 193

BACKGROUND

Percutaneous vertebroplasty, vertebral balloon kyphoplasty, and mechanical augmentation have been proposed as options to provide mechanical support and symptomatic pain relief in patients with osteoporotic vertebral compression, insufficiency fractures, vertebral hemangioma, or osteolytic lesions of the spine (i.e., multiple myeloma or metastatic malignancies). These procedures, sometimes referred to as vertebral augmentation, have been used in all levels of the spinal column including the sacrum and coccyx. When vertebroplasty or kyphoplasty is used to treat insufficiency fractures of the sacrum or coccyx they may be referred to as sacroplasty or coccygeoplasty, respectively.

- Percutaneous vertebroplasty is an interventional radiology technique involving the fluoroscopic- or CT-guided injection of polymethylmethacrylate (PMMA) through a needle inserted into a weakened vertebral body.
- Percutaneous kyphoplasty is a variant of vertebroplasty that is intended to restore the vertebral body height and alignment along with stabilizing the fracture, using one of the following techniques:
  - Balloon kyphoplasty involves the use of a specialized bone tamp with an inflatable

balloon to expand a collapsed vertebral body. PMMA is then injected into the created cavity to stabilize the vertebral body.

- Mechanical kyphoplasty describes techniques that do not involve a balloon device.
  - In radiofrequency kyphoplasty, ultrahigh viscosity cement is injected into the fractured vertebral body. Radiofrequency energy is used to achieve the desired cement consistency. The ultrahigh viscosity cement is intended to restore height and alignment to the fractured vertebra, along with stabilizing the fracture.
  - The Kiva® procedure uses shaped memory coil and a Kiva implant inserted into the vertebral body for structural support and to provide a reservoir for injection of bone cement. The proposed benefit of this technique is the adjustable height of the implant, which is made from a biocompatible polymer (e.g., PEEK-OPTIMA®), and a potential reduction in cement leakage.
  - Vertebral body stenting utilizes an expandable scaffold instead of a balloon to restore vertebral height. The proposed advantages of vertebral body stenting are to reduce the risk of cement leakage by formation of a cavity for cement application and to prevent the loss of correction that is seen following removal of the balloon used for balloon kyphoplasty.

Although the mechanism is unknown, percutaneous vertebroplasty and kyphoplasty are intended to provide analgesic effect either through mechanical stabilization of a fractured or otherwise weakened vertebral body or through thermal damage to intraosseous nerve fibers, since PMMA undergoes a heat-releasing (exothermic) reaction during its hardening process.

REGULATORY STATUS

Percutaneous vertebroplasty and kyphoplasty are surgical procedures and therefore, they are not subject to U.S. Food and Drug Administration (FDA) approval. However, the instruments and materials used within these procedures are subject to FDA approval. The Kiva® VCF Treatment System (Benvenue Medical) received FDA 510(k) marketing clearance in 2014. These systems, or rather the instruments and materials, are approved under FDA product codes: NDN, OAR, and HXG.

Instruments

Various systems for percutaneous vertebral body access and delivery of bone cement for vertebroplasty have received FDA approval. The Parallax® Contour® Vertebral Augmentation device one such example. This device creates a void in cancellous bone that can then be filled with bone cement. The void is created by removal of bone fragments; unlike balloon kyphoplasty, this procedure does not attempt to restore vertebral body height.

Percutaneous kyphoplasty requires the use of an inflatable bone tamp. One such tamp, the KyphX® inflatable bone tamp, received 510(k) marketing clearance from the FDA in July 1998. Other devices with FDA 510(k) marketing clearance include AVAmax® Vertebral Balloon system (Carefusion), NeuroTherm Parallax® Balloon Inflatable Bone Tamp (NeuroTherm, Inc.), Stryker iVAS® Balloon catheter, and Synthes Synflate™ Vertebral Balloon System (Synthes).

Bone cement

PMMA bone cement was available as a drug product prior to enactment of the FDA's device regulation and was at first considered what the FDA terms a "transitional device." It was transitioned to a class III device requiring premarketing applications. Several orthopedic

companies have received approval of their bone cement products since 1976. In October 1999, PMMA was reclassified from class III to class II, which requires future 510(k) submissions to meet “special controls” instead of “general controls” to assure safety and effectiveness. PMMA bone cements such as KyphX® HV-RTM, Kyphon® HV-R Bone Cement, Cortoss® Bone Augmentation Material, Spine-Fix® Biomimetic Bone Cement, StabiliT®, and Osteopal® V were issued 510(k) marketing clearance for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

Vesselplasty using Vessel-X®, (MAXXSPINE) and a similar procedure from A-Spine, are variations of vertebroplasty that are reported to reduce leakage of bone cement by containing the filler in an inflatable vessel. FDA clearance these products have not been identified.

EVIDENCE SUMMARY

For treatment of vertebral body fractures related to osteoporosis or malignancy with percutaneous vertebroplasty (VP), kyphoplasty (KP), or Kiva, the primary beneficial outcomes of interest are relief of pain and improvement in ability to function. Data from large, blinded, randomized controlled trials (RCTs) of sufficient long-term follow-up are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from vertebroplasty or kyphoplasty provides improves net health outcomes compared to sham or nonsurgical treatment. Further, adverse events, such as risk of additional fractures or cement leakage, must be considered in evaluating the benefits compared to the potential harms of these procedures. Therefore, the focus of the evidence summary below is on systematic reviews, technology assessments, RCTs, and clinical practice guidelines.

PERCUTANEOUS VERTEBROPLASTY

SYSTEMATIC REVIEWS

Xie (2017), in a meta-analysis of RCTs, evaluated efficacy and safety in percutaneous vertebroplasty and conservative treatment for patients with osteoporotic vertebral compression fractures.[1] Thirteen studies were selected (total N=1231 patients; 623 to vertebroplasty, 608 to conservative treatment); among them were the two sham-controlled trials described below. Outcomes included pain relief (from one week to six months), quality of life assessments, and the rate of adjacent-level vertebral fracture. Vertebroplasty was superior for pain relief at 1 week (mean difference [MD], 1.36; 95% CI, 0.55 to 2.17) and one month (MD=1.56; 95% CI, 0.43 to 2.70); it was inferior to conservative treatment for pain relief at six months (MD = -1.59; 95% CI, -2.9 to -0.27; $p<0.05$). Vertebroplasty showed improvement over conservative treatment for quality of life, as measured using the Quality of Life Questionnaire of the European Foundation for Osteoporosis (MD = -5.03; 95% CI, 7.94 to -2.12). No statistically significant differences were found between treatments for the rate of adjacent-level vertebral fractures (relative risk: 0.59; 95% CI, 0.43 to 0.81). Limitations included inclusion of several studies with inadequate blinding and heterogenous reporting of patient characteristics outcomes.

A 2015 Cochrane review by Buchbinder evaluated the evidence on vertebroplasty for the treatment of vertebral compression fractures.[2] Eleven RCTs and one quasi-RCT were included in the systematic review. Two trials identified compared vertebroplasty with a sham procedure (n=209 patients; Buchbinder [2009][3] and Kallmes [2009][4], detailed below), six compared vertebroplasty with usual care (n=566), and four compared vertebroplasty with kyphoplasty (n=545). The sham-controlled trials were at low risk of bias. All other trials were

judged to be at high risk of bias due to lack of blinding. Evidence was rated as moderate quality based on the low number of subjects in the sham controlled trials. Meta-analysis of the two sham-controlled trials indicated that vertebroplasty does not result in clinically significant improvements in pain, disability, quality of life, or treatment success. Results did not differ for patients with pain durations of six weeks or less compared to pain lasting more than six weeks. Sensitivity analysis indicated that studies comparing vertebroplasty to conservative management were likely to have overestimated the treatment effect. The rate of serious adverse events did not differ significantly between the vertebroplasty and control groups, but serious adverse events related specifically to the vertebroplasty procedure included osteomyelitis, cord compression, thecal sac injury, and respiratory failure.

In 2011, Staples published a patient-level meta-analysis of the two sham-controlled trials to determine whether vertebroplasty is more effective than sham in specific subsets of patients.[5] This subset analysis focused on duration of pain (< 6 weeks vs. > 6 weeks) and severity of pain (score < 8 or >8 on an 11-point numerical rating scale). Included in the analysis were 209 participants, 27% with pain of recent onset and 47% with severe pain at baseline. The primary outcome measures, pain scores and function on the RMDQ at one month, were not significantly different between groups. Responders' analyses were also conducted based on a 3-unit improvement in pain scores, a 3-unit improvement on the RMDQ, and a 30% improvement in each of the pain and disability outcomes. The only difference observed between groups was not statistically significant. This difference was a higher proportion of the vertebroplasty group achieving at least 30% improvement in pain scores, a result that may have been confounded by the greater use of opioid medications in that group. Overall, this analysis did not support the hypothesis that selected subgroups of patients, including those with pain of six weeks duration or less or those with severe pain, would benefit from vertebroplasty.

A systematic review of the safety and efficacy of vertebroplasty in malignancy was reported by Chew in 2011.[6] Thirty relevant studies were identified, totaling 987 patients. Included in the review were a single randomized controlled trial and seven prospective studies. Most centers reported treating no more than four vertebrae per session. Pain reduction ranged from 20% to 79%. Five deaths were attributable to vertebroplasty, two from chest infections following general anesthesia, one from a cement pulmonary embolus, and two from sepsis after emergency spinal decompression. Another 19 patients suffered a serious complication related to the procedure, with 13 requiring emergency spinal decompression. Reports of complications occurred most in studies with a mean cement volume of more than 4 ml, suggesting a possible association between the volume of cement injected and increased risk of adverse events.

RANDOMIZED CONTROLLED TRIALS

Select randomized controlled trials not already included in the systematic reviews above are detailed in this section. Two other RCTs by Buchbinder (2015) and Kallmes (2009) were included in the systematic reviews above.[2,4]

Randomized Controlled Trials with Sham Controls

In 2016, Clark reported results from the VAPOUR trial.[7] VAPOUR was a multicenter double-blind trial of vertebroplasty in 120 patients with vertebral fractures of less than six weeks in duration and back pain of at least 7 out of 10 on an NRS. Two authors had participated in the 2009 study published by Kallmes and the trial followed a similar protocol. Both outcomes assessors and patients were masked to treatment allocation, and independent statisticians

unmasked the data and prepared the trial report. The sham-vertebroplasty procedure included subcutaneous lidocaine but no periosteal numbing. Manual skin pressure and tapping on the needle was performed to simulate the needle advance, and the investigators discussed polymethylmethacrylate (PMMA) mixing and injection during the procedure. The primary outcome, the percentage of patients with an NRS score less than 4 out of 10 at 14 days after the procedure, was met in a greater percentage of patients in the vertebroplasty group (44%) than in the sham control group (21%). This between-group difference was maintained through six months. Other outcome measures were significantly improved in the vertebroplasty group at one or both time points. The benefit of vertebroplasty was found predominantly in the thoracolumbar subgroup, with 48% (95% CI, 27% to 68%) more patients meeting the primary endpoint (61% in the vertebroplasty group vs 13% in the control group). The investigators commented that the thoracolumbar junction is subject to increased dynamic load, and fractures at this junction have the highest incidence of mobility. No benefit from vertebroplasty was found in the non-thoracolumbar subgroup. Postprocedural hospital stay was reduced from a mean of 14 days in the control group to 8.5 days after vertebroplasty, even though physicians who determined the discharge date remained blinded to treatment. In the vertebroplasty group, there were two serious adverse events due to sedation and transfer to the radiology table. In the control group, two patients developed spinal cord compression; one underwent decompressive surgery and the other, not a surgical candidate, became paraplegic.

Kroon (2014) reported the 12- and 24-month outcomes of a double-blind RCT comparing VP (n=38) with sham procedure (n=40) for acute osteoporotic vertebral fractures.[8] The initial report of 6-month outcomes (Buchbinder 2009[3]) found no benefit of VP over sham procedure. Complete data were available for 67 (86%) and 57 (73%) of participants at 12 and 24 months, respectively. VP patients had significantly higher overall pain reduction at both time points compared to sham. There were no significant between-group differences in disability, quality of life, perceived recovery, or adverse event including subsequent vertebral fractures. The authors concluded that these outcomes provide evidence that use of VP as routine care for vertebral fractures is unsupported. Methodological limitations in the RCT included small sample size that may have had inadequate power to show significant differences in subsequent vertebral fractures.

Randomized Controlled Trials without Sham Controls

In 2016, Leali published a short report of a multicenter RCT with 400 patients with osteoporotic thoracic or lumbar vertebral compression fractures who were treated with vertebroplasty or conservative therapy.[9] Fractures were treated within two weeks of onset of pain. Details of randomization and rate of follow-up were not reported. At one day after treatment, the vertebroplasty group had a reduction in pain scores and improvement in physical function, with VAS pain scores decreasing from 4.8 (5.0 max) to 2.3 (p=0.023.) and the Oswestry Disability Index (ODI) improving from 53.6% to 31.7% (p=0.012). Sixty-five percent of patients treated with vertebroplasty had stopped all analgesics within 48 hours. The conservatively group showed no benefit in the first 48 hours, but by six weeks VAS and ODI scores were described as similar in the two groups (specific data was not reported). Evaluation of this study is limited by the incomplete reporting.

A 2016 RCT by Yang compared vertebroplasty to conservative therapy in 135 patients over 70 years of age with severe back pain due to an osteoporotic vertebral fracture after minor or mild trauma.[10] Vertebroplasty was performed at a mean of 8.4 days after pain onset. Patients in the conservative therapy group were placed in bedrest for at least two weeks after diagnosis

with analgesics, followed by bracing and assistive devices. All patients receiving vertebroplasty could stand and walk with a brace at one day posttreatment while only 12 (23.5%) patients could stand up and walk after 2 weeks of bedrest. The average duration of bedrest from pain onset was 7.8 ± 4.7 days (range, 2-15 days) in the vertebroplasty group compared to 32.5 ± 14.3 days (range, 14-60 days) in the conservative therapy group. At 1-year follow-up, there was a similar percentage of additional compression fractures, but a significantly higher complication rate in the conservative therapy group (35.3%) compared to the vertebroplasty group (16.1%; p<0.001). Complications included pneumonia, urinary tract infection, deep vein thrombosis, depression, and sleep disorders.

In 2014, Chen reported a nonblinded RCT comparing VP with conservative management.[11] Included patients (n=89) had MRI-confirmed chronic compression fractures with persistent severe pain for 3 months or longer. At 12 months follow-up, pain scores decreased from 6.5 to 2.5 in the VP group and from 6.4 to 4.1 in the control group (p<0.001). Complete pain relief was reported by 84.8% of VP patients and 34.9% of controls. The final Oswestry Disability Index (ODI) score in the VP group and the conservative management group was 15 and 32.1, respectively (p<0.001) and the final Roland Morris Disability Score was 8.1 and 10.7, respectively (p<0.001).

In 2011, Farrokhi reported blinded RCT that compared vertebroplasty with optimal medical management in 82 patients.[12] Patients had painful osteoporotic vertebral compression fractures that were refractory to analgesic therapy for at least four weeks and less than one year. The patients and the physicians involved in the treatment of the patients were not aware of the treatment that the other group was receiving. Control of pain and improvement in quality of life were measured by independent raters before treatment and at one week and 2, 6, 12, 24, and 36 months after the beginning of treatment. Radiologic evaluation to measure vertebral body height and correction of deformity was performed before and after treatment and after 36 months of follow-up. At one week, the mean VAS score decreased from 8.4 to 3.3 in the vertebroplasty group and from 7.2 to 6.4 in the conservative management group, with between-group differences that remained significant through 6 months of follow-up. Group differences on the Oswestry Disability Index lower back pain score were significantly lower in the vertebroplasty group throughout the 36 months of the study. New symptomatic adjacent fractures developed in one patient (2.6%) in the vertebroplasty group and six patients (15.4%) in the conservative management group. In one patient, epidural cement leakage caused severe lower-extremity pain and weakness that was treated with bilateral laminectomy and evacuation of bone cement.

VERTOS II, reported by Klazen in 2010, was an open-label randomized trial of 202 patients at 6 hospitals in the Netherlands and Belgium.[13] Out of 431 patients who were eligible for randomization, 229 (53%) had spontaneous pain relief during assessment. Participants with at least one painful osteoporotic vertebral fracture of six weeks or less in duration were assigned to undergo vertebroplasty or conservative management (ie, bedrest, analgesia, cast, physical support). The primary outcome was pain relief of 3 points measured on a 10-point VAS at one month and one year. A sample size of 100 per group was calculated to provide sufficient power to show a 25% difference in pain relief. All analyses were performed according to ITT principles. Clinically significant pain relief was defined as 30% change on the VAS (0-10 scale).

One hundred one subjects were enrolled into the treatment group and 101 into the control arm; 81% completed 12-month follow-up. There were no significant differences in the primary

outcome (pain relief of 3 points) measured at one month and one year. Vertebroplasty resulted in greater pain relief than did medical management through 12 months (<0.001); there were significant between group differences in mean VAS score at one month (2.6; 1.74 to 3.37; p<0.001) and at one year (2.0; 1.13 to 2.80; p<0.001). Survival analysis showed significant pain relief was quicker (29.7 vs 115.6 days) and was achieved in more patients after vertebroplasty than after conservative management.

Yi (2014) assessed the occurrence of new vertebral compression fractures after treatment with cement augmenting procedures (vertebroplasty or kyphoplasty) versus conservative treatment in an RCT with 290 patients (363 affected vertebrae).[14] Surgically treated patients were discharged the next day. Patients treated conservatively (pain medication, bedrest, body brace, physical therapy) had a mean length of stay of 13.7 days. Return to usual activity occurred at one week for 87.6% of operatively treated patients and at two months for 59.2% of conservatively treated patients. All patients were evaluated with radiographs and MRI at six months and then at yearly intervals until the last follow-up session. At a mean follow-up of 49.4 months (range, 36-80 months), 10.7% of patients had experienced 42 new symptomatic vertebral compression fractures. There was no significant difference in the incidence of new vertebral fractures between the operative (18 total; 9 adjacent, 9 nonadjacent) and conservative (24 total; 5 adjacent, 16 nonadjacent, 3 same level) groups, but the mean time to a new fracture was significantly shorter in the operative compared with nonoperative group (9.7 months vs 22.4 months).

SECTION SUMMARY

It remains unclear whether vertebroplasty provides additional beneficial effects compared to sham procedure for painful osteoporotic compression fractures. Findings from the most recent RCTs concur with earlier nonrandomized reports that vertebroplasty may be associated with significant improvements in pain and/or function. However, the lack of significant improvements in pain or function in the sham-controlled trials and in some other RCTs is suggestive that this treatment effect may not be universal. In addition, it remains unclear whether the potential benefits of the procedure outweigh harms (such as risk of additional vertebral fractures). Despite these concerns, use of VP has become increasingly widespread as a treatment of refractory vertebral fracture.

BALLOON KYPHOPLASTY

SYSTEMATIC REVIEWS

In a Bayesian network meta-analysis, Zhao (2017) examined the efficacy and safety of vertebroplasty, kyphoplasty, and conservative treatment (CT) for the treatment of osteoporotic vertebral compression fractures.[15] Sixteen RCTs were identified (total N=2046 participants; vertebroplasty, 816; kyphoplasty, 478; CT = 752). Eleven of the RCTs compared vertebroplasty with CT; two RCTs compared kyphoplasty with CT; and three RCTs compared kyphoplasty with vertebroplasty. Each trial assessed at least one of the following: VAS, the RMDQ, the European Quality of Life-5 Dimensions (EQ-5D), and the observance of any new fractures. Network meta-analysis demonstrated that kyphoplasty was superior to conservative therapy as assessed by VAS (mean difference [MD], 0.94; 95% CI, -0.40 to 2.39), EQ-5D (MD -0.10; 95% CI, -0.17 to -0.01), and RMDQ (MD=5.72; 95% CI, 1.05 to 10.60). Insufficient data were present to complete pairwise comparison of kyphoplasty with CT for some metrics. No significant differences were found between vertebroplasty and kyphoplasty for pain relief, daily function, and quality of life. Kyphoplasty was associated with the lowest risk of new fractures,

while vertebroplasty was the most effective treatment for pain relief. This review was limited by significant heterogeneity across measured outcomes and length of follow-up in studies; the presence of performing and reporting bias in studies was also a concern.

Huang (2014) published a systematic review with meta-analysis evaluating whether unilateral or bilateral KP was superior for effectiveness and safety.[16] No large studies were found that directly compared these two approaches. Five studies with 253 patients met inclusion criteria. No clinically significant difference between unilateral and bilateral KP was found for improvement in pain and function, kyphosis angle reduction, and anterior vertebral height restoration. The rate of adverse events was also similar between the two approaches. However, the quality of the evidence was graded as very low and the authors recommended high-quality RCTs be conducted to resolve this question.

RANDOMIZED CONTROLLED TRIALS

In 2009, Wardlaw reported on the findings of the FREE trial, a nonblinded industry-sponsored multisite RCT in which 300 adult participants with 1 to 3 painful osteoporotic vertebral compression fractures (VCF) of less than 3 months in duration were assigned to undergo kyphoplasty or conservative care.[17] Twenty-four-month results of this study were reported by Boonen in 2011 and by Van Meirhaeghe in 2013.[18,19] Scores for the primary outcome, 1-month change in 36-Item Short-Form Health Survey (SF-36) Physical Component Summary (PCS) score, were significantly higher for those in the kyphoplasty group. The difference between the 2 groups was 5.2 points (95% confidence interval, 2.9 to 7.4; $p<0.001$). Kyphoplasty was associated with greater improvements in SF-36 PCS scores at 6-month follow-up (3.39 points), but not at 12 or 24 months. Greater improvement in back pain was observed over 24 months for kyphoplasty (-1.49 points) and remained statistically significant at 24 months. Participants in the kyphoplasty group also reported greater improvements in quality of life and Roland-Morris Disability Questionnaire (RMDQ) score at short-term follow-up. At 12 months, fewer kyphoplasty patients (26.4% vs 42.1%) had received physical therapy or walking aids, back braces, wheelchairs, miscellaneous aids, or other therapy. Fewer kyphoplasty patients used opioid medications through 6 months (29.8% vs 42.9%) and fewer pain medications through 12 months (51.7% vs. 68.3%). Other differences between the groups were no longer apparent at 12 months; possibly due to natural healing of fractures.

In 2011, Berenson published results from an international randomized multicenter clinical trial.[20] They enrolled 134 patients with cancer who were at least 21 years of age. Participants had at least one and not more than 3 painful vertebral compression fractures (VCF). (These appear to be due to osteoporosis, rather than from a metastatic lesion.) The primary outcome was change in functional status from baseline at 1 month as measured by the Roland Morris Disability Questionnaire (RMDQ). Treatment allocation was not blinded, and the primary outcome at 1 month was analyzed using all participants with data both at baseline and at 1 month. Crossover to the balloon kyphoplasty arm was allowed after 1 month. The authors report baseline scores in the kyphoplasty and nonsurgical groups of 17.6 and 18.2, respectively and 9.10 and 18.0 at 1-month follow-up. P-value for the between group difference in scores p=0.0001. However, conclusions based upon this trial are limited due to lack of blinding and short-term (one month) follow-up.

In 2011, Edidin reported mortality risk in Medicare patients who had VCFs and had been treated with vertebroplasty, kyphoplasty, or nonoperatively.[21] This study was industry-funded. Using the U.S. Medicare dataset, they identified 858,978 patients who had VCFs between

2005 and 2008. The data set included 119,253 kyphoplasty patients and 63,693 vertebroplasty patients. Survival was calculated from the index diagnosis date until death or the end of follow-up (up to 4 years). Cox regression was used to evaluate the joint effect of multiple covariates, which included sex, age, race/ethnicity, patient health status, type of diagnosed fracture, site of service, physician specialty, socioeconomic status, year of diagnosis, and census region. After adjusting for covariates, patients in the operated cohort (vertebroplasty or kyphoplasty) were found to have a higher adjusted survival rate (60.8%) than patients in the nonoperated cohort (50.0%) and were 37% less likely to die. The adjusted survival rates for vertebroplasty or kyphoplasty were 57.3% and 62.8%, respectively, a 23% lower relative risk for kyphoplasty. As noted by the authors, a causal relationship cannot be determined from this study.

SECTION SUMMARY

Two moderate-sized unblinded RCTs compared kyphoplasty to conservative care and found short-term benefits in pain and other outcomes. Other RCTs, as summarized in a meta-analysis, reported that outcomes for kyphoplasty and vertebroplasty are similar. Two randomized trials that compared mechanical vertebral augmentation (Kiva) to kyphoplasty reported similar outcomes for the two procedures. A major limitation of the RCTs is the lack of a comparator sham procedure. Due to the possible placebo effect observed in the recent trials of vertebroplasty, the validity of results from non-sham-controlled trials are questionable. There are no RCTs of kyphoplasty for vertebral body metastasis. However, as with vertebroplasty, the use of kyphoplasty has become increasingly widespread as a treatment of refractory vertebral fracture.

MECHANICAL VERTEBRAL AUGMENTATION WITH KIVA®

SYSTEMATIC REVIEWS

No systematic reviews of mechanical vertebral augmentation with the Kiva® were identified.

RANDOMIZED CONTROLLED TRIALS

Tutton (2015) published results from an RCT that where vertebral augmentation with the Kiva® VCF System® was compared with balloon kyphoplasty in the KAST trial, a 2015 pivotal non-inferiority RCT.[22] This industry-sponsored multicenter open-label trial was conducted in 300 patients with one or two osteoporotic vertebral compression fractures. The Kiva group included 153 patients and the KP group included 147 patients. Included were patients with VAS for back pain of at least 70 mm out of 100 after two to six weeks of conservative care or a VAS of at least 50 mm after six weeks of conservative care, and an ODI of at least 30%. The primary endpoint at 12 months was a composite of a reduction in fracture pain by at least 15 mm on VAS, maintenance or improvement in function on ODI, and absence of device-related serious adverse events. The primary endpoint was met for 94.5% of patients treated with Kiva® and 97.6% of patients treated with kyphoplasty (Bayesian posterior probability of 99.92% for non-inferiority, using as-treated analysis). In the 285 treated patients, Kiva® resulted in a mean improvement of 70.8 points in VAS, compared with a 71.8 point improvement for kyphoplasty. There was a 38.1 point improvement in ODI for the Kiva® group, compared to a 42.2 point improvement for the kyphoplasty group. There were no device-related serious adverse events. The total volume of cement was 50% less with Kiva® and there was lower cement leakage compared with kyphoplasty (16.9% vs 25.8%, respectively).

In 2013, Korovessis reported a randomized trial comparing mechanical vertebral augmentation with the Kiva device versus balloon kyphoplasty in 180 patients with osteoporotic vertebral body fractures.[23] Mean follow-up was 14 months (range 13-15 months). The groups showed similar improvements in VAS for back pain, SF-36, and ODI. For example, there was a greater than 5.5 point improvement in VAS in 54% of patients in the Kiva group and 43% of patients in the balloon kyphoplasty group. Radiological measures of vertebral height were similar in the two groups. Kiva reduced the Gardner kyphotic angle, while residual kyphosis of more than five degrees was more frequently observed in the balloon kyphoplasty group. Patients and outcome assessors were reported to be unaware of the group assignment, although it is not clear if the Kiva device was apparent in the radiographs. Cement leakage into the canal occurred in two patients treated with balloon kyphoplasty, necessitating decompression, compared with none following the Kiva procedure.

SECTION SUMMARY

The Kiva procedure appears to be at least equivalent to KP in pain reduction and improved functional outcomes with a lower rate of cement leakage.

RADIOFREQUENCY-ASSISTED MECHANICAL VERTEBRAL AUGMENTATION

Current published evidence is limited to a few very small, short-term feasibility studies. These preliminary studies do not permit conclusions due to methodological limitations, including but not limited to the lack of randomized comparison to alternative treatments, small study populations, and the lack of long-term follow-up. One meta-analysis by Feng (2017) compared radiofrequency kyphoplasty with balloon kyphoplasty, however the conclusions are limited by the same methodological parameters outlined above.[24]

VERTEBRAL BODY STENTING

SYSTEMATIC REVIEW

In 2015, Martin-Lopez published results from a systematic review that examined the effectiveness and safety of stentoplasty in patients with osteoporotic vertebral body fractures.[25] Five studies were included in the review, two clinical trials and three observational studies. The authors found there was no difference between the two procedures in terms of reduction of kyphosis, time of exposure to radiation or postoperative loss of cement. Although stentoplasty in comparison to vertebroplasty showed an improvement of restoration of vertebral height (P=0.042), kyphosis correction and volume of bone cement, no differences were found between two procedures in terms of loss of vertebral body volume. Based on observational studies, stentoplasty improved vertebral height, pain and functional disability at six and 12 months follow-up, and corrected the angle vertebral fractures in\patients with osteoporotic vertebral body. The authors concluded that there was no advantage of stentoplasty over balloon kyphoplasty.

SACROPLASTY AND COCCYGEOPLASTY

Sacroplasty is an evolving technique with numerous methods (short axis, long axis, balloon-assisted short axis, and iliosacral screws). No randomized trials of sacroplasty have been reported. The evidence on sacroplasty is limited to several small case reports or series.[26-45] These initial pilot studies reported rapid pain relief with few complications. Due to the small

size of the evidence base, harms associated with sacroplasty have not been adequately studied. There are complications of cement leakage with sacroplasty that are not observed with vertebroplasty. Leakage of PMMA into the presacral space, spinal canal, sacral foramen, or sacroiliac joint may result in pelvic injection of PMMA, sacral nerve root or sacral spinal canal compromise, or sacroiliac joint dysfunction.[46] Coccygeoplasty has been reported, but no adequate clinical trial data has been published.

ADVERSE EVENTS

The most commonly reported adverse events for vertebroplasty or balloon kyphoplasty are new compression fractures and cement leakage. Cement leakage remains a concern, though it has been shown to be reduced in kyphoplasty relative to vertebroplasty. Most incidents of cement leakage were reported to be asymptomatic. In addition, there are case reports of cardiac perforation, cardiac tamponade, and embolism of cement into pulmonary vessels.

Zhang (2017) published a meta-analysis of comparative studies to evaluate the incidence of new vertebral fractures between vertebral augmentation, such as vertebroplasty and kyphoplasty, and no operation.[47] Twelve comparative studies were identified with a total of 1,328 patients (768 underwent operation and 560 did not undergo operation). There were no significant differences between groups for new nor existing vertebral fractures. In addition, there were no significant differences in bone mineral density (lumbar and femoral neck regions).

Zhan (2016) evaluated risk factors for cement leakage after vertebroplasty or kyphoplasty. Zhan conducted a systematic review with meta-analysis that included 32 studies with 2,872 patients.[48] Cement leakage incidence were 54.7% for vertebroplasty and 18.4% for kyphoplasty. The authors found that the significant risk factors were intravertebral cleft (OR=1.40; 95% CI, 1.09-1.78), cortical disruption (OR=5.56; 95% CI, 1.84-16.81), cement viscosity (OR=3.32; 95% CI, 1.36-8.07) and injected cement volume (WMD=0.59; 95% CI, 0.02-1.17). Other factors were not associated with significant risk including age, sex, and fracture type. The authors also concluded that more randomized controlled trials are needed to validate these findings.

Xiao (2015) published results from a systematic review and meta-analysis that compared complications between percutaneous vertebroplasty (PVP) and balloon kyphoplasty (BK) for the treatment of osteoporotic vertebral compression fractures.[49] Nineteen studies encompassing 1,787 patients (887 PVP, and 900 BKP) were included in the analysis. The authors reported that the two procedures suffer from equal risk of subsequent spinal fractures; however, PVP had a higher cement leakage rate when compare to BK.

Zhang conducted a systematic review with meta-analysis of four RCTs[3,13,50,51] (N=454) published through April 2013.[52] The aim was to analyze the causal relationship between vertebroplasty and new-onset vertebral fractures in osteoporotic vertebral fracture patients. Authors noted several limitations to the meta-analysis. The authors reported that the RCTs did not support a conclusion that VP significantly increased the occurrence of new postoperative or adjacent vertebral fractures. Due to inclusion of only four RCTs, some with modest sample sizes, could allow over- or under-estimation of results. In addition, there was heterogeneity between RCTs in fracture age, intervention, duration of follow-up, and study design. Attrition bias was also of concern due to moderately high drop-out rates.

Yi (2014) evaluated the occurrence of new vertebral compression fractures after treatment with cement augmenting procedures (vertebroplasty or kyphoplasty) versus conservative treatment in an RCT with 290 patients (363 affected vertebrae).[14] Patients treated conservatively (offered pain medication, bed rest, a body brace, and physiotherapy) had a mean length of stay of 13.7 days. Return to usual activity occurred at one week for 87.6% of operatively-treated patients and at two months for 59.2% of conservatively-treated patients. At a mean follow-up of 49.4 months (range, 36-80), 10.7% of patients had experienced 42 new symptomatic vertebral compression fractures. There was no significant difference in the incidence of new vertebral fractures between the operative (18 total, 9 adjacent and 9 nonadjacent) and conservative (24 total, 5 adjacent, 16 nonadjacent, and 3 same level) groups, but the mean time to a new fracture was significantly shorter in the operative compared to nonoperative group (9.7 vs 22.4 months).

In 2014 a study was published using the SWISSspine registry (SSR) which included 375 single-level osteoporotic vertebral fracture patients followed for a mean follow-up of 3.6 months following KP.[53] Post-KP adjacent segment fractures were found in 37 (10%) patients, occurring on average at 2.8 months postoperatively. Significant risk factors included preoperative segmental kyphosis >30 degrees (p=0.026), rheumatoid arthritis (p=0.038), and cardiovascular disease (p=0.047). Patients with postoperative adjacent segment fractures had significantly higher back pain at final follow-up.

In a retrospective analysis of 171 post-KP patients at a mean follow-up of 41 months, Civelek also found higher preoperative kyphotic angle to be a risk factor significantly associated with adjacent level fractures.[54] Female sex was also found to be a significant risk factor. The severity of osteoporosis was not a determining factor.

PRACTICE GUIDELINE SUMMARY

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

In 2010, the American Academy of Orthopaedic Surgeons (AAOS) Board of Directors approved a clinical practice guideline on the treatment of osteoporotic spinal compression fractures.[55] The Board approved a strong recommendation against the use of vertebroplasty for patients who “present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically ‘intact’.” This recommendation was based on five RCTs[3,4,56-58], two of which were graded Level I (defined as reliable), and three of which were graded Level II (defined as moderately reliable). In coming out with a strong recommendation, the committee expressed their confidence that future evidence is unlikely to overturn the existing evidence. The Board also downgraded the recommendation supporting the use of kyphoplasty from “moderate” to “limited” based upon low quality and inconclusive evidence comparing this procedure with conservative care and vertebroplasty, respectively.

AMERICAN SOCIETY OF ANESTHESIOLOGISTS AND THE AMERICAN SOCIETY OF REGIONAL ANESTHESIA AND PAIN MEDICINE

Practice guidelines from the American Society of Anesthesiologist (ASA) and the American Society of Regional Anesthesia and Pain Medicine (ASRA) support the use of “minimally invasive spinal procedures” (including vertebroplasty and vertebral augmentation), stating: “Consultants, ASA members, and ASRA members strongly agree that minimally invasive spinal procedures should be performed for pain related to vertebral compression fractures.”[59]

The practice guidelines go on to make the specific recommendation in favor of these procedures in “treatment of pain related to vertebral compression fractures” despite a review of the literature which found that available randomized sham-controlled trials had either not found differences associated with treatment groups, or that differences were inconsistent across available studies.

AMERICAN COLLEGE OF RADIOLOGY, AMERICAN SOCIETY OF NEURORADIOLOGY, AMERICAN SOCIETY OF SPINE RADIOLOGY, THE SOCIETY OF INTERVENTIONAL RADIOLOGY, AND THE SOCIETY OF NEUROINTERVENTIONAL SURGERY

The American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), the Society of Interventional Radiology (SIR), and the Society of NeuroInterventional Surgery (SNIS) along with the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CAN), and the Canadian Interventional Radiology Association (CIRA) published a joint position statement on percutaneous vertebral augmentation in 2014[60], which was revised in 2017[61]. This document states that percutaneous vertebral augmentation using vertebroplasty or kyphoplasty and performed in a manner in accordance with public standards is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures. The document also states that these procedures are offered only when nonoperative medical therapy has not provided adequate pain relief or pain is significantly altering the patient’s quality of life.

An updated 2012 joint practice guideline addresses the performance of vertebral augmentation in general and refers to all available percutaneous techniques used to achieve internal vertebral body stabilization, including vertebroplasty, balloon kyphoplasty, radiofrequency ablation and coblation, mechanical void creation, and injection of bone graft material or bone substitutes.[61] The ACR, ASN, ASSR, SIR, and SNIS consider vertebral augmentation to be an established and safe procedure, and provide guidelines for patient selection, qualifications and responsibilities of personnel, specifications of the procedure, equipment quality control, and quality improvement and documentation.

SOCIETY OF NEUROINTERVENTIONAL SURGERY

In 2014 the Society of NeuroInterventional Surgery (SNIS) published a report that included a systematic review with meta-analysis and the following recommendations:[62]

1. Kyphoplasty in selected patients is superior to conservative medical therapy in reducing back pain, disability and improving Karnofsky performance status and quality of life for patients with cancer
2. and disabling back pain from a vertebral fracture (AHA Class IIA, Level of Evidence B).
3. Vertebroplasty and kyphoplasty are reasonable therapeutic options in selected patients with cancer and severe back pain from a vertebral fracture that is refractory to conservative medical therapy (AHA Class IIA, Level of Evidence B).
4. Vertebroplasty and kyphoplasty are reasonable therapeutic options in selected patients with severe back pain from an osteoporotic vertebral fracture that is refractory to conservative medical therapy (AHA Class IIA, Level of Evidence B).

SOCIETY OF INTERVENTIONAL RADIOLOGY

In a 2014 quality improvement guideline on percutaneous vertebroplasty from SIR, vertebral augmentation was recommended for compression fractures refractory to medical therapy. Failure of medical therapy includes the following situations:[63]

1. Patients who are rendered nonambulatory because of pain from a weakened or fractured vertebral body, pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy;
2. Patients with sufficient pain from a weakened or fractured vertebral body that physical therapy is intolerable, pain persisting at that level despite 24 hours of analgesic therapy; or
3. Patient with a weakened or fractured vertebral body, and unacceptable side effects such as excessive sedation, confusion, or constipation because of the analgesic therapy necessary to reduce pain to a tolerable level.

AMERICAN COLLEGE OF RADIOLOGY

The American College of Radiology (ACR) published updated appropriateness criteria on the management of vertebral compression fractures in 2014.[64] While generally supportive of vertebroplasty and kyphoplasty in specified conditions, the guidelines state the following:

- Conservative management is the traditional first-line management for osteoporotic compression fractures.
- Controversy exists over the use of vertebral augmentation due to two previous independent level 1 trials that demonstrated no clinical validity for VP over the sham control groups. Conclusions from these studies have divided the medical community with respect to the efficacy of vertebral augmentation.
- Despite this controversy, increased use of vertebral augmentation for managing painful osteoporotic and malignant vertebral fractures has been the trend, with the literature favoring patient outcomes over conservative medical management up to 1 year.
- If VP is recommended for osteoporosis or malignant fractures, it should be used for patients who have failed or cannot tolerate conservative or traditional management.
- Kyphoplasty data are less extensive but have shown similar results to VP for uncomplicated vertebral compression fractures.
- Kyphoplasty may have an advantage over traditional VP in complex cases (e.g., burst fractures with neurological compromise) or fractures in which height restoration or deformity correction may be beneficial.
- This slight mechanical advantage over VP may also affect long-term outcomes.
- More level one studies are needed to determine the medical and societal cost of the palliative effect on pain related morbidity associated with osteoporotic vertebral compression fractures. Smaller sample studies and use trends indicate vertebral augmentation has benefits over conservative medical management for the first year.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

The National Institute for Health and Care Excellence (NICE) issued a 2013 technology appraisal guidance TA279, which stated that percutaneous vertebroplasty and percutaneous balloon kyphoplasty are recommended as treatment options for treating osteoporotic vertebral compression fractures in persons having severe, ongoing pain after a recent unhealed vertebral fracture, despite optimal pain management, and whose pain has been confirmed through physical exam and imaging to be at the level of the fracture. This appraisal does not

address balloon kyphoplasty with stenting, because the manufacturer of the stenting system (Synthes) states there is limited evidence for vertebral body stenting as it has only recently become available.[65]

In 2008, NICE issued CG75 on the diagnosis and management of adults with metastatic spinal cord compression. This guidance was last reviewed in 2014, and placed on the static list (no major ongoing studies identified and the next review will occur in 5 years). The guideline states that vertebroplasty or kyphoplasty should be considered for patients who have vertebral metastases, and no evidence of spinal cord compression or spinal instability, if they have mechanical pain resistant to conventional pain management and vertebral body collapse. Surgery should only be performed when all appropriate specialists, including the oncologist, interventional radiologist, and spinal surgeon agree. At present, there are relatively few patients in England receiving surgery; however, there is evidence to suggest that in a selected subset of patients, early surgery may be more effective at maintaining mobility than radiotherapy.[66]

SUMMARY

There is enough research to show that percutaneous vertebroplasty, kyphoplasty, or KIVA for the treatment of vertebral fractures improves health outcomes including but not limited to pain and/or function in select patients. The Kiva procedure may require less cement and result in fewer adverse events including cement leakage. In addition, practice guidelines recommend these procedures for vertebral fractures. Therefore, vertebroplasty, kyphoplasty, or KIVA may be considered medically necessary in select patients with vertebral fractures when policy criteria are met.

There is not enough research to show that percutaneous vertebroplasty, kyphoplasty, or KIVA for all other indications improves health outcomes including mechanical vertebral augmentation using techniques other than balloon kyphoplasty. In addition, there are no practice guidelines that recommend these techniques. Therefore, percutaneous vertebroplasty, kyphoplasty, or KIVA for all other indications is considered investigational including but not limited to percutaneous mechanical vertebral augmentation techniques using devices other than balloon devices (e.g., radiofrequency-assisted vertebral augmentation or vertebral body stents).

There is not enough research to show that sacroplasty or coccygeoplasty improves health outcomes. In addition, no practice guidelines recommend these procedures for any indication. Therefore, sacroplasty and coccygeoplasty are considered investigational.

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CODES

Codes	Number	Description
CPT	22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic
	22511	;lumbosacral
	22512	;each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)
	22513	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic
	22514	;lumbar

Codes	Number	Description
	22515	;each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)
	0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
	0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injection(s), including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed
HCPCS	None	

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