Washington State Health Care Authority

Final key questions

Vertebroplasty, kyphoplasty, or sacroplasty

May 14, 2024

Background

Vertebral compression fractures (VCFs) and sacral insufficiency fractures (SIF) often result in considerable pain, loss of function, and decreased quality of life. Patients with osteopenic vertebral or sacral fractures are at greater risk of morbidity and mortality, yet operative intervention (e.g., fusion with instrumentation) may be problematic in this elderly population, making less invasive methods more attractive. VCFs can also occur due to metastatic bone disease leading to disability and morbidity and again, operative interventions may not be feasible.

Vertebroplasty, kyphoplasty and sacroplasty are minimally invasive surgical procedures used to treat spinal pain believed to be caused by fractures in the vertebra or sacrum. These are all cementoplasty (augmentation) techniques intended to stabilize the fractured bone(s), but the mechanism of pain relief is not clear. Osteoporosis, vertebral metastasis and multiple myeloma are the most frequently reported indications for these procedures. Cementoplasty may reduce pain and improve stability of the bone.

Vertebroplasty involves injection of bone cement into a partially collapsed vertebral body under computed tomography (CT) or fluoroscopic guidance. Kyphoplasty is a modification of vertebroplasty that expands the partially collapsed vertebral body with an inflatable balloon or other mechanical device before the injection of bone cement. Sacroplasty is an extension of vertebroplasty, involving the injection of bone cement into the sacrum to repair sacral insufficiency fractures. These surgical procedures are less invasive than other spinal surgical procedures, but more invasive than conservative medical therapy. Vertebroplasty, kyphoplasty and sacroplasty are surgical procedures and are not subject to FDA approval, however materials and devices used as part of these procedures are subject to FDA approval.

Topic Background

A Health Technology Assessment titled: Vertebroplasty, Kyphoplasty, Sacroplasty, was published on November 5, 2010, by the Health Care Authority. New evidence has been published subsequent to the 2010 review and additional devices have been FDA approved. The scope for the rereview will be essentially the same as the original review with regard to key questions to be addressed and PICOTs inclusion and exclusion. It will reflect clarification of the inclusion/exclusion scope based on clinical expert input as clinical practice has evolved since 2010. The final scope for the rereview is consistent with the scope of the prior report.

As noted, the PICOTS for the rereview reflects clarification of the inclusion/exclusion scope based on clinical expert input as clinical practice has evolved since 2010. It also reflects consideration of public comments received to the posting of the draft key questions. The assessment update will be restricted to devices approved by the FDA for management of the FDA-approved conditions as described in PICOTS (Table 1).

Objectives

The aim of this report is to systematically review, critically appraise, analyze and synthesize research evidence evaluating the effectiveness and safety of vertebroplasty, kyphoplasty and sacroplasty for primary treatment of vertebral or sacral fracture due to osteoporosis or tumor/malignancy compared with placebo/sham, no treatment, surgery or common conventional treatment options to reflect evidence published subsequent to the 2010 report. Vertebroplasty and kyphoplasty will be compared with each other. The differential effectiveness and safety of these therapies for subpopulations will be evaluated, as will the cost effectiveness.

Draft Key Questions and Scope

Key Questions (KQ)
When used in patients with spinal pain due to vertebral fracture:

Key Question 1:
What is the evidence of effectiveness of vertebroplasty, kyphoplasty or sacroplasty, including consideration of short-term and long-term outcomes?

Key Question 2:
What is the evidence of the safety of vertebroplasty, kyphoplasty or sacroplasty? Including consideration of:

a. Adverse events type and frequency (mortality, major morbidity, other)
b. Revision/re-operation rates

Key Question 3:
What is the evidence that vertebroplasty, kyphoplasty or sacroplasty has differential efficacy or safety issues in sub populations? Including consideration of:

a. Gender
b. Age
c. Psychological or psychosocial co-morbidities
d. Diagnosis or time elapsed from fracture
e. Other patient characteristics or evidence-based patient selection criteria
f. Provider type, setting or other provider characteristics
g. Payer/beneficiary type: including worker's compensation, Medicaid, state employees

Key Question 4:
What is the evidence of cost-effectiveness of vertebroplasty, kyphoplasty and sacroplasty?

Table 1. Draft PICOTS Scope: Summary of inclusion and exclusion criteria

Study Component	Inclusion	Exclusion
Participants	Patients with spinal pain due to ***vertebral fracture*** secondary to • Osteoporosis • Malignancy Subgroups, special populations: • Gender	• Fractures due to high energy trauma

	• Age • Psychological or psychosocial co-morbidities • Diagnosis or time elapsed from fracture • Other patient characteristics or evidence-based patient selection criteria • Provider type, setting or other provider characteristics • Payer/beneficiary type: including worker's compensation, Medicaid, state employees	
Intervention	• Vertebroplasty • Kyphoplasty • Sacroplasty	• Cements, devices that are not FDA approved unless being studied in a Phase III trial • Spineoplasty graft consisting of mesh filled with bone chips instead of the traditional cement • Percutaneous cement discoplasty (PCD) - intervertebral disc is filled with percutaneously injected acrylic cement; may be used as prep or with vertebroplasty • Studies of exercise/rehab post augmentation • Stentoplasty, vertebral body stenting, • Vesselplasty
Comparators	• Sham procedure or placebo • Conservative care, conventional care • Other minimally invasive procedures (e.g., facet joint block, nerve block) • Surgical procedures • Vertebroplasty vs. kyphoplasty	• Comparisons of different cement types • Comparisons of surgical approaches or techniques • Comparison of different vertebroplasty techniques with each other or different forms of kyphoplasty with each other • Use of vertebroplasty, kyphoplasty or sacroplasty as an adjunct to other procedures (e.g., ablation) • Augmentation combined with zoledronic acid (ZOL) versus augmentation alone • Types of imaging guidance, other guidance, e.g., Robotic assisted vs. fluoroscopy • Stentoplasty/vertebral body stenting, • Vesselplasty
Outcomes	**Primary outcomes** • Functional outcomes (e.g., ODI) • Pain relief • Harms/Complications (e.g., procedure related, leakage, new fracture, medical complications, mortality, revision/re-operation) **Secondary outcomes**	• Measures that are not validated • Intermediate outcomes measures (e.g., radiographic measures of disc height)

	• Quality of life • Measures of disability (e.g., work lost) • Opioid use • Return to work/return to normal activity	
Studies	• **Key Question 1**: Comparative clinical studies with a focus on studies with least potential for bias (RCTs); NRSI with concurrent controls that control for confounding will be considered if RCT evidence is not available for KQ 1. • **Key Question 2**, safety, RCTs, NRSI with ≥250 patients that are specifically designed to evaluate safety that control for confounding will be considered; case series will be considered if adequate information is not available from comparative NRSIs and RCTs or for rare or long-term adverse events; systematic reviews may be considered for safety • **Key Question 3:** RCTs only • **Key Question 4:** Full formal economic studies	• Case reports • Case series, single arm studies, pre-post studies with fewer than 5 patients (for sacroplasty) • NRSIs for effectiveness or benefit for osteoporotic fractures (KQ1) • NRSI that do not control for confounding (exception for sacroplasty)
Publication	• Full-length studies published in English in peer reviewed journals, published HTAs or publicly available FDA reports • Full formal economic analyses (e.g., cost-utility studies) published in English in HTAs or in a peer-reviewed journal published after those represented in previous HTAs	• Abstracts, editorials, letters • Duplicate publications of the same study which do not report on different outcomes • Single reports from multicenter trials • Studies reporting on the technical aspects of these procedures • White papers • Narrative reviews • Articles identified as preliminary reports when results are published in later versions • Incomplete economic evaluations such as costing studies

FDA = Food and Drug Administration; HTA = Health Technology Assessment; ODI = Oswestry Disability Index; NRSI = Nonrandomized studies of interventions; RCT = Randomized Control Trial;