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Review Articles

Vertebroplasty and kyphoplasty for the treatment of vertebral compression fractures: an evidenced-based review of the literature

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Abstract

BACKGROUND: Vertebroplasty (VP) and kyphoplasty (KP) are routinely used to treat vertebral body compression fractures (VCFs) resulting from osteoporosis or vertebral body tumors in order to provide rapid pain relief. However, it remains debated whether VP or KP results in superior outcomes versus medical management alone in patients experiencing VCFs.
PURPOSE: To determine the level of evidence supporting VP or KP for the treatment of VCFs.
STUDY DESIGN: Systematic review of the literature.
PATIENT SAMPLE: Patients with osteoporotic or tumor-associated VCFs.
OUTCOME MEASURES: Self-reported and functional measures.
METHODS: We reviewed all articles published between 1980 and 2008 reporting outcomes after VP or KP for osteoporotic or tumor-associated VCFs and rated the level of evidence and grades of recommendation (per North American Spine Society [NASS] guidelines) supporting the use of VP or KP for the treatment of VCFs.
RESULTS: Seventy-four VP studies for osteoporotic VCF (1 level I, 3 level II, 70 level IV), 35 KP studies for osteoporotic VCF (2 level II, 33 level IV), and 18 VP/KP for tumor VCFs (all level IV) were reviewed. There is good evidence (level I) that VP results in superior pain control within the first 2 weeks of intervention compared with optimal medical management for osteoporotic VCFs. There is fair evidence (level II–III) that VP results in less analgesia use, less disability, and greater improvement in general health when compared with optimal medical management within the first 3 months after intervention. There is fair evidence (level II–III) that by 2 years after intervention, VP provides a similar degree of pain control and physical function as optimal medical management. There is fair evidence (level II–III) that KP results in greater improvement in daily activity, physical function, and pain relief when compared with optimal medical management for osteoporotic VCFs by 6 months after intervention. There is poor-quality evidence that VP or KP results in greater pain relief for tumor-associated VCFs.
CONCLUSIONS: Although evidence suggests that physical disability, general health, and pain relief are better with VP and KP than those with medical management within the first 3 months after intervention, high-quality randomized trials with 2-year follow-up are needed to confirm this. Furthermore, the reported incidence of symptomatic procedure-related morbidity for both VP and KP is very low.

Keywords: Vertebroplasty; Kyphoplasty; Vertebral compression fracture; Osteoporosis; Pathological fracture; Literature review

Introduction

VP and KP are percutaneous procedures for the treatment of medically refractory pain caused by acute or subacute VCF. VP and KP involve intraosseous injection of acrylic cement under local anesthesia and fluoroscopic guidance into vertebral bodies fractured owing to osteoporosis, tumor, or trauma. These minimally invasive techniques have become widely used by many spine surgeons,

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pain management specialists, and oncologists as an effective tool for rapid pain relief of osteoporotic and pathologic VCFs. The alternative to VP or KP, medical management, remains the gold standard and first line of treatment for VCFs. However, the annual cost of medical management of osteoporotic VCFs was estimated at $5–10 billion in 1995 and at $13.8 billion dollars in 2001 [1,2]. These significant medical costs and the long-term morbidity of VCFs have shifted management paradigms in many practices toward the goal of more rapid pain relief with VP and KP. In fact, since the introduction of VP and KP in 1987 and 1998, respectively, the number of PubMed citations has risen from an average of 3/year (1997–1999) to 33/year (2005–2007). Given the growing amount of outcome data reported in the literature, we provide here a systematic review of all studies to date reporting outcome after VP or KP for VCFs and rate the level of evidence to critically analyze the justification of VP and KP in this setting.

Methods

To initiate an evidence-based analysis of the literature on VP or KP for the treatment of VCFs, three clinical questions were asked: 1) Is VP versus optimal medical management associated with superior outcomes in patients treated for osteoporotic VCFs?; 2) Is KP versus optimal medical management associated with superior outcomes in patients treated for osteoporotic VCFs?; and 3) Is VP or KP versus optimal medical management associated with superior outcomes in patients treated for tumor-associated VCFs?

To answer these questions, search terms were identified and combined with appropriate Boolean connectors, and a search was carried out on English language publications on Medline (PubMed). The search sequence submitted was the following: *("Vertebroplasty"[MeSH] OR "Kyphoplasty" [MeSH] OR "Vertebroplasty"[title] OR "Kyphoplasty" [title]) AND (English[lang]) AND ("Treatment Outcome" [MeSH] OR "Outcome Assessment"[MeSH] OR ("outcome" [All Fields] OR "surgical outcomes"[All Fields]) Limits: English, Publication Date from 1980–2008.*

All abstracts obtained from this search criteria were reviewed. Case reports, technical notes, and animal or laboratory studies were discarded. Studies reporting outcomes of VP or KP for indications other than osteoporotic or tumor-associated VCFs were discarded. The remaining manuscripts were then read in their entirety and rated as level I–V according to the NASS's adopted, standardized levels of evidence tables [3]. Two authors independently assigned levels of evidence to each study. Any discrepancies in the assigned level of evidence were discussed between reviewers at the conclusion of evidence rating. If needed, a blind assessment was made by a third author to finalize the level of evidence. For level I, II, and III studies where VP or KP versus medical management was not the primary research question, the outcomes reported for VP or KP cohorts were included as level IV evidence.

Grades of recommendation were assigned for each study question based on the NASS's Clinical Guidelines for Multidisciplinary Spine Care [4]: *Good evidence* (level I studies with consistent findings), *Fair evidence* (level II or III studies with consistent findings), *Poor quality evidence* (level IV or V studies with consistent findings), or *Insufficient evidence* (inconsistent findings or lack of investigation) for or against recommending intervention.

Results

Vertebroplasty

There are 74 published studies to date reporting the outcomes of patients receiving VP for osteoporotic VCFs [5–73]. According to the level of evidence rating of the NASS (level I–V), there is only a single level I study to date (high quality prospective randomized controlled trial) comparing VP to medical management [70]. There are currently two ongoing randomized trials [28,38]. Voormolen et al. randomized 18 patients to VP and 16 patients to optimal medical management. VP was associated with significantly greater pain reduction, less analgesic use, and greater mobility and physical function when compared with that in optimal medical management 1 day and 2 weeks after treatment. Furthermore, 14 of the 18 patients randomized to medical management requested VP by 2 weeks. Although an initial aim of this study was to also compare 1-year outcomes, a 1-year comparison was not reported due to the high degree of treatment crossover at 2 weeks. In our opinion, this weakness in study design does not preclude a level 1 rating of the study's 2-week assessment by NASS criteria but should be considered a limitation of the study.

There are three level II studies (nonrandomized, prospective, controlled trials) published to date [6,19,20]. Alvarez et al. prospectively compared 101 patients receiving VP versus 27 receiving optimal medical management for osteoporotic vertebral body fractures (VBFs). VP was associated with significantly greater pain reduction 3 and 6 months after intervention. VP was also associated with a greater decrease in analgesia use, a greater improvement in disability score, and greater improvement in 36-item Short Form Health Survey of the Medical Outcomes Study (SF-36) general health and bodily pain subscores at 3 months. There were no differences between VP and optimal medical management in any outcome measure at 12 months. Diamond et al. prospectively compared 55 patients receiving VP versus 24 receiving optimal medical management for osteoporotic VCFs and found significantly greater reduction in pain and greater improvement in physical functioning 24 hours after intervention. There were no differences in VAS or Barthel functional index at 1.5, 6, or 12 months. Diamond et al. also performed a prospective, 2-year comparison of 88 patients receiving VP versus 38 receiving optimal medical management for osteoporotic VBFs. This study demonstrated a greater reduction