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Clinical Study

Cement leakage in percutaneous vertebroplasty for osteoporotic vertebral compression fractures: identification of risk factors

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Abstract

BACKGROUND CONTEXT: Percutaneous vertebroplasty (PVP) is a common treatment modality for painful osteoporotic vertebral compression fractures (OVCFs). The complication rate of PVP is low, but cement leakage occurs in up to 90% of the treated levels. Recent evidence suggests that sequelae of cement leakage may be more common and clinically relevant than previously thought. Preoperative appreciation of risk factors would therefore be helpful but has not been thoroughly investigated.

PURPOSE: Identification of preoperative risk factors for the occurrence of cement leakage in PVP for painful OVCFs.

STUDY DESIGN: Retrospective assessment of risk factors using multivariate analysis.

PATIENT SAMPLE: Eighty-nine patients treated with PVP for 177 painful OVCFs.

OUTCOME MEASURE: Occurrence of cement leakage.

METHODS: The influence of all known risk factors and other parameters potentially affecting the occurrence of cement leakage was retrospectively assessed using multivariate analysis. Patient age, sex, and spinal deformity index; fracture age, level, type, and semiquantitative severity grade (1–4), the presence of an intravertebral cleft and/or cortical disruption on preoperative magnetic resonance imaging (MRI), and the viscosity of bone cement were included. Cement leakage was assessed on direct postoperative computed tomography scanning of the treated levels. In addition to cement leakage in general, three fundamentally different leakage types (cortical, epidural, and anterior venous), with different possible clinical sequelae, were discerned, and their respective risk factors were assessed.

RESULTS: In 130 of 173 (75.1%) treated OVCFs, cement leakage was detected. Leakage incidence was found to increase approximately linear with advancing severity grade. High fracture semiquantitative severity grade (adjusted per grade relative risk [RR], 1.14; 95% confidence interval [CI], 1.05–1.24; p=.002) and low bone cement viscosity (medium vs. low viscosity: adjusted RR, 0.73; 95% CI, 0.61–0.87; p<.001) were strong risk factors for cement leakage in general. For cortical leakage (in 95% intradiscal leakage), the presence of cortical disruption on MRI (adjusted RR, 1.62; 95% CI, 1.16–2.26; p=.004) and an intravertebral cleft on MRI (adjusted RR, 1.43; 95% CI, 1.07–1.77; p=.017) were identified as additional strong risk factors.

CONCLUSIONS: High fracture severity grade and low viscosity of polymethylmethacrylate bone cement are general, strong, and independent risk factors for cement leakage. Using MRI assessment, cortical disruption and the presence of an intravertrebral cleft were identified as additional strong risk factors regarding cortical (intradiscal) cement leakage, thereby potentiating anticipation.

Keywords: Percutaneous vertebroplasty; Cement leakage; Risk factors; Osteoporotic vertebral compression fracture; Fracture severity

FDA device/drug status: Not applicable.

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EVIDENCE & METHODS

Context
Vertebroplasty is commonly used for the treatment of osteoporotic compression fractures. While leakage of cement is known as a common event, the risk factors for leakage have not been clearly delineated.

Contribution
In this retrospective study of vertebroplasty for 177 compression fractures, the authors noted that three-quarters of cases demonstrated some cement leakage. Fracture severity and low viscosity of injected cement were strong and independent predictors of leakage.

Implication
The findings are consistent with previous experience. Extra care should be taken in patients at greater risk for leakage and efforts to ensure adequate cement viscosity employed.

—The Editors

Introduction

Percutaneous vertebroplasty (PVP) has gained widespread acceptance and implementation, mainly as a treatment modality for painful osteoporotic vertebral compression fractures (OVCFs) [1–5]. Its benefit over conservative treatment has been proven in a large and high-quality randomized clinical trial [6]. However, results of recently published and long-awaited placebo-controlled randomized trials call this belief into question [7,8]. With discussion regarding generalizability of these results and the subsequent position of PVP ongoing [9–16], it is likely that patient selection criteria should be individually optimized, and a careful benefit versus risk analysis for each individual patient is warranted.

The complication rate of PVP is low, with 1.6% to 3.8% reported by meta-analyses [17,18]. Severe complications of PVP are rare, restricted to case reports, and mainly comprise sequelae of excessive cement leakage, like paraplegia [19], neurologic deficits [20,21], cardiac perforation [22,23], and even death [24].

The rate of occurrence of cement leakage itself appears variable, however, and reported incidences range from less than 5% to more than 80% [25–28]. When assessed using computed tomography (CT) scanning, known to be substantially superior to intraoperative fluoroscopy or postoperative radiography for detection of cement leakage [28,29], the incidence of leakage found is 63% to 87% [26–29].

Because of its generally asymptomatic character, cement leakage is commonly considered of minor importance and seen as procedure inherency, rather than a true complication. However, besides the aforementioned severe sequelae, recent evidence suggests that certain sequelae of cement leakage may be more common and clinically relevant than previously thought. The first two prospective studies on the occurrence of pulmonary cement emboli after PVP in OVCFs, which are concomitantly also the first to use routine CT thorax for examination, reported an unexpectedly high incidence: in 18 of 78 (23%) [30] and 14 of 54 (26%) [31] patients, one or more cement emboli were detected. Furthermore, several studies found an association between intradiscal cement leakage and occurrence of new adjacent OVCFs [32–35]. Although this association has not been found unanimously [36–39], avoidance of intradiscal cement leakage seems advisable, and further research is necessary.

With the benefit of PVP questioned and possible high incidences of cement leakage and clinically relevant sequelae, preoperative identification of risk factors for cement leakage, preferably on standard PVP work-up methods, would be helpful to make a balanced treatment decision. Moreover, appreciation of risk factors allows preoperative minimization and intraoperative anticipation with early detection of cement leakage. We assessed preoperative characteristics of 177 OVCFs in 89 patients treated with PVP and identified several significant risk factors for the occurrence of cement leakage.

Materials and methods

Between August 2002 and October 2008, 177 patients received primary PVP. One hundred four patients received PVP for one or more OVCFs, of whom 89 were under clinical follow-up at our institution and included in the present study (Table 1, Fig. 1). All patients met the following criteria: (1) one or more OVCFs confirmed by biopsy, (2) focal back pain in the midline refractive to at least 8 weeks of appropriate conservative treatment, (3) back pain related to the location of the VCF on radiography, and (4) the presence of bone marrow edema on magnetic resonance imaging (MRI) T2-weighted short-tau inversion recovery sequences in the corresponding collapsed vertebral body.

Vertebroplasty was performed on a biplane angiography unit using conscious sedation. A 10G vertebroplasty needle was gently hammered into the anterior third of the vertebral body, and a bone biopsy was obtained, followed by injection of polymethylmethacrylate (PMMA) bone cement until a satisfactionary distribution of the cement, that is, symmetrical filling of the central and anterior parts of the vertebral body, was obtained or when cement leakage was noted, in which case injection was temporarily halted and on reoccurrence of leakage terminated. When necessary, a second needle was advanced into the vertebral body through the contralateral pedicle, followed by injection of cement.

Different types of PMMA bone cement were used: the first 30 patients were treated using low (injection)-viscosity PMMA (OsteoPal-V; Hereaus Medical, Hanau, Germany)