

QUALITY OF LIFE FOLLOWING VERTEBROPLASTY

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Background: Percutaneous vertebroplasty may be indicated when a patient with a painful osteoporotic vertebral compression fracture remains intolerably symptomatic in spite of comprehensive, nonoperative management. Relief of pain and quality of life following percutaneous vertebroplasty, however, remain incompletely defined. We investigated these outcomes with use of a visual analog scale and a validated, osteoporosis-specific health-related quality-of-life instrument.

Methods: We performed a prospective study of consecutive patients who underwent percutaneous vertebroplasty. At the time of enrollment, all patients completed the Osteoporosis Quality of Life Questionnaire, a validated thirty-item, five-domain, 7-point response-option instrument that measures health-related quality of life in osteoporotic women with back pain due to vertebral compression fracture. At two weeks, two months, and six months postoperatively, all patients completed a validated extraction of the Osteoporosis Quality of Life Questionnaire. The minimal, clinically important difference in this 7-point scale is 0.5 unit per question. To assess pain, a visual analog scale (ranging from 1 to 10) was completed preoperatively, one day postoperatively, and at each evaluation thereafter.

Results: Forty-six consecutive patients (thirty-two women and fourteen men) underwent forty-nine percutaneous vertebroplasty procedures for the treatment of sixty-six vertebral compression fractures. The mean age of the patients was 74.3 years. The mean fracture age was 2.5 months. The mean pain rating decreased from 7.7 preoperatively to 2.8 one day after the vertebroplasty ($p < 0.001$), and it remained substantially improved at two weeks, two months, and six months postoperatively ($p < 0.001$). All five domains of the Osteoporosis Quality of Life Questionnaire were improved at two weeks postoperatively and remained improved at each evaluation point through six months ($p \leq 0.007$). Multivariate analysis demonstrated no consistent correlation between postoperative pain relief or any postoperative Osteoporosis Quality of Life Questionnaire domain score and gender, smoking history, previous or current steroid use, bone mineral density, dynamic mobility, or the presence of an intravertebral cleft. Immediate postoperative pain relief was weakly and positively associated with age ($p < 0.03$). Four incident vertebral compression fractures occurred in three (6.5%) of the forty-six patients, and five patients died within six months after the vertebroplasty. No deaths or serious adverse events appeared to be related to vertebroplasty.

Conclusions: Rapid and substantial relief of pain and improvement in the quality of life are observed following percutaneous vertebroplasty, and these improvements are maintained for at least six months. Percutaneous vertebroplasty can be performed safely in frail, elderly patients, with no apparent increase in the incidence of fractures postoperatively.

Level of Evidence: Therapeutic study, Level IV (case series [no, or historical, control group]). See Instructions to Authors for a complete description of levels of evidence.

Percutaneous vertebroplasty may be indicated when patients with painful osteoporotic vertebral compression fractures remain intolerably symptomatic in spite of comprehensive nonoperative management¹. Both retrospective²⁻⁹ and prospective¹⁰⁻¹⁵ studies have demonstrated quick and

substantial pain relief following percutaneous vertebroplasty and, on this basis, the procedure is being performed with increasing frequency¹. Long-term pain relief following this procedure, however, has been reported to be no better than that associated with continued nonoperative care¹⁵. Evidence of improvement in quality of life and functional capacity after percutaneous vertebroplasty has been limited to very few prospective studies^{11,13-15} that were compromised by small numbers of study patients^{11,13}, short follow-up periods¹⁵, and the use of



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nonvalidated¹⁴ or non-disease-specific health-related quality-of-life outcome measures^{11,13,15}. We are not aware of any previous prospective study in which functional outcomes following percutaneous vertebroplasty have been investigated with use of a validated, osteoporosis-specific health-related quality-of-life instrument. In the present study, we investigated quality of life and relief of pain following percutaneous vertebroplasty with use of the Osteoporosis Quality of Life Questionnaire (OQLQ) and the mini-OQLQ (both of which are validated, osteoporosis-specific health-related quality-of-life outcome instruments^{16,17}) and a standard visual analog scale¹⁸.

Materials and Methods

We performed an institutional review board-approved, prospective study of consecutive patients who were managed with percutaneous vertebroplasty at a tertiary referral center. All patients provided written, informed consent before enrollment in the study. Information on the indications for percutaneous vertebroplasty, the criteria for patient selection, radiographic and surgical technique, and postoperative monitoring and care have been detailed previously¹⁹. Patients were considered to be candidates for percutaneous vertebroplasty if they had severe pain, deemed to be related to the vertebral fracture, that was sufficient to impair activities of daily living and that had failed to improve in spite of comprehensive nonoperative therapy for a reasonable period of time. Osteoporotic vertebral compression fractures located between T5 and L5 had to be technically suitable for percutaneous vertebroplasty in the judgment of the operating surgeon. All patients were evaluated medically and were prepared for percutaneous vertebroplasty, and all provided written informed consent for the procedure. All patients also underwent an evaluation to identify and treat any causes of excess skeletal fragility.

After endotracheal intubation and the administration of general anesthesia, the patient was carefully positioned and padded in the prone position in extension on a four-poster frame by the operating surgeon. Under biplane fluoroscopic guidance without venography, percutaneous vertebroplasty was performed at the discretion of the operating surgeon with a monopedicular, bipedicular, or extrapedicular technique with use of polymethylmethacrylate with barium (Simplex P; Howmedica, Mahwah, New Jersey). The injection was terminated upon opacification of the intravertebral cleft and/or the biomechanically vulnerable vertebral segment (as determined with preoperative and intraoperative imaging) or when, in the judgment of the surgeon, the benefit of continued injection was surpassed by the desire to conserve native trabecular structure. Following percutaneous vertebroplasty, the patient was kept supine for four hours and thereafter was permitted to walk with assistance. The patient was observed overnight and was dismissed the following day. Postoperatively, all patients participated in a comprehensive spine-therapy intervention program that emphasized spinal biomechanics in activities of daily living, back strengthening, and measures designed to reduce the risk of falling. Bone mineral density was determined with use of a GE/Lunar Prodigy dual x-ray densitometer (with rare exception),

with the results being read by experienced, certified densitometrist and reported in accordance with the guidelines of the International Society for Clinical Densitometry²⁰.

At the time of enrollment, all patients completed the Osteoporosis Quality of Life Questionnaire (OQLQ)¹⁶, a validated, thirty-item, five-domain, 7-point response-option instrument that measures health-related quality-of-life in osteoporotic women with back pain due to vertebral compression fracture. The five domains assessed with this instrument are symptoms, physical function, activities of daily living, leisure, and emotional function. Two weeks, two months, and six months postoperatively, patients completed the mini-OQLQ¹⁷, a ten-item, five-domain, validated extraction of the OQLQ. Because the OQLQ is specifically validated for the evaluation of osteoporotic women, two gender-neutral questions regarding activities of daily living, similar to two gender-biased questions, were added at the end of the questionnaire to accommodate men who had been enrolled in this study. The gender-biased question "How difficult has it been for you to do housework in the last two weeks?" was mirrored by the gender-neutral question "How difficult has it been for you to work around the home in the last two weeks?"; and the question "How difficult has it been for you to vacuum in the last two weeks?" was mirrored by the question "How difficult has it been for you to do twisting chores, such as vacuuming or raking, in the last two weeks?". Patients of both genders answered all gender-biased and gender-neutral domain questions. Correlation between individual responses for these two domains was excellent ($r = 0.9$, $p < 0.0001$). The minimal, clinically important difference in this 7-point response-option scale has been estimated to be 0.5 unit per question¹⁷. Pain was rated by hand-marking of a linear visual analog scale, with "0" representing no pain and "10" representing the worst imaginable pain¹⁸. The visual analog scale was completed preoperatively, one day postoperatively, and at each postoperative evaluation thereafter. Fracture age was calculated as the best estimate of the interval between the onset of fracture pain and the vertebroplasty. Intravertebral clefts were defined at the time of vertebroplasty as low-resistance, confluent reservoirs for polymethylmethacrylate that were usually appreciated preoperatively on magnetic resonance images and occasionally on plain radiographs²¹. Statistical analysis of the primary outcomes of pain and health-related quality of life was assessed at each time-point with use of the Wilcoxon signed-rank test. A multivariate general linear model was used to assess the association between potential predictor variables and health-related quality-of-life outcomes. Six-month results are reported.

Results

Forty-six consecutive patients underwent forty-nine vertebroplasty procedures for the treatment of sixty-six painful osteoporotic vertebral compression fractures. Thirty-two (70%) of the forty-six patients were female, and fourteen (30%) were male. The mean age of all patients was 74.3 ± 10.9 years (range, 46.6 to 91.4 years), and the mean age for women was somewhat greater than that for men (76.2 compared with 70.1 years). Fifty-four (82%) of the sixty-six fractured vertebral

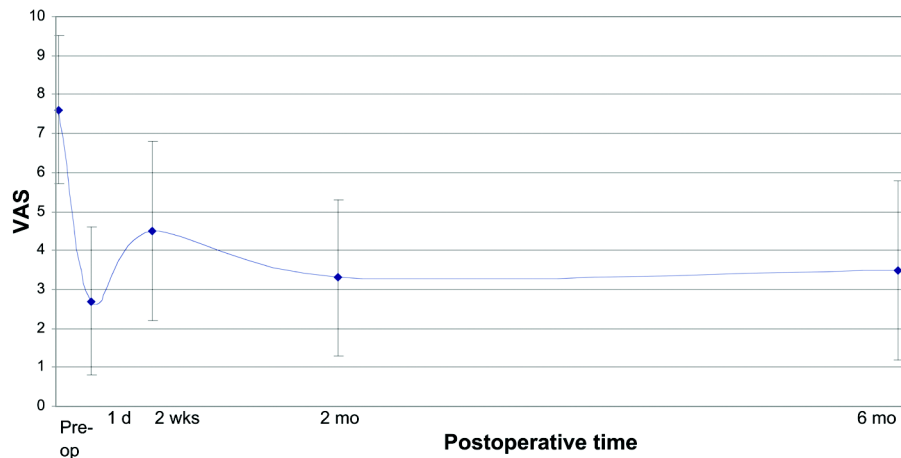


Fig. 1

Illustration depicting the preoperative and postoperative visual analog scale ratings.

bodies were filled by means of unilateral injection. Thirty-seven (76%) of the forty-nine vertebroplasty procedures involved unilateral filling only, six (12%) involved bilateral filling only, and six (12%) involved both unilateral and bilateral vertebral filling at different levels. Treated levels were distributed nonuniformly from T5 to L4 as thirty-three of the sixty-six fractures occurred at the thoracolumbar junction (T11 to L1). The mean fracture age was 2.5 ± 2.1 months (range, 0.3 to 9.0 months). The average bone mineral density T and Z scores for the lumbar spine were -2.6 and -1.3 , respectively. The average T and Z scores for the femoral neck were -2.2 and -0.8 , respectively. Fifty-nine percent of the patients had previously sustained at least one fragility fracture, and 61% were actively receiving osteoporosis treatment (primarily oral bisphosphonates) at the time of entry into the study. Fifty-four percent of the patients had previously taken systemic steroid medications, and 26% were currently taking steroids. Sixty-seven percent of the patients had previously smoked, with an average lifetime smoking history of fifty-eight pack-years. Twenty percent of the patients were active smokers.

The mean pain rating decreased from 7.7 ± 1.8 preoperatively to 2.8 ± 1.8 one day after percutaneous vertebroplasty ($p < 0.001$). Compared with preoperative pain rating, the pain ratings at two weeks, two months, and six months postoperatively remained substantially improved ($p < 0.001$). Pain increased slightly, but not significantly, between the first postoperative day and the sixth postoperative month ($p = 0.058$) (Fig. 1). Multivariate analysis indicated that immediate postoperative pain relief was not influenced by gender, baseline bone mineral density, past or current smoking status, past or current steroid use, or the presence or absence of dynamic mobility¹⁹ or intravertebral clefts. Immediate postoperative pain relief was weakly and positively associated with patient age ($p < 0.022$).

Two weeks postoperatively, all five quality-of-life domains of the OQLQ improved substantially and significantly ($p \leq$

0.001 for symptoms, activities of daily living [as assessed with both gender-neutral and gender-biased questions], and leisure; $p = 0.003$ for physical function; and $p < 0.02$ for emotional function) and remained improved at each evaluation point through the sixth month ($p \leq 0.001$ for symptoms, activities of daily living, leisure, and physical function; $p = 0.007$ for emotional function) (Fig. 2). Between the second and sixth postoperative months, the scores for physical function and emotional function improved slightly ($p < 0.05$) and no functional domain score worsened. The maximum postoperative gains in OQLQ domains were +2.4 (symptoms), +2.2 (leisure), +1.9 (non-biased activities of daily living), +1.8 (physical function), +1.8 (activities of daily living), and +1.0 (emotional function). Multivariate analysis demonstrated no consistent correlation between any specific postoperative OQLQ domain score and gender, patient age, smoking history, previous or current steroid use, bone mineral density, dynamic mobility, or the presence of an intravertebral cleft.

Ten cement leaks from sixty-six vertebrae (incidence, 15%) were detected intraoperatively or on radiographs or computerized tomographic scans made at two weeks postoperatively. Eight of the ten leaks were into adjacent disc spaces, and each leak had been anticipated preoperatively on the basis of the recognition of end-plate disruption as seen on radiographs or magnetic resonance images. One small leak into a ventrolateral segmental vein was detected intraoperatively but did not embolize or preclude the completion of cement injection. Another small ventrolateral soft-tissue leak was detected on computerized tomographic scans made two weeks postoperatively. No cement leak was symptomatic or was deemed serious. Four incident vertebral compression fractures occurred in three (6.5%) of the forty-six patients within six months after percutaneous vertebroplasty; two were contiguous to and two were remote from the initially treated vertebra. All incident fractures occurred in patients who had an unusually high risk of fracture because of prolonged immobilization, use

of high-dose glucocorticoids, or high-energy trauma. Five patients died within six months after vertebroplasty. Four patients in whom percutaneous vertebroplasty had been performed for palliation of nonmalignant, osteoporotic vertebral fracture pain died from complications or progression of pre-existing terminal cancer. One patient died from renal failure. No deaths or serious adverse events appeared to be related to vertebroplasty.

Discussion

Our finding of significant, clinically substantial pain reduction immediately following percutaneous vertebroplasty as determined with use of a disease-specific quality-of-life instrument affirms the results of other prospective studies¹⁰⁻¹⁵. Furthermore, we showed that pain relief is maintained for at least six months. The multivariate analysis of pain relief suggests that older patients may experience a greater degree of immediate postoperative pain relief than younger patients do. As there was no control group, we cannot exclude the possibility that continued comprehensive, nonoperative care might have resulted in a similar outcome. We believe, however, that pain relief of this rapidity, magnitude, and duration would not have resulted from continuing the same care that had already failed in these patients for an average of 2.5 months.

In the present study, patients with mobile, clefted vertebral compression fractures did not judge their pain to be more intense than did those with only fixed fractures. Previous authors have expressed surprise²² and disappointment²³ that pain relief following percutaneous vertebroplasty is not substan-

tially greater in patients with clefted or mobile fractures. Patients are currently selected for vertebroplasty on the basis of pain rather than vertebral morphometry. Since these patients are usually near their individual limit of tolerable pain and since pain relief following vertebroplasty is so substantial, it does not surprise us that a potential association between vertebral morphometry and the experience of pain might be obscured at the extremes of pain and pain relief. These data do not preclude the possibility that clefted, mobile vertebral compression fractures are more intensely painful, are more often painful, or are treated with percutaneous vertebroplasty more often, or sooner, than fixed vertebral compression fractures are. In this regard, and consistent with the findings in our previous report¹⁹, patients with clefted fractures in the present study presented for percutaneous vertebroplasty somewhat earlier than did those with only fixed fractures (average fracture age, 2.2 compared with 2.9 months; $p > 0.05$).

To our knowledge, the present study is the first prospective study in which functional outcomes after percutaneous vertebroplasty have been assessed with use of a disease-specific health-related quality-of-life instrument. Only two previous prospective studies^{11,13} have examined functional outcomes after percutaneous vertebroplasty with use of a validated health-related quality-of-life instrument. Those studies used more generic health-related quality-of-life instruments (the Nottingham Health Profile [NHP]¹¹ and the Musculoskeletal Outcomes Data Evaluation and Management Scale [MODEMS]¹³), which are more frequently employed for the evaluation of nonspecific low-back pain in younger, nonosteoporotic pa-

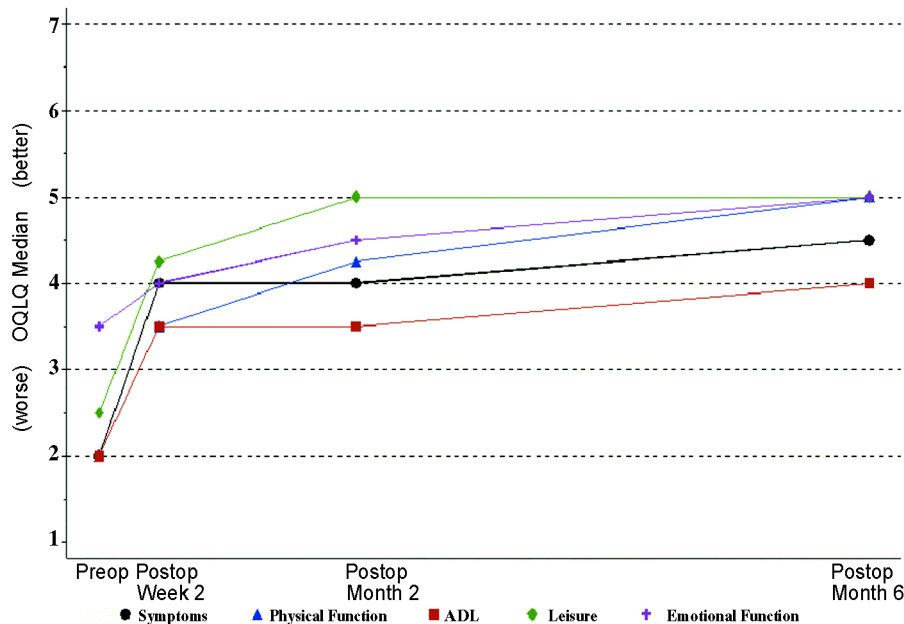


Fig. 2
Illustration depicting the median preoperative and postoperative scores for the functional domains of the Osteoporosis Quality of Life Questionnaire.

tients. The OQLQ and mini-OQLQ are specifically validated for the evaluation of health-related quality-of-life outcomes in osteoporotic women with back pain due to vertebral compression fractures. While there is good correlation between disease-specific and non-disease-specific instruments, there are some differences^{16,17}, and we believe that the more specific instrument enhances confidence in the measured outcome.

Our results indicate that quality of life improves immediately following percutaneous vertebroplasty and remains improved for at least six months. Diamond et al.¹⁵ also found significant ($p = 0.0001$) immediate postoperative improvement in pain (as assessed with a visual analog scale) and level of function (as assessed with the Barthel index) but reported that, six weeks after percutaneous vertebroplasty, the "clinical outcomes" for patients who had chosen vertebroplasty were no better than in patients who had chosen to continue nonoperative care. In that early-intervention study, patients were enrolled within six weeks after the fracture and the outcomes following percutaneous vertebroplasty were compared with those following continued nonoperative care. Treatment options were self-directed and therefore were probably influenced by individual awareness of the status of fracture repair as measured by the patients' own levels of pain and function. Until early predictors of failure of nonoperative care are validated, we recommend delaying percutaneous vertebroplasty in most circumstances until after the failure of reasonable comprehensive nonoperative care, which includes some, albeit arbitrary, element of time¹⁹. The use of percutaneous vertebroplasty for palliation in terminally ill patients has also been associated with rapid relief of pain and improvement in OQLQ functional domains²⁴. In our opinion, careful patient selection, comprehensive preoperative metabolic bone assessment, skilled surgical technique, and postoperative osteoporosis-specific rehabilitation all contribute to a favorable outcome following percutaneous vertebroplasty. Relief of pain and improved functional capacity following percutaneous vertebroplasty are likely to result in reduced morbidity²⁵, shorter durations of hospitalization^{15,26}, fewer institutionalizations²⁵, and an overall reduction in health-care costs related to osteoporosis and osteoporotic vertebral compression fracture.

The post-vertebroplasty incident fracture rate is an important issue. The estimation of the fracture rate following vertebroplasty must take into consideration the expected fracture rate in the study population, the integrity of fracture ascertainment, and the period of observation. Lindsay et al.²⁷ reported that almost 20% of osteoporotic women experience another radiographically apparent vertebral compression fracture within one year after an incident vertebral compression fracture. Vertebral fracture incidence is reportedly increased with increasing age²⁸, multiple medical comorbidities²⁹, a greater number of prevalent fractures²⁸, a greater severity of prevalent vertebral compression fractures³⁰, the degree of spinal kyphosis³¹, the rate of falling³², and glucocorticoid therapy³³. The subsequent fracture rate may be attenuated by osteoporosis-specific medical and rehabilitative care^{34,35}. The occasional temporal and spatial clustering of osteoporotic ver-

tebral compression fractures^{36,37} further confounds estimation of the expected incident vertebral compression fracture rate. An unexpectedly high fracture rate early in the postoperative period³⁸ might indicate an unusually frail cohort or might suggest an operative factor (such as a large polymethylmethacrylate filling volume³⁹) that may have adverse biomechanical consequences. Published rates of vertebral compression fracture following percutaneous vertebroplasty in osteoporotic patients have ranged from 0% to 52% over periods ranging from six weeks to five years, but generally seem to be declining as experience with percutaneous vertebroplasty increases^{2-15,38}. In a recent report, 13.5% of all patients and 25% of patients with prevalent fractures sustained new symptomatic vertebral fractures following kyphoplasty⁴⁰. The incident fracture rate in the present study (6.5% at six months) is comparatively low and is similar to the expected rate reported for a cohort of healthier osteoporotic patients who did not have surgery²⁷. Given the mean age, bone mineral density T score, prevalence of fractures, and rates of cigarette use and glucocorticoid exposure in the present study, one might have anticipated a greater refracture rate than was actually observed.

A reduced rate of polymethylmethacrylate leakage has been touted as an important safety advantage of kyphoplasty over percutaneous vertebroplasty⁴¹. In our experience, most cement leaks occur into adjacent discs through intravertebral cleavage planes and can be anticipated by careful scrutiny of preoperative and intraoperative imaging studies. It is not surprising that trabecular damming on the perimeter surface of an expanding intravertebral balloon might compact such channels and reduce leakage of radiographic contrast medium *in vivo*⁴¹. This observation does little to assuage our concern, however, that indiscriminant trabecular sacrifice may have unrecognized consequences in terms of vertebral biomechanics and tissue viability. We previously reported a low rate of polymethylmethacrylate leakage (7.7%) in association with percutaneous vertebroplasty¹⁹. Furthermore, most reported cement leaks appear to be clinically unimportant²⁻¹⁵. Finally, the rate of polymethylmethacrylate leakage is subject to considerable ascertainment and reporting bias⁴². We analyzed all intraoperative and postoperative videos, radiographs, and computerized tomographic scans for cement leaks, and thus we are confident that the leak rate in the present study is not underreported. The very low rate of cement leakage in the present study refutes the claims that kyphoplasty offers an advantage over vertebroplasty in this regard.

On the basis of the results of the present study, in which a visual analog scale and a disease-specific, validated health-related quality-of-life instrument were used to evaluate a population of severely osteoporotic patients with painful vertebral compression fractures, we conclude that percutaneous vertebroplasty is associated with rapid and profound relief of pain and improvement in the quality of life and that these improvements are maintained for up to six months. Percutaneous vertebroplasty can be performed safely and, when this procedure is used in conjunction with a comprehensive osteoporotic fracture-management program, there appears to be no in-

crease in the postvertebroplasty vertebral fracture rate. Percutaneous vertebroplasty may also be an appropriate palliative intervention at the end of life.

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