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BACKGROUND AND PURPOSE: **The patient populations that are most likely to benefit from percutaneous vertebroplasty (PVP) are uncertain. Our purpose was to evaluate the effect of the age of vertebral compression fracture (VCF) on clinical improvement after PVP.**

METHODS: **We performed a retrospective review of charts of patients who had undergone PVP for painful osteoporotic VCFs at our institution. The preprocedural and postprocedural outcome measurements of pain, mobility, and analgesic use were compared for 80 treatment sessions in 75 patients (122 total vertebrae treated). We assessed the association between the duration of pain before PVP and postprocedural outcomes by using multivariable analysis.**

RESULTS: **Age of fracture at time of PVP was not independently associated with postprocedural pain or activity. Increasing age of fracture was independently associated with slightly greater postprocedural analgesic requirement, at least for patients who required narcotics at baseline before PVP. Greater preprocedural analgesic requirement was independently associated with greater postprocedural analgesic requirement. Reduced preprocedural mobility was independently associated with reduced postprocedural mobility.**

CONCLUSION: **PVP is a highly efficacious therapy for relief of pain and improvement in mobility, regardless of fracture age. PVP also is efficacious in reducing analgesic requirement, although this effect may be slightly blunted in patients who require narcotics before the procedure and in those who have older fractures.**

Percutaneous vertebroplasty (PVP), first described in France in 1987 (1), is a therapeutic procedure performed for persistent pain or instability from osteoporotic or neoplastic vertebral compression fractures (VCFs). The clinical outcomes of pain severity, mobility, and analgesic requirement are commonly measured to evaluate the effectiveness of the procedure.

Eighty-four percent of VCFs are painful, with pain lasting 4–6 wk on average (2). A subgroup of patients with VCF experiences subacute or chronic pain that is refractory to conservative therapy, which usually consists of analgesic use, rest, and external bracing. Immobility makes these patients more susceptible to pneumonia, deep vein thrombosis, and pulmonary embolism (2). Immobilization also accelerates bone loss, which may contribute to further VCFs (2).

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Some investigators consider the age of fracture an important predictor of expected pain relief after PVP. Reports of recent series detailing the efficacy of PVP have described only patients with VCFs less than 1–4 mo old (3–5); however, clinical outcomes after PVP have not been directly correlated with the age of fracture. We performed a retrospective chart review to determine whether clinical outcomes after PVP are influenced by the age of fracture at the time of the procedure.

Methods

Case Selection

We performed a retrospective chart review of patients who had undergone PVP for VCF at our institution, a medium-sized academic medical center. We identified patients for whom a specific history regarding duration of back pain attributable to the VCF before PVP was available and for whom clinical outcomes were recorded both before and after PVP. Because precise dating of vertebral compression fractures often is difficult in patients with osteoporosis and because these patients typically present with a history of back pain for a specified duration, we used duration of pain before PVP as a surrogate measure for the age of VCF. We excluded patients who were treated for neoplastic VCFs. In this manner, we identified 80 treatment sessions for osteoporotic VCFs, representing 75 patients and a total of 122 treated vertebrae.

The following clinical variables had been assessed before and after PVP: Pain severity was assessed by using an 11-point

TABLE 1: Original scales used for outcome of percutaneous vertebroplasty

Scale and Score	Definition
Pain	
0	No pain
10	Worst pain in life
Mobility	
0	Full activity
1	Walks with assistance
2	Requires wheelchair
3	Bedridden, can sit
4	Flat bedrest
Analgesic use	
0	None
1	Over-the-counter analgesics
2	Prescription non-narcotics
3	As-needed oral narcotics
4	Regularly scheduled oral narcotics
5	Parenteral narcotics

graded scale (0, no pain; 10, worst pain in life); mobility, five-point graded scale (0, full activity; 4, flat bedrest); and analgesic use, six-point graded scale (0, none; 5, parenteral narcotics) . These scales, shown in Table 1, were developed in our department for use in our vertebroplasty patients, and they have not been formally validated.

Statistical Analysis

We used ordinal logistic regression modeling to assess the association between the outcome variables and the following predictor variables: duration of pain before PVP; age; sex; number of vertebral levels treated in the session of interest; use of preprocedural advanced imaging (MR imaging, CT, or radioisotope bone scanning); and preprocedural scores of pain, activity, and analgesic use. We had specified the inclusion of these variables in each model before constructing the models. The Spearman rank correlation then was used to evaluate the potential predictive power of each predictor variable to aid in our allowance for complexity in their relationships with the outcome variables (6).

We compared the preprocedural and postprocedural outcome measurements of pain, mobility, and analgesic use both graphically and with the Wilcoxon signed rank test. We assessed the correlation between the age of fracture at the time of PVP and the postprocedural outcomes of pain, activity, and analgesic requirement by using multivariable analysis. Statistical analysis was performed by using S-Plus statistical software (Insightful, Seattle, WA).

Results

Patient Characteristics

All patients had osteoporotic VCFs and had no evidence of neoplastic involvement of the treated vertebrae. The age range of our 75 patients was 40–92 y, with a mean age of 74 y (25th, 50th, and 75th percentiles were 70, 75, and 80 y, respectively). Seventy-five percent of the patients were female. The dates of the procedures ranged from 1995 to 2001. In 50 (62%) of 80 treatment sessions, a single vertebra was treated; in 18 (22%) treatment sessions, two vertebrae were treated; and in 12 (15%) treatment sessions, three vertebrae were treated. Preprocedural advanced imaging was used in 81% of cases (MR imaging, 21%; bone scanning, 40%; MR imaging and bone scanning, 10%; CT, 6%; MR imaging and CT, 2%; CT and bone scan, 1%; all three techniques, 1%) to screen for contraindications, complicating features, and acuity or state of fracture healing. The duration of pain before PVP varied from less than 1 wk to 104 wk and was positively skewed, with a mean of 19 wk. (The 25th, 50th, and 75th percentiles were 4, 10, and 24 wk, respectively.) Postprocedural pain, activity, and analgesic use scores were obtained by means of interview within 1 mo after the procedure (range, 1–22 d; mean, 7 d).

TABLE 2: Analysis of variance for postprocedural pain

Factor	Wald χ^2 Value	Degrees of Freedom	*P* Value
Preprocedural analgesia	3.80	1	.051
Duration of pain	2.87	1	.090
Sex	1.16	1	.282
Preprocedural pain	0.24	1	.626
Preprocedural activity	0.22	1	.639
Age	0.20	1	.657
Levels treated	0.02	1	.882
Advanced imaging	0.01	1	.932
Total	7.27	8	.507

Outcomes

Three ordinal logistic regression models were used to test for the effect of age of VCF on our three outcome measures, with all other variables in the models constant. Our ordinal logistic regression model for the outcome of postprocedural pain revealed no statistically significant individual predictor variable at the .05 level, although preprocedural analgesic use score and duration of pain before PVP showed the strongest associations with postprocedural pain in the model ($P = .051$ and $P = .090$, respectively) (Table 2). At bivariate analysis, postprocedural pain increased as preprocedural analgesic use increased. Postprocedural pain tended to increase slightly with duration of pain, at least in patients requiring higher levels of analgesia before the procedure, although this trend was not statistically significant.

The ordinal logistic regression model for postprocedural activity outcomes revealed that the postprocedural activity score was significantly associated with preprocedural activity, with all other variables constant ($P = .003$) (Table 3). At bivariate analysis, the postprocedural activity score correlated positively with the preprocedural activity score. The duration of pain before PVP did not correlate with postprocedural activity outcomes ($P = .857$).

The ordinal logistic regression model for postprocedural analgesic use outcomes revealed that postprocedural analgesic use score was significant-

TABLE 3: Analysis of variance for postprocedural activity

Factor	Wald χ^2 Value	Degrees of Freedom	*P* Value
Preprocedural activity	11.82	2	.003
Total nonlinear	8.05	2	.018
Nonlinear	7.93	1	.005
Levels treated	2.73	1	.098
Age	2.17	1	.141
Preprocedural analgesia	2.14	2	.343
Nonlinear	1.72	1	.190
Sex	0.41	1	.524
Preprocedural pain	0.17	1	.679
Advanced imaging	0.06	1	.814
Duration of pain	0.03	1	.857
Total	15.73	10	.108

TABLE 4: Analysis of variance for postprocedural analgesic use

Factor	Wald χ^2 Value	Degrees of Freedom	*P* Value
Preprocedural analgesia	20.25	2	<.001
Nonlinear	4.52	1	.033
Duration of pain	4.17	1	.041
Sex	2.41	1	.121
Preprocedural activity	0.54	1	.462
Preprocedural pain	0.26	1	.612
Advanced imaging	0.11	1	.739
Levels treated	0.07	1	.799
Age	0.02	1	.878
Total	25.76	9	.002

ly associated with preprocedural analgesic use score, holding all other variables constant ($P < .001$) (Table 4). Postprocedural analgesic use score was significantly associated with duration of pain before PVP, holding all other variables constant ($P = .041$). Postprocedural analgesic use increased as both preprocedural analgesic use and duration of pain increased, but this effect appeared more marked for preprocedural analgesic use than for duration of pain. Furthermore, the association between postprocedural analgesic use and duration of pain may not remain valid in cases with preprocedural analgesic use of less than 3 of 5, for which postprocedural analgesic use is also low.

The mean preprocedural and postprocedural pain scores were 9.4 and 1.9, respectively ($P < .001$). The mean preprocedural and postprocedural activity scores were 1.4 and 0.38, respectively ($P < .001$). The mean preprocedural and postprocedural analgesic use scores were 3.0 and 1.4, respectively ($P <. 001$).

Discussion

Although PVP has been applied clinically for more than 10 y, the inclusion and exclusion criteria for percutaneous vertebroplasty performed for osteoporotic VCFs have varied widely in the case series reported in the English-language literature (3–5, 7–15). Although the subjective failure of conservative therapy generally is used as an indication for the procedure, the time from fracture to PVP ranges from 2 wk to at least several months (3–5, 7–15). One series included only patients who had received less than 1 mo of conservative therapy before vertebroplasty (3), and another report included only patients who had received at least 3 mo of conservative therapy, although this latter study excluded those with chronic back pain (11). To our knowledge, the effect of age of fracture on patient outcomes has not been specifically measured to date. We attempted to provide evidence for the effectiveness of PVP for VCFs of varying age or duration of symptoms.

Our results suggest that PVP in osteoporotic VCF is highly efficacious for pain relief and improvement of patient mobility across a wide range of fracture ages, as measured with the duration of symptoms referable to a VCF. PVP also is effective in reducing the requirement for analgesia, although this effect may be slightly blunted in patients who require narcotics before the procedure and in those who have older fractures. Some patients may become habituated to or dependent on a certain level of analgesia and thus respond less to PVP with regard to analgesic use. Also, expected improvement in patient mobility after PVP may be slightly limited in patients with lower preprocedural activity levels.

Several recent case series (3–5, 7–15) have reported significant or dramatic pain relief with PVP in as many as 90% of cases of osteoporotic VCFs. The mechanism of pain relief from PVP remains uncertain. The stabilization of microfractures, as well as vascular, chemical, and thermal factors, have been proposed as mechanisms (16). Findings of these case series also have suggested improvements in mobility and reductions in analgesic requirements as outcomes of vertebroplasty (3–5, 7–9, 11–15).

Our study is limited by its sample size and the selection and review biases inherent in many retrospective observational studies. In fact, patients in our practice with older fractures historically have been told that the efficacy of PVP may be less certain in patients with such fractures, and this practice may have resulted in the over-selection of only those patients with more severe symptoms among those with older VCFs. The accuracy and uniformity of data gathered retrospectively often are poorer than for data gained prospectively. We cannot be certain how the patients with more complete records selected for our cohort differ from patients who were not selected. Also, in our practice, most patients undergo radioisotope bone scanning or MR imaging to evaluate the age or state of healing of the compression fractures, to aid in patient selection for PVP. This practice limits the generalizability of our findings to centers where bone scanning or MR imaging is not performed as frequently. We report statistically significant improvements in

pain, mobility, and analgesic use, but we had no control group for comparison. We cannot know the extent to which factors such as the placebo effect, regression to the mean, and natural history of the disease may have biased conclusions made from these data (17).

We inferred the ages of VCFs by using the duration of new, focal back pain that corresponded with a radiologically depicted fracture. Certainly, the accuracy and precision of this surrogate are unknown and probably limited. Patients seek treatment after having pain of a given duration, however, and the age or state of healing of a fracture often is inferred from the patient history and with imaging techniques, as it was in our study. The prediction of how patients with particular pain histories and imaging findings may respond to therapies, such as PVP, may have more clinical value than does the correlation of the often-unknowable exact fracture age with therapeutic outcomes.

Because of limitations in the patient records and sample size, we were restricted in the number of variables that we could gather and test. If we were developing a model for prediction in other patients, our logistic regression models would have tested more variables than would be advisable, given our sample size; thus, we limited the use of these models to hypothesis testing. Overfitting the models would have caused more concern if we used them in prediction.

Inclusion and exclusion criteria for PVP merit further study, preferably with prospective randomized trials with improved instruments for measuring outcomes. We expect that patient outcomes substantially depend on selection criteria, such as the state of healing of the fractures and preprocedural outcomes scores, as well as many other variables.

Conclusion

PVP is a highly efficacious therapy for pain relief and improvement in mobility, regardless of fracture age or duration of symptoms. PVP also is effective in reducing the requirement for analgesia, although this effect may be slightly blunted in patients with older fractures. In our practice, patient selection for PVP is not based on the age of VCF but largely on evidence of nonhealing on bone scans or MR images and the degree of persistent pain.

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