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TECHNICAL NOTE

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SUMMARY: Administration of comprehensive outcomes measures in elderly patients presenting for vertebroplasty is considered difficult. We administered a battery of 11 outcomes questionnaires with a total of 82 questions, both in person before vertebroplasty and by telephone after vertebroplasty in 20 consecutive patients (mean age, 74.5 years; 80% women). Initial and follow-up interviews required an average of 17.4 ± 0.36 minutes (range, 14–21 minutes) and 27.2 ± 0.73 minutes (range, 16–33 minutes), respectively.

Percutaneous vertebroplasty in many centers has become the standard of care for patients with painful, osteoporotic vertebral fractures. Even in the setting of widespread adoption of the vertebroplasty technique, few studies using validated, functional outcomes scales have been published.[1] Furthermore, the use of a wide battery of outcomes assessments on a single vertebroplasty cohort has not previously been reported. As vertebroplasty research evolves with time, including implementation of randomized blinded trials, we believe that it would be useful to assess the feasibility of using multiple outcomes measures in the elderly, debilitated patient cohort typical for vertebroplasty.

Our group has recently completed a National Institutes of Health (NIH)–funded, prospective, randomized, blinded trial of percutaneous vertebroplasty. In anticipation of this trial, we conducted a pilot study to assess the feasibility of implementing multiple outcomes measures, some quite lengthy, in the vertebroplasty population. Our primary focus in this pilot study was to assess the duration of time required to administer multiple measures, both in person and by telephone, to determine not only whether such measurement outcomes would be feasible in this patient population but also to allow us to optimize planning of coordinator time and effort. The current study describes the results of this pilot trial.

We obtained approval from the institutional review board (IRB) before initiating this pilot study. Between June 2, 2003, and September 10, 2003, a total of 52 consecutive patients presenting for consideration of vertebroplasty for painful, vertebral fractures were screened. Twenty-two patients were not offered or they deferred the vertebroplasty procedure. Six additional patients were deemed ineligible for the trial, leaving 24 patients eligible for enrollment. Of these 24 patients, 20 (83%) enrolled in the pilot trial.

After the 20 participants signed an IRB-approved informed consent, they were interviewed, and a timing study was completed. The participants were patients who were to undergo a vertebroplasty (13 because of osteoporosis, 1 because of trauma, and 6 because of tumor involvement). These patients had been seen by the vertebroplasty practitioner and had been scheduled for a percutaneous vertebroplasty procedure. Of the 20 participants in the trial, 16 (80%) were women and 100% were white. The ages of the patients ranged from 60 to 89 years (average age, 74.5 ± SD years).

The preprocedure outcomes questionnaires were administered in person by the study coordinator. The study coordinator recorded the answers on a paper copy of the questionnaires. The start time of the questionnaires was recorded at the beginning of the interview, and the finish time was recorded when all the questions had been answered.

One month after the vertebroplasty procedures, the patients again were administered the questionnaires, this time over the telephone. The same questionnaires were used with the addition of 1 questionnaire asking about any doctor or hospital visits that may have occurred in the month after the vertebroplasty. The study coordinator recorded the answers on a paper copy of the questionnaires. The start time of the questionnaires was recorded at the beginning of the interview, and the finish time was recorded when all the questions had been answered.

The multiple questionnaires involved in this research were pain and quality-of-life questionnaires. The measures and the number of items per measure are listed in the Table. The numeric rating scale is an 11-point scale that rates the intensity of pain from 0 (no pain) to10 (the worst possible pain).[1] The Pain Medication questionnaire asked participants if they had taken any pain medication in the last 24 hours ("yes" or "no"). If the answer was yes, the type of medication was recorded, along with the dose and the number of times per day the medication was ingested.

The Roland scale, which consists of 23 questions relating to back pain and disability, was completed.[2,3] The Study of Osteoporotic Fractures Activities of Daily Living questionnaire consists of 6 questions relating to activities done in a typical day.[4] Another questionnaire, the Euro Quality of Life, contains 5 questions regarding mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[5] Questions were asked regarding pain frequency and pain bothersomeness. The main health service questionnaire called the Short-Form Health Survey with 36 questions is used to measure health status.[6] This form is invaluable in measuring the sometimes subtle changes in health that follow medical interventions. Many patients who experience compression fractures of the vertebrae have changes in their posture and the alignment of the spine. The Osteoporosis Assessment Questionnaire asks about feelings regarding body image.[7] Questions were asked about the impact of pain on daily activities. At the 1-month follow-up telephone call, all of these questionnaires were used as well as 1 more questionnaire requesting information about

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Outcome measures of questionnaires and number of questions in each instrument

Outcome Measures	Number of Questions
NRS	1
Pain Medication questionnaire	2
Modified Roland Scale	23
SOF ADL	6
Euro QOL	5
Pain frequency index	1
Pain bothersomeness index	1
SF-36 Version 1	36
OPAQ—Body image domain	3
Pain impact on activities	2
Back pain resource use	2
Total number of questions	82

Note:—NRS indicates numeric rating scale; SOF ADL, Study of Osteoporotic Fractures and Activities of Daily Living questionnaire; Euro QOL, Euro Quality of Life; SF-36, Short-Form Health Survey with 36 questions; OPAQ, Osteoporosis Assessment Questionnaire.

any physician office visits or hospital visits the patient may have had since the vertebroplasty procedure.

Among 20 patients initially enrolled, all patients were able to answer all questions at baseline, preprocedure, and during in-person interviews. The length of time to complete the in-person, preprocedure questionnaires was 17.5 ± 2.4 minutes (range, 14–21 minutes). At 1 month, 4 patients (20%; 95% confidence interval) were lost to follow-up (1 death from lymphoma, 2 not answering the telephone, and 1 withdrawing from the study). All 16 patients who underwent the follow-up interview completed all questions. The length of time required to complete the telephone-administered, postprocedure questionnaires was 27 ± 5.5 minutes (range, 16–33 minutes). The difference in time was noted and was included in the budget information for the NIH trial. The difference in duration was statistically significant ($P < .001$).

In our study, we demonstrated that, even in elderly patients with painful vertebral compression fractures, multiple outcomes measures can be administered in a relatively short period. These multiple outcomes measures included 82 total questions among 11 outcomes measures. In-person interviews were completed in approximately 17 minutes, which we believe is quite feasible in the setting of randomized trials. Telephone-administered interviews comprised a significantly longer duration but still were completed in less than 30 minutes on average. These data suggest that a wide battery of outcomes measures can readily be administered in the vertebroplasty population.

Validated, functional outcomes measures have previously been reported in the vertebroplasty population.[5,8-11] Global health measures have not been reported in the vertebroplasty population but have been published in kyphoplasty cohorts. Our data presented here suggest that wide arrays of outcomes measures can be applied to the vertebroplasty population, which may facilitate the completion of prospective trials.

Our study had several limitations. The patient population was somewhat heterogeneous regarding causes of the fractures. However, the mean age of the cohort was similar to that of many previous vertebroplasty studies. Also, 20% of the patients were lost to follow-up, which is higher than would typically be acceptable in a large, prospective trial.

The outcomes presented, including a high rate of successful completion of the questionnaires both in person and by telephone, offer encouragement that a wide array of outcomes measures can be administered to the vertebroplasty population. Future trials of vertebroplasty, when possible, should include appropriate outcomes measures.

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Erratum

In the Acknowledgment section of "A Pilot Study of the Use of Pain Questionnaires in Vertebroplasty Research" (*AJNR Am J Neuroradiol* 2009;30:1364–65), the name of Dr. Arash Ehteshami Rad was misspelled.

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