Have Referral Patterns for Vertebroplasty Changed since Publication of the Placebo-Controlled Trials?

M.T. Luetmer and D.F. Kallmes

AJNR Am J Neuroradiol 2011, 32 (4) 647-648
doi: https://doi.org/10.3174/ajnr.A2371
http://www.ajnr.org/content/32/4/647
Since the development of spine augmentation, there has been a rapid rise in the use of vertebroplasty in the United States. Vertebroplasty and kyphoplasty combined have increased 12,900% from 1993 to 2004, and rates of vertebroplasty in Medicare enrollees nearly doubled from 2001 to 2007. Furthermore, the procedure was endorsed in 2007 by several American neurologic surgical and radiologic societies that deemed it to be a safe and effective treatment of osteoporotic and neoplastic vertebral fractures. Recent blinded placebo-controlled trials have cast doubt on the efficacy of vertebroplasty. Whether these publications have influenced the practice of vertebroplasty remains unknown. The purpose of this study was to determine whether referral patterns and rates of vertebroplasties at the Mayo Clinic have changed since publication of the placebo-controlled trials.

Materials and Methods
The study was approved by our local institutional review board. This retrospective study compared the number of patients who were evaluated for vertebroplasty and those treated with vertebroplasty before the publication of INVEST and the Australian Trial, between January 5, 2004, and June 2, 2010. We catalogued age, sex, number of treated vertebrae, physician referring the patient for vertebroplasty, and the referring department. We calculated the mean number of referrals per month before and after August 2009, which was the month of publication for both trials. We also calculated rates for specific referring physician types.

Results
During the full study, 1188 patients were referred, of whom 807 underwent treatment at 1378 levels for a total of 943 separate vertebroplasty procedures. The mean number of vertebroplasty referrals per month has dropped significantly from 18.9 ± 5.3 (95% CI, 17.7–20.2) before publication to 11.3 ± 3.1 (95% CI, 9.1–13.5) referrals per month after publication (P = .0001). Before publication, 67.3 ± 14.0% (95% CI, 64.0%–70.7%) of patients referred for vertebroplasty underwent vertebroplasty, compared with 76.0 ± 14.9% (95% CI, 65.4%–86.6%) after publication (P = .11).

Conclusions
The number of vertebroplasty referrals at our center has decreased significantly since the publication of INVEST and the Australian Trial, yet we continue to offer the procedure to a high proportion of referred patients.

ABBREVIATIONS: CI = confidence interval; INVEST = INvestigational Vertebroplasty Efficacy and Safety Trial; PMR = Physical Medicine and Rehabilitation

Received August 17, 2010; accepted after revision September 12.
From the College of Saint Benedict/Saint John’s University (M.T.L.), St. Joseph, Minnesota; and Department of Radiology (D.F.K.), Mayo Clinic, Rochester, Minnesota.
Please address correspondence to David F. Kallmes, MD, Mayo Clinic, 200 First St SW, Rochester, MN 55905; e-mail: Kallmes.david@mayo.edu
DOI 10.3174/ajnr.A2371

2 vertebroplasty sessions, 20 (2.5%) of 807 treated patients had 3 vertebroplasty sessions, and 13 (1.6%) of 807 treated patients had ≥4 total vertebroplasty sessions (including those before January 5, 2004). The mean number of levels treated per session was 1.5 ± 0.8; median, 1 level; range, 1–6 levels. Of those 807 patients undergoing vertebroplasty, 516 (64%) were women with a mean age of 74.6 ± 11.7 years; median, 77 years; range, 23–96 years. Two hundred ninety-one (36%) were men, with a mean age of 71.3 ± 13.0 years; median, 74.0 years; range, 32–97 years. Age was at the time of the first vertebroplasty. Of those 381 patients evaluated for but not receiving vertebroplasty, 221 (58%) were women, with a mean age of 73.5 ± 13.0 years; median, 76 years; range, 31–96 years. One hundred sixty (42%) of 381 were men, with mean age of 67.5 ± 13.7 years; median, 70 years; range, 22–97 years. The age was at the time of the first evaluation.

The mean number of vertebroplasty referrals per month dropped significantly from 18.9 ± 5.3 (95% CI, 17.7–20.2) before publication of INVEST to 11.3 ± 3.1 (95% CI, 9.1–13.5) referrals per month after publication (P = .0001). Before publication, 67.3 ± 14.0% (95% CI, 64.0%–70.7%) of patients referred for vertebroplasty were offered vertebroplasty, compared with 76.0 ± 14.9% (95% CI, 65.4%–86.6%) after publication (P = .018).

Refferrals were received from >20 different departments and 420 different referring physicians. The mean number of referrals per month from the Spine Center and PMR and Orthopedics decreased significantly after the publication (Table). There was no statistically significant difference between the mean number of referrals from the Department of Hematology per month before and after the publication.

**Discussion**

In the current study, we found that at our single center, the number of patients referred for consideration of vertebroplasty decreased significantly after the publication of INVEST and the Australian Trial, compared with the rate of such referrals during the 5 years preceding publication of that trial. While we have not specifically queried any referring physicians regarding reasons for changing referral patterns, we believe that the relatively sudden drop in the rate of referral reflects a response to the results published in the placebo-controlled trials. Notably, we continue to offer vertebroplasty to a high proportion of referred patients, indicating that our own belief in the efficacy of the procedure outweighs its risks.

The rate of referrals from the Department of Hematology, most for patients with multiple myeloma, did not change after publication of INVEST and the Australian Trial. Because the INVEST trial specifically excluded patients with myeloma, referring hematologists may believe that the results of the trial do not apply to these types of patients.

Numerous commentaries and editorials have questioned the efficacy of spine augmentation in light of the placebo-controlled trials.7–12 Even in light of the trials and commentaries, we continue to perform vertebroplasty relatively frequently. Indeed, we noted in the current study a trend toward an increase in the proportion of referred patients who undergo the procedure. This increase in the percentage of referrals leading to vertebroplasty may indicate that physicians are more stringent than previously regarding whom they refer for vertebroplasty.

**Conclusions**

The number of vertebroplasty referrals has decreased nearly 50% since the publication of INVEST and the Australian Trial, yet we continue to offer the procedure to a high percentage of referred patients.

**Acknowledgments**

We thank Arash Ehteshami Rad, MD, and Leigh A. Gray for advice regarding patient data collection, data analysis, and manuscript preparation.

**References**