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

BACKGROUND AND PURPOSE: Our aim was to determine whether referral patterns and rates of vertebroplasties at the Mayo Clinic have changed after the publication of the INVEST and the Australian Trial. In August of 2009, we performed a retrospective review of patients undergoing vertebroplasties and those patients who were referred for but did not receive vertebroplasties before and after the recently published placebo-controlled vertebroplasty trials.

MATERIALS AND METHODS: After approval by our local institutional review board, we retrospectively evaluated all patients referred for vertebroplasty 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, $67.3 \pm 14.0\%$ (95% CI, 64.0%–70.7%) of patients referred for vertebroplasty underwent vertebroplasty, compared with $76.0 \pm 14.9\%$ (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

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 2005.^{1,2} 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.³

Recent blinded placebo-controlled trials have cast doubt on the efficacy of vertebroplasty.^{4,5} 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 INVEST⁶ and the Australian Trial, between January 5, 2004, and August 6, 2009, with the number of patients evaluated

and treated after the publication from August 7, 2009, to June 2, 2010. Patients included were those who were referred for vertebroplasty and/or received ≥ 1 vertebroplasty between January 5, 2004, and June 2, 2010. Patients enrolled in research trials were included. A single investigator (M.T.L.) performed a chart review of patient and procedure records to evaluate age, sex, number of treated vertebrae, physician referring the patient for vertebroplasty, and the referring department. Both the evaluations leading to vertebroplasty and those not leading to vertebroplasty were grouped into months by evaluation date. A number of previous case series from our institution have been published by using some portions of this same patient data base.^{4,6} However, we have never previously performed a detailed analysis of referral patterns and rates of vertebroplasty.

Statistical Analysis

We compared the mean number of total referrals per month and the mean number of referrals per month by department by using the Student *t* test. We divided the number of patients treated with vertebroplasty by the total number of those referred for vertebroplasty evaluation, and these ratios were compared pre- and post-INVEST by using the Student *t* test.

Results

A total of 1188 patients underwent 1382 vertebroplasty evaluations during the entire study period. Eight hundred seven (68%) of 1188 referred patients underwent treatment at 1378 vertebral levels in 943 separate vertebroplasty sessions. Six hundred eighty-nine (85.4%) of 807 treated patients had 1 vertebroplasty session, 85 (10.5%) of 807 treated patients had

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Mean number of referrals per month from referring departments before and after publication of INVEST and the Australian Trial

| Referring Department | Mean No. of Referrals per Month before Publication | Mean No. of Referrals per Month after Publication | P Value |
|----------------------|--|---|---------|
| Spine Center and PMR | 6.3 ± 2.8, 95% CI, 5.7–7.0 | 3.4 ± 1.3, 95% CI, 2.4–4.4 | .0001 |
| Hematology | 2.2 ± 1.6, 95% CI, 1.8–2.6 | 2.6 ± 1.9, 95% CI, 1.2–4.0 | .564 |
| Orthopedics | 1.6 ± 1.4, 95% CI, 1.3–2.0 | 0.6 ± 1.0, 95% CI, –0.1–1.3 | .0099 |

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 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 ($P = .1083$).

Referrals 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, re-

ferred 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.

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