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INTERVENTIONAL UPDATE

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Continued Support for Vertebral Augmentation

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A 2009 edition of the New England Journal of Medicine[1] contained two studies that have created controversy regarding treatment of symptomatic vertebral body compression fractures. The studies concluded that vertebroplasty is no better than a sham control procedure in relieving compression fracture pain. These results are discordant with more than 15 years of medical literature and the experience of thousands of physicians. In the following months after release of this article, many professional societies drafted statements to counter these conclusions and the negative response from the lay press. Mostly these statements call attention to methodology weakness in these trials.

STUDY WEAKENESSES

The first trial enrolled 131 patients despite screening about 2,000 and an initial protocol calling for 250. Most feel that this resulted in significant selection bias. More concerning is the inclusion of patients with fractures up to 12 months old and no requirement for MRI or bone scan to confirm fracture acuity. Also, patients with pain scores as low as 3 out of 10 were accepted. These methods are counter to the careful patient selection process maintained in daily practice. How did investigators avoid treating healed fractures, possibly a full year old, in subjects with other etiologies for back pain? And finally, note that 44% of patients in the control group were allowed to "cross-over" and undergo vertebral augmentation. This leaves us with a small control group and many patients eventually requiring vertebroplasty, even within the study group. What about all the patients who were not enrolled?

The likelihood of selection bias and very small number of patients ultimately recruited in the second trial is no more assuming. The study excluded 90% of patients screened. Reasons for exclusion were not specifically reported or discussed. Several hundred patients declined enrollment. Despite a patient population drawn from four large medical centers, 78 patients were enrolled over a four year period. A single typical medical center will treat 78 compression fracture patients in less than a year. For many, a technical flaw in the procedures performed invalidates the study results. That is, the mean volume of PMMA (acrylic) administered at the fracture site was 2.8 cubic centimeters. This is much lower than usually injected and lower than volumes reported in other trials. At most vertebrae, such a small amount of PMMA is inadequate for fracture cleft filling, let alone, filling the vertebral body or restoring axial stability.

CONCLUSION

In closing, let us remember that "conservative" care of elderly patients with acute compression fractures

is not benign. Narcotics are often not well tolerated, and changes in mentation may increase fall risk. Prolonged bed rest leads to de-conditioning, greater bone loss and greater risk of medical complications. Having carefully considered these two papers, our practice has not changed. Interventional therapy needs to be considered, as rapid relief of pain and immobility are desirable. Patients and caregivers benefit from vertebral augmentation procedures. Please do not hesitate to contact me with your questions or concerns at 231.935.2861.

1 Rachelle Buchbinder, Ph.D., Richard H. Osborne, Ph.D., Peter R. Ebeling, M.D., John D. Wark, Ph.D., Peter Mitchell, M.Med., Chris Wriedt, M.B., B.S., Stephen Graves, D. Phil., Margaret P. Staples, Ph.D., and Bridie Murphy, B.Sc., "A Randomized Trial of Vertebroplasty for Painful Osteoporotic Vertebral Fractures", *New England Journal Of Medicine* (August 6, 2009): 557-568.

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