Augmented Reality

0'''

W e read with interest the article by Hirsch et al¹ in the January 2020 issue of the *American Journal of Neuroradiology* (*AJNR*).¹ If their results are valid, vertebral augmentation would indeed be a highly efficacious medical procedure. Unfortunately, given the information presented in their article, one cannot conclude that vertebral augmentation conveys as strong a mortality benefit as they state. While we applaud the authors for highlighting the morbidity and mortality associated with vertebral compression fractures, we have serious methodologic concerns that draw into question their conclusions.

Our foremost methodologic concern is that it is unclear on which article and/or dataset the analysis for this study was based. The only reference in the Materials and Methods section refers to an article describing changing augmentation practices with time.

Furthermore, the authors allowed patients to have had their augmentation procedures up to 1 year after the incident vertebral fracture, but it is not clear when the "clock started" for measuring death, the outcome of interest. Is time to death measured from the incident vertebral compression fracture, or in the augmentation group, are they measuring from the date of the augmentation procedure? Only patients surviving up to the augmentation procedure could have had augmentations; it appears that patients who died <1 year following their incident fractures could only contribute to the nonsurgical management group. This would result in a survival bias favoring the procedure group. Thus, the patient populations in each arm were unlikely to have been the same and could have had differential mortality rates.

It is also unclear how the authors arrived at the actual number needed to treat. Why did they choose to use the survival curves and hazard ratios from another article, rather than generating such curves from their own data with appropriate comparison group ascertainment? McAlister² noted that if investigators want to use

O^m Indicates open access to non-subscribers at www.ajnr.org

http://dx.doi.org/10.3174/ajnr.A6587

the number needed to treat to compare treatments, they must examine therapies in similar populations with the same condition at the same stage, using the same comparator, time period, and outcomes. The implied target population of the article by Hirsch et al is patients with vertebral compression fractures who would be considered appropriate for vertebral augmentation.¹ However, they included International Classification of Diseases, Ninth Revision, Clinical Modification diagnosis codes that would represent patients highly unlikely to undergo augmentation and who likely have high rates of mortality. For example, code 805.0 refers to closed cervical fractures, which are not typically treated with vertebral augmentation. These fractures are commonly traumatic, and in the elderly age group, they have a 1-year mortality rate of >30%.3 It is unlikely that these patients would be in either procedural group, yet they contribute to the mortality in the management group.

It is unclear which Current Procedural Terminology (CPT) codes they used to define augmentations and operations. Although the authors state that they excluded patients who had fusion surgery, they do not describe their methods for identifying these patients, and they do not include all of the procedure codes for vertebral augmentation used in their study time period. They are missing CPT codes 22520–22 for vertebroplasty. In addition, CPT code 22289, which was included, is for an unlisted spine procedure and is not specific for vertebral augmentation. At a minimum, they should have explained why they chose these codes and performed a sensitivity analysis to demonstrate the impact of altering their codes.

Fundamentally, using observational data to infer causation is problematic.⁴ The conclusion of this article, "Only 15 patients need to be treated to save one life at 1 year," is likely incorrect, even if all the prior concerns were adequately addressed. If vertebral augmentation did impart such a large absolute risk reduction of death at 1 year, it is likely that this finding would have been demonstrated in a randomized controlled trial. A previous analysis of individual patients demonstrated that before adjustment for age, sex, and comorbidities, vertebroplasty was actually associated with higher rates of mortality compared with no vertebroplasty.⁵ This observed difference vanished after adjustment, highlighting the need for careful baseline matching in observational studies, or, better yet, randomized controlled trials with adequate power to assess mortality.

This work was supported by University of Washington Clinical Learning, Evidence and Research (CLEAR) Center for Musculoskeletal Disorders funded by National Institutes of Health/National Institute of Arthritis and Musculoskeletal and Skin Diseases P30AR072572. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. It was also supported by the Faculty of Radiologists (Royal College of Surgeons in Ireland) Health Services Research Scholarship. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Faculty of Radiologists.

In summary, because of methodologic concerns, we remain skeptical that there is a mortality benefit of vertebral augmentation and urge readers to review all of the evidence critically.

Disclosures: Michael O'Reilly—RELATED: Grant: Faculty of Radiologists (Royal College of Surgeons in Ireland), Comments: Health Services Research Scholarship*; UNRELATED: Grants/Grants Pending: Radiological Society of North America, Comments: Research Fellow Grant R1912.* Patrick J. Heagerty—RELATED: Grant: University of Washington, Comments: National Institute of Arthritis and Musculoskeletal and Skin Diseases P30 grant.* David F. Kallmes—UNRELATED: Patents (Planned, Pending or Issued): KyphEZE Inc, Comments: patents for spine augmentation; Stock/Stock Options: Superior Medical Editing, Comments: Founder. Jeffrey G. Jarvik—UNRELATED: Grants/Grants Pending: National Institutes of Health/National Institute of Arthritis and Musculoskeletal and Skin Diseases*; Royalties: Wolters Kluwer/UpToDate, Springer Publishing, Comments: royalties as a chapter author, royalties as a book coeditor, paid to the individual; Travel/Accommodations/Meeting Expenses Unrelated to Activities Listed: Association of University Radiologists GE Radiology Research Academic Fellowship, Comments: travel reimbursement for Faculty Board of Review. *Money paid to the institution.

REFERENCES

- Hirsch JA, Chandra RV, Carter NS, et al. Number Needed to Treat with Vertebral Augmentation to Save a Life. AJNR Am J Neurorad 2020;41:178–82 CrossRef Medline
- McAlister FA. The "number needed to treat" turns 20—and continues to be used and misused. CMAJ 2008;179:549–53 CrossRef Medline
- 3. Godat LN, Kobayashi LM, Chang DC, et al. **Improving life expectancy:** a 'broken neck' doesn't have to be a terminal diagnosis for the elderly. *Trauma Surg Acute Care Open* 2018;3:e000174 CrossRef Medline

- Collins R, Bowman L, Landray M, et al. The magic of randomization versus the myth of real-world evidence. N Engl J Med 2020;382:674– 78 CrossRef Medline
- McDonald RJ, Achenbach SJ, Atkinson EJ, et al. Mortality in the vertebroplasty population. AJNR Am J Neuroradiol 2011;32:1818–23 CrossRef Medline

M.K. O'Reilly Department of Radiology

©P.J. Heagerty

Department of Statistics

🕒 L.S. Gold

Department of Radiology University of Washington Seattle, Washington

D.F. Kallmes

Department of Radiology Mayo Clinic Rochester, Minnesota

I.G. Jarvik

Department of Radiology University of Washington Seattle, Washington