Vertebroplasty in osteoporotic compression fracture Angene Johnson 14 April 2017 Draft 1

<u>Case</u>: Our patient was a 93 year old woman with known history of severe osteoporosis. She presented to the emergency department with her third episode of acute on chronic lower back pain in a six month period. Imaging was considered difficult to interpret due to the severity of her underlying disease, but CT demonstrated an L4 compression fracture, absent on a previous scan obtained months before. On this and previous admissions, she expressed desire to avoid medical testing and procedures, due to fear, discomfort, and desire not to prolong the life she was increasingly dissatisfied with, as her functional status declined. However, after conservative management with a trial of bracing and medical therapy did not relieve symptoms, vertebroplasty was proposed, and she ultimately underwent the procedure.

Subsequently, she continued to experience severe lower back pain. Eventually over the next few weeks, with up-titration of her pain regimen and improved management of her anxiety, symptoms improved. Unfortunately, on post-procedural x-ray there was concern for new compression fractures at the levels of L3 and T12; this let to recommendation for repeat CT and possible further vertebroplasty, which caused emotional distress, and at this point she ultimately declined further evaluation.

Society guidelines: The 2011 American Academy of Orthopedic Surgeons clinical practice guideline on "The Treatment of Symptomatic Osteoporotic Spinal Compression Fractures" recommends "against vertebroplasty for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.

Alternately, in a consensus statement on percutaneous vertebral augmentation by several professional organizations including the Society of Interventional Radiology (SIR), American Association of Neurological Surgeons(AANS), the American College of Radiology (ACR), and the Society of NeuroInterventional Surgery (SNIS), the groups state "It is the position of the Societies that percutaneous vertebral augmentation (PVA) with the use of vertebroplasty or kyphoplasty is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures, when performed in a manner in accordance with published standards" ii

Available evidence: a number of papers evaluate the effects of vertebroplasty, and a 2015 Cochrane review identified twelve randomized or quasi-randomized controlled trials; these include the studies referenced by both society papers discussed above. Control groups included non-operative therapy, alternate procedure (typically kyphoplasty) and sham procedure, while outcomes assessed included pain, disability, quality of life. patient assessment of treatment success, incident fractures and other, and other adverse events. Pooled analysis was limited by trial heterogeneity; in the six trials comparing vertebroplasty to usual care, there were small statistically significant improvements in pain in pain at all evaluated time points, but variable results with regard to disability depending on time point assessed. However, in the two included trials comparing vertebroplasty to sham procedure, there was no statistically significant difference in pain or disability, assessed at multiple time points from one week to one year (and up to two years in one trial).ⁱⁱⁱ In the sham procedure trials, the control group intervention included subcutaneous and periosteal anesthetic infiltration, as well as tapping the vertebral body with a blunt stylet ^{iv} or pressure on the patient's back.^v

A third study comparing vertebroplasty with placebo procedure, was published in the October 2016 Lancet. The VAPOUR trial was a multicenter, randomized, double-blind, placebo-controlled trial performed in Australia; 120 patients >60 years old, pain duration <6 weeks, pain severity >7/10, and 1 or 2 imaging confirmed fractures were randomized to vertebroplasty vs. placebo. The sham procedure differed from the two previous trials in that only local (no periosteal) anesthetic infiltration was performed. At time points assessed between three days and six months post procedure, statistically significant benefit to vertebroplasty was identified in both proportion of patients with pain score <4 and mean reduction in pain score (ranging 1.3-1.8 points at various time intervals). Of note, this study was funded by the manufacturer of the cement product used in the trial.^{vi}

Conclusions: Our patient received minimal pain management prior to undergoing vertebroplasty, (acetaminophen and 2.5mg oxycodone q6 PRN) - presumably due to concerns about opioid use in the setting of her age and general frailty. However, when the procedure didn't provide pain relief, she tolerated uptitration of opioids well, indicting she may not have received an adequate trial of conservative management – typical mean duration of pain in study participants was on the order of several weeks, whereas our patient underwent vertebroplasty within a matter of days after development of symptoms. As the currently available data does not clearly demonstrate significant benefits of vertebroplasty, and in light of our patient's advanced age, poor baseline functional status, and general preference to avoid medical testing and procedures, indication for the procedure was not clear in this case.

¹ Esses, Stephen, et. al. "The treatment of symptomatic osteoporotic spinal compression fractures." *Journal of the American Academy of Orthopedic Surgeons.* Volume 19(3), March 2011, p 176–182. Online. Available: http://dy3uq8jh2v.search.serialssolutions.com/?sid=Entrez:PubMed&id=pmid:21368100.

Barr, John, et. al. "Position Statement on Percutaneous Vertebral Augmentation: A Consensus Statement Developed by the Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Canadian Interventional Radiology Association (CIRA), and the Society of NeuroInterventional Surgery (SNIS)." *J Vasc Interv Radiol* 2014; 25:171–181. Online, Available: http://www.jvir.org/article/S1051-0443(13)01487-5/pdf>.

Buchbinder, Rachelle, et.al.."Percutaneous vertebroplasty for osteoporotic vertebral compression fracture." *Cochrane Database of Systematic Reviews* 2015, Issue 4. Art. No.: CD006349. DOI: 10.1002/14651858.CD006349.pub2.

Online. Available: < http://onlinelibrary.wiley.com.hsl- ezproxy.ucdenver.edu/doi/10.1002/14651858.CD006349.pub2/full#CD006349-tbl-0001>.

iv Buchbinder, Rachelle, et. al. "A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures." N Engl J Med 2009; 361:557-568. Online. Available: http://dy3uq8jh2v.search.serialssolutions.com/?sid=Entrez:PubMed&id=pmid:19657121.

V Kallmes, David et. al. "A randomized trial of vertebroplasty for osteoporotic spinal fractures. NEngl J Med 2009; 361:569-579. Online, Available http://dy3uq8jh2v.search.serialssolutions.com/?sid=Entrez:PubMed&id=pmid:19657121.

vi Clark, William, et. al. "Safety and efficacy of vertebroplasty for acute painful osteoporotic fractures (VAPOUR): a multicenter, randomized, double-blind, placebo-controlled trial." The Lancet; 2016; 388: 1408-1416. Online. Available">http://www.sciencedirect.com.hsl-ezproxy.ucdenver.edu/science/article/pii/S0140673616313411>">http://www.sciencedirect.com.hsl-ezproxy.ucdenver.edu/science/article/pii/S0140673616313411>">http://www.sciencedirect.com.hsl-ezproxy.ucdenver.edu/science/article/pii/S0140673616313411>">http://www.sciencedirect.com.hsl-ezproxy.ucdenver.edu/science/article/pii/S0140673616313411>">http://www.sciencedirect.com.hsl-ezproxy.ucdenver.edu/science/article/pii/S0140673616313411>">http://www.sciencedirect.com.hsl-ezproxy.ucdenver.edu/science/article/pii/S0140673616313411>">http://www.sciencedirect.com.hsl-ezproxy.ucdenver.edu/science/article/pii/S0140673616313411>">http://www.sciencedirect.com.hsl-ezproxy.ucdenver.edu/science/article/pii/S0140673616313411>">http://www.sciencedirect.com.hsl-ezproxy.ucdenver.edu/science/article/pii/S0140673616313411>">http://www.sciencedirect.com.hsl-ezproxy.ucdenver.edu/science/article/pii/S0140673616313411>">http://www.sciencedirect.com.hsl-ezproxy.ucdenver.edu/science/article/pii/S0140673616313411>">http://www.sciencedirect.com.hsl-ezproxy.ucdenver.edu/science/article/pii/S0140673616313411>">http://www.science/article/pii/S0140673616313411>">http://www.science/article/pii/S0140673616313411>">http://www.science/article/pii/S0140673616313411>">http://www.science/article/pii/S0140673616313411>">http://www.science/article/pii/S0140673616313411>">http://www.science/article/pii/S0140673616313411>">http://www.science/article/pii/S0140673616313411>">http://www.science/article/pii/S0140673616313411>">http://www.science/article/pii/S0140673616313411>">http://www.science/article/pii/S0140673616313411>">http://www.science/article/pii/S0140673616313411>">http://www.science