New York Society of Interventional Pain Physicians

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NYSIPP POSITION STATEMENT

Percutaneous Vertebral Augmentation (PVA)

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Position Statement

The New York Society of Interventional Pain Physicians (NYSIPP) strongly supports the use of Percutaneous Vertebral Augmentation (PVA) with the use of vertebroplasty or kyphoplasty in appropriate patients with symptomatic Vertebral Compression Fracture(s) (VCF). Patients in this category have either failed conservative nonoperative therapies or have symptomatic VCF. Based upon review of the body of peer reviewed published evidence, approval by the United States Food and Drug Administration (FDA), real world experience, and long-term patient outcomes, NYSIPP recommends qualified physicians consider the use of this modality based upon clinical need and presentation. Because of proven safety and durable effectiveness, PVA systems are within the standard of care for their indicated use.

Based upon the body of peer-reviewed published evidence, FDA approval, recognition under a Medicare National Coverage Determination, and robust support from esteemed entities like the RAND/UCLA and available consensus statement such as seen in JVIR, NYSIPP further recommends policymakers and payers enable timely access to PVA when prescribed by a qualified physician who has used his or her best medical judgement in caring for those patients with symptomatic VCF.

Background

PVA can be further subdivided into vertebroplasty and kyphoplasty. Regarding vertebroplasty, multiple case series and retrospective and prospective nonrandomized studies and more recently, randomized controlled trials have shown statistically significant improvement in pain and function, particularly ambulation. (1)

Kyphoplasty was subsequently introduced as an alternative approach for vertebral augmentation. It is similar to vertebroplasty and has been referred to as “balloon-assisted vertebroplasty”. Kyphoplasty entails the inflation of a percutaneously delivered balloon in the vertebral body, followed by injection of bone cement into the cavity created by the balloon. The balloon was intended to restore the vertebral body height in addition to creating the cavity. (1)

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Bipedicular approach has traditionally been utilized, but more recently unipedicular approach with curved needle approach has gained popularity. Numerous PVA kits are available to qualified physicians, with companies manufacturing these kits such as Stryker, Medtronic (Kyphon), Zavation, etc.

Conclusion and Recommendations

NYSIPP strongly advocates for the utilization of PVA by qualified, trained physicians for patients with VCF who meet several criteria. The body of level I-IV published evidence, long term outcomes demonstrating durable treatment effect, relatively low complication rate, as well as cost effectiveness makes this an essential tool in the management of patients with VCF. This includes disabling pain and high medical co-morbidity. The most pronounced factors were positive advanced imaging findings on MRI or CT in combination with worsening symptoms (3). Pain that prevents ambulation or physical therapy represents a rather simple and dependable measure of “severe” pain and “significant” disability (1). We find the following guideline utilized by the ACR and a multidisciplinary consensus statement helpful for a call to action to strongly consider PVA for severely affected patients with VCF (1,2):

1. For a patient rendered nonambulatory as a result of pain from a VCF, pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy; or
2. For a patient with sufficient pain from a VCF such that physical therapy is intolerable, pain persisting at that level despite 24 hours of analgesic therapy; or
3. For a patient with pain from a VCF, unacceptable side effects such as excessive sedation, confusion or constipation as a result of the analgesic therapy necessary to reduce pain to a tolerable level.

Prolonged arbitrary time periods of medical management do not have a role in the current treatment of patients with VCFs. It is clear from available clinical data that early intervention for patients severely affected by VCF produces better clinical outcomes and that this is also cost effective (1,2) Follow-up visit at 2-4 weeks post PVA as well as osteoporosis education are also indicated (3).

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References

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2. McGraw JK Barr JD, Cardella JF et al. Practice Guidelines for the Performance of Percutaneous Vertebroplasty; American College of Radiology 2009.
3. Joshua A. Hirsch, Douglas A Beall, M. Renee Chambers et al. Management of vertebral Fragility Fractures: A Clinical Care Pathway Developed by a Multispecialty Panel Using the RAND/UCLA Appropriateness Method. The Spine Journal 18 (2018) 2152-2161