INTRA-OPERATIVE COMPLICATION OF LUMBAR KYPHOPLASTY INSTRUMENTATION IN NON-OSTEOPOROTIC PATIENTS WITH COMPRESSION FRACTURES

Calvin R. Chen, DO and Steve M. Aydin, DO

Background: Vertebral augmentation is a surgical procedure used to stabilize fractured vertebrae and reduce pain in patients with compression fractures. When intra-operative and post-operative complications do occur, they can have dire consequences. Some of the common risks associated with kyphoplasty are worsening of the fracture, infections, spinal cord compression, etc. Typically, we do not consider the risk of instrumentation failure.

Objectives: In 2 cases, we describe patients who has undergone kyphoplasties with live fluoroscopic guidance. Both procedures used a unipedicular approach and the CareFusion system (Becton Dickinson, Franklin Lakes, NJ). The CareFusion AVAFlex curved augmentation needle was used, and intra-operatively the handle broke off at the neck making it difficult to remove the cannula and curved needle. To remove the system, an Arthrex Reamer (Arthrex Inc., Naples, NY).was used with Chuck Key (Arthrex Inc., Naples, NY).

Study Design: Case report.

Setting: Outpatient Interventional Pain Clinic. Methods: The vertebral body was accessed with an AVAFlex curved needle, a CareFusion AVA-

From : Physical Medicine and Rehabilitation, Northwell Health-Hofstra School of Medicine, NY| Donald and Barbara Zucker School of Medicine at Hofstra/Northwell

Author for correspondence: Calvin R. Chen, MD

Address: Donald and Barbara Zucker School of Medicine at Hofstra/ Northwell, Physical Medicine and Rehabilitation, 1554 Northern Blvd, 4th Floor PM&R, Manhasset, NY 11030

E-mail: cchen00723@gmail.com

Max vertebral balloon, and Cement injection with polymethylmethacrylate, were used. The removal of the AVAFlex cannula was attempted with a gripping and pulling motion of the blue handle on the cannula, which resulted in the handle breaking at the most distal portion of the cannula. The cannula was then removed using the Arthrex Reamer with Chuck Key. The entire cannula was successfully removed from the vertebral body after cement had been delivered.

Results: The density of bone tissue in a traumatic compression fracture of a nonosteoporotic individual will be higher and less porous when placing the needle and cannulas. Also, it is important to have an understanding of the different instruments that are available in the operative setting.

Limitations: Small sample size.

Conclusion: Instrumentation experience, understanding how to handle instrument failures, bone health of the patient, and the history of mechanism for compression fracture should all be considered when performing kyphoplasty.

Key words: Kyphoplasty, vertebroplasty, compression fracture, instrumentation failure

Vertebral compression fractures are the most common type of fractures in patients with osteoporosis, affecting an estimated 1.5 million Americans every year (1). Annually in the United States, about 700,000 osteoporotic related vertebral compression fractures are reported. Roughly 8% of all postmenopausal women over the age of 50 years old and about 27% of women in their eighth decade will experience a compression fracture during their lifetime. The prevalence of this condition has been known to increase with age (2,3). Vertebral compression fractures can severely reduce one's quality of life and limiting functionality by causing progressive kyphosis of the thoracic spine, which decreases pulmonary function as well as contributing to chronic pain, clinical depression and increased morbidity and mortality (4). Traditional treatment strategies for osteoporotic vertebral compression fractures consist of bed rest, analgesic medications, a course of physical therapy as well as bracing when needed. However, in the advanced geriatric population, these "conservative" modalities can lead to an increased rate of demineralization due to decreased mobility. Surgical treatment may be considered in patients with vertebral compression fractures if spinal instability or neurologic compromise is present, although the success rate of surgery is limited by the patient's bone quality and comorbidities. As for minimally invasive techniques to treat painful vertebral compression fractures refractory to conservative treatment modalities, there are currently 2 widely used percutaneous vertebral augmentation techniques for cement application into the vertebral body: vertebroplasty and kyphoplasty (5).

Vertebral augmentation is a surgical procedure used today to stabilize fractured vertebrae and to reduce pain in patients with compression fractures. Percutaneous vertebroplasty was first introduced in Europe in 1984 by an interventional neuroradiologist, Dr. Herve Deramond. Dr. Heramond used the technique for the aggressive treatment of aggressive spinal angionas. This process involved the injection of acrylic cement via insertion of a trocar into the vertebral body under live radiographic image guidance. This procedure would also become useful in the treatment of vertebral fractures secondary to benign and malignant metastatic tumors in addition to osteoporotic compression fractures (6,7).

Kyphoplasty was developed shortly after vertebroplasty by Dr. Mark Reiley, an orthopedic surgeon, in the early 1990s. This procedure utilized an inflatable balloon device, known as a balloon tamp, which is placed percutaneously into the vertebral body to potentially restore vertebral body height, create a stable cavity for the cement, and minimize the associated kyphotic deformity before the cement injection.

Like with all interventional procedures, both intraoperative and post-operative complications can occur, which can have dire consequences to the patient. Although these complications are relatively rare, some of the most common risks associated with vertebral augmentation are worsening of the compression fracture, infections, spinal cord compression, and cement extravasation (8). To this day, minimally invasive spine interventionalists traditionally do not consider the risk of instrumentation failure intraoperatively during either procedure. We are reporting on 2 kyphoplasty procedures performed with a unilateral approach for vertebral augmentation where a curved spinal needle was used. By utilizing this method, the procedure is known as a unipedicular approach. In both cases, the handle of the instrumentation broke off due to increased stress on the curvilinear needle as opposed to using a regular trocar or driller.

INDICATIONS FOR VERTEBROPLASTY AND KYPHOPLASTY

According to the guidelines of national societies (9), the main indications of vertebroplasty and kyphoplasty are:

- Intractable pain from osteoporotic vertebral compression fractures of more than 2 weeks and refractory to conventional medical treatments
- Painful vertebrae from aggressive primary tumors
- Painful vertebrae with osteolysis after malignant infiltration
- Painful fracture with osteonecrosis
- Chronic nonunion of fracture fragments after trauma

CONTRAINDICATIONS

According to the Interventional Radiology Quality assurance guidelines for percutaneous vertebroplasty, contraindications for vertebroplasty and kyphoplasty are as follows (10):

- Retropulsion of bone into the spinal canal
- Unmanageable or uncorrectable coagulopathy
- Improvement of symptoms with conservative management
- Asymptomatic vertebral body fracture
- Septicemia/Sepsis
- Allergy to bone cement
- Pregnancy
 - Tumor mass with involvement of the spinal canal

MECHANISM OF ACTION

The pain reduction during both procedures has been attributed to the mechanical effects of reconstruction and stabilization of the endplates and the vertebral body segment. Also, it is also theorized that the injected bone cement could block the local blood supply in the vertebral body, and lead to damage of the nerve endings. The heat generated by bone cement polymerization can damage the surrounding nerve endings, but increased vertebral strength and decreased pressure in the compressed vertebra can alleviate the pain. Vertebroplasty provides stabilization and pain relief, without improvement in the vertebrae's deformity. In comparison, a kyphoplasty procedure creates a cavity for cement, and potentially helps realign fractured vertebrae and restores vertebral height. The procedure uses a balloon tamp to create a void for introduction of PMMA (polymethylmethacrylate). While both procedures depend on mechanical stabilization by injection of PMMA cement, there is controversy on whether height restoration is clinically significant.

PROCEDURE

Both kyphoplasty and vertebroplasty are performed in a fully operational radiology suite or an operating room. The procedure requires trocars, cement, contrast media and a fluoroscope. Fluoroscopy is used during the procedure to define the anatomy for the most optimal needle placement. The chosen procedure can be performed under local anesthesia with conscious sedation, however, for the more uncooperative or agitated patients, general anesthesia may be necessary. The skin should always be prepared and draped in a sterile fashion.

Kyphoplasty performed under the unipedicular approach utilizes the insertion of a J-type needle on only one side of the vertebrae. This would not only reduce the procedural operating time and patient radiation exposure but also post-procedural pain for the patient as well. The needle is guided to the center of the vertebral body with the confirmation of live fluroscopy to ensure even cement delivery into the vertebrae (11). With only a single needle used in the unipedicular approach for cement delivery, an increase in stress tension due to the required anglation on the needle equipment to deliver the cement is expected and an increased potential for needle equipment failure is probable (12).

CASE 1

The first case is a 57-year-old male with no significant history of osteoporosis, who was determined to have a compression fracture after a fall from a ladder. The fracture was confirmed on an MRI and CT scan, and noted to be a wedge-like fracture at the L1 level. He was managed with non-interventional treatments for the initial 12 weeks post-injury. MRI with T2 STIR imaging determined edema and inflammation in the vertebral body. It was determined that a kyphoplasty would be performed at the L1 level using a unipedicular approach and with the use of the CareFusion system (Becton Dickinson, Franklin Lakes, NJ). The L1 vertebral body was accessed with an AVAFlex (Stryker, Kalamazoo, MI), curved needle, CareFusion AVAMax vertebral balloon, and cement injection with polymethylmethacrylate. Intra-operatively the handle broke off at the neck making it difficult to remove the cannula and curved needle.

At first, the removal of the AVAFlex cannula was attempted with a gripping and pulling motion of the blue handle on the cannula, which resulted in the handle breaking at the most distal portion of the cannula (Fig. 1).



Fig. 1. AVAFlex Cannula.

The cannula was then removed using the Arthrex Reamer (Arthrex Inc., Naples, NY) with a Chuck Key (Arthrex Inc., Naples, NY) (Fig. 2). The entire cannula was successfully removed from the L1 vertebral body after the cement had been delivered.

CASE 2

The second case is a 29-year-old male with no significant history of osteoporosis and was determined to have a compression fracture after a fall while snowboarding. The compression fracture was confirmed on both MRI and CT scans located at the superior endplate of T12. The patient was initially monitored and conservatively treated with non-interventional approaches. The patient's symptoms still persisted, and it was determined that a kyphoplasty would be performed at the T12 level using a unipedicular approach with the CareFusion/Stryker system. The T12 vertebral body was accessed with an AVAFlex curved needle, CareFusion AVAMax vertebral balloon, and a cement injection with polymethylmethacrylate. Intra-operatively, the handle abruptly broke off at the neck, which made it difficult to remove the cannula and curved needle.

Similar to Case 1, removal of the curved needle cannula was attempted with a gripping and pulling motion of the blue handle on the cannula, which resulted in the handle breaking at the most distal portion of the cannula (Fig. 1).

The cannula was then, attempted to be removed with a large surgical clamp. This was attempted by clamping onto the exposed metal cannula's remaining portion with the surgical clamp. The first retrieval attempt with the surgical clamp was unsuccessful. The second retrieval attempt included the use of an Arthrex Reamer with a Chuck Key



Fig. 2. Arthrex Reamer.

in the same fashion as Case 1. The entire cannula was successfully removed from the patient's T12 vertebral body after the cement had been delivered.

COMPLICATIONS

Reported complications that are significant are low (< 10%) and include increased in pain, spinal cord compression, worsening of radiculopathies, pulmonary embolism, infections, and rib fractures (13). With any penetrative procedure, risk of vital organ and tissue damage is possible. Cement leakage is also a risk of the procedure and can be caused by the cement composition itself, the procedure operator, or the cement delivery instrumentation used. In patients with metastasis or myeloma with a pathologic fracture, cement leakage leading to radiculopathy or spinal cord injury can be more common when compared to osteoporotic fractures. Uncommonly reported complications include anaphylaxis, increased pain due to thermal necrosis, and equipment failure.

RESULTS

There is class I evidence to support the superiority of vertebral augmentation procedures over non-surgical management (14). A study by Papanastassiou (15) found that vertebral augmentation was superior to non-surgical management in the treatment of osteoporotic vertebral compression fractures in terms of reducing pain and subsequent fractures. They also noted that balloon kyphoplasty was superior to vertebroplasty and non-surgical management in terms of quality of life. Currently, there are various bone cements available ranging from the more traditional radiopacifiers cements to hybrid polymer cements being used by clinicians for vertebroplasties and balloon kyphoplasties (16). Even though research has shown positive results from both interventional procedures in the short term, long-term effects of the cement's bioactive composition and additives have not been extensively studied.

In addition, regardless of which procedure is chosen, outcomes often depend on the imaging equipment, adequate cement opacification and operator experience. Although uncommon, the curved spinal needle used to access the vertebral compression body in an unipedicular approach can malfunction and mechanically break off. With the use of an Arthrex Reamer, intraoperative retrieval of the broken end of the needle is possible. Perhaps, further investigations of the etiology of equipment failures in the unipedicular vertebral augmentation approach should be done and a protocol to safely, as well as rapidly, remedy any situations of needle breakage should be developed.

CONCLUSION

Kyphoplasty and vertebroplasty can offer significant and immediate relief for patients suffering from back pain due to compression fractures. It is a relatively safe and beneficial procedure for the patient; however equipment failures, as noted in our 2 cases, can occur intraoperatively. Having a needle retrieval protocol with the use of an Arthrex Reamer and Chuck Key can help aid in retreving a broken cannula and curved needle intraoperatively. It is imperative to note that the density of bone tissue in a traumatic compression fracture of a non-osteoporotic individual will be higher and less porous when placing the needle and cannulas, which potentially increases the stress forces on the needle. In addition, it is important to have a clear understanding of the different instrumentation devices that are available in the operative setting of either procedure.

There has been a rise in clinicians who have been performing kyphoplasty procedures using the unipedicular approach over the more traditional bipedicular approach. The unipedicular approach is commonly used with patients who suffered one or more vertebral osteoporotic fractures. Radiation exposure from intraprocedural fluoroscopy, risk of cement leakage and total procedural time with the unipedicular method have all been found to be reduced (17). Despite these benefits, an increase in procedural equipment failure is possible as our 2 cases have shown. Instrumentation experience, understanding how to handle various instrumental failures, bone health of the patient, and the patient's mechanism for compression fracture should all be considered when performing kyphoplasty or vertebroplasty. Deciding on the appropriate needle approach with a uni-pedicular or bi-pedicular technique is equally imperative for a successful procedural outcome.

REFERENCES

- Alexandru D, So W. Evaluation and management of vertebral compression fractures. *Perm J* 2012; 16:46-51.
- Balkarli H, Demirtas H, Kilic M, Ozturk I. Treatment of osteoporotic vertebral compression fractures with percutaneous vertebroplasty under local anesthesia: Clinical and radiological results. International Journal of Clinical and Experimental Medicine 2015; 8:16287-16293.
- Wang H, Sribastav SS, Ye F, Yang C, Wang J, Liu H, Zheng Z. Comparison of percutaneous vertebroplasty and balloon kyphoplasty for the treatment of single level vertebral compression fractures: A meta-analysis of the literature. *Pain Physician* 2015; 18:209-222.
- Yuan WH, Hui-Chen H, Kaun-Lin L. Vertebroplasty and balloon kyphoplasty versus conservative treatment for osteoporotic vertebral compression fractures: A meta-analysis. *Medicine* 2016; 95:31.
- Savage JW, Schroeder GD, Anderson PA. Vertebroplasty and kyphoplasty for the treatment of osteoporotic vertebral compression fractures. *Journal American Academy Orthopaedic Surgeons* 2014; 22:653-664.
- Health Quality Ontario Pron Gaylene Holubowich Corinne Kaulback Kellee, Pron G, Holubowich C, Kaulback K. Vertebral augmentation involving vertebroplasty or kyphoplasty for cancer-related vertebral compression fractures: A systematic review. Ontario Health Technology Assessment Series 2016; 16:1-202.
- Ke ZY, Wang Y, Zhong YL, Chen L, Deng ZL. Percutaneous vertebroplasty combined with percutaneous pediculoplasty for lytic vertebral body and pedicle lesions of metastatic tumors. *Pain Physician* 2015; 18:E347-E353.
- Tsai PJ, Hsieh MK, Fan KF, Chen LH, Yu CW, Lai PL, Niu CC, Tsai TT, Chen WJ. Is additional balloon Kyphoplasty safe and effective for acute thoracolumbar burst fracture? *BMC Musculoskeletal Disorders* 2017; 18:393.
- 9. Marcia S, Saba L, Marras M, Suri JS, Calabria E, Masala S. Percutaneous stabilization of lumbar spine: A literature review and new options in treating spine pain. *British Journal of Radiology*

2016; 89:20150436.

- Baerlocher MO, Saad WE, Dariushnia S, Barr JD, McGraw JK, Nikolic B.; Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for percutaneous vertebroplasty. *Journal of Vascular Interventional Radiol*ogy. 2014; 25:165-170.
- 11. Lee JH, Lee, J, Jin Y. Surgical techniques and clinical evidence of vertebroplasty and kyphoplasty for osteoporotic vertebral fractures. *Osteoporosis and Sarcopenia*, 2017; 3:82-89.
- Xiang GH, Tong MJ, Lou C, Zhu SP, Guo WJ, Ke CR. The role of unilateral balloon kyphoplasty for the treatment of patients with OVCFs: A systematic review and meta-analysis. *Pain Physician* 2018; 21:209-218.
- Papanastassiou ID, Eleraky M, Murtagh R, Kokkalis ZT, Gerochristou M, Vrionis FD. Comparison of unilateral versus bilateral kyphoplasty in multiple myeloma patients and the importance of preoperative planning. *Asian Spine Journal* 2014; 8:244-252.
- Wardlaw D, Cummings SR, Van Meirhaeghe J, Bastian L, Tillman JB, Ranstam J, Eastell R, Shabe P, Talmadge K, Boonen S. Efficacy and safety of balloon kyphoplasty compared with nonsurgical care for vertebral compression fracture: a randomised controlled trial. *Lancet* 2009; 373:1016-1024.
- Papanastassiou ID, Phillips FM, Meirhaeghe JV, Berenson JR, Andersson GBJ, Chung G, Small BJ, Aghayev K, Vrionis FD. Comparing effects of kyphoplasty, vertebroplasty, and nonsurgical management in a systematic review of randomized and nonrandomized controlled studies. *Eur Spine J* 2012; 21:1826-1843.
- He Z, Zhai Q, Hu M, Cao C, Wang J, Yang H, Li B. Bone cements for percutaneous vertebroplasty and balloon kyphoplasty: Current status and future developments. *Journal of Orthopaedic Translation* 2015; 3:1-11.
- Zhang L, Liu Z, Wang J, Feng X, Yang J, Tao Y, Zhang S. Unipedicular versus bipedicular percutaneous vertebroplasty for osteoporotic vertebral compression fractures: A prospective randomized study. BMC Musculoskeletal Disorders 2015; 16:145.