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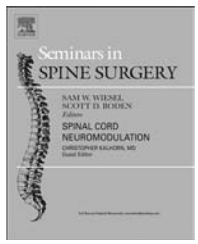

Complications associated with cement augmentation techniques in spinal surgery

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A B S T R A C T

Metabolic conditions can compromise the integrity of the spine, placing patients at risk of pain, progressive spinal deformity, and failure of instrumentation used in treatment of spinal pathology. Vertebroplasty, kyphoplasty, sacroplasty, and augmented pedicle screws are frequently performed procedures developed to help combat these issues. These procedures are infrequently associated with significant issues, but serious complications from these surgeries can occur. Consequently, it is critical that treating surgeons be aware of the most common complications associated with cement augmentation procedures, as well as understand how to minimize their occurrence, diagnose them swiftly, and manage them appropriately when needed.

1. Introduction

Conditions affecting bone metabolism have the propensity to lessen structural integrity of the spinal column and place patients at risk of pain, progressive spinal deformity, and failure of instrumentation used in treatment of spinal pathology. As a consequence of the frequency with which such conditions are encountered in management of spine patients, several techniques have been developed to improve mechanical properties of diseased bone via augmentation procedures including vertebroplasty, kyphoplasty, sacroplasty, and cement augmented pedicle screws. These procedures are centered around the use of cement to supplement structural integrity of native bone to improve pain and facilitate instrumentation of the diseased spine.

Though these procedures have been widely implemented and are frequently performed, they are not without their risks. In addition to the risks inherent to any surgical intervention on the spine, augmentation techniques have the unique potential for migration of cement into a location that threatens neurologic or vascular structures. Cement extravasation into the neural foramina or into the spinal canal can result in neurologic complications, and cement leakage into the perivertebral vasculature can result in pulmonary cement embolism (PCE). Some have also hypothesized that cement augmentation procedures increase the risk of subsequent fractures by creating a stiff fulcrum amidst adjacent weak, osteoporotic bone.

It is critical that the treating physician be aware of the unique potential complications of these commonly performed augmentation procedures as well as understand how to reduce the risk of their occurrence and appropriately manage them if needed.

2. Vertebroplasty and kyphoplasty

2.1. *Vertebroplasty*

Vertebroplasty involves percutaneous passage of a cannulated needle through the pedicle and into the vertebral body

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with subsequent injection of polymethylmethacrylate (PMMA) cement. The procedure can be performed unipedicularly or bipedicularly. Indications include painful osteoporotic compression fractures or neoplastic lesions of the vertebral body refractory to conservative therapy, as well as progressive deformity secondary to compression fractures.[1,2] Proposed mechanisms for the treatment effect of vertebroplasty include reduced fracture micromotion, improved structural support of the vertebra, and thermal ablation of nerve endings.[2]

Potential complications of vertebroplasty are consistent with any other minimally invasive intervention on the spine but include additional risks related to cement injection. Vertebroplasty requires injection of cement under pressure in order to permeate cancellous bone, theoretically increasing the risk of cement leakage into undesired locations. Additionally, the procedure stabilizes the compromised vertebra without addressing sagittal plane deformity. This theoretically creates a stiff apex at a kyphotic segment, potentially leading to asymmetric anterior loading of the adjacent osteoporotic vertebral bodies and placing them at risk of fracture. A number of studies have sought to report on the frequency and severity of these unique potential complications of vertebroplasty.

A 2008 retrospective analysis reported on 532 osteoporotic compression fractures treated with vertebroplasty and assessed the rate of PCE, defined to be venous migration of PMMA toward the lungs visualized on intra-operative fluoroscopy. Authors identified an embolism rate of 2.1%.[3] On computed tomography (CT) the emboli were peripherally distributed and without reactive changes out to one year. All patients were asymptomatic.

A subsequent randomized trial of 202 consecutive patients compared complication rates between vertebroplasty and conservative treatment.[4] CT evidenced cement leakage in 72% of cases. All patients were asymptomatic through 1-year follow-up. The authors additionally noted that there was no significant difference in the incidence of new vertebral compression fractures between cohorts. A follow-up analysis of the same study identified PCE in 26% of patients available for 2 year follow-up CT.[5] All of these patients were asymptomatic. Emboli were peripherally located and without reactive change.

A retrospective analysis performed in 2012 compared detection of cement leakage between intra-operative fluoroscopic assessment and post-operative CT imaging.[6] Leakage was identified in 82% of patients. Despite the high rate of leakage noted, all patients were asymptomatic. CT was more sensitive than intra-operative fluoroscopy in identification of extravasation. Cement leakage was associated with increased cement volume and number of levels treated.

Most recently, a randomized trial comparing conservative treatment with vertebroplasty reported on complications of each.[7] Cement leakage was identified in 52% of vertebrae with PCE reported in two patients (2.9%). All patients were asymptomatic and required no further treatment. The authors found no significant difference in subsequent fracture between vertebroplasty and conservative treatment through 3-year follow-up.

In summary, analyses on vertebroplasty have reported rates of cement extravasation ranging from 52–82% with PCE reported in 2–26%. All patients in these analyses were asymptomatic. No differences in the rate of adjacent level fracture were identified between vertebroplasty and conservative management. Risk of cement leakage has been associated with the number of levels treated and the volume of cement injected.

2.2. Kyphoplasty

Kyphoplasty is similar to vertebroplasty with the exception that prior cement injection, a balloon bone tamp is inflated to attempt endplate reduction and to form a cavity for cement injection. This potentially improves kyphotic alignment while reducing pressure needed for injection. Balloon tamp inflation also possibly results in local impaction grafting, creating a dense cancellous shell surrounding the cavity for cement injection, thereby reducing risk of cement extravasation.

Again, kyphoplasty carries with it all risks inherent to surgical intervention on the spine in addition to the unique risks associated with cement injection. The primary focus of complications of kyphoplasty safety has been the effects of cement extravasation and sequelae, as well as the relationship between kyphoplasty and adjacent level fracture.

A 2005 analysis reported on the use of kyphoplasty to supplement fractures during posterior fusion for traumatic vertebral fractures.[8] Post-operative radiographs and magnetic resonance imaging (MRI) identified cement extravasation in 5 patients (25%). All patients were asymptomatic throughout follow-up.

Several years later a multicenter randomized controlled trial compared kyphoplasty to conservative treatment.[9] Cement extravasation was noted in 51 vertebrae (27%) with the most common sites being endplate or intradiscal leakage. There were no cases of extravasation into the foramina or spinal canal, and no cement embolisms were noted. One post-operative soft tissue hematoma was reported at the surgical site.

In summary, analyses of the safety of kyphoplasty relative to non-operative treatment have reported cement leakage in 25–27% of cases. No cases of PCE were documented, and the only post-operative complication reported was a soft tissue hematoma.

2.3. Comparing vertebroplasty to kyphoplasty

While the surgical procedures and indications for vertebroplasty and kyphoplasty are similar, the variation in technique allows for variation in complications. As such, several studies have sought to compare complications between vertebroplasty and kyphoplasty.

One prospective analysis sought to compare vertebroplasty to kyphoplasty in the same vertebrae in a series of patients undergoing kyphoplasty.[10] After positioning of cannulae, prior to inflation of balloon tamps, contrast was injected and its extravasation tracked to simulate vertebroplasty. After flushing of contrast, the balloon tamps were inflated and contrast was again injected to simulate kyphoplasty. Leakage occurred in 100% of vertebrae when using the vertebroplasty technique but only in 60% of vertebrae using the kyphoplasty technique.

A subsequent analysis again compared cement leakage between vertebroplasty and kyphoplasty utilizing post-operative CT.[11] Extravasation was reported in 49% of kyphoplasty cases and in 88% of vertebroplasty cases. Additionally, vertebroplasty was associated with one case of symptomatic PCE and one case of infection.

These analyses were followed by a multicenter prospective randomized trial comparing the safety of the two procedures.[12] The extravasation rate was significantly lower with kyphoplasty (73%) than with vertebroplasty (81%). One patient in each cohort presented with symptoms attributable to PCE. The authors also reported no significant difference in the rate of subsequent vertebral fracture between kyphoplasty and vertebroplasty and conservative therapy.

There have also been a number of systematic reviews and meta-analyses comparing conservative management, vertebroplasty, and kyphoplasty.[13–18] These studies have reported rates of cement leakage of 20–41% and 7–18% with vertebroplasty and kyphoplasty, respectively. One study reported no difference in rates of cement leakage between vertebroplasty and kyphoplasty.[18] Cement leakage into the spinal canal and epidural space was reported more commonly with vertebroplasty than with kyphoplasty.[14,16] Rates of PCE in both vertebroplasty and kyphoplasty were reported to vary from 0 to 26%.[17] Neurologic symptoms occurred in < 1% of cases for either procedure. Factors associated with increased risk of extravasation included using less viscous cement, increased injection pressure, vertebrae cephalad to T7, and greater cement volume.[14] Other complications reported included transverse process fracture, pedicle fracture, rib/sternal fracture, pneumonia, pulmonary embolism, and myocardial infarction (all < 1% of cases). Rates of general complications were reported to be 2.6% in vertebroplasty and 1.3% of kyphoplasty cases. None of the studies reported an increased rate of vertebral fracture after vertebroplasty or kyphoplasty compared to conservative treatment.

In summary, analyses comparing vertebroplasty to kyphoplasty have nearly ubiquitously shown increased rates of cement extravasation, PCE, and general surgical complications with vertebroplasty. Rates of cement leakage have been reported to range from 20–100% for vertebroplasty and from 7–81% with kyphoplasty. However, while the rates of cement leakage have been high in both techniques, nearly all cases have been asymptomatic. Even in the event of PCE, studies have shown emboli to most commonly be asymptomatic, peripherally located and without reactive changes in the lung. Additionally, it does not appear that vertebroplasty or kyphoplasty increase the rate of subsequent vertebral fractures on the basis of current literature.

3. Sacroplasty

Sacroplasty is a minimally invasive technique for percutaneous cement augmentation developed for the management of sacral insufficiency fractures and osteolytic lesions of the sacrum. Sacroplasty can be performed via one of two techniques: short axis or long axis.[19] In the short axis technique, the cannulated needle is inserted perpendicular to the posterior cortex of the sacrum. Using medial to lateral angulation the needle is then advanced into the fracture site. The long axis technique involves insertion of the cannulated needle longitudinally from caudad to cephalad, entering the sacrum at the level of S4 and moving cephalad between the sacral foramina and the sacroiliac joint.

Similar to vertebroplasty and kyphoplasty, a primary focus of analyses of complications of sacroplasty has been the frequency and effect of cement extravasation during the procedure. Due to the fused nature of the sacral vertebral segments, issues with adjacent level fracture after sacroplasty are of a lesser concern.

In 2013 a retrospective analysis reported on consecutive patients who underwent CT-guided sacroplasty for sacral insufficiency fractures or osteolytic lesions of the sacrum.[19] Cement extravasation occurred in one patient (0.05%) resulting in radiculopathic pain which resolved with conservative treatment. No other complications were noted.

The same year a second retrospective analysis of 58 consecutive patients undergoing 67 sacroplasties was published.[20] Among the cohort 84.5% of patients had a sacral neoplasm while 15.5% had osteoporotic insufficiency fractures. All patients underwent post-operative radiographs and CT. Two patients (3.4%) sustained temporary neurologic deficits secondary to cement extravasation, and two patients (3.4%) required surgical decompression for foraminal and canal extravasation. All complications occurred in patients with neoplasms.

In 2014 another study reported a retrospective study of 53 patients with 97 sacral fractures secondary to neoplasm, osteoporosis, or minor trauma who underwent CT guided sacroplasty. There were no complications identified in this analysis.[21]

In summary, cement extravasation has been reported to be very infrequent in sacroplasty (0.05–3.4%), and few complications of the procedure have been documented. One potential explanation for the low rate of extravasation relative to vertebroplasty and kyphoplasty reported in these analyses is their use of CT guidance rather than 2-dimensional fluoroscopy. Analyses also indicate that cement leakage is more frequent in lytic neoplasms.

4. Screw augmentation

Pedicle screw augmentation was developed to improve mechanical stability of instrumentation in osteoporotic or osteolytic vertebrae. Augmentation can be carried out via two techniques. In one technique the pedicle is prepared for screw placement in the standard fashion, but prior to placement of the screw a cannulated needle is used to inject cement through the tapped pedicle screw path. An alternative technique involves cannulated and fenestrated pedicle screws which can be placed in a standard fashion followed by cement injection via the screw itself. Complications for pedicle screw augmentation include those associated with traditional pedicle screw placement, along with the considerations of cementation. Consequently, analysis of the safety of augmentation of pedicle screws has largely focused on the risk and sequelae of cement leakage during the procedure (Figs. 1–3).

A 2008 retrospective analysis was the first to report complications associated with screw augmentation.[22] In the analysis, cement was injected prior to screw placement. Extravasation was noted in 26% of screws, and none of these cases were symptomatic. Other reported procedural complications included infection, adjacent compression fracture, and stroke.

The following year a retrospective analysis of augmented pedicle screws was reported.[23] In this analysis, injection of PMMA was carried out through a fenestrated tap prior to placement of the pedicle screw. Asymptomatic leakage was noted in 9 patients (39%). One case of PCE was documented. All cement extravasation was asymptomatic. One patient developed a wound infection post-operatively. Interestingly, the authors found no association between extravasation and cement volume, number of levels augmented, or augmentation location.

A retrospective analysis published in 2011 compared injection of cement prior to screw placement to injection via cannulated screws.[24] Injection prior to screw placement was associated with a 14% rate of cement extravasation relative to a 9% rate with injection via cannulated screws. Only one patient had symptoms associated with cement extravasation and these resolved with conservative treatment. An inverse relationship between leakage and bone mineral density was noted.

This was followed by a prospective analysis of pedicle screw augmentation via a fenestrated, cannulated screw system.[25] Appropriate screw position was confirmed with intra-operative 3D CT prior to cement injection. Extravasation was assessed via post-operative CT imaging. Perivertebral cement extravasation was documented in 88 patients (93.6%) and 165 vertebrae (73.3%). Pulmonary cement embolism occurred in 4 patients (4.1%). All incidents of extravasation were asymptomatic and required no further treatment. The authors reported the general surgical complications including pedicle perforation, CSF leakage, blood loss, and post-operative seroma.

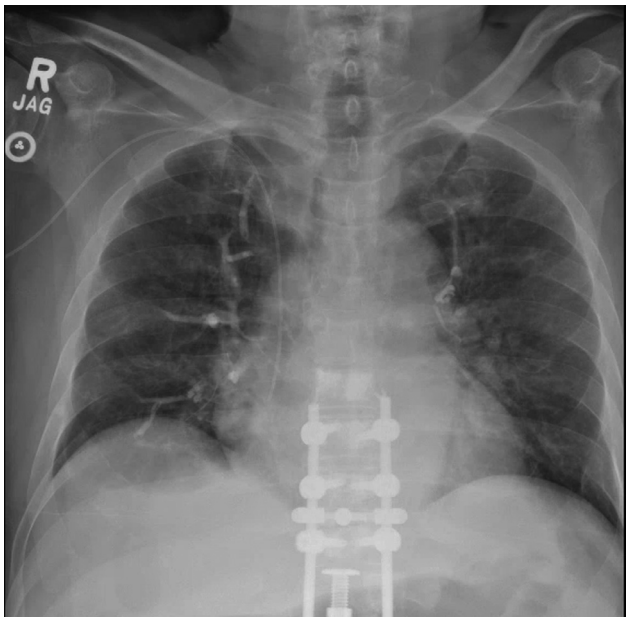

Fig. 1 – Post-operative chest radiograph obtained after a patient developed respiratory compromise following vertebral PMMA augmentation via cannulated pedicle screws. Bilateral cement emboli were noted, leading to further workup with a chest CT.

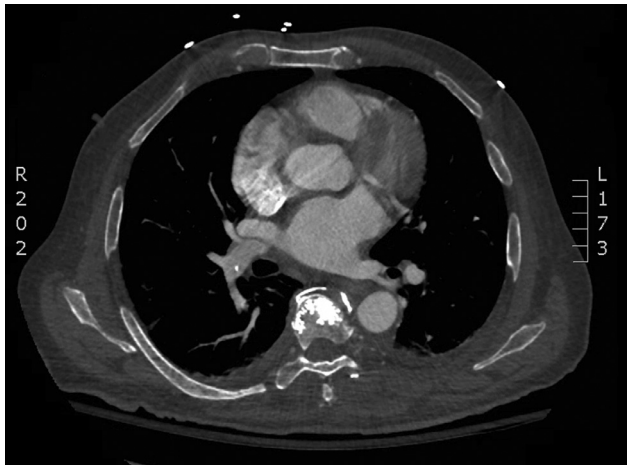

Fig. 2 – Axial CT scan cut evidencing PMMA within the segmental vertebral vessels of the same patient.

Most recently a retrospective analysis reported on 165 patients undergoing cement augmented pedicle screw instrumentation for osteoporotic fractures, spinal metastases, degenerative spine disease, infection, or trauma.[26] All patients underwent post-operative radiograph or CT. Asymptomatic cement extravasation was noted in 110 patients (67%) resulting in symptoms in 9 patients (5%). Two patients (1%) experienced neurologic deficits associated with epidural extravasation which required surgical decompression. Two patients (1%) went into cardiogenic shock secondary to central pulmonary artery and right atrial embolism, respectively, resulting in death. Anaphylaxis occurred in 2 patients (1.2%). The authors noted that patients with thoracic instrumentation and pathologic fractures had a higher rate of pulmonary cement embolism.

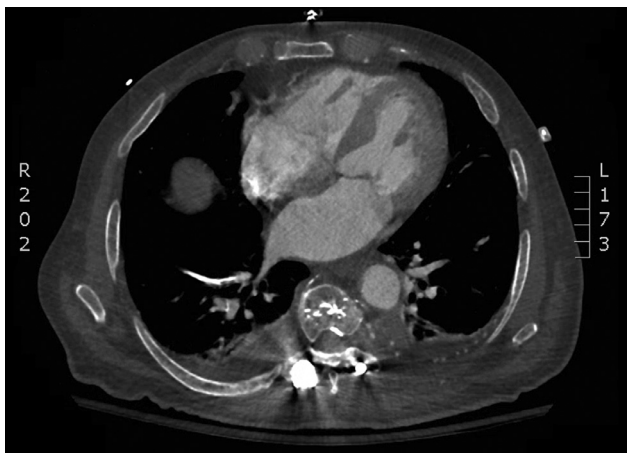

Fig. 3 – Axial CT scan cut evidencing PMMA cement embolism within the pulmonary artery of the same patient.

In summary, reported rates of cement extravasation have varied wildly between analyses, ranging from 9–94%. In direct comparison, augmentation via cannulated screws resulted in reduced rates of extravasation relative to injection of cement between tapping and screw placement. While a majority of studies reported predominantly minor and asymptomatic complications, severe complications were documented including neurologic deficits requiring decompression, anaphylaxis, and even death secondary to cement extravasation. Wide variability in these reported results is likely a function of both technique and patient selection as analyses generally pooled osteoporotic fractures, degenerative disease, trauma, infection, and spinal metastases. Given this wide variability, further assessment of the safety of screw augmentation in future analyses would be of benefit, and vigilance for PCE during the procedure as well as in the peri-operative setting is critical.

5. Means of risk reduction and complication management

Reported surgical complications including local hematoma, surgical site infection, pedicle or vertebral body breach, and dural injury are not unique to cement augmentation procedures. These complications can generally be minimized via utilization of proper surgical techniques, pre-operative planning, intra-operative imaging, meticulous hemostasis, and standard peri-operative antibiotic prophylaxis. The most common complication unique to cement augmentation procedures is clearly cement extravasation and its sequelae.

Multiple studies have reported a higher rate of cement extravasation with vertebroplasty compared to kyphoplasty. Anatomically, fractures more cephalad than T7 have been associated with increased rates of leakage.[14] In the case of sacroplasty, osteolytic neoplasms were associated with increased rates of cement leakage.[20] Other factors associated with cement extravasation included high pressure injection of cement and reduced cement viscosity.[14]

In regard to pedicle screw augmentation, analyses have reported reduced extravasation rates with cement injection through cannulated screws rather than with injection prior to screw placement.[24] Additionally, surgeons should be aware that augmentation of screws in pathologic fractures and in thoracic fractures is associated with increased rates of extravasation.[26]

Thus, on the basis of current literature, the best means to minimize risks of cement extravasation include performing kyphoplasty in lieu of vertebroplasty, injecting high viscosity cement, and injecting at a low pressure. Lower injection pressures can potentially be achieved via using a bipedicular technique. Extravasation via pedicle screw augmentation can be minimized via utilization of cannulated, fenestrated screws. Radiographic scrutiny is also critical during the injection phase as intra-operative fluoroscopy has been shown to be of limited sensitivity in detection of PCE.[6]

With the high frequency of local cement extravasation and PCE encountered in cement augmentation procedures, it is critical that surgeons have a heightened concern for these particular complications and their serious sequelae. Though a vast majority of cases of cement leakage are asymptomatic, severe complications have been reported.[27–36] In patients with new onset neurologic deficits following cement augmentation, the surgeon should have a low threshold to obtain axial imaging and consider surgical decompression. Aberrations in cardiorespiratory function should also be swiftly investigated with chest radiographs or advanced imaging.

Once a symptomatic PCE has been diagnosed it must be appropriately addressed. A 2008 systematic review of reported complications of vertebroplasty sought to determine optimal management of cement embolism.[37] After identifying a risk of pulmonary embolism ranging from 3.5 to 23% when treating osteoporotic fractures, the authors concluded that asymptomatic embolism requires no treatment. In the setting of symptomatic embolism or central embolism, the authors recommended heparinization followed by a 6-month course of coumadin therapy.

6. Conclusions

Multiple analyses have proven vertebroplasty, kyphoplasty, sacroplasty, and cement augmentation of pedicle screws to be safe procedures with low complication rates. Cement augmentation carries with it a universally high risk of cement extravasation, though extravasation is most frequently asymptomatic. It is critical that a treating physician be aware of the risk factors for cement extravasation and take steps to address these factors as well as to have a heightened suspicion for the role of cement extravasation in development of post-operative neurologic deficits or cardiorespiratory compromise.

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