



REVIEW ON PERCUTANEOUS VERTEBROPLASTY VS KYPHOPLASTY FOR OSTEOPOROTIC VERTEBRAL COMPRESSION FRACTURE

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ABSTRACT

Most common secondary cause of osteoporosis is vertebral compression fracture in spine. This fracture cause onset of severe, acute and chronic pain and reduction in vertebral height leads to spinal instability as well as kyphotic deformity. The incidence of this compression fracture is approximately 20% in patients older than 70 years with potential 700,000 osteoporotic fractures annually. Percutaneous Vertebroplasty (PVP) and Kyphoplasty (PKP) are not only minimal invasive procedure for efficient treatment for alleviating immediate pain relief, but also restore the vertebral height to maintain the stability of spine. This literature review presents a qualitative overview on the current status of both vertebral augmentation procedures and compares the efficacy and safety of both procedure in clinical outcome and complicational aspect. According to this, PKP although it is costly, its clinical outcomes are superior and complications are minimum as compare to PVP. Moreover, it sheds light on ongoing and future research for minimizing complication and maximizing efficacy and safety of these procedures.

Keywords: Percutaneous Vertebroplasty, Percutaneous Kyphoplasty, Osteoporotic Vertebral Compression Fractures

INTRODUCTION

Vertebral Compression Fracture (VCF) is one of the most common cause due to osteoporosis causing onset of severe, acute and chronic pain, reduction in vertebral height & shape and finally with deformity in spine. These consequences may lead to anxiety, depression, and devastating impact on interpersonal relationships and social roles¹. The incidence of vertebral compression fractures (VCFs) secondary to osteoporosis is estimated to be approximately 20% in patients older than 70 years, yielding a potential 700,000 insufficiency fractures annually² the incidence is difficult to quantify but approximately 30% come to medical attention³. The painful VCFs are typically treated with optimal pain management (OPM) consisting of analgesics, bed rest and external bracing initially. However, this approach is unsatisfactory when it is long period and this can lead to exacerbation of the underlying osteoporosis and failure in pain relief and stabilization of vertebral lesions⁴. In selected patients who fail to respond to nonsurgical management, cement augmentation and/or surgical intervention may be indicated.

Basically, Percutaneous Vertebroplasty (PVP) and Kyphoplasty (PKP) are the minimal invasive technique effective in relieving pain and stabilizing the spine caused by acute and sub-acute VCFs. PVP is percutaneous injection of bone cement into the cancellous or spongy bone of the vertebral body (VB) to alleviate pain which prevent the further compression fractures, vertebral height, and kyphotic deformity. Galibert et al⁵ in 1987 first introduced percutaneous vertebroplasty technique for the treatment of painful vertebral angiomas. Since then it is further expanded the treatment for osteoporotic VCFs and burst fractures, metastatic spinal lesions, as well as traumatic VCFs fractures⁶ and now a days Garfin et al.^{7,8} suggested procedure for the Vertebroplasty procedure is mostly and widely used treatment. The hypothesis of chemical and thermal effect^{9,10}, mechanical stabilization by cessation of the cleft motion after curing of the bone cement are most probable mechanism of pain relief after the treatment¹¹.

Percutaneous Kyphoplasty in other hand is similar to Vertebroplasty as it is the modification of it which is actually developed to restore vertebral body height and minimize the associated kyphotic deformity by inserting an inflatable balloon tamp inside the vertebral body to create low-pressure cavity and injecting the bone cement safely.

Several literature review articles that assess the efficacy and safety of these procedures in comparison to medical management. And the basic and direct clinical outcome of both procedure are (i) rapid pain relief, (ii) improved body functioning, and (iii) vertebral height gain or improved spinal alignment.

DISCUSSION

Percutaneous Vertebroplasty Vs Kyphoplasty Clinical Outcomes:

The AAOS Clinical Practice Guideline¹² Summary 2011 also strongly recommends the vertebroplasty technique as the principal treatment out of 11 recommended treatments for spinal compression fractures. This strong recommendation is based on evidence of Level I (vertebroplasty with sham procedure) and II (without sham procedure studies as control). Level I consist two randomized trials^{13,14} studies which report no any statistically significant difference between the two procedures in pain (using the visual analog scale) & function (Roland Morris Disability Questionnaire). Also it says that vertebroplasty works better in patients who have more pain than those who were included in these trials. The baseline pain in both of these trials was approximately 7 (scale from 0-10) but the other comparative studies had a baseline pain of approximately 8 and also had mainly negative outcomes^{15,16,17}. Moreover it reports that vertebroplasty works better with certain fracture types but there are no prospective studies reporting the significant differences in outcomes based on fracture type. The next level II contained three trails which also reported similar results. One of these studies showed pain as clinically important at 24 hours, statistically significant but not clinically in 6 weeks and neither statistically nor clinically important after 6 weeks period in the observations done up to 2 years period³⁰ it might be statistically significant & possibly clinically important at 1 day but inconclusive at 2 weeks³¹ and inconclusive results at 3 months³⁰.

McGirt et al.¹⁸ reviewed large volume of literature regarding PVP and PKP that performed for VCFs between 1980 and 2008. The study was divided into five levels (I to V) as: (i) Level I studies with consistent findings (Good Evidence); (ii) Level II or III studies with consistent findings (Fair Evidence); (iii) Level IV or V with consistent findings (Poor Quality Evidence); and (iv) studies with inconsistent findings or lack of evidence (Insufficient Evidence) according to the clinical guidelines of North America Spine Society (NASS)¹⁹. Among 74 published articles on PV until 2008, only 1 article classified as Level I (randomized control trial), 3 articles as Level II (nonrandomized control trials), while the remaining 70 classified as Level IV. They carried out a randomized study on 34 patients with painful osteoporotic VCFs. Patients were randomly divided into 2 groups: one treated with PV and the other with optimum pain medication (OPM). The PVP group showed immediate pain relief when compared to the OPM group. There was immediate pain relief and greater improvement in physical functioning in the PV group. However, there were no differences in PVP and OPM groups in terms of VAS (visual analog score for back pain) or Barthel functional Index at 1, 5, 6, 12, or 24 months. Incidence of adjacent VCFs did not increase for 2 years in the PVP cohort. The remaining 70 nonrandomized studies in the Level IV category showed substantial and rapid pain relief, although there was no control OPM group. This recommendation concluded that physical disability, general health, and pain relief are better with PV and PK than those with medical management and the incidence of procedure-related morbidity for both PVP and PKP is very low. McGirt also reviewed 35 articles with PKP for the osteoporotic

VCFs. Among them, no article were on Level I, and Level II study was published in 2 separate cohort literatures^{20,21}. In the first, there was greater pain relief and faster return to daily activity was reported within 3–6 months treatment to OPM whereas the second compared the outcomes of the patients treated with KP and OPM after 1 year, reporting greater reduction in pain at 12 months, improvement in physical functioning at 6 months, and reduction in back pain within 12-month, and fewer incidences of new adjacent VCFs in PKP compared to the OPM cohort. The remaining 33 articles qualified as Level IV evidence, showing substantial, consistent, and rapid pain relief. Taylor et al.²² also found that there is good relief of pain but ratio of benefit to harm for both procedures and balloon kyphoplasty appears to offer the better adverse event profile to medical management. Hulme et al.²³ also published a systematic review comparing PVP and PKP, including 69 clinical studies with more than 80% osteoporotic VCFs. The review examines the outcomes of 4456 vertebroplasty and 1624 kyphoplasty procedures. Pain relief, physical function (disability score), vertebral height gain (kyphotic angle restoration) were observed and found similar outcome in both groups with a mean kyphotic restoration angle of 6.6°. The pain relief was 87% with vertebroplasty and 92% with kyphoplasty. However, there was no vertebral height gain or correction in kyphotic deformity in 39% of vertebroplasty and 34% of kyphoplasty cases. The restoration of vertebral height depends on the age of the fracture^{24,25} although not validated globally²⁶. However, there is a wide variation in measurement scales and lack of prospective data comparing both approaches.

Xigong Li et al had none randomize cohort study of 12 months follow up comparing both PVP and PKP for 96 painful osteoporotic VCFs (51 PVP and 46 PKP). Beside significant pain relief and restoration of vertebral height and reduction in kyphotic angle^{27,28}, he concluded that both procedure increase height but kyphoplasty more than vertebroplasty. In vertebroplasty, restoration of height is according to patient position, bolsters insertion, and type of anesthesia and in kyphoplasty it is more specific to the expansion of the inserted balloon tamp during the procedure. Mathis et al.²⁹ found that the height gain in PV was increased (approx. 3–4 mm) and reduction in kyphotic angle (9°), while Lieberman et al.³⁸ reported an average height restoration (approx. 3 mm per vertebra) after kyphoplasty. This raises the issue of reliability of kyphoplasty in restoration of vertebral height compared to Vertebroplasty; however, the controversy lies in increasing vertebral height³⁰ as well as extent of pain. There are no much clinical trials available that show the maximum height gain after kyphoplasty. Therefore, debate still exists regarding the superiority of one procedure over the other⁴³. Both procedures resulted in improved vertebral height gain and kyphotic deformity. But Grafin et al¹⁸ showed that kyphoplasty improves height of the fractured vertebra, kyphosis by over 50% although 95% improvement in both procedure. Also they conclude that, if these procedures are performed within 3 months from the onset of the fracture (onset of pain), there is some height improvement and 95% clinical improvement if it is done after 3 months. Moreover, kyphoplasty offers the additional advantage as realignment of the spinal column which may help in improving pulmonary, GI function that and decrease early morbidity consequences related to these fractures.^{18,31}

Percutaneous Vertebroplasty Vs Kyphoplasty Complication:

Intraoperative and postoperative complications are relatively low in both procedures. In the retrospective analysis by Rhyne, among 52 patients with 82 painful osteoporotic VCF, 49 patients with mean 9-month follow-up interval, no any medical or procedural complications were reported³². Similarly, Ortiz and others, 2005, reported outcomes of 65 kyphoplasties performed in 48 patients. 99% of patients reported 100% improvement in their fracture-related pain and no any complications noted³³.

Cement leakage is another frequent common problem³⁵, particularly in lytic lesions⁵¹, and has been reported in up to 30–70% of cases; but are found asymptomatic³⁶ while symptomatic leaks represent only a small portion and they the main source of pulmonary and neurological complications.

Cement extravasation was the most complication occurs in 8.6% of their patients³⁸. PMMA may extravasate into the vascular tree, the disc space, the anterior and lateral soft tissues and the spinal canal. Disk space leakage is probably the most common. In both vertebroplasty and kyphoplasty procedures, cement can leak through the fracture cleft. Therefore, in a superior endplate fracture, the PMMA extends from the body through the cleft into the superior disk space. Use of more viscous cement has been shown to decrease extravasation in a vertebroplasty model³⁷. Other authors, such as Heini, have concluded that control of PMMA flow with directional cannulas could decrease leak rates³⁸. In a recent study, Ren et al³⁹ concluded that clinical factors such as cement viscosity, injected cement volume, and vertebral body wall incompetence were associated with the incidence of cement leakage. These investigators also found that patients with a history of pulmonary diseases were prone to lung-related complications. So, reduction in cement leakage-related complications may be due to use of high-viscosity cement; kyphoplasty in selected cases; and relatively small volume injection⁴³.

One of the advantage of Kyphoplasty over Vertebroplasty is low the risk of cement extravasation⁴⁰. Previous systematic reviews or meta-analysis have shown that kyphoplasty has a substantially lower incidence of cement leakage than vertebroplasty^{46,47}. The presumed differences in leakage rate are confirmed in current comparative study, in which the incidence of cement leakage is significantly higher in the vertebroplasty group, at 34.6%, than in the kyphoplasty group, at 9.1%. The less frequent cement leakage with kyphoplasty is probably because this technique creates a cavity that allows for a more viscous cement to be injected under lower pressure⁴¹. This study confirms that Kyphoplasty and Vertebroplasty are safe and effective treatments for patients with painful osteoporotic VCFs. During the 12-month follow-up, both procedures demonstrated similar good clinical outcomes and kyphoplasty offered a higher degree of spinal deformity correction and resulted in less cement leakage than vertebroplasty⁴⁶.

Next complication of PVP and PKP is adjacent secondary fractures⁴² however, the exact cause of the new compression fracture is due to the result of a natural progression of osteoporosis or due to stiffness

caused by augmentation with bone cement is still a subject of controversy^{43,44} In a comparative study on new vertebral fractures after vertebral augmentation procedures, Movrin et al found that the rate of adjacent level fractures widely varied for both PV (8–52%) and PK (3–29%)⁴⁵.

Rupture of earlier versions of the inflatable tamps used during kyphoplasty was also reported with some frequency. Subsequent generations of the balloons seem to fail much less frequently. In all cases, however, the ruptured balloon is easily withdrawn without clinical consequences.⁴⁶ While symptomatic leaks represent only a small portion of leaks overall, these leaks are also the main source of pulmonary and neurological complications with both vertebroplasty and kyphoplasty procedures.

Other complications on the procedure reported are embolic complications such as pulmonary embolism^{20,47} cement emboli in venacava and pulmonary arteries⁴⁸ and in renal vasculature⁴⁹, and death⁵⁰. The actual cause of these events is not so clear, however, cement with low viscosity and a large number of levels treated concurrently may play a role for these⁵¹. Some reported rare complications include acute pericarditis⁵¹, osteomyelitis which is treated successfully with antibiotics⁵² and cardiac perforation⁵³, and fat and bone marrow embolization⁵⁴.

Recent Updates:

PVP and PKP are the standard procedure for the osteoporotic as well as other cause of VCFs but still there occur complication intraoperative and post-operative periods. Not only to focus on the design and development of materials, newer techniques are also into practice in order to minimize the associated complications, maximize efficacy and safety, and broaden the area of implementation. Some new emerging techniques are as follows:

Cement-Directed Kyphoplasty (CDK) ⁵² is a new emerging procedure with combined benefits of both PKP and PVP, consisting of percutaneous unipedicular placement of a device within a cavity and allowing direct the flow of cement toward the anterior region of the vertebral body and More viscous cement is injected, which causes the flow of cement into the vertebral body under greater directional control. i.e., guides cement in the anterior, superior, and inferior directions, but limits posterior flow allowing cement disperse into the spaces in the cancellous bone, along fracture planes, and toward the endplates of the vertebral body, interdigitating with the trabeculae. The cement ultimately serves to stabilize the fracture and provide long-term mechanical reinforcement. The overall objective of this system is to position the cement-directing implant in the center of the vertebral body using a unipedicular approach and to direct the cement flow toward the anterior, superior, and inferior regions relative to the implant location. Cement is intended to fill the span between the endplates, flowing into cracks and voids and interdigitating with intact cancellous bone. Moreover Posterior cement flow is physically limited by the cement director, potentially reducing the risk of leakage into the basivertebral vein and spinal canal⁵² but Additional prospective randomized studies are

further needed to compare CDK with conventional vertebroplasty, BKP, and medical treatment alone.

Radiofrequency Kyphoplasty or Radiofrequency Targeted Vertebral Augmentation(R-TVA)⁵⁵. There is delivery of radiofrequency (RF)-activated, warm, highly viscous bone cement (PMMA) in controlled way using a hydraulic by using an articulating osteotome to the fractured vertebrae. RF energy increases working time for the physician by allowing the consistent flow of ultra-high viscous bone cement without premature hardening. This procedure shows improvement in height restoration⁵⁶. This comparatively new procedure requires more randomized trials to establish its efficacy over the existing vertebral augmentation procedures.

Rotter et al⁵⁷ reported an alternative procedure called "vertebral body stenting" (VBS) to overcome the procedural disadvantages and loss in vertebral height with PV and PK. They compared the efficacy of this new procedure with kyphoplasty in cadaveric samples, and found substantially less height reduction when compared to kyphoplasty [total anterior height gain – kyphoplasty: 8.0 ± 9.4 ; VBS: 13.3 ± 7.6]. Therefore, VBS can be considered as a promising candidate for vertebral augmentation.

A number of newer procedures, such as arcuoplasty, have recently been described, but little data are available at this point

CONCLUSION

PVP and PKP are the main stay of treatment for the management of osteoporotic vertebral body compression fractures. They provide pain relief by stabilizing the fracture and maintain the mobility by maintaining the vertebral height and reducing the kyphotic angle although there is some acceptable complication. However, further clinical trials need to be done comparing these various approaches to have better information for the decision choose vertebroplasty or kyphoplasty. As the cost of kyphoplasty is significantly higher than Vertebroplasty, kyphoplasty shows advantages as it is safer and/or to provide added clinical benefit such as greater stability, better pain relief, or reduced operating time. Most published studies demonstrate equivalent results in stability and pain relief, as well as complication rates, though some have suggested lower rates of cement extravasation. Recent techniques CDK, R-TVA, arcuoplasty are evolved in order to minimize or avoid the complication that is encountered during both procedure and these need to have more trails and research.

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