Kyphoplasty: State of the art

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Abstract: During the last decade, technological advances for the treatment of osteoporotic vertebral compression fractures have provided quick pain reduction and prevention of further damage, through repair of kyphotic deformity.

This entity is the major cause of additional vertebral deterioration and even in some cases can end in death.

The substantial pain relief, reinstatement without inertia stiffness and restoration of kyphotic deformities are the major parameters of a successful treatment. Kyphoplasty offers successful treatment of this pathology. *(p36-45)*

Key words: *Kyphoplasty, vertebroplasty and vertebral compression fractures*

Introduction

Kyphoplasty is a minimally invasive procedure designed to restore the kyphotic deformity and decrease pain. It was first described by Galibert, et al as percutaneous vertebroplasty in 1987.[15] Since 1993, it has been utilized to treat painful osteoporotic compression fractures. Vertebral compression fractures are known to occur in 20% of people over the age of 70 and in 16% of postmenopausal women.[9] They are the leading cause of disability and morbidity in the elderly.[26,28,53] One third of all osteoporotic vertebral body compression fractures become chronically painful.[46] The treatment of this condition accounts for significant direct costs, as reported by America's Bone Health study.[44]

It has been shown that fractures of osteoporotic aetiology, unfavourably affect the quality of life with not only deterioration of patient's physical health, but also their mental function. Their effects are proportionally related to the severity of the spinal deformity and are partially dependent on pain which may be incapacitating, persisting for months and which may then become chronic.[20,.21,49]

Dermatomal radiating pain around the trunk may accompany vertebral compression fractures.

Chronic pain after vertebral fracture may result from incomplete vertebral healing with progressive bony collapse or altered spine kinematics as a consequence of the spinal deformity.[1] Other developments can be seen such as pseudarthrosis at the involved vertebra.[2]

Over the past decade, vertebroplasty, involving the percutaneous injection of polymethyl methacrylate (PMMA) directly into a fractured body, has been used to stabilize osteoporotic vertebral compression fractures. Substantial pain relief in the majority of patients treated with vertebroplasty has been reported.[8,16,25,30,36,45,55]

Material and methods

Between January 2004 and August 2007, 88 cases (61 females and 27 males) of kyphoplasty, performed by our team, were studied. Sixty-eight were managed via transpedicular approach and 20 via extrapedicular. Forty-one cases were treated unilaterally and 47 bilaterally. Decision for operation was based on the accessibility, form of the pathological vertebra and extent of collapse.

Most patients were treated for vertebral fractures involving a single level (Table 1).

Aetiology of the fractures was divided into four groups: trauma, osteoporosis, tumours (multiple myeloma and osteolytic tumour metastasis; breast/prostate) and chronic use of steroids (Table 2).

Traumatic cases were defined as a documented vertebral fracture almost immediately after a fall, in the absence of osteoporosis, tumours or chronic steroid use.

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Three oncologic cases were treated: one patient with multiple myeloma, one with prostatic cancer and one with vertebral involvement of a breast carcinoma.

Chronic steroid therapy (a dose equivalent to more than 10 mg prednisone per day for more than 3 weeks) was documented in only 2 cases. Osteoporosis related to age, menopause and bedridden state, which was the most prevalent in our study. Osteoporotic fractures were defined on the basis of careful clinical evaluation and confirmed by scintigraphy.

Vertebral compression fracture was confirmed through careful correlation of the patient's history, clinical examination and radiographic studies using x-rays, CT scan and MRI (Figs. 1, 2 and 3).

The majority of osteoporotic compressive fractures (Table 2) are focused around the thoraco-lumbar junction: 15 cases at the level of T12 and 54 cases at the level of L1 (Table 3). Patients were treated as shown in Table 4.

Patients presenting with back pain due to malignancies, rheumatic disease or neurological compromise were excluded.

Table 1 - The number of vertebrae (levels) treated in a single procedure

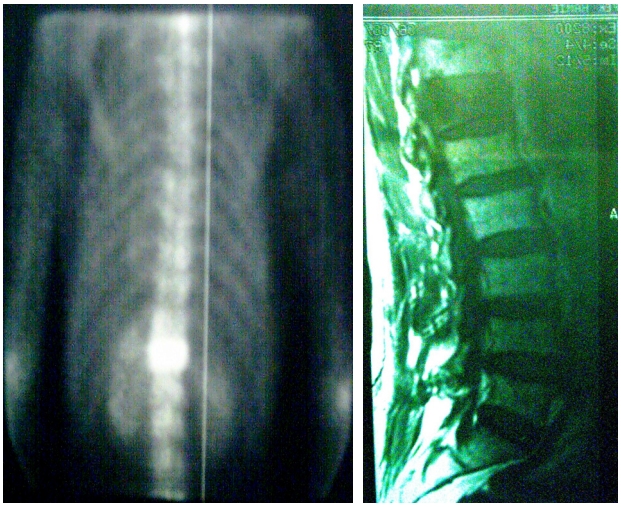
Levels	No. of cases
1	73
2	10
3	3
4	2

Table 2 - Aetiology and number of patients with chronology of treatment

Aetiology	No. of cases	% of cases	Cases	Time of treatment (days post accident)
Trauma	5	5.7	2 1 1 1	2 31 45 50
Osteoporosis	78	88.6	5 65 6 2	in the first 10 days between 10-60 days between 60-90 days later than 90 days
Tumours	3	3.4	1 1 1	3 50 65
Corticosteroids	2	2.3	1 1	48 72
Total number	**88**	**100**	-	

Table 3 - Number of compression fractures cases at each vertebral level

Level of fracture	T7	T8	T11	T12	L1	L2	L3	L4
No. of cases	1	2	5	15	54	3	5	3



Figures 1 and 2 -MRI and scintigraphy of a fresh T12 fracture

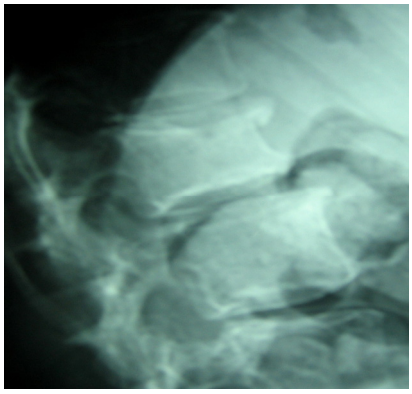


Figure 3 -The same T12 vertebral compressive fracture seen on x-ray

Table 4 - Period of symptoms prior to the treatment of vertebral compression fractures

Duration of symptoms before treatment (days)	1-3	3-10	10-20	20-30	30-40	40-50	50-60	60-90	More than 3 months
No. of cases	3	5	26	15	22	5	3	7	2

Operative technique

Patients were managed under local anaesthesia through intravenous conscious assisted sedation and less frequently under general anaesthesia, in a prone position using a radiolucent operating room table.

Double C-arm fluoroscopy is positioned. A 3 mm incision is made at the level of the pedicle of the fractured vertebra. An 11 gauge biopsy needle is advanced into the fractured vertebral body via trans or extra-pedicular approach, depending on the fracture configuration and patient's anatomy (Fig. 4).

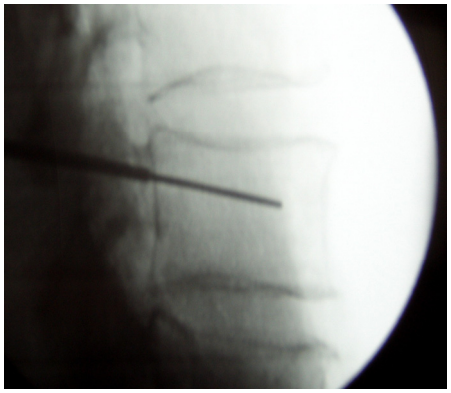
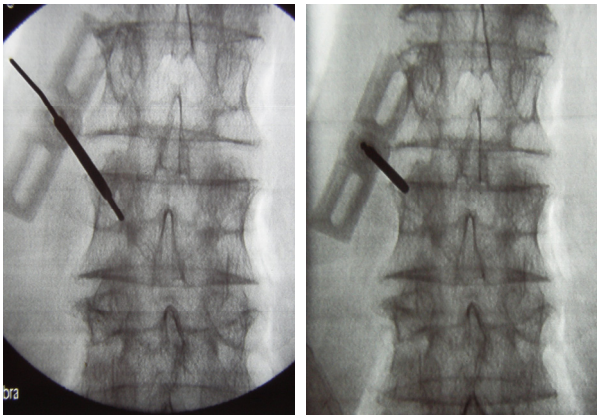


Figure 4 - Transpedicular 11 gauge biopsy needle

A working cannula is inserted over the needle's trajectory; the exchange of the needle to the working cannula is completed via a series of obturators (Figs. 5 and 6).

Once the working cannula is positioned, the needle is removed (Figs. 7 and 8).



Figures 5 and 6 - Replacement of needle to working cannula. The working cannula will host the inflatable balloon tamp and then the cement cannulae

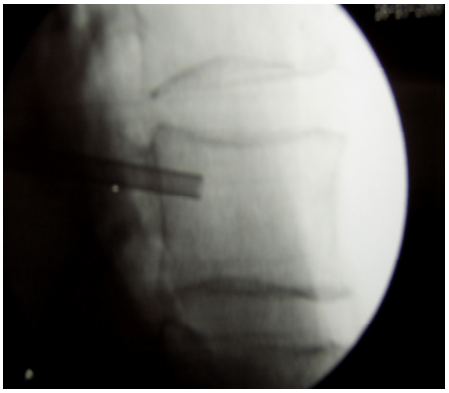


Figure 7 - A lateral view of a trans-pedicular working cannula

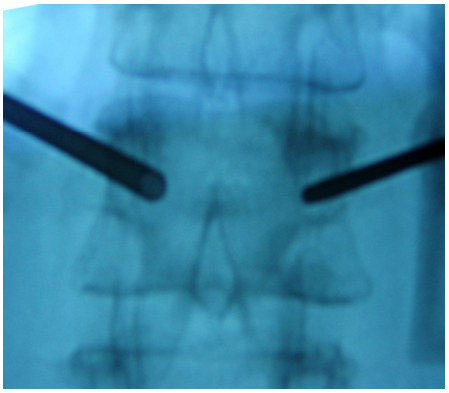


Figure 8 - A/P view of a biopsy needle (right) which is quickly switched to a working needle (left)

An inflatable bone tamp is advanced under the collapsed end plate (Fig. 9).

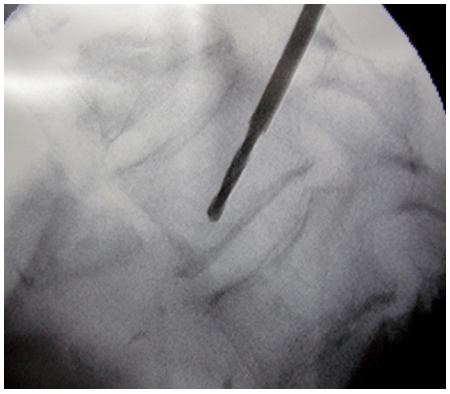


Figure 9 - Advanced balloon into the fractured body

Once inserted through the cannula into the vertebral body, the inflatable balloon tamps are expanded using fluoroscopic

control. The volume and pressure are usually managed using the built-in digital manometer.

The balloon is slowly deployed under fluoroscopic guidance until maximum fracture reduction is accomplished.

Reaching a cortical wall (Fig. 10) or "balloon kissing" (in case of simultaneous bi-pedicular approach) stops the expansion (Fig. 11).

***Technique summary*:** Inflatable balloon tamp (IBT) inflation continues until one of these points is reached:

1. Fracture reduction is achieved.
2. Maximal balloon pressure is reached.
3. Maximal balloon volume is reached.
4. Cortical wall contact occurs.

Balloon is deflated (Figs. 15, 16 and 17) and subsequently removed. Cement is mixed and loaded into several cannulae.

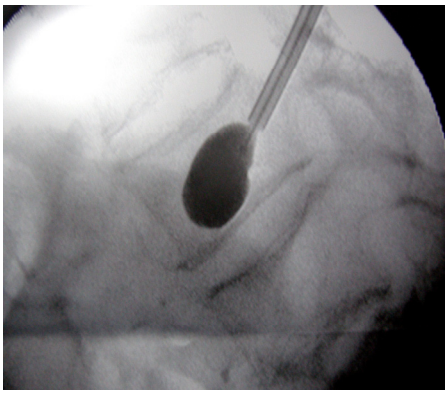


Figure 10 - The balloon reaches the cortical wall

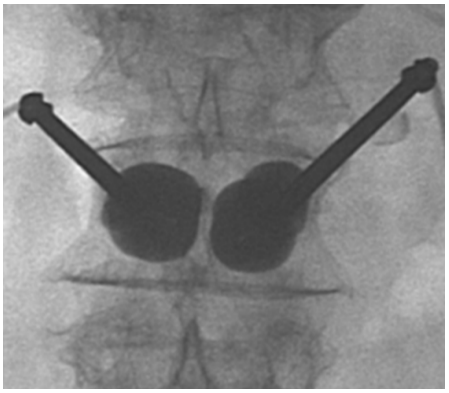
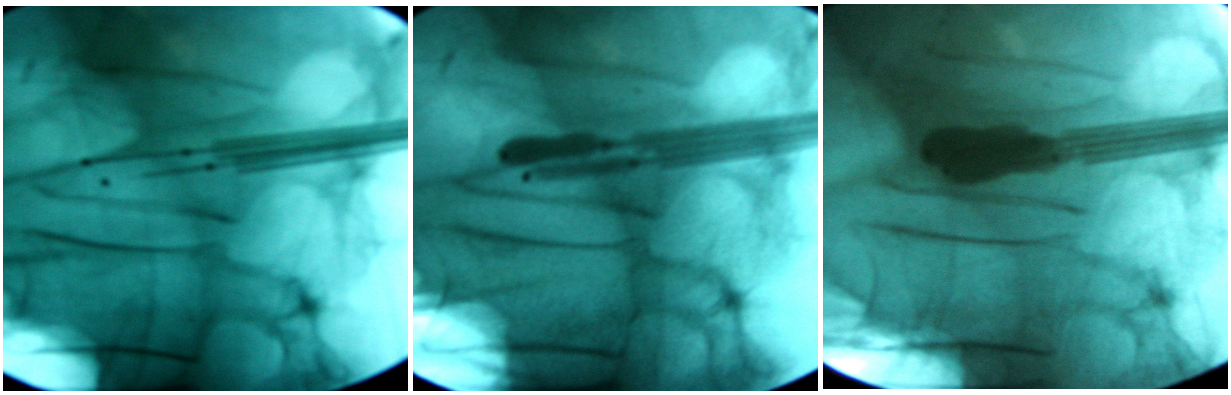
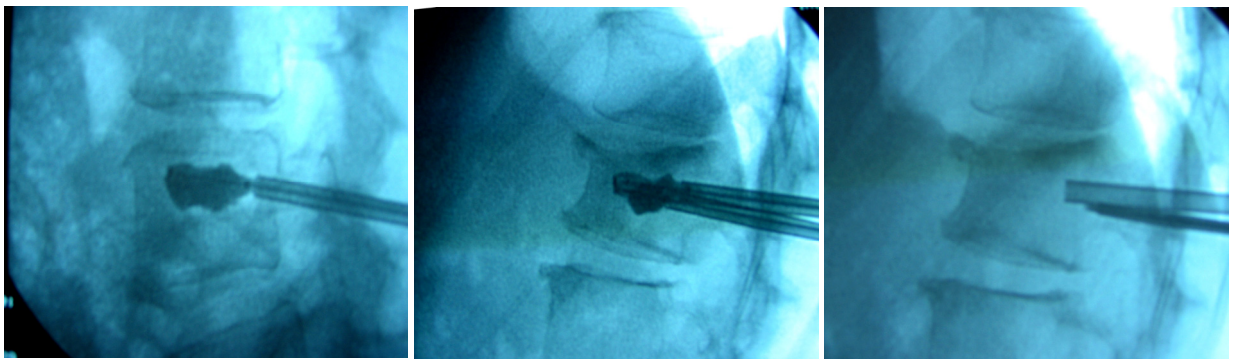


Figure 11 - "Balloon kissing" in bilateral approach



Figures 12, 13 and 14 - Showing balloon inflation



Figures 15, 16 and 17 - Showing balloon deflation

Figure 18 ← Slow body filling with bone void filler

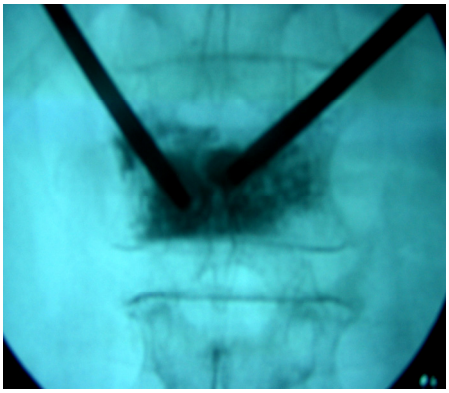
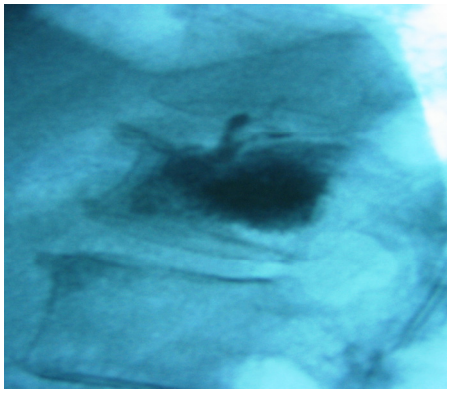


Figure 19 → End of the procedure with total filling



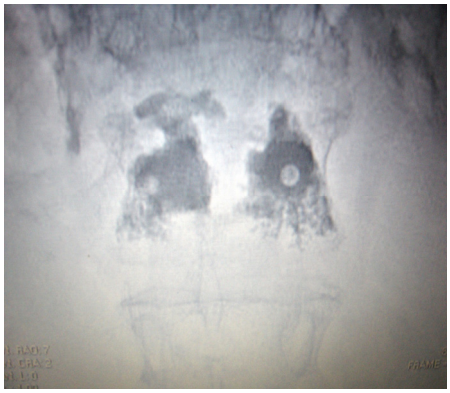


Figure 24 - Extravasation of cement into the disc space

Further detailed analysis was performed on the osteoporotic sub-population and yielded the following results, (Table 5):

- Patients who presented within the first 45 days from onset of symptoms showed optimal results.
- Those presenting between 45 - 60 days from onset of symptoms had total pain relief with partial angle repair of kyphotic.
- Those presenting between 60 - 90 days from onset of symptoms had pain resolution only when supplemented with oral analgesics of moderate potency with acceptable reduction of kyphotic deformity.

Table 5 - Time period of treatment of osteoporotic vertebral compression fractures

Period of treatment of vertebral osteoporotic compression fractures	Pain relief	Kyphotic deformity restoration
Before 45 days	+++	Very good
45 - 60 days	++	Good
60 - 90 days	+	Acceptable
After 90 days	+	Poor

+++: total pain resolution
++: pain resolution with occasional administration of oral analgesics of low potency
+: pain resolution with occasional administration of oral analgesics of moderate potency

Patients presenting later than 90 days from onset of symptoms had same pain relief as the previous group with poor reduction of the kyphotic deformity.

Discussion

Our study was focused on the ultimate time period prior in which a kyphoplasty is capable of reducing the kyphotic deformity and relieving the pain caused by vertebral compression fractures.

It was shown that compressed vertebral fractures can be successfully treated by kyphoplasty if a patient presents within the first 45 days from onset of symptoms. During this time period most kyphotic deformities were restored, moreover, an enormous percentage of kyphoplasties offered full pain relief.

The difference between unilateral and bilateral approach, pedicular and extrapedicular approaches, extravasation, embolization and cement volume were not assessed in this study. Moreover, no quantitative comparison was accomplished between kyphoplasty and vertebroplasty.

Improvement of height was not studied in this article but the literature reports a significant expansion of the collapsed vertebral body post kyphoplasty.[4,13,17,18,32,50,55,57]

Tendency for the development of a significant kyphosis in our patients has been observed at the thoracolumbar junction. Kyphotic deformity in an osteoporotic spine may create a biomechanical environment causing additional deformities, because it shifts anteriorly to the centre of gravity and subsequently creates a longer movement arm; resulting in greater flexion bending movement around the apex of the kyphosis. This will promote further increases in kyphotic angulation and additional fractures.[7,56]

Clinical studies showed that the risk of a second vertebral fracture in the first year after an uncorrected vertebral compression fracture rises 5 - 25 times above the baseline risk. At particular risk is the vertebra adjacent to the previously fractured one.[40,41,54] Prevention of progressive kyphotic deformity or correction of an existing deformity may therefore be important, both in reducing the adjacent level fracture risk and in preventing the consequences of spinal kyphosis such as impaired pulmonary function.[24,47]

Traditionally, the treatment of most patients with painful vertebral compression fractures includes bed rest, analgesia and/or bracing with appropriate anti-osteoporosis medication.[13,34,38] Nowadays, surgical treatment emphasizes restoring anatomy by correcting deformity and eliminating pain.

Although medical treatment appears to be reasonable, anti-inflammatory and narcotic medications are often poorly tolerated by the elderly leading to GI side effects, predisposing to confusion and thereby increasing the risk of fall and further fractures. Bed rest can lead to overall muscle and bone deterioration. Moreover, bracing is poorly appreciated being expensive and significantly restricting diaphragmatic excursion. On the other hand, none of these treatments is able to directly address the fracture - the

source of spinal deformity and pain.[14]

Indications suggesting kyphoplasty include stabilization of painful osteoporotic vertebral fractures, painful metastatic vertebra, Kummel's disease, pseudo-Kümmel's disease and painful vertebral haemangioma.

Preoperative planning for kyphoplasty requires radiographic studies to identify the fracture, regard for patient's age (acute *vs*. old) and the nature (healed *vs*. non-healed) of the fracture.

Magnetic resonance imaging is useful for detecting oedema in acute vertebral fracture, malignancy or infection; excluding pathologic entities and confirming pain level, especially with short tall inversion recovery (STIR) weighted sequences which eliminates "fat" and enhances fluids. Short tall inversion recovery is also most efficient in determining new fractures.

Thoracolumbar junction fractures and fractures due to steroid-induced osteoporosis, occurring in vertebra with extremely low bone mineral density are predisposed to progressive collapse and deformity so that earlier kyphoplasty may have been warranted.[57]

Phillips recommended a 6-week trial of conservative care in patients with acute vertebral compression fractures as well as fractures of relatively minor degrees of vertebral collapse, during which a series of radiographs are obtained. Progressive collapse of the vertebral body or non-response to conservative care pain suggests a kyphoplasty.[44]

Brief review of the literature

Pain relief: Our results are consistent to those reported in the literature where most authorities reported partial or complete pain relief within 72 hours of kyphoplasty.[8,11,12,16,25,30,36,45,55] Whereas, an overall 60 - 100% success was reported after vertebroplasty.[16,25,30,36] Wong, et al reported that 80 of 85 patients have good to excellent pain relief after kyphoplasty.[57] In addition to decreased pain, improved functional levels have been reported in many studies.[2,27,29,35,36,52] Lieberman, et al observed highly significant improvement in physical function, vitality, mental health and social function scores of the SF-36 questionnaire after kyphoplasty.[32] Zoarski, et al used the Musculoskeletal Outcomes Data Evaluation and Management Scale (MODEMS) based on the 4 modules; treatment score, pain and disability, physical function and mental function. Thirty patients were studied. Measurements were registered before the procedure and 2 weeks after vertebroplasty. Significant improvement in all 4 modules of the MODEMS were demonstrated.[58] Pain reduction after "vertebroplasty" was studied by Grados, et al. He presented a longer-term follow-up of a cohort of 40 patients with osteoporotic vertebral compression fractures treated with vertebroplasty, where 25 of these patients were available for follow-up at a mean of 48 months. Pain decreased on a 100-point visual analogue scale, from a mean of 80 mm before vertebroplasty to 37 mm after one month. These results remained stable over time, with a pain score of 34 mm at final follow-up.[23]

The mechanism of pain relief in these procedures is uncertain and may be related to cement "stabilization" of the fractured vertebral body or deafferentation related to heating of nerve endings as the cement cures.

***Kyphotic deformity restoration*:** Lieberman, et al reported height restoration in 70% of 70 fractured vertebra treated with kyphoplasty.[32] Belkhoff, et al showed a 97% reversal of deformity with kyphoplasty, with a 30% reversal with vertebroplasty.[4] Phillips, et al reported on a series of 40 patients treated with kyphoplasty that local kyphosis improved by a mean of 14.[44]

Reinstatement of initial stiffness: Tohmeh, et al demonstrated that vertebral augmentation with unipedicular cement injection was sufficient to restore inertia after an osteoporotic fracture.[51]

Complications

Published reports have noted a low complication rate of 6% for kyphoplasty versus vertebroplasty, with most complications resulting from extravertebral cement leakage causing spinal cord, nerve root compression or pulmonary embolism, seen in vertebroplasty; when adequately using higher pressures, liquid cement will create it's own pathway.[8,11,12,16,25,27,30,36,45,55]

***Cement embolus*:** Cement to the lungs was one of the major and most frequent statistically noted complications, resulting in fever and reduced PaO_2 but with no disturbance in pulmonary activity. The pressurized injection of cement during vertebroplasty has also raised concern for embolization of cement, unreacted PMMA monomer, or bone marrow to the lungs via the venous system. Occasional cases of symptomatic and lethal PMMA pulmonary embolism with vertebroplasty have been reported.[2,31,42,43]

***Extravasation*:** Moreland, et al studied the effect of extravasation of cement into the epidural space, necessitating an open surgical decompression in 2 of 3 patients leaking.[39]

During vertebroplasty (cement injection without ballon use), the "high-pressure" injection of low viscosity cement directly into cancellous bone makes the cement flow

difficult to control and creates an unpredictable risk of cement extravasation outside of the vertebral body.[57] This phenomenon may also appear with kyphoplasty. Cortet, et al assessed the occurrence of cement leakage to be as high as 65% in patients with osteoporotic fractures. Cement leakage into the paravertebral soft tissues was noted in 6 cases; into the peridural space in 3 cases, into the disc space in 3 cases and into the lumbar venous plexus in one case.[7] Cyteval, et al noted cement leakage in 8 of 20 patients after vertebroplasty, with leakage into the intervertebral disc in 5 patients, into the neural foramen in 2 patients and into the lumbar venous plexus in one patient.[12] A higher rate of extravasation has been reported in patients with metastases or haemangiomas compared with patients with osteoporosis.[55,57] With the previous creation of free space into the body of the vertebra, a precise quantity of cement was put inside the formed cavity, without the need of exerting high pressure. Discontinuing cement injection once cement leaks out of the vertebral body, or fills the perivertebral veins, remains the best technique for reducing the risks of complications. Lieberman, et al had 8% of clinically insignificant cement leaks.[32]

***Radiculopathy*:** One of the complications not reported in the literature was radiculopathy post-kyphoplasty which was reported post-vertebroplasty by Chiras, et al in 4% of patients likely related to intraforaminal cement leakage and noted frequent leaks of into the perivertebral veins.[8]

Potential problems with PMMA include the exothermic reaction during the procedure since temperature may reach 100 degrees, causing thermal damage to adjacent structures.

***Cardiopulmonary toxicity*:** Moreland, et al also investtigated the cardiopulmonary effects of cement injection during vertebroplasty in sheep. Immediately after cement injection, there was a fall in heart rate and arterial pressure, with a second fall in arterial pressure occurring after a mean of 18 seconds after cement injection associated with fat emboli passing through the heart and getting trapped in the lungs.[1,39]

Some do not advocate performing kyphoplasty on more than 3 vertebral levels in one sitting because of the potential for deleterious cardiopulmonary effects related to cement and/or fat embolization to the lungs.[14]

Epidural haematoma requiring surgical decompression was also documented.[49]

Postoperative paraparesis was registered by some authors.[49]

***Intraosseus venography*:** McGraw, et al found that intraosseus venography predicted the subsequent flow of PMMA during vertebroplasty in 83% of cases.[37] Whereas, Gaughen, et al reported that venography did not improve effectiveness or safety of vertebroplasty. They showed a correlative extravasation in only 14 of the 22 cases.[19]

***Volume of cement*:** In an ex-vivo study of experimental osteoporotic compression fractures, injection of 2 ml of PMMA with barium sulfate restored vertebral strength and the ability of the vertebral body to bear load, whereas 4 - 8 ml of cement was required to restore stiffness and resistance to micro-motion.[5]

***Alternate biomaterials*:** Alternate biomaterials can be used for young patients. A number of alternate biomaterials, including carbonated apatite, bioactive cement, and calcium phosphate, were shown to provide significant improvement in compressive strength and load to failure of vertebral bodies.[3,6,33,48] Toxicity profiles and long-term stability of these materials still need further study.

Conclusion

Based on the fact that osteoporotic vertebral compression fractures are associated with a 16% reduction with expected 5-year survival and knowing that only less than one-third of these fractures are diagnosed, the chief objective of successful treatment is an early discovery and the use of the crucial period (45 days from the onset of symptoms) during which kyphoplasty can successfully treat pain and kyphotic deformities, restoring vertebral body height and by this means, improving the spinal sagittal balance and the spinal alignment.[10,22] This will improve the pulmonary mechanics, decrease pain and reduce the risk of adjacent level vertebral fracture.

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