Original Research Article

Surgical Outcomes of Bone Cement Augmented Screw Fixation, Cannulated Screws and Vertebroplasty in Osteoporotic Spine

Abstract

Background:Osteoporosis is a skeletal condition characterized by decreased density of normally mineralized bone; it leads to decreased bone mechanical strength, thus making the skeleton more liable to fracture,**Aim and Objectives**: The Aim of this study was to evaluate the surgical outcome of bone cement augmented screw fixation, cannulated screws and vertebroblasty in osteoporotic spine, **Subjects and methods**: This study was conducted upon 30 adult patients with osteoporotic spine subjected to bone cement augmentation in the department of Neurosurgery, Tanta University Hospitals between January 2020 and January 2021, **Results**: Fixation was done to 20 patients, 8 patients were with cannulated screws and 12 patients were with augmented usual screws. Vertebroplasty was done to 10 patients.Oswestry Disability Index **(**ODI) ranged from 64-85 with mean 78±18.8 before surgery and 21-44 after surgery with mean 33±15.6**.** Pain was evaluated using a 11 point Visual Analog Scale for Pain (VAS Pain) Scale from 0 (no pain) to 10 (worst experienced pain) before and after the procedure. It was ranged from 7-9 pre-operatively with a mean value 8.2±1.8 and from 1-3 post-operatively with a mean value 2.3±1.6.**Conclusion**: Vertebroplasty is a successful, effective, rapid image guided therapy for painful vertebral lesions regardless its duration and may be the only solution for generally unfit patient. Cement augmented pedicle screw technique is effective and safe in the osteoporotic spine with lumbar degenerative diseases, with better fusion rates and less screw loosening incidence if used carefully and properly, it can be a safe and effective treatment in patients who need spinal fixation accompanying severe osteoporosis.

Keywords: vertebroblasty, cannulated screws, osteoporotic, Cement augmented pedicle screw.

Introduction:

Osteoporosis is a skeletal condition characterized by decreased density of normally mineralized bone; it leads to decreased bone mechanical strength, thus making the skeleton more liable to fracture. The loss of bone occurs silently and progressively.

Often there are no symptoms until the first fracture occurs. Osteoporosis risk increases by age, family history, some races as white or Asian, post-menopausal females, smoking, alcohol and certain medications as steroids. Vertebral fractures are the most common among osteoporotic fractures.[1,2]

Vertebral compression fracture (VCF) is an important cause of severe debilitating back pain, adversely affecting quality of life, physical function, psychosocial performance, mental health and survival. The fractures may be as a result of bone weakness by osteoporosis, trauma, or tumors such as metastases, multiple myeloma, and hemangioma. [3]

Loss of trabecular architecture weakens the bone and decreases the mechanical hold of the pedicle screws, compromising the strength and hastening osteolysis around the screws. Multiple cyclic loading leads to clear zone formation around the screws preventing osseous integration at screws bone interface resulting in screw loosening and screw pullout in osteoporotic spine.[4]

CT and MRI spine and DEXA scan are very important methods to diagnose osteoporotic patients and determine which method will be convenient with them to be well managed. [5]

Bone cement augmented screw fixation and cannulated screws are done in unstable osteoporotic spine. Vertebroplasty is done in stable osteoporotic spine. [6]

PercutaenousVertebroplasty (PV) is a therapeutic, image guided procedure that involves injection of radio-opaque cement into a partially collapsed vertebral body, in an effort to relief pain and provides stability. [7]

The majority of complications of vertebroplasty are mild and transient. Potential complications include allergy, local trauma to nerve roots or spinal cord, fracture of the lamina, pedicle, or ribs, hemorrhage, infection, spinal stenosis, pulmonary emboli, paravertebral leakage, venous leakage, or leakage into the spinal canal and inter vertebral foramen could occur.[8]

Vertebroplasty has gained widespread popularity, mostly because of significantly high rates of success, low incidence of complications, brief surgical time, minimal sedation, minimal recovery period, and short or no hospital stay. [9]

Patients and Methods

This study was conducted upon 30 adult patients with osteoporotic spine subjected to bone cement augmentation in the department of Neurosurgery, Tanta University Hospitals between January 2020 and January 2021.

Inclusion criteria: Painful stable traumatic vertebral compression fractures after failure of conservative medical treatment, painful pathological vertebral fracture due to benign or malignant tumor, such as myeloma or metastatic lesion and patient with unstable osteoporotic spine in need for fixation.

Exclusion criteria: Osteoporotic vertebral fracture that is completely healed or is clearly responding to conservative management, presence of uncontrolled coagulopathy, presence of discitis, osteomyelitis or sepsis, asymptomatic vertebral body compression fracture, greater than 70 % collapse of the vertebral body (needle placement may be difficult) with stable spine and patients with spinal deformities.

Preoperative protocol:

Personal history: Age, sex, special habits e.g. smoking and menstrual history for females.

Past and medical history: History of back trauma, history of malignancy other where in the body, history of medications as steroids, hypertension (HTN), D.M and renal or hepatic failure.

Clinical:

1) General examination: For detection of other system co-morbidities which could interfere with general anesthesia.

2) Neurological examination including: Motor system: Muscle state, tone and power. Sensory system: Superficial and deep sensation.Special tests: Straight leg raising test, crossed leg raising test and femoral stretch test.

Back examination: Inspection: Deformity (kyphosis, exaggerated lumber lordosis and scoliosis), visible step and Para vertebral muscle spasm, presence of ecchymosis and previous surgery incision. Palpation: Tenderness, Palpable step and Para vertebral muscle spasm.

IV. Investigations:

I. Routine laboratory work up: Complete blood count, prothrombin time and activity, liver and renal function tests and random blood sugar and Virology

II. Imaging:

Plain radiographs: Anteroposterior and lateral views. Dynamic views shows: presence or absence of instability.

CT spine: Evaluatatoin of the integrity of the posterior wall of the vertebral body to avoid the risk of cement leakage into the spinal canal during injection.

MRI spine with or without contrast**:** Show vertebral body edema which is an especially sensitive sign of an active fracture, Visualization of soft tissue, neural structures, lumbar canal stenosis and disc prolapsed and shows if there is a begnin or malignant lesion.

DEXA scan**:** used to measure bone density in spine to detect osteoporosis.

Conservative Treatment: Prior surgery trial of conservative treatment was done first for stable patients who had no neurological deficit as bed rest, anti-inflammatory drugs, physiotherapy, lumbar bracing, vitamin D and calcium supplement.

Surgical intervention:

Pre-operative preparation: Preoperatively, radiographic studies were obtained and evaluate the extent and level of injection needed.

Surgical technique:

Anethesia, Patient Positioning, and Imaging:A general anesthetic was applied and the patient was positioned in prone position on the operating table.

Exposur of posterior spine elements: A midline incision was done. The midline dissection was continued and the paraspinous muscles were dissected off the spinous process and lamina by the use of electro cauterization.

Decompression: Removal of spinous processes of the level to be decompressed was done, and laminectomy was done .The lateral recesses were decompressed.

In Cases of Transpedicular Cannulated Screw Fixation: The first step in insertion of pedicle screws was to identify pedicle landmarks. The bone cement metallic injection cannulas were first inserted empty into the polyaxial fenestrated screw heads to check the proper fit and entry trajectory sealed to avoid cement emersion into the screw heads, which could preclude rod insertion**. Figure (1)**

- **The PMMA cement was prepared**

Cement preparation and mixing: the container of the powder was set on flat surface and the cap was opened .The vial of the liquid was opened and mixed with the powder into the powder container. The container was closed and manually shaked for one minute until a liquid and homogeneous mass was achieved.

Loading the spine gun and application of extension tube then filling the extension tube then connecting the metallic injection cannulas to extension tube supplying cement by turning the handle clockwise under continuous monitoring of filling of the vertebra using C arm **Figure (2,3)**

Then filling is done into the injection cannulas, which can hold 1.5mL of cement. Injection was performed with a tooth-paste like consistency of the cement. Per screw, approximately 2 mL of cement was injected in the lumbar spine and 1.5 mL of cement in the thoracic spine. For every 0.3–0.5 mL of cement injection, cement distribution was checked with fluoroscopic images in lateral projection. In case of evidence of epidural, intradiscal, or prevertebral/intravenous cement extravasation, the injection of cement was stopped.

In cases of Bone Cement Augmented Screw Fixation:

Tapping was performed under the fluoroscopic guidance taking the location in which the bone cement would be injected. A bone biopsy needle was inserted into the tapping site, located in the anterior third of the vertebral body. **Figure (4)**

Bone cement was injected under the C-arm guide, through a bone biopsy needle, and it was allowed to be maximally localized in the vertebral body area. The bone biopsy needle contained approximately 1.5-2.5 cc of bone cement, and therefore vertebra was injected. Permanent transpedicular screws were inserted as soon as possible after the injection of bone cement under the C-arm guide and the track for the screw can be also injected with bone cement using insulin syringe. **Figure (5,6)**

Bone cement augmented transpedicular screwing was performed in adjacent vertebra using the same method. It took anywhere from a few minutes to 10 minutes for the bone cement to become completely hardened, and therefore the rod was connected after at least 10 minutes.

Operative Technique of Vertebroplasty

A spinal needle was positioned, as a guide, with its tip in the center of the pedicle. A small skin incision (5 mm) was made. The needle tip was positioned along the line drawn through the middle of the pedicle then advanced carefully, under the fluoroscopy guidance. About0.3- to 0.5-mL of the PMMA mix is repeatedly injected with immediate checks of flouroscopy. **Figure (6)**

After final needle removal, the puncture sites were cleaned, sutured and dressed with sterile dressing and betadine ointment. Most patients are able to return to their home the same day of the procedure.

Follow up

Clinical outcome: All patients are evaluated in the outpatient clinic at a regular period after 2 weeks from the operation then after 3 and 6 months. Oswestry Disability Index (ODI): was used for pre and postoperative disability assessment in all

cases. The 10 factors which constitute the [ODI] criteria for assessing patient functional impairment are pain intensity, ease of personal care, lifting, working, sitting, standing, sleeping, sex life, social life and travelling. **Also pain before and after surgery was compared with [VAS] scale:** VAS is a straight horizontal line of fixed length usually 100 mm. The ends are defined as the lower limits of the parameter to be measured oriented from the left (the best) to right (worst).

Radiological follow up: Approximately one day after surgery, CT scan was done to ensure that instrumentation was in good position and efficacy of injection and exclusion of leakage and other complications. **Figure (8)**

At 3 and 6 months after surgery plain x-rays were done to assess pedicle screw, and fusion. **Figure (7,9)**

If patient complain reoccured new images were done to discover the cause of the new back pain. The flexion-extension lateral radiographs were done to all patients to assess the fusion and stability during the follow-up visits by ensuring if there was evidence of lucency developed around the screws.

Results

Fixation was done to 20 patients, 8 patients were with cannulated screws and 12 patients were with augmented usual screws. Vertebroplasty was done to 10 patients. **Table (1)**

Postoperative hospitalization ranged from 2-3 days with a mean value 2.17 ± 0.83 days in patients with cannulated screws, ranged from 2- 4 days with a mean value 3 ± 1 days in patients with usual augmented screws and ranged from 0-2 days with a mean value 1 ± 1 days in patients with Vertebroplasty.**Table (2)**

As regard to motor deficit improvement according to MRC muscle power scale in which motor power is divided into 6 grades from G0 which refers to no muscle contraction to G5 which refers to normal motor power 3 (60%) patients were improved, one patient (20%) was moderately improved and one (20%) patient were not improved.**Table (3)**

ODI ranged from 64-85 with mean 78±18.8 before surgery and 21-44 after surgery with mean 33±15.6**. Table (4)**

Pain was evaluated using a 11 point Visual Analog Scale for Pain (VAS Pain) Scale from 0 (no pain) to 10 (worst experienced pain) before and after the procedure. It was ranged from 7-9 pre-operatively with a mean value 8.2±1.8 and from 1-3 post-operatively with a mean value 2.3±1.6.**Table (5)**

System stability was 100 % in all cases of fixation and only 2 % screw loosening but not affect stability of the patient after follow up at least 6 months. **Table (6)**

As regards to complications, Infection was found in 2 (6.7%) patients,cement leakage was found in three patients (10%) and screw loosening was fond in 2 (6.7%) patients of fixation. **Table (7)**

Table 1: Procedure done to all studied patients

		Patients (n = 30)
Procedure	Cannulated screws	8
	Augmented usual screws	12
	Vertebroplasty	10

Table 2: Postoperative hospitalization of all studied patients

		Patients (n = 30)
Postoperative hospitalization (days) in cannulated screws	Mean ± SD	2.17 ± 0.83
	Range	2-3
Postoperative hospitalization (days) in usual augmented screws	Mean ± SD	3 ±1
	Range	2-4
Postoperative hospitalization (days) in vertebroplasty	Mean ± SD	1 ±1
	Range	0-2

Table 3: Motor deficit improvement of all studied patients according to MRC muscle power scale

		Patients (n = 5)
Motor deficit improvement	Improved	3 (60%)
	Moderately improved	1 (20%)
	Not improved	1 (20%)

Table (4): Clinical outcome based on the Oswestry Disability Index (ODI) in all studied patients before and after surgery

	Patients(n = 30)	
Result	Preopertaive	Postopertaive
Range	64-85	21-44
Mean	78±18.8	33±15.6

Table (5): Clinical outcome based on the Visual Analogue Scale (VAS) in all studied patients before and after surgery

	Patients(n = 30)	
Result	Preopertaive	Postopertaive
Range	7-9	1-3
Mean	8.2±1.8	2.3±1.6

Table 6: System stability and Screw loosening in all patients of fixation according to radiological follow up

		Patients (n = 20)
Stability	System stability	100 %

	Screw loosening	2 %

Table 7: Complications of all studied patients

		Patients (n = 30)
Complications	**Superfascial Wound Infection**	2 (6.7%)
	Cement Leakage	3 (10%)
	Screw loosening	2 (6.7%)
	No	23 (76.6%)

Discussion

In this study, thirty patients with osteoporotic spine were admitted and operated in The Department of Neurosurgery, Tanta University Hospitals in the period between January 2020 to January 2021. Fixation was done to twenty of them; eight patients were with cannulated screws and twelve patients were with augmented usual screws. Vertebroplasty was done to ten patients.

In our study PMMA was used in all patients because it is the cement of choice for screw augmentation as it has properties like biocompatibility with fewer allergies. It is mechanically strong and if Barium or Strontium is added then it has good radio-opacity [(10)].**Wuisman et al.** [(11)] used calcium apatite cement in their study in seven patients with a progressive osteoporotic spinal deformity. Thirty-nine spinal segments (64 screws) were augmented. Screw augmentation failure occurred in only one patient. However, it may get integrated with the surrounding bone and get resorbed with time. Eventually, resorption of the cement matrix around the screws may loosen the purchase in bone and may lead to pull-out.

As regards to complications cement leakage (CL) is the most common complication, which may progress in pulmonary cement embolism. CL was classified according to Yeom's classification depending on the site of leakage, cement leaks could be classified into three types: those via the basivertebral vein (type B), via the segmental vein (type S) and through a cortical defect (type C). Type-B leaks usually proceed via the vascular foramen and in the spinal canal where they spread along the epidural venous plexus. Type-S leaks usually proceed horizontally, along the segmental veins. Therefore, they often resemble a small paravertebral leak on anteroposterior X-ray radiographs. They are, however, actually long leaks in many cases, and may reach the neural foramina. Type-C leaks occur via a cortical defect around a vertebral body, including the spinal canal. [(12)]

Janssen I et al. [6] and **Martı´n-Ferna´ndez et al.** [13] in their large studies, have reported that CL rates of 66.7% and 62.3%, respectively. Although, majority of CL were asymptomatic requiring no further treatment, morbidity and mortality associated with cement usage were significant. **Janssen I et al.** [6] noticed 30-day mortality of 1.8% in their study group and suggested against liberal use of cement augmentation. They have concluded that technical improvement in instrumentation or cementing technique has not decreased the rates of CLs and associated complications.

Strategies have been suggested to reduce the incidence of CL. Fenestrated screws have been preferred choice for cement augmentation. A total of 8 studies used fenestrated screws and their used has been more frequent instudies reported after year 2010. Pilot hole preparation into the pedicle followed by cement injection and screw placement was done in numerous studies. **Sawakami et al.** [14] performed augmentation by manually covering thescrews with PMMA cement before placing it into the pedicles. **Chang MC et al.** [15] suggested inserting the cement cannula 5 mm short of the selected screw length to avoid anterior cement breach. **Wuisman et al.** [11] showed that 5 of their 7 cases had cement leak when retrograde type ofcement injection was used from pressurization effect during screw insertion and advocated for direct method of cement injection.

Additional vertebroplasty was done using PMMA cement in few studies. **Aydog˘an et al.** [16] performed vertebroplasty in all cases along with cement placement adjacent to the instrumented levels.**Chang et al.** [15] used additional laminal hooks at levels adjacent to CAPS. Amount of cement per screw ranged from 1 to 3 cm.Frequency of CL were higher in cases where multiple vertebrae have been instrumented rather than the amount f the cement used. **Hu et al.** [17] suggested that rate of CL was higher with lower BMD and was not dependent on amount of cement injected per vertebra. Consistency of cement at the time of injection was not widely studied. However, few studies did recommend using tooth-paste like consistency to avoid extravasation.

Fusion procedure was done in nine studies over the patients with non-malignant affection of vertebra. Most common of procedure to be performed was posterolateral fusion. Interbody fusion was done in cases with neurological impairment and severe vertebral height loss. **Cho et al.** [18] performed corpectomy with interbody fusion in all cases of Kummell's disease. **Sawakami et al.** [14] in their comparative study has found better fusionrates in cemented group as compared to the non-cemented group.

In our study Infection was found in 2 (6.7%) patients and leakage was found in three patients (10%) of type (B) and type (S) leakage. There was low rate of infection due to prophylactic antibiotic and complete sterilization and the only 2 cases with superfascial wound infection were diabetics.

In our study postoperative hospitalization ranged from 2-4 days in cases of fixation with a mean value 2.17 ± 0.83 days and amount of cement injected ranged from 2-10 cc with a mean value 6.27 ± 2.48 cc.

In accordance with our data **Huang YS e**t al. [19] the mean volume of cement was 9.8 ml (8.5–11.5), and the mean hospital stay was 7.9 days (6-11).

In accordance with our data **Pesenti S et al.** [20] Mean length of stay was 6.4 days (ranging from 4 to 14 days). All patients used grade III analgesics before the surgical procedure.

In this study, Pain was evaluated using a 11-point Visual Analog Scale for Pain (VAS Pain) Scale from 0 (no pain) to 10 (worst experienced pain) before and after the procedure. It was ranged from 7-9 pre-operatively with a mean value 8.2±1.8 and from 1-3 post-operatively with a mean value2.3±1.6

ODI ranged from 64-85 with mean 78±18.8 before surgery and 21-44 after surgery with mean 33±15.6. As regard to deficit improvement, 19 (63.3%) patients were improved, one patient (3.3%) was moderately improved and 10 (33.3%) patients were not improved.

In accordance with our data **Mo GYe**t **al**. [21] .The preoperative VAS and ODI of the PSA group were7.75 ± 0.75 and 36.61 ± 2.17, respectively, and they were higher than the postoperative. Similarly, the preoperativeVAS and ODI of TPS group were 7.64 ± 0.91 and 37.14± 2.17, respectively, which were higher than the post-operative. They were statistically significant. There was nosignificant difference between the two groups

In accordance with our data **Seo JH et al.** [22]The mean VAS improved from 9.0 before the surgery to 1.8 after the surgery, and the mean Oswestry disability questionnaire scale changed from 79.1% to 39.2% in osteoporotic spine fractures or idiopathic scoliosis. The VAS improved from 7.9 to 1.9 for the patients with various spinal diseases, and the mean Oswestry disability questionnaire scale improved74.5% before the surgery to 40.2. In both groups, a significant improvement in VAS and Oswestry disability questionnaire was achieved ($p<0.01$). 146 patients out of 157 patients were graded as having excellent.

In our review, cement augmentation provided improved anchorage for the pedicle screws in the osteoporotic vertebral body. Improvement in pain parameters were maintained after surgery. Cement augmentation provided desired resilience to the vertebra to withstand corrective forces for deformity correction.

System stability in our study was 100 % in all cases of fixation and only 2 % screw loosening but not affect stability of the patient after follow up at least 6 monthsand also in **Wang HS et al.**[23] there was no appreciable screw loosening or pullout at final follow-up and all patients achieved successful bone fusion but in **Mo GYet al**.[21] 2/172 screws loosening and 1/56 segment non-union occurred using PMMA cement augmented traditional screws and in **Klingler JH et al.** [24] One screw loosening was noted (0.6%) after a mean follow-up of 12.8 months using cannulated screws.

In regular follow up 3 cases developed new back pain one at three months, two at six month. After new imaging done new vertebral compressed fracture discovered this level also injected so this was not recurrence understanding of how vertebroplasty affects the risk of future fractures, two issues are particularly important to patient care.

In our study, Better outcome with increased volume of cement injected the only hazard is increased risk of cement leakage. But one case of leakage occur in spite small amount used due to disrupted anatomy of vertebrae. This cope with **Kaufmann TJ et al** [25] There exists significant variability in the volume of polymethylmethacrylate cement injected during percutaneous vertebroplasty. Larger cement volumes injected may be associated with better clinical outcomes, but larger volumes may also be associated with greater risk of complications related to cement leakage.

That larger volumes of cement generally lead to better outcomes through increased filling of the vertebral body, increased strength and stiffness, and improved internal casting and immobilization of the fracture.

Unfortunately, larger volumes of cement may also increase the risk for complications related to leakage, such as disc space injection, epidural or neural foraminal extension of cement, and pulmonary embolism.

Conclusion

Vertebroplasty is a successful, safe, effective, rapid image guided therapy for painful vertebral lesions regardless its duration and may be the only solution for generally

unfit patient. Cement augmented pedicle screw technique is effective and safe in the osteoporotic spine with lumbar degenerative diseases, with better fusion rates and less screw loosening incidence if used carefully and properly, it can be a safe and effective treatment in patients who need spinal fixation accompanying severe osteoporosis. The cannulated screws are safer with lower risk of cement leakage and less blood loss with lower duration of surgery but more expensive than augmented usual pedicle screws.

Figure legends

Figure (1) showing a cement metallic injection cannula and a cannulated screw

Figure (2) showing the mixing of the liquid and the powder into the powder container

Figure (3) showing application of extention tube to the gun

Figure (4) showing application of transpedicular two bone biopsy needles for bone cement injection

Figure (5) showing injection of the bone cement

Figure (6) showing fluoroscopic image during bone cement injection

Figure (7) Post operative X–ray dorsolumber spine after D10-D11-L1-L2 fixation with traditional screws and bone cement

Figure (8) Post operative CT lumbosaccral spine after L3-L4-L5 fixation with traditional screws and bone cement and L2 vertebroplasty

Figure (9) Post operative X-ray lumbosaccral spine after L4-L5 fixation with cannulated screws and bone cement

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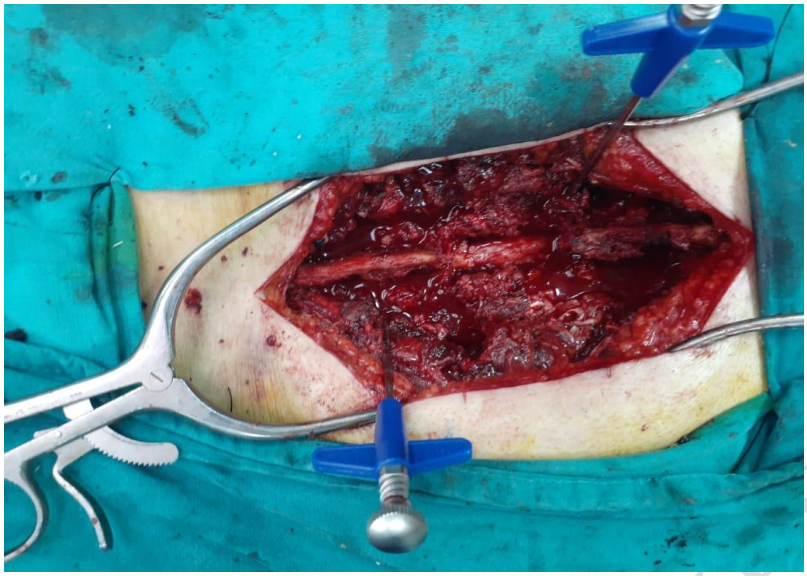

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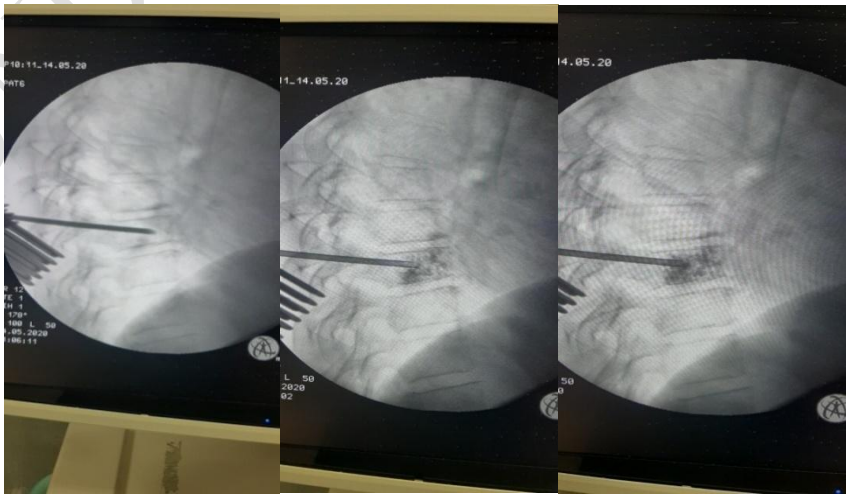

Figure (6) showing fluoroscopic image during bone cement injection

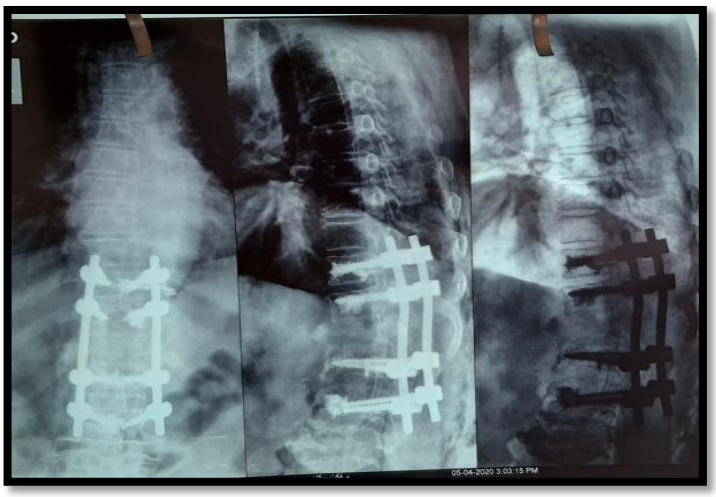

Figure (7) Post operative X–ray dorsolumber spine after D10-D11-L1-L2 fixation with traditional screws and bone cement

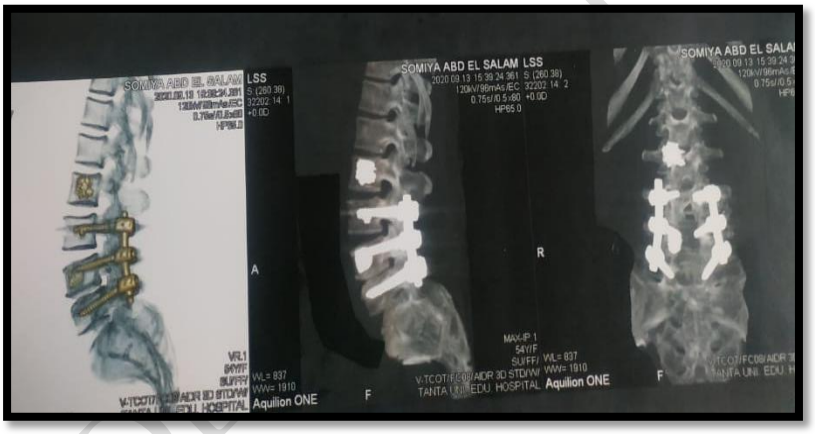

Figure (8) Post operative CT lumbosaccral spine after L3-L4-L5 fixation with traditional screws and bone cement and L2 vertebroplasty

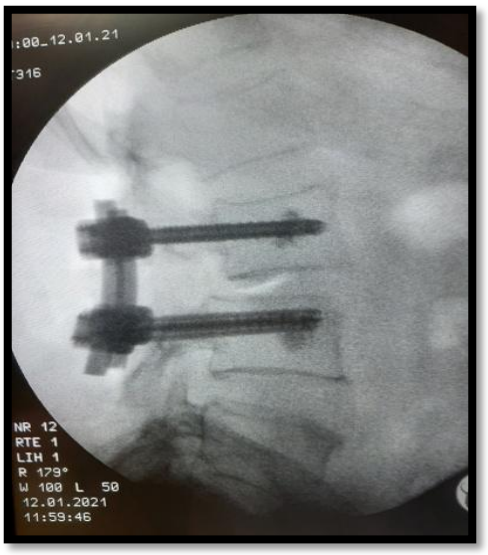

Figure (9) Post operative X-ray lumbosaccral spine after L4-L5 fixation with cannulated screws and bone cement