Chronic obstructive pulmonary disease (COPD) patients with osteoporotic vertebral compression fractures (OVCFs): Improvement of pulmonary function after percutaneous vertebroplasty.

Poster No.: C-0794  
Congress: ECR 2014  
Type: Scientific Exhibit  
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Keywords: Lung, Musculoskeletal spine, Interventional non-vascular, CT, MR, Vertebroplasty, Outcomes  
DOI: 10.1594/ecr2014/C-0794

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Aims and objectives

Osteoporosis represent a significant cause of morbidity and mortality which is becoming increasingly prevalent with the aging of the population [1, 2]. Vertebral Compression Fractures (VCFs) are the most common fractures associated to osteoporosis, although they often remain unidentified in about half of patients that do not experience pain symptoms. Due to the peculiar kinetic of the spine, 80% of pathological vertebral fractures are located at the dorsal-lumbar passage; the most frequent sites of osteoporotic vertebral fractures are in decreasing order L1, D12 and L2 [3]. VCFs usually causes back pain, more or less intense depending on the site and number of the fractures and their severity, which may affect patient’s quality of life. Other consequences of VCFs are represented by spinal misalignment and kyphosis. In this manner it reduces the activities of daily living, causes respiration dysfunction and increases the prevalence of lung disease [4, 5].

Osteoporosis has been widely recognized as a major comorbidity in chronic obstructive pulmonary disease (COPD) patients, present in 36-60% of patients with COPD. Its prevalence in COPD patients is 2-fold to 5-fold higher than in age-matched subjects without air-flow obstruction. The underlying causes of osteoporosis in COPD remain unclear, but several factors significantly correspond to reduced bone density in COPD, including older age, female sex, and body mass index (BMI). However, the relationship to other factors, such as tobacco smoking, physical inactivity, and corticosteroid therapy, are still controversial [6, 7, 8].

Percutaneous vertebroplasty (VTP) is a minimally invasive technique employing the injection of liquid polymethylmethacrylate (PMMA) cement into a fractured vertebral body [9, 10].

VTP was first reported in the literature in 1987 by Gailbert et al., for the treatment of a cervical vertebral hemangioma [11].

In the following years, evolution of cement, and expansions of indications have resulted in several useful vertebral augmentation procedures [12,13].

VTP is now considered a safe and effective procedure for the treatment of Osteoporotic VCFs (OVCFs) [14, 15, 16, 17, 18, 19].

Pain relief and improvement of mobility, function, and vertebral height after VTP is immediate, mantained for at least 1 year and significantly better than conservative medical treatment [20, 21, 22].

The aim of our study was to investigate the effects of VTP and the changes of respiratory function in COPD patients with single dorsal VCFs due to osteoporosis.
Methods and materials

Material and Methods

Patient population and Preoperative management

From September 2011 to August 2013, we observed in our department 123 patients with COPD affected by OVCFs. All patients referred symptoms characterized by severe back pain occurring no more than 3 months earlier, without radicular pain and symptoms suggestive for neurological involvement not responsive to conservative treatment.

The diagnosis and selection of patients was made by pulmonologist and interventional radiologist in consensus on the basis of clinical history and physical examination; treatment indications were made by an interventional radiologist on the basis of imaging findings.

All patients presented a VCF at spine radiography. Diagnosis was confirmed by spine CT and/or MR examination, in order to determine the presence of bone marrow edema and to exclude the presence of endospeical bone fragment (Figure 1).

Inclusion criteria were a single dorsal vertebral involvement, with MR findings of bone marrow edema, without endospeical bone fragments and refractory pain to conventional medical treatment from at least 3 months. The osteoporotic condition was assessed by bone densitometry and spirometry was performed before and after treatment.

A total of 45 patients were enrolled (29 men; 16 women; mean age: 71,4 years, range 65-77 years) and underwent VTP treatment. All patients continued their drug therapy for osteoporosis and COPD and were encouraged to terminate their analgesic or anti-inflammatory therapy the days after VTP procedure.

The study protocol was approved by our inner ethical committee, and written informed consent was obtained from all patients before VTP procedure.

Percutaneous procedure - Operative technique and Devices

All procedures were performed under fluoroscopic guidance in angiographic suite (Allura Xper FD 20; Philips Healthcare, Best, The Netherlands) with patient in prone position and spine extended.

Upon completing the informed consent process, the patient is placed in the prone position on the angiography table. Monitoring of blood pressure, heart rate, and pulse oximetry is done continuously throughout the procedure.
Oxygen supplied via a nasal cannula is used when necessary. The procedure is performed under strict sterile conditions.

The vertebral body to be treated is localized under fluoroscopic control and the skin overlying this area is prepped and draped.

Due to COPD condition all procedure were performed under local anesthesia.

The vertebral access was monolateral in all cases.

A small skin incision was made to access the pedicles. The fracture level was observed, and fluoroscopically guided (Allura, Philips, Netherlands) unilateral transpedicular approach was performed, with an 13Gauge bone biopsy needle. The needle was introduced into the fractured vertebral body through the left pedicle. The cement was injected inside with uniform distribution under fluoroscopic control (Figure 2).

After the procedure, the patient is placed supine and asked to remain flat for 3 hours to allow complete curing of the PMMA prior to axial loading.

The duration of the whole procedure was approximately 28 minutes.

In the absence of complications, patients were discharged at least 4-6 hours after the procedure.

Antibiotics were administered 1 day before and 4 days after the procedure.

**Clinical assessment and Follow-up**

All patients underwent physical and neurological examination prior and after VTP procedure.

During the screening period, the use of analgesic and anti-inflammatory drugs as well as osteoporosis and COPD therapy was recorded. No deaths were observed in the twelve-month follow-up period.

Pain intensity was evaluated by a ten-point visual analogue scale (VAS) score (0 = absence of pain, 10 = unbearable pain) administered before, at 1 week, 3 and 12 months by procedure.

Spirometric examination was performed before (baseline) and at 1 week, 3 and 12 months after treatment. In accordance with literature we considered as benchmarks percentage vital capacity (VC %), percentage forced vital capacity (FVC %), and percentage forced expiratory volume in 1 second (FEV\textsubscript{1} %).
Statistical Analysis

The correlations between VAS score and VC, VAS score and FVC, VAS score and FEV\textsubscript{1} were evaluated by non-parametric Spearman test. The difference between the baseline, 1-week, 3 and 12 months values of VAS score, VC, FVC and FEV\textsubscript{1} were evaluated using the Wilcoxon matched-pairs signed rank test. A $P$ value lower than 0.05 was considered significant. Data were expressed as mean value± standard deviation (SD). Statistical analyses were performed using a commercial software (GraphpadPrism5, SanDiego, CA).
Results

Twelve-months follow up was complete for all the 45 patients. A significant variation \( (P_{\text{value}} < 0.001) \) between the VAS-score values, VC and FVC values obtained before procedure and those obtained at 1 week, 3 and 12 months after treatment. A broad decrease in pain was observed at 1 week after the procedure, with a subsequent slight but continuous decrease over time (Table 1); VC % and FVC % values slightly and continuously improve over time, reaching a plateau at 3 months (Table 2, 3). FEV\(_1\) values did not significantly differ between the pre-VTP ones and the ones obtained 1 week after the procedure \( (P_{\text{value}} = 0.6840) \), at 3 months \( (P_{\text{value}} = 0.5140) \) and at 12 months follow up \( (P_{\text{value}} = 0.9496) \) (Tables 4). A significant correlation was observed between VAS-score values and VC % \( (P_{\text{value}} = 0.0167) \) (Graph 2a), and VAS-score values and FVC % \( (P_{\text{value}} = 0.0028) \) (Graph 2b); the correlation between the VAS-score values and FEV\(_1\) values resulted not significant \( (P_{\text{value}} = 0.6583) \) (Graph 2c).
Fig. 1: Magnetic Resonance images show an acute T7 compression fractures with deformity of the vertebral body. (A) Sagittal T1-weighted: low signal intensity in the collapsed T7 vertebral body compared to the normal bone marrow in other vertebral body. (B) Sagittal T2-STIR: high signal intensity because of bone marrow edema.

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**Fig. 2**: Fluoroscopic biplanar control postprocedure in the lateral (A) and anteroposterior (B) view. Optimal and uniform distribution of polymethylmethacrylate (PMMA) within the bodies of T6. Postprocedural fluoroscopic control is necessary to ensure that the PMMA does not extend into the prevertebral space, the dural sac, or in the paravertebral vessels.

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Fig. 3

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Fig. 4

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**Fig. 5**

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![Graph showing FVC % comparison over time](image)

**Fig. 6**

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![Graph showing FEV1 % comparison over time](image)
Correlation of VAS vs VC%

Fig. 7

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Fig. 8

Correlation of VAS vs FVC%

Spearman $r = -1.00$

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Fig. 9

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Fig. 10

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**Fig. 11**

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**Fig. 12**

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Fig. 13

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Conclusion

OVCFs are known to result in impaired respiratory function through reduction of thoracic mobility and postural deformity, especially in patients which already present a pulmonary disease, as COPD patients [23]. Also low back pain is a very significant and complaint symptom especially in older women with OVCFs who have to lie in bed to reduce their normal motions. Back pain due to acute and subacute OVCFs restrict thoracic movement and can represent a factor contributing to ventilatory disturbance in COPD patients, influencing the involvement of accessory muscles to improve the change of air volume and increasing muscular effort [24, 25].

Tanigawa et al. affirmed that VTP reduce pain associated with OVCFs and improves restrictive ventilatory impairment, but this improvement requires approximately 1 month to occur. In their study, no significant difference of VC and FVC were noted between values before and 1 day after VTP, while a significative improvement was observed at 1 month; furthermore, no significant difference was identified in FEV$_1$ before VTP and either 1 day or 1 month after treatment.

In our study VTP was performed in moderate - severe COPD patients (according to GOLD severity scale) with symptomatic thoracic OVCFs to relieve their back pain, with a subsequent assessment of related functional outcome, through evaluation of spirometric parameters such as Vital Capacity (VC), Forced Vital Capacity (FVC) and FEV$_1$.

Consistent with previous results reported in literature [20, 26, 27, 28] VAS score assessment demonstrates a signifiocantly higher improvement of symptoms with a significant pain reduction 1 week after VTP with a maintenance during the long-term follow-up without further significant modification.

In accordance with the study mentioned above, we observed a progressive increase of spirometric parameters such as VC and FVC already one week after VTP with a growing evolution throughout the entire follow-up period, and an evolution that differ from VAS score. This data are aligned also with those reported in another trial by Dong et al. showing an improvement of pulmonary function after both VTP and Kyphoplasty (KPT). In this study, VC, FVC and Maximum Voluntary Ventilation (MVV) were significantly increased three days after procedures, with only MVV improving three months later and a significant correlation between the decreased values of pain scores and the percentage of improvement of FVC and MVV [5]. MVV values reflect the respiratory muscle endurance and is reduced in osteoporotic patients due to their inactivity. Women with osteoporosis typically have impaired lung volumes, restricted rib mobility, reduced respiratory muscle endurance and isometric muscle strength [29]. Since both VC and FVC directly correlate with restrictive respiratory impairment, we can assume that the analgesic effect of VTP reduces restriction of thoracic movement due to back pain, favoring ventilatory improvement in COPD patients. Considering the different timing observed between the
evolution of the VAS score and spirometric parameters, the reduction of pain can't be considered as a factor which by itself significantly increases the respiratory function, however, favoring the thoracic movements in time, determines a greater exercise of respiratory muscles and an improvement of the restrictive syndrome.

Tanigawa et al. evaluated the effects of VTP on respiratory function in patients with OVCFs, dividing patients into thoracic, thoraco-lumbar, lumbar, and overlapping groups (patients who underwent VTP also for thoracic vertebrae) according to the level of the treated vertebrae. Data analysis showed that VC% improved significantly in the thoracic and overlapping groups. This improvement in VC% is justified by assuming that compression fractures of the thoracic vertebrae are directly involved in the deformation of the chest and the treatment of dorsal vertebrae increased thoracic capacity [24]. According to this study we believe that relief of pain due to OVCFs of lumbar vertebrae is not related to pulmonary function, and decided to limit VTP to the treatment thoracic vertebra, excluding the treatment of lumbar vertebral segments.

Some previous study underlined the role of reduction of kyphosis and restored vertebral height in the improvement of pulmonary function in OVCFs patients [5, 30, 31]; in these studies the authors underline the role of KPT both to relief back pain and to restore vertebra body height and kyphotic wedge angle. Dong et al affirmed that patients with thoracic OVCFs may obtain more benefit from KPT than VTP because of reduction of local kyphotic angle (LKA) and alleviation of back pain related to hyperkyphosis [5]. Other studies affirmed that improvement of sagittal alignment and restoration of vertebral body height did not influence respiratory air exchanges and LKA did not have a correlation with any parameters of pulmonary function. Yang et al suggested that, despite reduction of LKA in their patients' was clinically significant, correlations with lung functional parameters remained not significant: as for VTP, balloon KPT can contribute just to relieve pain, which was demonstrated be the major cause of impairment of lung volumes and reduction of respiratory muscle endurance [25]. A systematic review on osteoporosis-related kyphosis and respiratory function impairment demonstrates that declines in VC secondary to kyphosis seem modest and directly related to the number of vertebral fractures or degree of kyphosis [32]. Therefore, although in a study by Tanigawa et al. a comparison of single and multiple level treatment showed a significant improvements of pulmonary function after 1 month in the multiple level group, in our trial we strengthen the latter views demonstrating that also patients treated by VTP in just one vertebral body can obtain an improvement of their pulmonary values (VC% and FEV1,%) as a result of a significant reduction in pain symptoms.

We have to consider the limitations of our study. As mentioned above, we chose to evaluate only patients with a single vertebral collapse in order to facilitate statistical evaluation of the results; this represent one of the limitations of our study as it would be appropriate to assess the impact of multiple vertebral collapse on pulmonary function and the effects of multiple VTP treatment.
Another limitation of our study is the absence of a control group. An optimal evaluation of the effect of VTP on respiratory function in COPD patients would require a randomized controlled study comparing VTP with a control group such as a conservative treatment group, a sham-treated group or a group receiving respiratory rehabilitation.

In addition, the choice to observe our patients in a three-months period may have some disadvantages due to the short follow-up. In fact, in a short period of observation there’s a lower incidence of respiratory complications, such as Acute COPD exacerbations, which might affect the results. In this respect, it would be useful to evaluate the long-term effectiveness of VTP on the incidence of this complications.

Regarding the use of VTP compared to KPT, in addition to the considerations listed above, we can consider the shorter operation time of VTP, smaller amount of PMMA injected which reduces the incidence of complications [33] as well as the lower cost of VTP [11,12, 34, 35, 36].

In conclusion, VTP improves restrictive ventilatory impairment and quality of life in patients with moderate and severe COPD affected by single thoracic OVCFs, and recommend this treatment in the management of this patients.
References


